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Role of endoscopic ultrasound in the preoperative assessment of patients with oesophageal cancer

J Vickers MD FRCS
Research Registrar
University of Bristol Department of Surgery, Bristol Royal Infirmary

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Despite encouraging results from Europe and America, endoscopic ultrasound (EUS) has yet to become established in the United Kingdom. The aims of this prospective study were to investigate its value in the assessment of patients with benign and malignant oesophageal conditions, and in particular to assess its reliability for local tumour (T) and lymph node (N) staging in patients with oesophageal cancer.

EUS was performed in 90 patients: 23 were normal controls, 17 had benign oesophageal diseases and 50 had operable oesophageal cancer. Detailed measurements of the oesophageal wall and regional nodes were made and the accuracy of EUS for locoregional tumour staging was compared with final histology.

EUS visualised the normal oesophageal wall as a multilayered structure, thicker distally than proximally. Distal stenotic conditions caused thickening of the proximal wall and loss of this gradient. EUS was highly accurate for both local tumour (92% correct) and lymph node staging (86% correct) and was better than computed tomography, magnetic resonance imaging and open staging performed by the surgeon. Fine needle aspiration biopsy using radial scanning EUS guidance was shown to be feasible.

EUS is a valuable technique for investigation of both benign and malignant oesophageal conditions. It provides highly accurate local tumour and regional lymph node staging data in patients with oesophageal cancer.

Oesophageal cancer is an aggressive tumour with significant clinical impact. The incidence of adenocarcinoma is rising rapidly in the Western world *(1)*. Overall, 5-year, survival is only 5–10% *(2)*. Potentially curative radical surgery, alone or in combination with other modalities, carries significant risk to the patient, and is appropriate only when there is some prospect of cure. The rational selection of patients for surgical treatment is crucial and should take account of tumour stage *(3)*.

Endoscopic ultrasound (EUS) combines high-frequency ultrasound and conventional endoscopy. EUS has been in clinical use in Europe and America for over a decade, where studies indicate that it provides accurate local tumour (T) and lymph node (N) staging in patients with upper gastrointestinal tumours *(4-6)*. The accuracy in T and N staging in oesophageal cancer is stated to be between 75% and 95% *(7,8)*. Relatively few studies have attempted to study changes which accompany benign disease or to make detailed comparisons with the surgical findings in the operated patient. An appreciation of the EUS characteristics of the normal oesophageal wall and associated regional nodes is important in order reliably to interpret the EUS appearances of pathological oesophageal conditions. Failure to refer to such 'background' characteristics could lead to errors when assessing EUS images of patients with oesophageal cancer, since the development of oesophageal cancer is associated with benign conditions such as Barrett's oesophagus or achalasia. In addition, there is nearly always an element of obstruction with oesophageal cancer which might influence oesophageal wall thickness. The use of EUS in the UK has been severely limited by lack of expertise and cost of the equipment. There have been no British studies of its value for staging oesophageal cancer.

EUS has several potential advantages over other staging investigations. Image resolution is extremely high, of the order of 0.2 mm *(9)*. Consequently, EUS can demonstrate the precise depth of invasion of a tumour through the oesophageal wall and can detect lymph nodes down to a few millimetres in size. It also demonstrates their

Present appointment and correspondence to: Mr J Vickers, Specialist Registrar in General Surgery, Gloucestershire Royal Hospital, Great Western Road, Gloucester GL1 3NN

internal structure, allowing prediction of individual lymph node status, based on sonographic characteristics rather than size alone *(10)*.

EUS is not a diagnostic technique. Image morphology alone does not provide a pathological diagnosis. Fine needle aspiration cytology (FNAC) under EUS guidance represents a possible solution to this problem, making use of the high image resolution of EUS to guide a biopsy needle into a specific target area within or deep into the upper GI tract wall. EUS guided FNAC has now been widely reported using linear scanning instruments *(11,12)* but has not been achieved using radial scanning systems, except for occasional reports *(13)*.

This prospective study aimed to investigate the role of EUS in patients with a variety of oesophageal conditions and, in particular, to determine its accuracy as a preoperative locoregional staging investigation for patients with oesophageal cancer.

Patients, methods, materials

A series of 90 patients was prospectively evaluated using an Olympus EU-M20 endoscopic ultrasound system. This is a radial scanning echo endoscope which scans at frequencies of either 7.5 or 12 MHz. All EUS scans were performed, interpreted and reported by a single endoscopist.

Patients were divided into three groups:

(a) Normal oesophagus ($n=23$)
(b) Benign oesophageal pathology ($n=17$)
(c) Oesophageal cancer ($n=50$)

All patients underwent preliminary diagnostic oesophagogastroscopy. Patients with benign oesophageal pathologies (group b) included patients with gastro-oesophageal reflux disease (GORD) (6), Barrett's oesophagus (7), submucosal tumours (2) and achalasia (2). Each patient in groups (a) and (b) underwent four-quadrant measurements of the proximal and distal oesophageal wall from which average values of wall thickness were derived. The location, number and morphology of regional lymph nodes detected was recorded.

The patients in the oesophageal cancer group (c) were all considered fit for surgery. Each underwent preoperative staging with either computed tomography (CT) or magnetic resonance imaging (MRI) in addition to EUS. All underwent oesophagectomy. The principal surgeon assessed the locoregional tumour stage at the time of surgery by inspection and palpation both of the *in situ* tumour and the resected surgical specimens, according to a uniform protocol. A total of six surgeons carried out the resections. More than half were performed by a single surgeon in the author's hospital and the remainder performed at hospitals within the region. Resected specimens were subjected to a standardised histological examination. Statistical analysis was performed where appropriate using non-parametric tests.

The study was made up of a number of linked experiments using EUS, conducted both *in vivo* and *in vitro*, to achieve the following objectives:

1 To determine the EUS characteristics of the oesophageal wall and regional lymph nodes in patients with a normal oesophagus and in patients with benign oesophageal diseases.
2 To assess the accuracy of EUS for local tumour and lymph node staging (TN) in patients with oesophageal cancer.
3 To compare local tumour and lymph node staging using EUS, CT, MRI and surgical staging.
4 To determine the EUS characteristics most indicative of lymph node metastasis.
5 To develop a safe and reproducible technique for EUS guided fine needle aspiration cytology.

Results

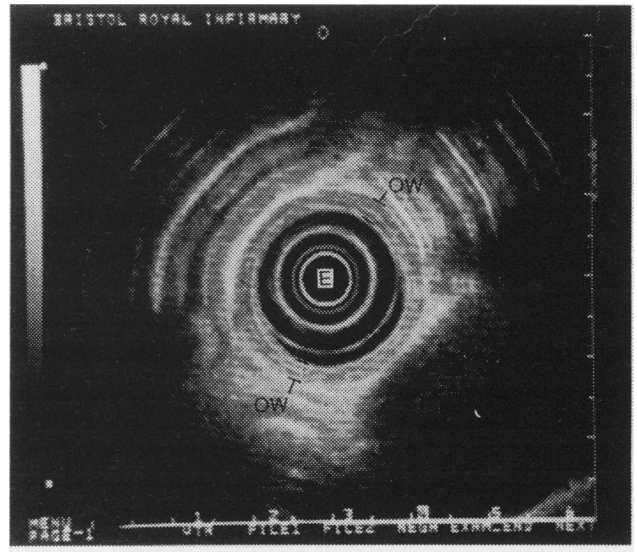
Oesophageal wall measurements

Normal oesophagus

The normal oesophageal wall appeared as a three- or five-layered structure of alternating high and low echo densities (Fig. 1). The median thickness of the distal oesophageal wall was 3 mm. The wall in the distal half of the oesophagus was thicker than in the proximal half ($P=0.025$) (Table I). Thickening of an individual EUS wall layer of 2 mm or greater was observed in eight of the 23 (35%) patients.

Benign oesophageal diseases without strictures

There was no difference in wall thickness between patients from groups (a) and (b) ($P>0.15$; Mann–Whitney U test). As with the normal oesophagus, the distal oesophageal wall tended to be thicker than the



(E = echo endoscope, OW = oesophageal wall)

Figure 1. EUS image of normal oesophagus (five layers).

Table I. Wall thickness measurements—all groups

	Proximal wall median (range)	*Distal wall median (range)*	*P values*
Normal oesophagus			
Max. thickness (mm)	3 (2–3)	3 (2–4)	0.025
Min. thickness (mm)	2 (2–3)	3 (1–3)	
Benign: no strictures			
Max. thickness (mm)	3 (2–3)	3 (3–4)	0.046
Min. thickness (mm)	2 (2–3)	3 (2–3)	
Benign: distal strictures			
Max. thickness (mm)	3 (3–4)	3 (3–5)	0.41
Min. thickness (mm)	3 (2–3)	3 (2–3)	

proximal wall ($P=0.046$, Table I). Thickening of an individual wall layer of greater than 2 mm occurred in four of the 9 (44%) patients. All four had histologically proven Barrett's oesophagus. In one case this was confined to the muscle layer, but in the remaining three the thickening was in the mucosa/submucosa.

Benign oesophageal diseases with stenoses

Distal oesophageal stenosis owing to benign disease occurred in eight patients. Six had strictures owing to GORD and two had achalasia. Compared with normal controls (group a), there was a significant increase in the overall thickness of the proximal oesophageal wall in the presence of distal oesophageal stenosis ($P=0.006$). The gradient of increasing wall thickness from proximal to distal seen in the normal oesophagus was lost in patients with distal stenosis. Thickening of a single wall layer of 2 mm or more occurred in seven of the eight patients with distal stenosis (88%), and affected the muscle layer exclusively in 6 (75%). These changes reflect the subtle alterations that occur as a result of chronic obstruction.

Lymph node evaluation

Normal oesophagus. Lymph nodes were detected by EUS in 17 of 23 patients with a normal oesophagus (74%). The maximum number found per individual was three nodes.

Benign oesophageal diseases without strictures

Lymph nodes were detected in 6 (67%) of the nine patients. There was no difference compared with normal individuals.

Benign oesophageal diseases with strictures

The number of lymph nodes detected was higher than in patients without strictures. Mediastinal nodes were detected in six of eight patients (75%) with a median of two nodes per patient (range 0–3)

Locoregional staging accuracy in patients with oesophageal cancer

Local tumour staging

There was close approximation between EUS and histology for local tumour staging (Table II). Surgical staging was less reliable, with a tendency to underestimate the extent of local spread. Compared with histological stage, four staging errors (8%) were made using EUS; three T_2 tumours incorrectly designated T_3 and a single T_3 lesion was understaged as T_2. Nine surgical staging errors were made (18%) compared with final histology. Eight were understaging errors, all T_3 tumours incorrectly designated T_2 by surgical staging, and one was overstaging of a T_2 tumour as T_3.

Sensitivity and specificity values for T stage are shown in Table II. Of full thickness tumours (T_3/T_4), 97% were accurately detected by EUS with high sensitivity and positive predictive value (PPV). Surgical staging was inferior to EUS. Figure 2 shows an EUS image of an oesophageal tumour.

Lymph node (N) stage

Forty-one patients were designated N_1 by EUS and eight were N_0. The median number of nodes detected per patient (not categorised as either malignant or benign) was

Table II. EUS *vs* surgical staging: evaluation of T staging accuracy

n=50	*T_1*	*T_2*	*T_3*	*T_4*	*Sens*	*Spec*	*PPV*	*NPV*	*κ*
EUS-T	n=1	n=8	n=40	n=1	97	73	0.93	0.89	0.72
Histol.-T	n=1	n=10	n=38	n=1	–	–	–	–	–
Surg.-T	n=1	n=17	n=31	n=1	79	91	0.97	0.56	0.59

T stage designation as either full (T_3 or T_4) or partial (T_1 or T_2) thickness tumour
Sens, sensitivity; Spec, specificity; PPV, positive predictive value; NPV, negative predictive value; κ values were all calculated against histological stage

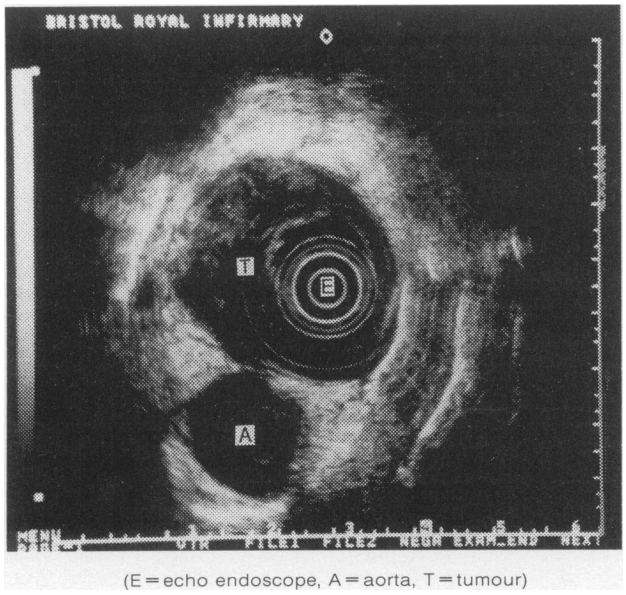
4 (interquartile range = 3–6). Malignant nodes associated with an oesophageal tumour are shown in Fig. 3.

Seven (14%) lymph node staging errors were made by EUS. Six were overstaging errors. Ten (20%) staging errors occurred with surgical staging, of which seven were understaging. Sensitivity and specificity values for EUS and surgical lymph node staging are shown in Table III.

Lesions causing oesophageal obstruction

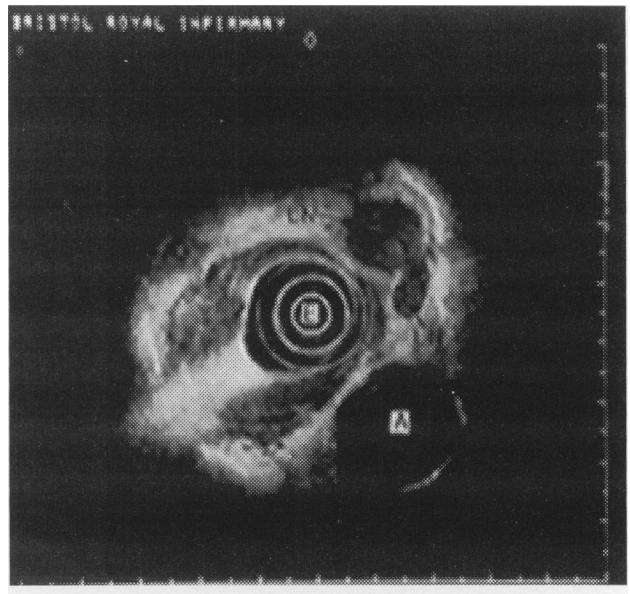
Of 50 tumours, 11 (22%) had caused sufficient luminal stenosis to prevent passage of the echo endoscope beyond the lesion. In these patients, the EUS scan was incomplete because the distal oesophagus, stomach, lesser and greater curve lymph nodes, and coeliac nodes could not be imaged.

All 11 of the obstructing tumours were full-thickness (T_3) on final histology. Despite the limited EUS examination performed on these patients, EUS correctly identified all the tumours as T_3. EUS designated all 11 of these tumours as N_1, even though nodes could only be visualised in the mediastinum. Two of these patients were designated N_0 on histology. EUS therefore correctly predicted T stage in every patient, and correctly predicted N stage in 82% of patients, without scanning distal to the tumour.



(E = echo endoscope, A = aorta, T = tumour)

Figure 2. EUS image of oesophageal tumour.



(E = echo endoscope, A = aorta, LN = lymph node, T = tumour)

Figure 3. EUS image of oesophageal tumour with malignant regional lymph nodes.

Individual lymph node detection

Table IV compares the predicted malignant involvement of lymph nodes detected by EUS with all malignant nodes detected by histology. More lymph nodes in total were detected by histology than EUS, although the total numbers of malignant nodes detected by each modality were virtually the same. Most of the additional nodes detected histologically were benign.

EUS identified almost the same total number of mediastinal lymph nodes as did final histology (197 *versus* 204), with a tendency to overestimate the malignant status of individual nodes (93/197 for EUS *versus* 64/204 for histology). Far fewer abdominal lymph nodes were detected by EUS than by histology (EUS = 39, histology = 234). This remained the case even after exclusion of the 11 patients with obstructing oesophageal lesions (EUS = 39, histology = 173).

The detection rates of neoplastic nodes by EUS and histology for each individual patient were evaluated to determine agreement. EUS tended to overestimate lymph node involvement, although where overestimation occurred, it was usually by only a single lymph node at most

Table III. EUS *vs* surgical staging: evaluation of N staging accuracy

n = 49	N_0	N_1	*Sens*	*Spec*	*PPV*	*NPV*	κ
EUS-N	*n* = 8	*n* = 41	97	54	0.85	0.88	0.61
Histol.-N	*n* = 13	*n* = 36	—	—	—	—	—
Surg.-N	*n* = 17	*n* = 32	81	75	0.91	0.56	0.47

N stage designation as either node positive (N_1) or node negative (N_0)
Sens, sensitivity; Spec, specificity; PPV, positive predictive value; NPV, negative predictive value; κ values were all calculated against histological stage

Table IV. Total lymph nodes detected by EUS and histology

	EUS	*Histology*
All nodes	236	438
Malignant nodes	113	123
Benign nodes	123	315
Malignant:benign ratio	1:1.09	1:2.56

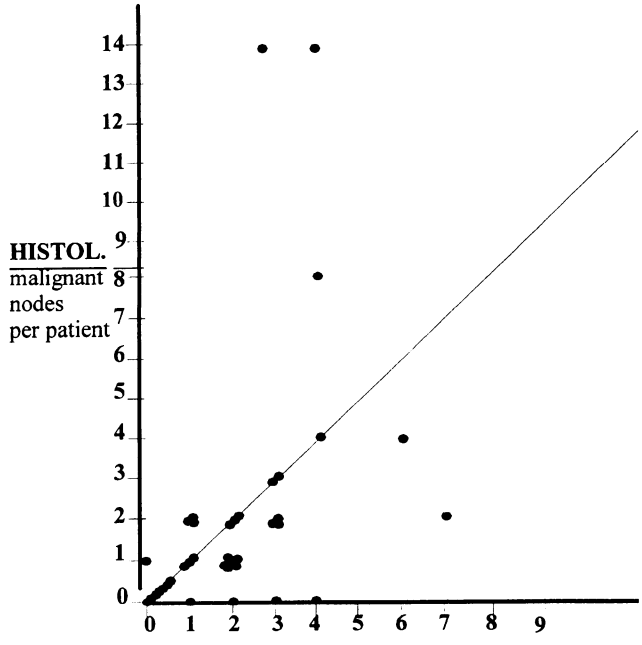


Figure 4. Agreement for malignant node detection: EUS *vs* histology.

(Fig. 4). Significant discrepancies in lymph node counts (>4) between EUS and histology, occurred in only three patients (6%). Malignant lymph node counts matching within a single node using both EUS and histology were achieved in 30 patients (79%).

Comparison of EUS with CT and MRI

Of the patients with oesophageal cancer, 49 underwent preoperative staging with CT or MRI as well as preoperative EUS.

EUS was superior to both CT and MRI scanning for both local tumour and lymph node staging. Both CT and MRI detected the primary oesophageal tumour in every patient, but neither technique could predict the degree of transmural spread in any patient (T_{1-3}). In seven of 39 patients, CT incorrectly predicted local irresectability (T_4). MRI similarly overstaged resectable tumours as T_4 in six of ten patients.

Neither CT nor MRI scanning were reliable for lymph node staging, compared with EUS. Both failed to correctly predict node staging in over one-half of the patients studied.

Morphological characteristics of lymph nodes

EUS detected a total of 236 lymph nodes in 50 patients with resectable oesophageal tumours. Data from all 236 nodes were analysed to determine which lymph node characteristics were the most important in predicting nodal metastasis.

Node size, echo density and heterogeneity were the most useful indicators of lymph node metastasis ($P<0.00001$). Lymph node grouping patterns were less reliable and lymph node shape was of no predictive value (Table V).

Radial scanning fine needle aspiration biopsy

Preliminary *in vitro* studies using post-mortem oesophagus mounted in a water bath showed that the minimum diameter of needle that could be visualised by radial scanning EUS was 0.8 mm.

Modifications of a 0.8 mm metal tipped transbronchial needle were used *in vivo* to obtain fine needle aspirates of tumours in 13 patients. Aspirates were obtained exclusively from the submucosal portion of primary oesopha-

Table V. Individual analysis of lymph node characteristics using EUS

n(total) = 236	*Malignant nodes*	*Benign nodes*	*P value**
Node count	113	123	
Node size (no. > 5mm diameter)	98 (86.7%)	44 (35.8%)	< 0.00001
Echo density (no. hypoechoic)	101 (89.3%)	58 (47.2%)	< 0.00001
Heterogeneity (no. homogeneous)	99 (87.6%)	55 (44.7%)	< 0.00001
Grouping (no. solitary)	66 (58.4%)	53 (43.1%)	= 0.0504
Shape (no. round)	76 (67.2%)	67 (54.5%)	= 0.0899

* χ^2 test

geal tumours where the oesophagus appeared visually normal at conventional endoscopy. Biopsies were only accepted as positive if the needle was clearly visualised by EUS lying within submucosal tumour tissue at the time of biopsy and if the cytology grade of the aspirate obtained was C_4 or C_5.

In vivo biopsies yielded diagnostic tissue aspirates in nine of the 13 patients (69%). The lesion was clearly identified lying within the submucosal part of the target lesion in all 13 of the attempted biopsies. There were no complications associated with the procedure.

Discussion

Studies of the oesophageal wall and regional lymph nodes in patients with either a normal oesophagus or benign oesophageal disease by EUS provided valuable background data. The oesophageal wall was frequently thickened in the presence of distal oesophageal stenosis, while the gradient of increasing oesophageal wall thickness from proximal to distal, observed in the normal oesophagus, was absent in patients with stenosis. The EUS layer most commonly thickened was the echo-poor muscle layer, probably reflecting hypertrophy of this layer owing to increased peristalsis. Similar effects might also occur with stenosing oesophageal cancers, and should be considered when evaluating such tumours with EUS. Thickening of the submucosal layer was found in some of the patients with Barrett's oesophagus, an observation also made by Shrivastava *et al. (14)*

There was a small background count of lymph nodes in normal individuals. Wiersema *et al. (15)* reported similar findings, although with a slightly higher node count. The lymph node count was increased in the presence of inflammatory, and/or stenotic conditions, probably reflecting a population of enlarged, reactive nodes which are easier to detect than smaller, normal ones. This should be considered in patients with malignant disease where there is a coexistent inflammatory component.

EUS was highly accurate in predicting local tumour infiltration and was superior to open surgical assessment. It was not as reliable in predicting the extent of lymph node involvement, particularly in node-negative patients, but was still superior to surgical assessment. Penetration of a tumour through the whole thickness of the oesophageal wall is an important determinant of long-term survival and local recurrence *(16,17)*. EUS can identify patients with partial-thickness tumours in whom a surgical cure may be possible, if they are also lymph node-negative. Patients with full-thickness tumours are less likely to be cured by surgery alone, but with the continuing development of chemoradiotherapy techniques, EUS enables the pretreatment stage to be accurately determined, which should identify appropriate patient groups for neo-adjuvant therapies. The preoperative identification of individuals with contiguous organ invasion, which renders tumours irresectable can rationalise the use of surgical resources and prevent unnecessary operations. Although all the patients in this study had potentially resectable tumours, other studies have shown EUS to be generally reliable for detecting contiguous invasion (T_4 lesions) *(18)*.

Lymph node stage also affects survival. Only 50% of patients with lymph node mestastases will be alive 2 years after resection, and only 15% survive more than 5 years *(19)*. Recent evidence suggests that the presence of large numbers of involved nodes (>7) is associated with reduced survival *(20,21)*. Consequently, a subgroup of patients might once again be identifiable, who might benefit from non-surgical alternative therapies or combined modality approaches.

EUS is clearly not without limitations, however. There is a tendency to overstage nodes in the mediastinum and difficulty in detecting some nodes in the abdominal cavity. Overstaging errors may be the result of incorrect classification of enlarged reactive nodes as malignant or owing to errors in the interpretation of ultrasonic lymph node characteristics. The majority of abdominal nodes that were 'missed' by EUS were small and benign, although approximately one-half of the malignant abdominal nodes were also missed. However, small, malignant abdominal nodes rarely occurred in isolation. In this study, lymph node staging by EUS was correct in 85% of all patients, and the individual identification of malignant nodes matched final histology to within a single node in 80% of patients.

Malignant oesophageal obstruction leading to incomplete EUS examination occurred in 22% of patients ($n=11$). Neither the T nor N staging accuracy of EUS was greatly affected by obstruction of the lumen. Most of the obstructing tumours that were encountered were T_3 N_1 lesions and this was almost always detectable on limited mediastinal scanning alone. However, it is true that important prognostic information about regional abdominal and coeliac node involvement, which might affect both therapeutic options and prognosis, is unavailable if abdominal EUS cannot be performed. The advent of specific small-diameter echo endoscopes which have recently been introduced should overcome this limitation in future.

EUS-guided FNAC using radial scanning echo endoscopy is a feasible technique. This has great potential for obtaining a tissue diagnosis from lesions deep to the mucosa which were inaccessible to conventional biopsy techniques. In this study, no attempts were made to biopsy distant lesions in the mediastinum lying separate from the gastrointestinal tract wall, such as mediastinal lymph nodes, but this is clearly where the future of the technique lies. The monitoring of patients after radical surgery or in association with novel adjuvant treatments might also be enhanced by EUS-guided tissue biopsy.

EUS provides unrivalled locoregional staging for oesophageal cancer. Management protocols can be developed based on EUS staging in conjunction with whole-body imaging techniques (CT/MRI) to determine haematogenous metastases. The logical develop-

ment of clinical trials designed to evaluate multimodality treatments demands accurate pretreatment staging and EUS should be considered an essential prerequisite in such studies.

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