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Comparison of diagnostic accuracy between linear EUS and miniprobe EUS for submucosal invasion in suspected early gastric cancer

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Disclosure statement

The authors declare that they have no competing interests.

Abbreviations

Gastric cancer (GC), early gastric cancer (EGC), Endoscopic ultrasonography (EUS), endoscopic submucosal dissection (ESD), endoscopic mucosal resection (EMR), submucosal(SM), Receiver operating curve (ROC), EUS-guided fine needle aspiration (EUS-FNA), positive predictive value (PPV), negative predictive value (NPV), odds ratio (OR).

Abstract

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Objective: This study assessed the accuracy of linear endoscopic ultrasound (EUS) in diagnosing submucosal (SM) invasion and compared linear EUS with mini-probe EUS in suspected early gastric cancer (EGC) patients.

Methods: Patients diagnosed with biopsy-verified suspected EGC were analysed retrospectively. They were all examined by linear EUS or miniprobe EUS for preoperative diagnosis of invasion depth and underwent endoscopic or surgical treatment for radical resection. The invasion depth evaluated by EUS and pathology were categorized into no invasion of SM and invasion of SM or deeper. We compared the diagnosis of EUS with postoperative pathology results.

Results: A total of 105 patients were included in the final analysis. We found that the overall prediction accuracy of linear EUS (n = 57) for SM invasion in suspected EGC was higher than that of mini-probe EUS (n = 48), but no statistically significant differences were noted (82.5% vs 72.9%, p = 0.344). The negative predictive value (NPV) of linear EUS was significantly higher than that of mini-probe EUS (100% vs 82.8%, p = 0.037). The binary logistic regression analysis identified that tumor size (p = 0.036), the presence of ulceration (p < 0.001) and the EUS type (p = 0.027) were independent risk factors for the diagnosis of SM invasion by EUS. The area under the receiver operating curve (ROC) was 0.889 and 0.719 for linear and mini-probe EUS, respectively.

Conclusion: Linear EUS diagnosed suspected EGC for SM invasion with higher accuracy than mini-probe EUS. Additionally, large and ulcerative lesions may lead to overestimation.

Keywords: Endoscopic ultrasound. Early gastric cancer. Diagnosis.

Introduction

Gastric cancer (GC) is currently the fifth most common cancer and the fourth major cause of cancer-associated mortality worldwide[1], which poses a severe threat to the health and life of humans. According to the depth of invasion, GC can be divided into EGC and advanced gastric cancer. EGC has a favorable prognosis, with a 5-year survival rate of more than 90%[2]. Surgery is a classical and effective treatment for EGC. However, with the development of minimally invasive endoscopic techniques,

endoscopic submucosal dissection (ESD) and endoscopic mucosal resection (EMR) have become preferred treatments for EGC. It has been confirmed that endoscopic therapy has less trauma, faster recovery and a lower cost of hospitalization than surgery[3]. Preoperative assessment for endoscopic treatment involves determining tumor size, histological type, and invasion depth, with or without the presence of ulceration[4]. Among all the factors, invasion depth is the most critical factor for selecting endoscopic resection or surgery as an appropriate strategy. Incorrect judgments may lead to overtreatment or undertreatment.

At present, it is still a challenge to determine the invasion depth of EGC. EUS can objectively delineate the layers of the gastric wall, and it is considered the most accurate method for local tumor staging of gastrointestinal cancer[5]. Various studies reported that the accuracy of EUS for EGC staging ranged from 64.8% to 92%[6]. There are three basic methods for staging EGC with EUS: linear EUS, radial EUS and miniprobe EUS. Currently, most results have focused on radial EUS or miniprobe EUS, and fewer studies are available using linear EUS to predict the invasion depth in EGC. Compared with the other two types of EUS, an important advantage of linear EUS is the ability to conduct EUS-guided fine needle aspiration (EUS-FNA) of malignant appearing lymph nodes and other metastatic lesions. A new study[7] reported that linear EUS was more accurate for predicting SM invasion than radial EUS in suspected EGC patients. However, the comparison of diagnostic accuracy between linear EUS and miniprobe EUS for invasion depth in EGC has not been described. Considering the advantage in N staging, if linear EUS has high accuracy in predicting SM invasion in EGC, it will be a good choice for suspected EGC preoperative evaluation. Therefore, we conducted this retrospective study to assess the accuracy of linear EUS in diagnosing SM invasion and compare linear EUS with mini-probe EUS in suspected EGC patients.

Patients and Methods

From March 2018 to November 2021, patients diagnosed with biopsy-verified suspected EGC who underwent EUS were included in this study at the Second Affiliated Hospital of Anhui Medical University. The criteria for selecting the patients were as follows: 1) suspected EGC under white-light endoscopy; 2) diagnosis confirmed by

pathological biopsy; 3) underwent linear EUS or miniprobe EUS for pretreatment T staging; and 4) received curative treatment by either ESD or surgical resection. Cases with insufficient clinicopathologic data were excluded. All work was conducted with the formal approval of the Second Affiliated Hospital of Anhui Medical University Ethics Committee (NO. SL-XJS2019-033). The study followed the principles of the Declaration of Helsinki.

Information to be recorded

Individual clinicopathologic data from electronic hospital records were collected as follows: 1) Age and gender of patients; 2) The location of the tumor, such as upper, middle or lower parts dividing by the lines connected to the trisected points on the lesser and greater curvatures [8]; 3) Tumor size, divided into $\leqslant$ 3.0 cm and > 3.0 cm according to the lesion diameter; 4) EUS and pathology for evaluating invasion depth of EGC, divided into no invasion of SM and invasion of SM or deeper; 5) Histological type of tumor, divided into differentiated carcinoma (well or moderately differentiated tubular adenocarcinoma and papillary adenocarcinoma) and undifferentiated carcinoma (poorly differentiated adenocarcinoma, mucinous adenocarcinoma and signet ring cell carcinoma or other types).

EUS equipment and examination procedure

EUS staging was performed by endoscopists using a linear array echoendoscope (EU-ME2, GF-UCT260, Olympus, Tokyo, Japan; EG-3270UTK, Pentax, Tokyo, Japan) for linear EUS examination and a miniature ultrasound probe (SP-702, 15MHz, Fujifilm, Tokyo, Japan) for mini-probe EUS examination (Figure 1). To improve acoustic coupling with the gastric wall, the air in the stomach was fully aspirated and we filled the stomach with normal sterile water in both linear EUS and mini-probe EUS operations. In our endoscopy center, further EUS examination will be performed after a diagnosis of biopsy-verified suspected by white-light endoscopy. Patients underwent different EUS examinations according to their treatment team. Each EUS examination was performed by two experienced endosonographers who completed more than 800 EUS procedures. The depth diagnosis was fixed after EUS. If their diagnoses were discordant, a final diagnosis was achieved following discussion.

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EUS staging

T staging was performed based on AJCC 7th edition TNM staging system [9]. The endoscopic criteria were as follows: Tis for tumors confined to the epithelial layer without invading the basement membrane; T1a for tumors limited to the mucosa (combination of the first layer, hyperechoic and second layer, hypoechoic); T1b for tumors invading the submucosa (the third layer, hyperechoic); T2 for tumors invading the muscularis propria (the fourth layer, hypoechoic); T3 for tumors invading the subserosa without interruption of the serosa; T4 for tumors invading the serosa or adjacent organs. (the fifth layer, hyperechoic). GC presents as hypoechoic lesions on EUS with one or more layers of fuzzy, irregular, interrupted, thickened or disappeared. All diagnoses of invasion depth by EUS were classified into two groups: no invasion of SM and SM invasion. If the tumor was without SM invasion, ESD was performed, while if the tumor invaded SM or deeper, surgical excision was required according to current indications of ESD[4]

Histopathologic staging

Postoperative pathological staging was performed according to AJCC 7th edition[9] standard by two experienced pathologists blinded to the EUS diagnosis. The depth of submucosal invasion was divided into two sublevels: within 500 μm from the muscularis mucosa (SM1) and more than 500 μm or deeper (SM2).

Statistical analysis

Data are expressed as frequencies, percentages or means ± standard deviations as appropriate. Comparisons between proportions were made with the chi-square test. Binary logistic regression was used to analyse the factors that significantly affected the diagnostic accuracy of linear EUS. The odds ratio (OR) and relevant 95% CI were calculated. All statistical tests were two-sided with a statistical significance of $p < 0.05$.

Results

Clinical characteristics

A total of 105 patients were included in the final analysis. Among them, 57 patients underwent linear EUS, and 48 patients underwent mini-probe EUS examination. The baseline characteristics of the patients were similar between the two groups (Table 1).

Comparison of diagnostic accuracy between linear EUS and miniprobe EUS for SM invasion in suspected EGC

We found that the overall prediction accuracy of linear EUS and mini-probe EUS for SM invasion in suspected EGC were 82.5% and 72.9%, respectively. The overall accuracy of linear EUS was higher than that of mini-probe EUS, but no statistically significant differences were noted ($p > 0.05$). In this study, the diagnostic sensitivity, specificity, positive predictive value (PPV) and NPV of linear EUS for SM invasion were 100%, 77.8%, 54.6%, and 100%, respectively. The diagnostic sensitivity, specificity, PPV and NPV of mini-probe EUS for SM invasion were 68.8%, 75.0%, 57.9%, 82.8%, respectively. The NPV of linear EUS was significantly higher than that of mini-probe EUS (100% vs 82.8%, $p = 0.037$). In addition, the false positive rate was 22.2% for linear EUS and 25.0% for mini-probe EUS. The false negative rate was 0 for linear EUS and 31.3% for mini-probe EUS (Table 2). We used the ROC to evaluate the diagnostic performance of linear EUS and miniprobe EUS for SM invasion of EGC, and the area under the ROC curve was 0.889 for linear EUS and 0.719 for miniprobe EUS (Figure 2).

Binary logistic regression of risk factors affecting the diagnosis of SM invasion by EUS

All incorrect EUS diagnoses were reviewed. Binary logistic regression showed that tumor size ($p = 0.036$, OR 5.629, 95% CI 1.115-28.430), the presence of ulceration ($p < 0.001$, OR 29.579, 95% CI 5.583-156.703) and the EUS type ($p = 0.027$, OR 5.114, 95% CI 1.201-21.777) were independent risk factors for the diagnosis of SM invasion by EUS (Table 3).

Discussion

The invasion depth is one of the most crucial considerations for preoperative staging of EGC[4]. To our knowledge, this is the first comparative study to predict the invasion depth between linear EUS and miniprobe EUS in suspected EGC. In our study, we mainly discussed the accuracy of EUS in the prediction of SM invasion, which is used to direct treatment decisions. Our results indicate that linear EUS diagnosed suspected EGC for SM invasion with higher accuracy than mini-probe EUS. The accuracy was significantly reduced when lesion had ulceration and a diameter greater than 3 cm.

Linear EUS is widely used in the diagnosis and treatment of pancreatic and biliary

diseases[10]. However, the depth diagnostic performance for suspected EGC using linear EUS has received relatively less research attention. A prior study showed that for gastric cardia cancer, the overall accuracy of linear EUS for invasion depth was 71%, and the sensitivity for T1, T2, and T3 lesions was 100%, 31% and 75%, respectively[11]. In a prospective randomized trial of 43 patients with UGI malignancies, transverse-array EUS and linear EUS had 88% agreement on tumor T staging[12]. A recent comparative study by Lan et al[7] suggested that the accuracy of linear EUS and radial EUS for T1b staging of EGC was 90.9% and 69.2%, respectively, and linear EUS was more accurate for determining SM invasion and therapeutic strategy in suspected EGC patients than radial EUS. In the current study, the ANOVA of accuracy was not statistically significant, but EUS type was proven to be an independent risk factor for the accuracy of EUS after we used binary regression analysis to remove potential confounding factors. Therefore, we believe that linear EUS has a much higher accuracy for SM invasion in suspected EGC than miniprobe EUS. A possible explanation for this might be that linear EUS can provide exquisite imaging quality and processing ability. Linear EUS can easily adjust the image display range and realize image amplification, contrast, overall gain, remote gain and near gain. Miniprobe EUS has a high frequency of resolution in the near field but weak resolution in the far field[13]. In contrast, linear EUS has better resolution for deeper lesions, which can explain the higher sensitivity and NPV of linear EUS in diagnosing SM invasion compared with mini-probe EUS in suspected EGC. Higher sensitivity for SM invasion makes clinical decisions adequate and thereby avoids unnecessary endoscopic resection in patients.

We also investigated the clinicopathologic factors affecting the diagnosis of SM invasion by EUS in suspected EGC. In the study, the accuracy was significantly reduced when lesions had ulcerations and diameters greater than 3 cm. Several studies[14, 15] have also revealed a significantly decreased accuracy of EUS in the presence of ulcerative changes. Ulcerative lesions with different degrees of inflammation, edema or fibrosis were seen as hypoechoic lesions on EUS similar to tumor invasion. Large tumors are associated with incorrect diagnoses of tumor invasion depth by EUS[16-18]. The reason may be that the large tumor was beyond the effective scanning range of

EUS. In previous studies, the stomach was divided into upper, middle and lower parts and the upper third of the stomach was the most challenging position for EUS diagnosis[15, 19, 20]. The reason may be the thin submucosal layer and prominent vasculature at this position[20], and may also be difficult to fill this position with normal sterile and locate the EUS probe close the lesion due to the angle of EUS scope[21]. However, tumor location did not independently affect the diagnostic accuracy of linear EUS in our research. According to our experience, it is slightly difficult to operate linear EUS in the gastric antrum, especially the greater curvature, and gastric angle. The gastric antrum is not easily filled by water and it is difficult to make the imaging plane of linear EUS perpendicular to the target lesion of the greater curvature of gastric antrum. It became easier to fill water in the gastric antrum when patients were asked to take the prone position. A small-caliber non-therapeutic linear endoscope is more easily operated and to be used when the target lesion loacted at the greater curvature of gastric antrum. The folded structure of gastric angle and frequent peristalsis may increase our operating time. In our study, the diagnostic accuracy reached to 72.7%(16/22) in the gastric antrum and gastric angle part. No cases were excluded from the study or switched to mini probe EUS because of operational difficulties. In our research, differentiation type[15, 22] did not independently affect the diagnostic accuracy of EUS, which may be related to the small sample size of our study.

In previous studies, EUS was selected based on the appearance of the lesion. However, in our study, patients underwent different EUS examinations according to their treatment team, thus avoiding human bias. Moreover, we only analysed suspected EGC for SM invasion to simulate actual clinical practice.

There are several limitations to discuss in this paper. First, this was a single-centre retrospective study with a relatively small sample size. Second, potential selection bias may exist in our study because most cases are mucosal cancer. However, we believe our findings are very important and timely, and multicenter, large sample studies are needed to confirm the results.

In conclusion, linear EUS has higher accuracy and sensitivity in determining SM

invasion than miniprobe EUS, which is expected to be widely used in preoperative T staging of EGC. Particular attention should be given that EUS-based diagnosis may be overestimated for large and ulcerative lesions.

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Jianmei Zhou and Qiao Wang contributed equally as co-first authors.

Author contributions

The research initiative and study concept were taken and designed by Xiangpeng Hu and Jun Liu. Hui Li, Shu Zhang, Li Tao, Qianqian Fang and Fan Xu recorded the data and performed the analysis. Jianmei Zhou and Qiao Wang drafted the manuscript. All authors have read and approved the submitted version of the paper.

Data availability statement

The data used and analysed during the current study are available in the databases of the Second Affiliated Hospital of Anhui Medical University.

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Table 1 Baseline characteristics of patients between linear and mini-probe EUS group.

Variable	Total, n (n = 105)	Linear EUS (n = 57)	Mini-probe EUS (n = 48))	P value
Age, (years)	63.34±8.501	63.00±8.401	63.75±8.690	0.655
Sex	105(100%)	57(100%)	48(100%)	0.064
Male	68(64.8%)	32(56.1%)	36(75.0%)	
Female	37(35.5%)	25(43.9%)	12(25.0%)	
Location	105(100%)	57(100%)	48(100%)	0.449
Upper	59(56.2%)	30(52.6%)	29(60.4%)	
Middle	25(23.8%)	13(22.8%)	12(25.0%)	
Lower	21(20.0%)	14(24.6%)	7(14.6%)	
Tumor size, cm	105(100%)	57(100%)	48(100%)	0.567
⩽3.0 cm	91(86.7%)	48(84.2%)	43(89.6%)	
>3.0 cm	14(13.3%)	9(15.8%)	5(10.4%)	
Ulceration	105(100%)	57(100%)	48(100%)	0.372
No ulcer	78(74.3%)	40(70.2%)	38(79.2%)	
Ulcer present	27(25.7%)	17(29.8%)	10(20.8%)	
Differentiation	105(100%)	57(100%)	48(100%)	0.248
Differentiated	92(87.6%)	52(91.2%)	40 (83.3%)	
Undifferentiated	13(12.4%)	5(8.9%)	8 (16.7%)	
Histological invasion depth	105(100%)	57(100%)	48(100%)	0.187
No invasion of SM	77(73.3%)	45(78.9%)	32 (66.7%)	
Invasion of SM or deeper	28(26.7%)	12(21.1%)	16 (33.3%)	

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Table 2 Comparison of diagnostic accuracy between linear EUS and mini-probe EUS for SM invasion in suspected EGC

Statistics	Linear EUS	Mini-probe EUS	*P* value
Accuracy, [95% CI]	0.825 [0.706-0.902]	0.729 [0.590-0.834]	0.344
Sensitivity, [95% CI]	1.000 [0.758-1.000]	0.688 [0.444-0.858]	0.053
Specificity, [95% CI]	0.778 [0.637-0.875]	0.750 [0.579-0.868]	0.791
PPV, [95% CI]	0.546 [0.347-0.731]	0.579 [0.363-0.769]	1.000
NPV, [95% CI]	1.000 [0.901-1.000]	0.828 [0.655-0.924]	0.037*
False positive rate, [95% CI]	0.222 [0.125-0.363]	0.250 [0.133-0.421]	0.791
False negative rate, [95% CI]	0 [0-0.243]	0.313 [0.142-0.556]	0.053

PPV: positive predictive value; NPV: negative predictive value; *: p <0.05.

Table 3 Table 3 The binary logistic regression of risk factors affecting the diagnosis of SM invasion by EUS

Variables	binary logistic regression		
	OR	95% CI	*P* value
Age	0.959	0.893-1.029	0.243
Sex	2.121		
Male	1(reference)		0.350
Female	0.472	0.098-2.279	
Location			
Upper	0.309	0.062-1.543	0.152
Middle	1(reference)		
Lower	0.334	0.057-1.957	0.224
Size			0.036*
⩽ 3.0 cm	1(reference)		
> 3.0 cm	5.629	1.115-28.430	

Ulceration			<0.001*
No ulcer	1(reference)		
Ulcer present	29.579	5.583-156.703	
Differentiation			0.811
Differentiated	1(reference)		
Undifferentiated	0.801	0.130-4.930	
Histological invasion depth			0.076
No invasion of SM	1(reference)		
Invasion of SM or deeper	0.231	0.046-1.169	
EUS type			0.027*
Linear EUS	1(reference)		
Mini-probe EUS	5.114	1.201-21.777	

*: p <0.05.