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线阵内镜超声对胆总管微结石的诊断价值

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摘要 目的 探讨线阵内镜超声(EUS)对胆总管微结石的诊断价值。方法 选取于医院就诊并经EUS诊断为胆总管微结石和胆泥患者资料,从中筛选出住院期间行磁共振胆胰管造影(MRCP)检查和内镜逆行胰胆管造影(ERCP)诊治的患者共85例。以治疗性ERCP/内镜下十二指肠乳头括约肌切开术(EST)结果为金标准。将EUS、MRCP及诊断性ERCP结果(EUS组、MRCP组和诊断性ERCP组)分别与金标准相比较,计算3种检查方法的灵敏度、特异度、阳性预测值、阴性预测值及准确度。结果 85例患者中EUS组阳性共63例,假阳性5例;阴性共22例,假阴性1例。MRCP组阳性共49例,假阳性4例;阴性共36例,假阴性14例;诊断性ERCP组阳性共59例,假阳性10例;阴性共26例,假阴性10例。EUS组诊断胆总管微结石的灵敏度、特异度、阳性预测值、阴性预测值和准确度分别为98.3%、80.8%、92.1%、95.4%和92.9%;MRCP组为76.3%、84.6%、91.8%、61.1%和78.8%;诊断性ERCP组为83.1%、61.5%、83.1%、61.5%和76.5%。EUS诊断胆总管微结石准确度高于MRCP组($\chi^2=6.986, P<0.05$)和诊断性ERCP组($\chi^2=8.900, P<0.05$)。EUS组、MRCP组和诊断性ERCP组曲线下面积(AUC)值分别为0.895、0.804、0.723,95%CI分别为(0.802~0.988, $P<0.001$)、(0.702~0.907, $P<0.001$)和(0.598~0.848, $P=0.001$)。结论 在诊断胆总管微结石方面,EUS具有较高的诊断价值,可作为治疗性ERCP术前首选检查方法。

关键词 胆总管微结石;胆泥;内镜超声;磁共振胆胰管造影术;内镜逆行胰胆管造影术;诊断

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胆总管微结石作为胆总管结石的一种,其定义仍存在争议,多数研究将胆总管微结石与胆泥混合使用。胆总管微结石和胆泥与反复胆道疼痛、急性复发性胰腺炎及特发性胰腺炎等相关^[1-3]。基于此,2023年欧洲的一份关于急性胰腺炎可能诱因的胆总管微结石和胆泥的共识,明确定义胆总管微结石(结石直径 ≤ 5 mm且后方伴声影)和胆泥(离散的、高回声物质且后方不伴声影)^[2]。腹部B超、CT和磁共振胆胰管造影(magnetic resonance cholangio-pancreatography, MRCP)作为常规筛查胆总管结石手段,但这三种检查方法对胆总管微结石和胆泥的诊断准确性均较低^[1,4]。EUS结合内镜直视和超声成像技术,可提供高质量胆管影像,使得EUS对胆总管内的微结石和胆泥较为敏感,且无需射线及造影剂^[5]。诊断性内镜逆行胰胆管造影(endoscopic retrograde cholangiopancreatograph, ERCP)诊断胆总

管结石的灵敏度67%~94%,特异性92%~100%,然而,对胆总管微结石的误诊率达60%以上且为有创性^[6-7]。该研究回顾性分析EUS、MRCP和诊断性ERCP分别在诊断胆总管微结石中的作用,为其临床推广应用提供支持。

1 材料与方法

1.1 病例资料 选取2017年11月—2024年4月就诊安徽医科大学第一附属医院并经EUS诊断为胆总管微结石和胆泥的患者资料。从中筛选出住院期间行MRCP检查和ERCP诊治的患者共85例。纳入标准:经EUS检查诊断为胆总管微结石和胆泥且同时行MRCP检查和ERCP诊治的患者。排除标准:经EUS检查诊断为胆总管微结石和胆泥,但未行ERCP诊治或未行MRCP检查。

1.2 研究方法

1.2.1 EUS 采用日本富士胶片公司SU-9000型超声内镜,扫描模式为140°电子线阵扇形扫描。将超声探头置于十二指肠降部、球部和胃腔,扫描十二指肠乳头和胆总管末端,沿胆总管走向缓慢退至肝门部胆管,观察管腔内有无高回声和伴随声影。通常来说胆总管结石直径 ≤ 10 mm被认为是胆总管小

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结石^[8]。根据最新共识^[2],胆总管微结石定义为结石直径≤5 mm 且后方伴声影,胆总管内胆泥定义为腔内离散的、高回声物质且不伴声影。本研究中 EUS 阳性为 EUS 诊断胆总管微结石; EUS 阴性为 EUS 诊断胆泥。

1.2.2 MRCP 采用飞利浦 Ingenia 3.0 T 磁共振,观察胆道系统结构及充盈缺损情况。

1.2.3 ERCP 本研究中诊断性 ERCP 为治疗性 ERCP/内镜下十二指肠乳头括约肌切开术(endoscopic sphincterotomy , EST) 取石术前的胆管造影结果,观察有无充盈缺损影或透光区,诊断性 ERCP 阳性为可见明确的充盈缺损影或透光区,诊断性 ERCP 阴性为造影剂显示不佳或未见明显充盈缺损影;治疗性 ERCP/EST 结果为金标准,取出成型结石为阳性,而未取出、取出胆泥或泥沙样结石为阴性。

1.2.4 观察指标 收集患者的一般资料,术前 EUS、MRCP 资料以及治疗性 ERCP/EST 取石术前的胆管造影结果,以治疗性 ERCP/EST 取出结石或证实无结石为金标准,比较 EUS、MRCP 和诊断性 ERCP 对胆总管微结石的诊断价值。

1.3 统计学处理 采用 SPSS 25.0 和 Graphpad prism 8.0.2 软件对数据统计学分析,计算 EUS、MRCP 和诊断性 ERCP 诊断胆总管微结石和胆泥的灵敏度、特异度、阳性预测值、阴性预测值和准确度,灵敏度、特异度采用受试者工作特征(receiver operating characteristic , ROC) 曲线检验。计量资料以($\bar{x} \pm s$) 表示,计数资料以频数(%) 表示,计数资料组间比较采用 χ^2 检验或 Fisher 确切概率法。 $P < 0.05$ 为差异有统计学意义。

2 结果

2.1 一般资料 共选取 311 例经 EUS 诊断为胆总管微结石和胆泥患者,226 例因各种原因未行 ERCP 诊治或未行 MRCP 检查,最终 85 例患者被纳入研究,其中男性 40 例,女性 45 例,年龄 27 ~ 85(55.96 ± 14.52) 岁。

2.2 检查结果 59 例经 ERCP/EST 证实有微结石,26 例证实无微结石。59 例胆总管微结石患者中,经 EUS 确诊 58 例(阳性率 98.3%),1 例未发现结石(仅发现胆总管内松散泥沙样高回声物质不伴后方声影,因此归为胆泥);经 MRCP 确诊 45 例(阳性率 76.3%),14 例发现胆囊结石、胆囊炎、胆总管扩张或未见明显异常,未发现胆总管微结石;经诊断性 ERCP 确诊 49 例(阳性率 83.1%),10 例未发现

结石(ERCP/EST 取石术前胆管造影不佳或造影未发现充盈缺损影或透光区,导致造影假阴性)。26 例阴性患者中,经 EUS 确诊 21 例,5 例阴性误诊为微结石,其中 1 例经 ERCP/EST 未见结石,4 例仅发现胆泥或泥沙样结石,原因可能是 ERCP 术前自发排石,导致假阳性;经 MRCP 确诊 22 例,4 例阴性患者误诊为胆总管微结石,其中 1 例经 ERCP/EST 未见结石,3 例仅发现胆泥或泥沙样结石,原因亦可能是 ERCP 术前自发排石,导致假阳性;经 ERCP 确诊 16 例,10 例阴性误诊为胆总管微结石。见表 1。EUS 组灵敏度明显高于 MRCP 组(98.3% vs 76.3% , $\chi^2 = 12.911$, $P < 0.001$) 和诊断性 ERCP 组(98.3% vs 83.1% , $\chi^2 = 8.121$, $P = 0.004$)。EUS 组准确度明显高于 MRCP 组(92.9% vs 78.8% , $\chi^2 = 6.986$, $P = 0.008$) 和诊断性 ERCP 组(92.9% vs 76.5% , $\chi^2 = 8.900$, $P = 0.003$) ,MRCP 与诊断性 ERCP 的准确度差异无统计学意义(78.8% vs 76.5% , $\chi^2 = 0.136$, $P = 0.713$)。见表 2 和图 1。EUS 组、MRCP 组和诊断性 ERCP 组曲线下面积(area under curve , AUC)、95% CI 分别为(AUC = 0.895 , 95% CI: 0.802 ~ 0.988); (AUC = 0.804 , 95% CI: 0.702 ~ 0.907) 和(AUC = 0.723 , 95% CI: 0.598 ~ 0.848)。见图 2。

表 1 EUS、MRCP 和诊断性 ERCP 的检查结果与金标准比较(n)
Tab.1 Comparison of the results of EUS , MRCP and diagnostic ERCP with gold standard (n)

Methods	Gold standard	
	Positive	Negative
EUS		
Positive	58	5
Negative	1	21
MRCP		
Positive	45	4
Negative	14	22
Diagnostic ERCP		
Positive	49	10
Negative	10	16

3 讨论

胆总管微结石多由胆囊结石排出到胆道引起的,部分患者可出现反复胆道疼痛、反复发作急性胰腺炎等^[1-3]。本研究中 85 例患者均有不同程度的腹痛、黄疸、胆管扩张、肝功能异常等,其中 22 例为急性胆源性胰腺炎,40 例为胆囊术后,22 例存在胆囊结石。

表 2 EUS、MRCP 和诊断性 ERCP 对胆总管微结石的诊断准确性比较 [n(%)]

Tab.2 Comparison of diagnostic accuracy between EUS , MRCP and diagnostic ERCP in common bile duct microlithiasis [n(%)]

Groups	Sensitivity (n = 59)	Specificity (n = 26)	PPV	NPV	Accuracy (n = 85)
EUS	58 (98. 3)	21 (80. 8)	58/63 (92. 1)	21/22 (95. 4)	79 (92. 9)
MRCP	45 (76. 3)	22 (84. 6)	45/49 (91. 8)	22/36 (61. 1)	67 (78. 8)
Diagnostic ERCP	49 (83. 1)	16 (61. 5)	49/59 (83. 1)	16/26 (61. 5)	65 (76. 5)
χ^2 value	12. 911 ^a	0. 134 ^a	0. 002 ^a	8. 400 ^a	6. 986 ^a
	8. 121 ^b	2. 342 ^b	2. 295 ^b	7. 760 ^b	8. 900 ^b
	0. 837 ^c	3. 519 ^c	1. 831 ^c	0. 001 ^c	0. 136 ^c
P value	<0. 001 ^a	0. 714 ^a	0. 965 ^a	0. 004 ^a	0. 008 ^a
	0. 004 ^b	0. 126 ^b	0. 129 ^b	0. 005 ^b	0. 003 ^b
	0. 360 ^c	0. 061 ^c	0. 176 ^c	0. 973 ^c	0. 713 ^c

a: EUS vs MRCP; b: EUS vs Diagnostic ERCP; c: MRCP vs Diagnostic ERCP.

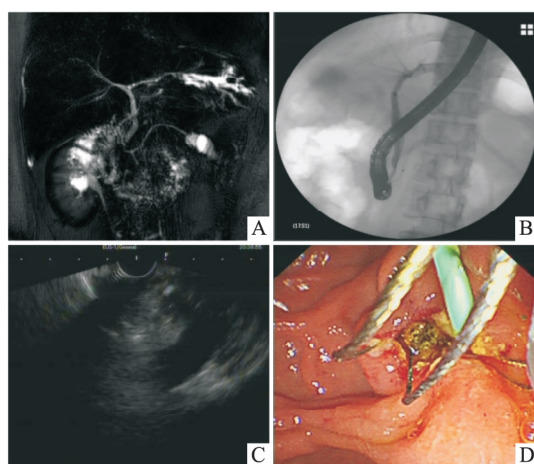


图 1 同一例患者 EUS、MRCP 和诊断性 ERCP 检测胆总管微结石的结果比较

Fig.1 Comparison of the results of EUS , MRCP and diagnostic ERCP for detecting common bile duct microlithiasis in the same patient

A: MRCP showing none microlithiasis in common bile duct; B: Diagnostic ERCP showing insufficient contrast agents in the terminal common bile duct and none filling defect in the common bile duct; C: EUS showing a stone 4.6 mm (in diameter) with acoustic shadowing in the terminal common bile duct near the duodenal papilla opening; D: Extracting a shaped brown stone under ERCP/EST.

MRCP 基于胆汁和胰液中含有大量自由水 ,在检测过程中采用 T2 加权成像技术 ,获取胆胰管图像 ,在诊断胆总管结石方面有较高的准确性 ,且具有无电离辐射、非侵入性等优势 ,但 MRCP 也存在诊断上的不足 ,如成像角度、静态成像等技术的影响 ,而且胆总管微结石常受高信号的胆汁掩盖而不易显露 ,导致 MRCP 诊断胆总管微结石的灵敏度下降 ,假阴性率增加^[4,7,9-11]。EUS 将内镜与高分辨的超声显像相结合 ,贴近病变且使胆胰管不受胃肠气体的影响 ,从而更加清晰的显像 ,尤其线阵 EUS ,不仅

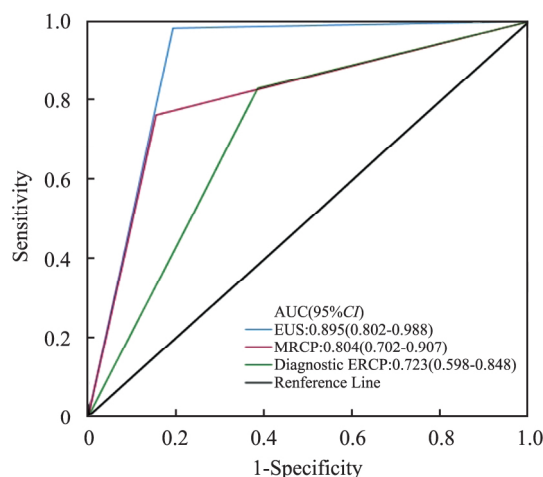


图 2 EUS、MRCP 和诊断性 ERCP 诊断胆总管微结石的 ROC 曲线
Fig.2 The ROC curve of EUS , MRCP and diagnostic ERCP for diagnosing common bile duct microlithiasis

可以清楚显示胆总管微结石 ,还可以显示较为松散的胆泥^[5,12]。一项荟萃分析显示^[13] ,EUS 和 MRCP 诊断胆总管结石的特异性均较高 (0. 90 vs 0. 92) 且差异无统计学意义 ,但 EUS 的灵敏度优于 MRCP (0. 97 vs 0. 87) ,EUS 的整体诊断 OR 明显高于 MRCP(162. 5 vs 79. 0) ,主要原因是在检测微结石方面 ,虽然两者的特异性差异不具有显著性 ,但是 EUS 的敏感性显著高于 MRCP。本研究中 ,59 例经金标准诊断胆总管微结石患者中 ,EUS 组真阳性 58 例 (阳性率 98. 3%) ,MRCP 组 45 例(阳性率 76. 3%) ,EUS 诊断胆总管微结石的灵敏度明显高于 MRCP 组。诊断胆总管微结石准确性方面 ,EUS 组也明显高于 MRCP 组(92. 9% vs 78. 8%) 。EUS 组的 AUC 高于 MRCP 组(0. 895 vs 0. 804) ,与上述研究结果一致。因而对高度怀疑胆总管微结石 ,而 MRCP 阴性 ,则应该通过 EUS 明确诊断。若 EUS 已经确诊 ,则不必再行 MRCP。

一项研究^[14]显示,EUS诊断胆总管结石的准确性与ERCP相当,但不良事件的发生率较低。因此,在临床诊断时,对于风险不确定的患者,在ERCP术前行EUS可以避免不必要的ERCP。另一项荟萃^[15]分析对4项临床随机对照研究在疑似胆总管结石患者进行ERCP之前实施EUS(EUS优先策略)和直接ERCP(ERCP优先策略)的疗效比较,EUS优先策略可以使67.1%的患者避免ERCP,从而减少不良事件的发生。但对于胆总管微结石或胆泥的诊断,尤其胆总管末端或乳头附近结石,可能由于镜身角度、乳头位置及胆道造影剂显影不佳等因素,导致造影假阴性,诊断性ERCP的假阴性率较高^[7]。本研究中,诊断性ERCP组真阳性49例(真阳性率83.1%),假阴性率38.5%(10/26),而EUS组真阳性58例(真阳性率98.3%),假阴性率4.5%(1/22),EUS诊断胆总管微结石的灵敏度明显高于诊断性ERCP组(98.3% vs 83.1%),EUS组准确度(92.9% vs 76.5%)和AUC(0.895 vs 0.723)均明显高于诊断性ERCP组。而假阴性率,EUS组明显低于诊断性ERCP组(4.5% vs 38.5%),与上述研究结论基本一致。

本研究中,最终纳入研究病例数相对较少,考虑有以下3个方面原因:首先,本研究中严格按照胆总管微结石和胆泥的最新共识定义,筛选入组病例;其次,部分患者行了腹部B超或CT提示胆总管扩张、胆总管结石,未再行MRCP;最后,部分患者虽住院完成MRCP检查,但因各种原因未进一步行ERCP诊治。以上患者在本研究中均予以除外。

综上所述,在诊断胆总管微结石方面,与MRCP和诊断性ERCP相比,EUS具有明显优势,可成为ERCP术前筛查的首选检查方法。可以尽可能避免后续不必要的诊断性ERCP,从而减少不良事件的发生,让患者更获益。

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Diagnostic value of endoscopic ultrasonography for common bile duct microlithiasis

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Abstract *Objective* To investigate the diagnostic value of linear array endoscopic ultrasonography (EUS) for common bile duct microlithiasis. *Methods* Data of patients who attended in the hospital and diagnosed as common bile duct microlithiasis and biliary sludge by EUS were selected. A total of 85 patients with magnetic resonance cholangiopancreatography (MRCP) examination and ERCP treatment during hospitalization were enrolled. The results of endoscopic retrograde cholangiopancreatography/endoscopic sphincterotomy (ERCP/EST) were the gold standard for diagnosis. The results of EUS , MRCP , and diagnostic ERCP were compared with the gold standard , and the sensitivity , specificity , positive predictive value , negative predictive value , and diagnostic accuracy of the three methods were calculated , respectively. The chi-square test was used for comparison of the above indices. *Results* Of all 85 patients , 63 had positive EUS results , among whom 5 had false positive results; 22 had negative EUS results , among whom 1 had false negative results. Of all 85 patients , 49 had positive MRCP results , among whom 4 had false positive results; 36 had negative MRCP results , among whom 14 had false negative results. Of all 85 patients , 59 had positive diagnostic ERCP results , among whom 10 had false positive results; 26 had negative diagnostic ERCP results , among whom 10 had false negative results. The sensitivity , specificity , positive predictive value (PPV) , negative predictive value (NPV) , and accuracy of EUS in diagnosing common bile duct microlithiasis were 98. 3% , 80. 8% , 92. 1% , 95. 4% and 92. 9% , respectively. For MRCP , these values were 76. 3% , 84. 6% , 91. 8% , 61. 1% and 78. 8% , respectively. For diagnostic ERCP , these values were 83. 1% , 61. 5% , 83. 1% , 61. 5% and 76. 5% , respectively. The EUS group had a significantly higher accuracy than the MRCP group ($\chi^2 = 6. 986$, $P < 0. 05$) and diagnostic ERCP group ($\chi^2 = 8. 900$, $P < 0. 05$) . The areas under the ROC curves (AUC) and 95% CI of EUS group , MRCP group and diagnostic ERCP were 0. 895 (95% CI: 0. 802 - 0. 988 , $P < 0. 001$) , 0. 804 (95% CI: 0. 702 - 0. 907 , $P < 0. 001$) and 0. 723 (95% CI: 0. 598 - 0. 848 , $P = 0. 001$) , respectively. *Conclusion* EUS has a high diagnostic value in the diagnosis of common bile duct microlithiasis and thus can be used as the preferred examination before therapeutic ERCP.

Key words common bile duct microlithiasis; biliary sludge; endoscopic ultrasonography; magnetic resonance cholangiopancreatography; endoscopic retrograde cholangiopancreatography; diagnosis

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