

· 肝纤维化及肝硬化 ·

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不同无创诊断模型对代偿期乙型肝炎肝硬化显著门静脉高压食管胃静脉曲张的诊断价值

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摘要: **目的** 代偿期乙型肝炎肝硬化显著门静脉高压患者发生食管胃静脉曲张(GOV)风险较大,通过评价不同无创诊断模型对GOV的诊断价值,为早期诊断GOV提供依据。**方法** 选取2017年11月—2023年11月广东省中医院就诊的代偿期乙型肝炎肝硬化显著门静脉高压患者108例,根据胃镜下是否伴发GOV将患者分为GOV组和非GOV组(NGOV组)。收集患者的年龄、性别、影像学、实验室指标等结果。计数资料组间比较采用 χ^2 检验;正态分布的计量资料两组间比较采用成组 t 检验;非正态分布的数据两组间比较采用Mann-Whitney U 检验。采用受试者操作特征曲线(ROC曲线)评估FIB-4、LOK指数、LPRI、APRI、AAR等5种评分模型的诊断价值;利用二元Logistic回归构建联合模型,将联合模型与5种评分模型单独应用时的ROC曲线下面积(AUC)比较;采用DeLong检验对各无创诊断模型的AUC值进行两两比较。**结果** GOV组55例,NGOV组53例。GOV组的年龄高于NGOV组[(52.64 $\pm$ 1.44)岁 vs (47.96 $\pm$ 1.68)岁],ALT[42.00(24.00~117.00) U/L vs 82.00(46.00~271.00) U/L]、AST[44.00(32.00~96.00) U/L vs 62.00(42.50~154.50) U/L]、PLT[100.00(69.00~120.00) $\times 10^9$ /L vs 119.00(108.50~140.50) $\times 10^9$ /L]低于NGOV组,差异均有统计学意义(统计值分别为3.230、-3.065、-2.351、-3.667, P 值均 <0.05)。ROC曲线分析显示, FIB-4、LOK指数、LPRI、AAR单独诊断GOV的AUC分别为0.667、0.681、0.730、0.639(P 值均 <0.05),GOV阳性诊断率分别为69.97%、65.28%、67.33%、58.86%,AUC值比较差异均无统计学意义(P 值均 >0.05),APRI单独应用无诊断价值($P>0.05$)。利用二元Logistic回归构建联合模型LAF,AUC为0.805,GOV阳性诊断率为75.80%,明显高于FIB-4、LOK指数、LPRI、AAR单独应用时的AUC值(Z 值分别为-2.773、-2.479、-2.206、-2.672, P 值均 <0.05)。**结论** FIB-4、LOK指数、LPRI、AAR对代偿期乙型肝炎肝硬化显著门静脉高压患者发生GOV诊断价值相似,APRI单独应用无诊断价值,联合模型LAF的诊断效能最佳,对临床推广和应用具有一定参考价值。

关键词: 肝硬化; 乙型肝炎; 高血压, 门静脉; 食管和胃静脉曲张

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Value of different noninvasive diagnostic models in the diagnosis of esophageal and gastric varices with significant portal hypertension in compensated hepatitis B cirrhosis

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Abstract: Objective To investigate the value of different noninvasive diagnostic models in the diagnosis of esophageal and gastric varices since there is a high risk of esophageal and gastric varices in patients with compensated hepatitis B cirrhosis and significant portal hypertension, and to provide a basis for the early diagnosis of esophageal and gastric varices. **Methods** A total of 108 patients with significant portal hypertension due to compensated hepatitis B cirrhosis who attended Guangdong Provincial Hospital of Traditional Chinese Medicine from November 2017 to November 2023 were enrolled, and according to the presence or absence of esophageal and gastric varices under gastroscopy, they were divided into esophageal and gastric varices group (GOV group) and non-esophageal and gastric varices group (NGOV group). Related data were collected, including age, sex, imaging findings, and laboratory markers. The chi-square test was used for comparison of categorical data between groups; the least significant difference *t*-test was used for comparison of normally distributed continuous data between groups, and the Mann-Whitney *U* test was used for comparison of non-normally distributed continuous data between groups. The receiver operating characteristic (ROC) curve was plotted to evaluate the diagnostic value of five scoring models, i.e., fibrosis-4 (FIB-4), LOK index, LPRI, aspartate aminotransferase-to-platelet ratio index (APRI), and aspartate aminotransferase/alanine aminotransferase ratio (AAR). The binary logistic regression method was used to establish a combined model, and the area under the ROC curve (AUC) was compared between the combined model and each scoring model used alone. The Delong test was used to compare the AUC value between any two noninvasive diagnostic models. **Results** There were 55 patients in the GOV group and 53 patients in the NGOV group. Compared with the NGOV group, the GOV group had a significantly higher age (52.64 ± 1.44 years vs 47.96 ± 1.68 years, $t = 0.453$, $P < 0.05$) and significantly lower levels of alanine aminotransferase [42.00 ($24.00 - 17.00$) U/L vs 82.00 ($46.00 - 271.00$) U/L, $Z = -3.065$, $P < 0.05$], aspartate aminotransferase [44.00 ($32.00 - 96.00$) U/L vs 62.00 ($42.50 - 154.50$) U/L, $Z = -2.351$, $P < 0.05$], and platelet count [100.00 ($69.00 - 120.00$) $\times 10^9/L$ vs 119.00 ($108.50 - 140.50$) $\times 10^9/L$, $Z = -3.667$, $P < 0.05$]. The ROC curve analysis showed that FIB-4, LOK index, LPRI, and AAR used alone had an accuracy of 0.667, 0.681, 0.730, and 0.639, respectively, in the diagnosis of esophageal and gastric varices (all $P < 0.05$), and the positive diagnostic rates of GOV were 69.97%, 65.28%, 67.33%, and 58.86%, respectively, with no significant differences in AUC values (all $P > 0.05$), while APRI used alone had no diagnostic value ($P > 0.05$). A combined model (LAF) was established based on the binary logistic regression analysis and had an AUC of 0.805 and a positive diagnostic rate of GOV of 75.80%, with a significantly higher AUC than FIB-4, LOK index, LPRI, and AAR used alone ($Z = -2.773, -2.479, -2.206$, and -2.672 , all $P < 0.05$). **Conclusion** FIB-4, LOK index, LPRI, and AAR have a similar diagnostic value for esophageal and gastric varices in patients with compensated hepatitis B cirrhosis and significant portal hypertension, and APRI alone has no diagnostic value. The combined model LAF had the best diagnostic efficacy, which provides a certain reference for clinical promotion and application.

Key words: Liver Cirrhosis; Hepatitis B; Hypertension, Portal; Esophageal and Gastric Varices

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肝硬化患者大约一半合并有食管胃静脉曲张(gastroesophageal varices, GOV)^[1], GOV破裂出血年发生率为5%~15%, 6周病死率为20%, 因此, 代偿期肝硬化患者应尽早确定是否存在GOV^[2]。Baveno VII共识^[3]建议将肝硬度值

(liver stiffness measurements, LSM) ≥ 25.0 kPa作为确定乙型肝炎肝硬化患者伴有显著门静脉高压的无创诊断标准, 并建议此类患者行胃镜检查筛查GOV。有研究表明肝纤维化4因子指数(FIB-4)、LOK指数、AST/PLT比值

(APRI指数)、AST/ALT比值(AAR)等常见肝纤维化无创诊断模型,对乙型肝炎、丙型肝炎或酒精性相关肝硬化患者的GOV无创诊断有一定临床价值,但诊断准确度一般,胃镜作为侵入性检查仍是目前确定GOV的主要方法^[4-5]。存在显著门静脉高压肝硬化患者发生GOV风险较高^[6],而以上模型针对代偿期乙型肝炎肝硬化显著门静脉高压患者GOV诊断价值是未知的,所以探索这类模型对GOV的诊断价值是有必要的。关于LSM和PLT建立的评分指数(LPRI),目前有研究表明其对慢性乙型肝炎患者肝纤维化的诊断和分期有一定价值^[7],而对代偿期乙型肝炎肝硬化显著门静脉高压患者GOV的诊断价值尚待研究。故本研究以胃镜检查为GOV诊断金标准,评估不同无创诊断模型对Baveno VII共识中有胃镜检查指征人群GOV的诊断价值。

1 资料与方法

1.1 研究对象 选取2017年11月—2023年11月广东省中医院肝病科门诊或住院部治疗的代偿期乙型肝炎肝硬化显著门静脉高压患者,根据胃镜下是否伴发GOV将患者分为GOV组和非GOV组(NGOV组)。慢性HBV感染诊断标准:血清HBsAg和/或血清HBV DNA阳性6个月以上^[8];肝硬化诊断标准:组织学、B超、LSM、CT或磁共振成像(MRI)等检查提示肝硬化^[9];显著门静脉高压诊断标准:LSM $\geq$ 25.0 kPa^[3]。纳入标准:(1)符合慢性HBV感染诊断标准;(2)符合肝硬化诊断标准;(3)符合显著门静脉高压诊断标准;(4)临床资料完整。排除标准:(1)合并其他病因导致的肝损伤(如酒精性肝病、药物性肝损伤、自身免疫性肝病);(2)合并其他嗜肝病毒感染;(3)既往有腹水、食管静脉曲张破裂出血或肝性脑病等肝硬化失代偿期事件;(4)伴有肝癌或其他系统肿瘤;(5)既往有如肝移植、经颈静脉肝内门体分流术、脾切除、食管胃静脉套扎等手术史。

1.2 研究方法

1.2.1 收集资料 包括人口学资料、姓名、性别、年龄、临床诊断、现病史、既往史、个人史;血清学指标:ALT、AST、TBil、Alb、ALP、GGT、PLT、国际标准化比值(INR);FibroScan检测的LSM;腹部B超/CT/MRI、肝组织病理学、胃镜检查结果。

1.2.2 计算公式 (1)FIB-4=年龄 $\times$ AST/(PLT $\times$ ALT^{1/2});(2)LPRI=LSM $\times$ 100/PLT;(3)LOK指数=(1.26 $\times$ AST/ALT)+(5.27 $\times$ INR)-(0.008 9 $\times$ PLT)-5.56;(4)APRI=[(AST/AST正常值上限) $\times$ 100]/PLT;(5)AAR=AST/ALT;

(6)阳性预测值=(Se $\times$ P)/[Se $\times$ P+(1-Se) $\times$ (1-P)];阴性预测值=(Sp $\times$ P)/[(1-Se) $\times$ P+Sp $\times$ (1-P)](P为样本人群患病率,Se和Sp分别代表诊断试验的敏感度和特异度)。

1.3 统计学方法 利用SPSS 26.0进行数据分析。正态分布的计量资料以 $\bar{x}\pm s$ 表示,两组间比较采用成组 t 检验。非正态分布的计量资料用 $M(P_{25}\sim P_{75})$ 表示,两组间比较采用Mann-Whitney U 检验。计数资料组间比较采用 χ^2 检验。采用受试者操作特征曲线(ROC曲线)评估模型的诊断价值;使用Spearman进行评分模型与GOV的相关性分析;利用二元Logistic回归构建联合模型,将联合模型与各种评分模型单独使用情况下的ROC曲线下面积(AUC)进行比较,采用Delong检验对各诊断模型AUC进行两两比较。利用公式计算AUC的阳性预测值和阴性预测值。 $P<0.05$ 为差异具有统计学意义。

2 结果

2.1 一般资料 共纳入108例患者,GOV组55例,NGOV组53例。其中男87例(80.56%),女21例(19.44%),平均(50.34 $\pm$ 11.67)岁。GOV组患者年龄高于NGOV组,而ALT、AST、PLT水平低于NGOV组,差异均有统计学意义(P 值均 <0.05);两组患者其余指标差异均无统计学意义(P 值均 >0.05)(表1)。

2.2 FIB-4、LOK指数、LPRI、APRI、AAR单独或联合应用对GOV的诊断价值比较 ROC曲线分析显示,FIB-4、LOK指数、LPRI、AAR单独应用对GOV有诊断价值(P 值均 <0.05),AUC分别为0.667、0.681、0.730、0.639,AUC值两两比较差异均无统计学意义(Z 值分别为1.165、0.857、1.173、-0.237、0.386、0.834, P 值均 >0.05);APRI单独应用对GOV无诊断价值($P>0.05$);利用二元Logistic回归分析构建LPRI、APRI、FIB-4联合模型LAF,LAF=-2.357+0.058 $\times$ LPRI-0.329 $\times$ APRI+0.334 $\times$ FIB-4,联合模型LAF与FIB-4、LOK指数、LPRI、APRI、AAR的AUC值比较发现,联合模型LAF的AUC值最大,为0.805,且比较差异均有统计学意义(Z 值分别为-2.773、-2.479、-2.206、-4.885、-2.672, P 值均 <0.05)(表2,图1)。

3 讨论

《指南》^[2]指出,代偿期乙型肝炎肝硬化显著门静脉高压患者易发生腹水、GOV及破裂出血、肝性脑病等失代偿事件,GOV破裂出血死亡率高,因此早期识别GOV对于阻断疾病发生发展极为重要。胃镜为GOV诊断金

表1 两组患者基线资料比较

Table 1 Comparison of baseline characteristics among the two groups of patients

指标	GOV组(n=55)	NGOV组(n=53)	统计值	P值
男/女(例)	48/7	39/14	$\chi^2=3.230$	0.072
年龄(岁)	52.64±1.44	47.96±1.68	$t=0.453$	0.037
LSM(kPa)	32.40(26.60~38.90)	29.90(26.70~35.80)	$Z=-1.025$	0.306
ALT(U/L)	42.00(24.00~117.00)	82.00(46.00~271.00)	$Z=-3.065$	0.002
AST(U/L)	44.00(32.00~96.00)	62.00(42.50~154.50)	$Z=-2.351$	0.019
TBil(mmol/L)	24.30(15.80~36.18)	22.90(15.70~41.25)	$Z=-0.246$	0.805
Alb(g/L)	39.36(34.00~43.50)	39.36(38.85~43.40)	$Z=-0.998$	0.318
ALP(U/L)	110.00(84.00~126.00)	115.60(86.00~115.60)	$Z=-0.291$	0.771
GGT(U/L)	88.00(43.00~120.27)	99.00(65.50~160.50)	$Z=-1.692$	0.091
INR	1.18(1.13~1.22)	1.18(1.14~1.22)	$Z=-0.461$	0.645
PLT($10^9/L$)	100.00(69.00~120.00)	119.00(108.50~140.50)	$Z=-3.667$	<0.001

表2 各无创模型单独或联合应用对GOV诊断效能的比较

Table 2 Comparison of the diagnostic efficacy of non-invasive diagnostic models alone or in combination for esophageal and gastric varices

指标	临界值	AUC(95%CI)	P值	敏感度(%)	特异度(%)	阳性预测值(%)	阴性预测值(%)	P值 ¹⁾
FIB-4	3.425	0.667(0.564~0.770)	0.003	65.5	69.8	69.97	67.97	0.005
LOK	0.777	0.681(0.580~0.781)	0.001	70.9	60.4	65.28	61.90	0.014
LPRI	0.397	0.730(0.635~0.824)	<0.001	66.5	75.5	67.33	77.42	0.028
AAR	0.245	0.639(0.535~0.743)	0.013	83.5	39.6	58.86	72.66	0.007
APRI	0.546	0.466(0.355~0.576)	0.537	96.4	13.2	53.54	80.82	<0.001
LAF	-0.185	0.805(0.722~0.887)	<0.001	80.0	73.6	75.80	56.56	

注:1)P值表示联合模型LAF与其他模型AUC比较结果。

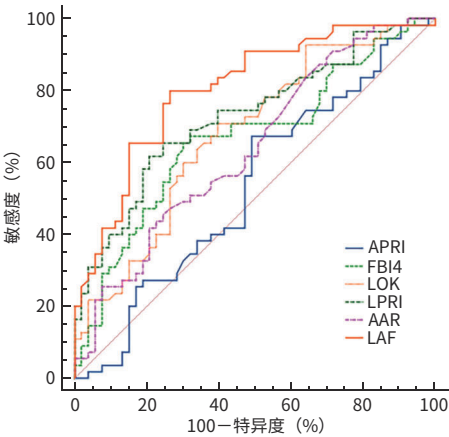


图1 不同无创诊断模型诊断GOV的ROC曲线分析

Figure 1 ROC curve analysis of different non-invasive diagnostic models for esophageal and gastric varices

标准,因其为有创检查,有一定出血风险,无创诊断模型的研究一直是临床研究热点。关于代偿期乙型肝炎肝硬化患者GOV无创诊断模型,目前尚无指南或是共识推荐,而不同研究^[4,10-13]对FIB-4、LOK指数、APRI、AAR关于代偿期乙型肝炎肝硬化人群的GOV诊断价值的认识也存在分歧。因此,重新评估FIB-4、LOK指数、APRI、

AAR对于Baveno VII共识中有胃镜检查指征人群GOV诊断价值是有必要的。本研究以胃镜检查为GOV诊断的金标准,探讨不同无创诊断模型对Baveno VII共识有胃镜检查指征人群GOV的诊断价值。

本研究发现GOV组和NGOV组患者在年龄、ALT、AST、PLT方面差异显著,其余指标差异无统计学意义。进一步建立ROC曲线以评价诊断效能,发现各指标单独应用时,LPRI评分最佳,LOK指数、FIB-4、AAR、APRI次之。相关文献^[14]报道,LSM联合APRI、FIB-4,在一定程度上能够提高肝硬化患者食管静脉曲张的诊断效能。利用二元Logistic回归构建LPRI、APRI、FIB-4联合模型LAF,并将联合模型LAF和其他模型单独应用时的AUC比较,结果显示联合模型LAF诊断效能更优,差异均具有统计学意义。

FIB-4、APRI、AAR、LOK指数和LPRI^[7,15-20]最初用于评估病毒性肝炎患者肝纤维化及其程度,后来有研究^[21-22]表明,FIB-4、APRI、AAR、LOK指数可用于乙型肝炎肝硬化患者GOV诊断。本研究发现,FIB-4、LOK指数、AAR的AUC值均在0.6~0.7,对代偿期乙型肝炎肝硬化显著门静脉高压患者的GOV诊断效能相似,有一定

临床价值,但准确度一般。Deng等^[23]在一项荟萃分析中发现,FIB-4、LOK指数、AAR对代偿期乙型肝炎肝硬化患者GOV诊断效能相似,与本研究结论一致。Deng等^[23]研究中纳入的人群和本研究中的研究对象存在交叉,这可能是影响研究结果的原因,但仍需要更多的研究论证。另外,本研究还发现APRI单独应用对GOV无诊断价值,这与Deng等^[4]研究结论截然不同,本研究只纳入乙型肝炎肝硬化患者,Deng等研究人群中还纳入了丙型肝炎、酒精性相关肝硬化患者,这可能是造成这一结果偏差的原因^[24]。本研究首次探索了LPRI对代偿期乙型肝炎肝硬化显著门静脉高压患者GOV诊断效能,发现LPRI单独应用诊断GOV的AUC超过0.7,对临床诊断GOV有一定价值,但有待更多的代偿期乙型肝炎肝硬化显著门静脉高压患者的研究进一步验证。联合FIB-4、APRI、LPRI构建模型LAF,AUC达到最大,具有较好的敏感度和特异度,这表明几个无创诊断模型中联合模型LAF的诊断效能最佳,而且ALT、AST、PLT、LSM、年龄、INR等指标容易获得,值得临床推广。

综上所述,FIB-4、LOK指数、LPRI、AAR对代偿期乙型肝炎肝硬化显著门静脉高压患者GOV诊断价值相似,APRI单独应用无诊断价值,联合模型LAF诊断效能最佳,对临床实际诊断GOV提供了参考价值。本研究优势在于基于Baveno VII共识显著门静脉高压无创诊断标准和胃镜“金标准”下获得的样本量,但仅为回顾性、单中心研究,样本量尚少,未来仍需大样本、多中心数据进一步研究验证。

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读者·作者·编者

《临床肝胆病杂志》关于伦理审查的要求

根据《世界医学协会赫尔辛基宣言》《涉及人的健康相关研究国际伦理准则》和我国《涉及人的生物医学研究伦理审查办法》《人体器官移植条例》《人类辅助生殖技术和人类精子库伦理原则》《药物临床试验伦理审查工作指导原则》等的相关规定以及国际通行的动物福利和伦理准则,本刊要求:

凡是动物实验研究,必须符合我国实验动物管理和使用相关规定,并经由动物伦理委员会审批;凡是涉及人的生物医学研究,无论是前瞻性研究、横断面研究、回顾性研究,还是在人体上或使用取自人体的标本等进行的研究,亦或是采用心理学、流行病学、社会医学方法对人群进行的调查研究,都需要得到患者知情同意、通过伦理委员会审批。作者须在研究方法中列明开展伦理审查的机构委员会名称及审查文件批号。

本刊伦理内容规范书写格式如下:

本研究方案经由***医院伦理委员会(或实验动物伦理委员会)审批,批号:ABC1234,患者均签署知情同意书(或符合实验室动物管理与使用准则)。