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· 临床研究 ·

## 肝纤维化严重程度预测指标分析与预测模型构建

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### 摘要

**背景与目的:** 肝纤维化的严重程度与肝切除术后并发症的发生率密切相关, 全面且准确地对患者的肝纤维化程度进行术前评估对于手术方式的选择及患者的预后至关重要。本研究试图探索能否通过某些检查指标亦或是由这些指标所构建的预测模型来准确且全面地预测患者肝纤维化的严重程度。

**方法:** 选择2018年9月—2019年12月期间共计106例肝切除术治疗患者的临床数据进行回顾性分析, 并根据术后病理切片的肝纤维化等级(Laennec分期系统)分为无或低级别肝纤维化组(50例)和高级别肝纤维化组(56例)。先将两组患者的检查指标全部进行单因素分析, 选出其中有统计学差异的指标纳入多因素Logistic回归分析, 筛选出独立预测指标并建立综合预测模型。最后建立受试者工作特征(ROC)曲线, 评价独立预测指标及综合预测模型的预测效果。

**结果:** 单因素分析结果显示, 两组之间白细胞(WBC)、血小板(PLT)、凝血酶原时间(PT)、血肌酐(Cr)、吲哚氰绿15分钟滞留率(ICG15)、门静脉宽度及门静脉流速的差异具有统计学意义(均 $P<0.05$ )。多因素回归分析结果显示, ICG15与门静脉宽度为高级别肝纤维化的独立预测指标(均 $P<0.05$ ), 以此建立综合预测模型为 $\text{Logit}(P) = -6.026 + 0.44 \times \text{ICG15} + 0.299 \times \text{门静脉宽度}$ 。该综合模型预测高级别肝纤维化的ROC曲线的AUC为0.88, 截断值为0.359时, 敏感度为89.3%, 特异度为74%。该模型的预测效果优于两个独立预测指标。

**结论:** ICG15与门静脉宽度是肝纤维化的严重程度独立评价指标, 联合ICG15与门静脉宽度的综合预测模型能对患者肝纤维化严重程度进行更为准确的术前评估, 具有一定的临床参考价值。

### 关键词

肝切除术; 肝硬化; 比例危险度模型

中图分类号: R657.3

## Analysis of prediction indicators and prediction model construction for severity of liver fibrosis

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### Abstract

**Background and Aims:** The severity of liver fibrosis is closely related to the incidence of complications after hepatectomy. Thus, a comprehensive and accurate preoperative assessment of the patient's liver fibrosis is of great importance for surgical procedure selection and prognosis of patients. Thus, this study was aimed to explore whether certain indicators or a prediction model constructed from these indicators can accurately and comprehensively predict the severity of liver fibrosis in patients.

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**Methods:** The clinical data of 106 patients who underwent hepatectomy from September 2018 to December 2019 were collected for retrospective analysis, and those patients were divided into none/low-stage fibrosis group (50 patients) and high-stage fibrosis group (56 patients) based on the histological classification of liver fibrosis (Laennec staging system). Firstly, all the tested indexes of the two groups of patients were assessed by univariate analysis, and then those with significant differences were included in the multivariate regression analysis to screen out the independent prediction indicators and establish an integrated prediction model. Finally, the receiver operating characteristic (ROC) curve was established to evaluate the predictive efficacy of the independent predictive indicators and the integrated prediction model.

**Results:** Results of univariate analysis showed that there were significant differences between the two groups in terms of white blood cell (WBC), platelet (PLT), prothrombin time (PT), creatine (Cr), indocyanine green retention rate at 15 minutes (ICG15), width of portal vein and velocity of portal blood flow (all  $P < 0.05$ ). Results of multivariate regression analysis revealed that ICG15 and the width of portal vein were independent predictors for high-stage liver fibrosis (both  $P < 0.05$ ), and the established integrated predictive model based on the two variables was  $\text{Logit}(P) = -6.026 + 0.44 \times \text{ICG15} + 0.299 \times \text{width of portal vein}$ . Moreover, the area under ROC curve (AUC) of the integrated predictive model was 0.88, with a sensitivity of 89.3% and a specificity of 74% at the cut-off value of 0.359. The predictive efficacy of the integrated prediction model was superior to either prediction indicator alone.

**Conclusion:** ICG15 and the width of portal vein are independent evaluation indicators for the severity of liver fibrosis, and the integrated prediction model combined with ICG15 and portal vein width offers more accurate preoperative assessment of the severity of liver fibrosis in patients, which has certain clinical reference value.

#### Key words

Hepatectomy; Liver Cirrhosis; Proportional Hazards Models

CLC number: R657.3

随着外科手术技术的进步<sup>[1]</sup>, 肝脏手术的安全性已经得到了极大的提升, 围术期病死率已经降至5%以下<sup>[2-3]</sup>, 但是术后并发症的发生情况仍不容乐观<sup>[4]</sup>。而严重的肝纤维化则会在很大程度上增加发生术后并发症的风险<sup>[5]</sup>, 如肝功能衰竭<sup>[6-7]</sup>, 腹腔积液<sup>[8]</sup>等。肝脏手术术前对于肝纤维化诊断的金标准仍为肝穿刺活检这一有创检查<sup>[9]</sup>, 而穿刺活检本身存在一定的风险<sup>[10]</sup>且可能存在样本误差<sup>[11-12]</sup>。目前用于患者的肝脏情况术前评估的其他途径通常包括: 生化指标(如血常规、凝血功能及肝肾功能等)、Child-Pugh分级、吲哚氰绿清除实验<sup>[13]</sup>、门静脉超声检查<sup>[14]</sup>等这些途径的优点在于风险低且创伤小或者没有创伤, 而缺点则是单一的检查仅仅只能从某一个角度间接地了解患者的肝脏情况, 相对来说较为片面。而本研究的目的则是找出哪些检查对于肝纤维化的术前预测更有意义, 以及能否联合其中某些检查建立一个肝纤维化的术前预测模型, 以此来更加全面且准确地预测患者肝纤维化的严重程度, 进一步降低肝切

除术后发生并发症的风险。

## 1 资料与方法

### 1.1 一般资料

收集2018年9月—2019年12月期间共计106例患者的临床数据进行回顾性分析。纳入标准: (1) 年龄18~75岁; (2) 首次行肝切除术。排除标准: (1) 术前肝功能Child-Pugh分级为C级; (2) 胆道梗阻; (3) 肾功能不全; (4) 术前严重心、脑、肺等其他重要脏器疾病。本研究已经被湘雅医院伦理委员会批准(IRB[S]NO:202005056), 所有患者均对本研究知情, 且签署了知情同意书。

### 1.2 病理分级

取所有患者手术标本中的健康肝组织进行研究, 且每个样本都由2名经验丰富的病理科医生依据Laennec病理分级标准<sup>[15]</sup>进行分级。将Laennec分级为0、1、2和3级的患者归为无或低级别肝纤维化组; Laennec分级为4级的患者则被归为高级

别肝纤维化组。所有病理切片都经过HE染色并由Olympus BX53显微镜进行检查。

### 1.3 研究设计

将患者依据肝纤维化程度分为无或低级别肝纤维化组和高级别肝纤维化组。第一步,先将两组患者的所有检查指标进行单因素分析,以筛选出其中有统计学差异的指标;第二步,再将以上指标纳入多因素Logistic回归分析,筛选出独立预测指标并建立预测模型;第三步,建立受试者工作特征(ROC)曲线,评价独立预测指标及综合预测模型的预测效果。

### 1.4 检查指标

所有患者均在入院后第2天清晨空腹采外周静脉血送检,生化指标包括白细胞(WBC)、血小板(PLT)、白蛋白(ALB)、血清总胆红素(TBIL)、凝血酶原时间(PT)、血肌酐(Cr)和乙型肝炎表面抗原(HBsAg)。结合生化指标及临床表现得到Child-Pugh分级。吲哚氰绿清除试验记录患者吲哚氰绿15分钟滞留率(ICG15)。门静脉超声检查记录患者的门静脉宽度及流速。

### 1.5 统计学处理

计量资料采用均数±标准差( $\bar{x} \pm s$ )表示,组间比较采用t检验;计数资料采用例数百分率[n(%)]表示,组间比较采用 $\chi^2$ 检验。将差异有统计学意义的指标纳入二分类Logistic回归分析,筛选出独立预测指标并利用其建立回归模型,采用ROC曲线评价预测模型诊断效率。使用SPSS 26分析全部数据,以 $P < 0.05$ 为差异有统计学意义。

## 2 结果

### 2.1 单因素分析结果

本研究共纳入106例患者,其中男97例;女9例。所有患者均因肝脏恶性肿瘤行肝脏切除术,其中肝细胞癌(HCC)患者97例;胆管细胞癌(ICC)患者9例。依据肝纤维化严重程度将其中50例归入无或低级别肝纤维化组;56例归入高级别肝纤维化组。单因素组间比较结果显示,两组之间WBC、PLT、PT、Cr、ICG15、门静脉宽度及门静脉流速的差异具有统计学意义(均 $P < 0.05$ )(表1)。

表1 两组患者相关指标的单因素分析

Table 1 Univariate analysis of related indicators of the two groups of patients

因素	无或低级别组 (n=50)	高级别组 (n=56)	$\chi^2/t$	P	因素	无或低级别组 (n=50)	高级别组 (n=56)	$\chi^2/t$	P
性别[n(%)]					ALB(g/L, $\bar{x} \pm s$ )	41.48 ± 4.33	40.22 ± 3.68	1.616	0.109
男	44 (88.0)	53 (94.6)	1.500	0.221	TBIL( $\mu\text{mol/L}$ , $\bar{x} \pm s$ )	13.53 ± 6.13	13.50 ± 5.86	0.030	0.976
女	6 (12.0)	3 (5.4)			PT(s, $\bar{x} \pm s$ )	13.55 ± 0.87	14.18 ± 2.01	-2.062	0.035
HBsAg[n(%)]					Cr( $\mu\text{mol/L}$ , $\bar{x} \pm s$ )	78.99 ± 10.10	85.84 ± 22.41	-2.063	0.042
阳性	45 (90.0)	54 (96.4)	1.770	0.183	Child-Pugh评分( $\bar{x} \pm s$ )	5.22 ± 0.42	5.18 ± 0.47	0.476	0.635
阴性	5 (10.0)	2 (3.6)			ICG15(%, $\bar{x} \pm s$ )	4.31 ± 2.18	10.19 ± 5.27	-7.648	<0.001
年龄(岁, $\bar{x} \pm s$ )	51.34 ± 12.19	54.54 ± 11.94	-1.363	0.176	门静脉宽度(mm, $\bar{x} \pm s$ )	10.14 ± 1.87	11.98 ± 2.18	-4.645	<0.001
WBC( $\times 10^9/\text{L}$ , $\bar{x} \pm s$ )	5.53 ± 1.62	4.66 ± 1.61	2.770	0.007	门静脉流速(cm/s, $\bar{x} \pm s$ )	21.82 ± 5.26	20.04 ± 3.03	2.159	0.039
PLT( $\times 10^9/\text{L}$ , $\bar{x} \pm s$ )	173.32 ± 89.07	126.66 ± 65.20	3.099	0.002					

### 2.2 多因素 Logistic 回归分析结果

将上述在单因素分析中筛选出来具有统计学差异的指标纳入多因素二分类Logistic回归分析中,并通过逐步向前法最终得到独立预测指标为ICG15与门静脉宽度(均 $P < 0.05$ )(表2),同时可建立基于以上两项检查指标的回归模型:Logit(P) = -6.026 + 0.44 × ICG15 + 0.299 × 门静脉宽度。

### 2.3 预测价值分析

分别对ICG15、门静脉宽度以及联合以上两项指标的回归模型建立预测高级别肝纤维化的ROC

曲线。结果显示:ICG15的曲线下面积(AUC)为0.86,截断值为5.05时,敏感度为85.7%,特异度为72%。门静脉宽度的AUC为0.73,截断值为10.75时,敏感度为71.4%,特异度为66%。综合预测模型的AUC为0.88,截断值为0.36时,敏感度为89.3%,特异度为74%。由此可见,ICG15与门静脉宽度这两项检查指标均对高级别肝纤维化有良好的预测效果,而综合预测模型相比单项检查则能更好地反映患者肝纤维化的严重程度(图1)。

表 2 多因素 Logistic 回归分析

Table 2 Multivariate Logistic regression analysis

因素	OR	95% CI	Wald	P
ICG15	1.552	1.270~1.898	18.367	<0.001
门静脉宽度	1.349	1.042~1.746	5.165	0.023

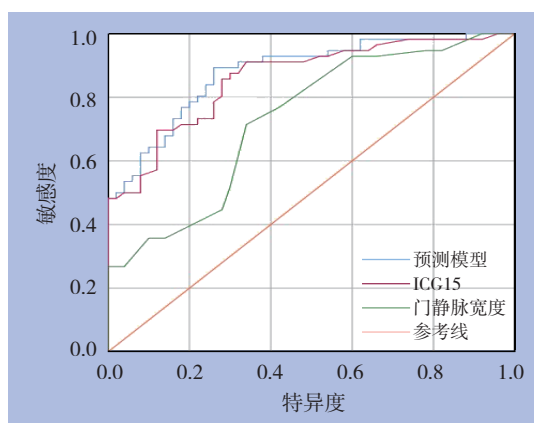


图 1 综合预测模型、ICG15 及门静脉宽度预测高级别肝纤维化的 ROC 曲线

Figure 1 ROC curves of the integrated prediction model, ICG15 and portal vein width to predict high-stage fibrosis

### 3 讨论

对于肝脏恶性肿瘤和部分良性肿瘤而言, 外科手术仍是一线治疗方案<sup>[16-17]</sup>, 而术后并发症的发生则极大地影响了患者的恢复情况和生活质量, 同时浪费了宝贵的医疗资源<sup>[18-19]</sup>。如何降低肝切除术后并发症的发生概率便成为了近年来重点关注的议题<sup>[20-21]</sup>, 肝纤维化的严重程度则是其最为关键的影响因素之一<sup>[22]</sup>。肝纤维化越严重意味着肝切除术后残余肝的功能越差, 肝功能恢复所需要的时间也越长, 发生术后肝功能衰竭等严重并发症的可能性也就越大<sup>[23-24]</sup>。因此, 只有通过准确的术前预测, 才可以依据不同患者肝纤维化的严重程度, 制定出对患者最有利的个性化治疗方案, 包括如手术切除范围、手术方式, 甚至是整体治疗方案上决策<sup>[25]</sup>。力争在保证治疗效果的同时, 尽可能地降低肝切除术后并发症的发生率。

本研究依据患者的手术病理切片资料, 以 Laennec 病理分级为标准, 将所有患者分为无或低级别肝纤维化和高级别肝纤维化两组。在第一步中将目前最为常用的检查指标纳入组间对比。结果显示两组间 WBC、PLT、PT、Cr、ICG15、门静

脉宽度及门静脉流速具有统计学差异。随后在第二步中将以上差异指标纳入多因素回归分析, 得到独立预测指标为 ICG15 与门静脉宽度, 并以此为基础建立综合两项指标的预测模型。最后通过建立预测高级别肝纤维化的 ROC 曲线, 验证了 ICG15 与门静脉宽度这两个独立指标对高级别肝纤维化具有良好的预测效果, 而联合两项指标的综合预测模型的预测效果更是优于独立指标。

常规的生化检查及以其为基础的 Child-Pugh 分级虽然简单易行且运用广泛, 但是也存在明显的局限性。第一, Child-Pugh 分级标准中关于临床症状 (如腹水及肝性脑病) 的评判, 容易受到主观因素的影响; 其次, Child-Pugh 分级对于轻度肝纤维患者的评估意义有限, 而对于肝硬化失代偿期患者的评估效果更好; 另外, 由于我们也很难通过常规的生化检查结果和 Child-Pugh 分级来了解患者肝脏的储备功能, 所以其对于肝切除术前的风险评估价值也相对有限<sup>[23]</sup>。吲哚氰绿清除实验则是利用了肝细胞对吲哚氰绿选择性摄取且不参与肝肠循环的特性, 而由此所得到的指标 ICG15 则可以用于反映肝脏的储备功能、评估手术风险<sup>[26-27]</sup>。本研究得到 ICG15 为高级别肝纤维化的独立预测指标, 与 Moller 等<sup>[28]</sup>的研究结果相符。肝脏纤维化程度越严重, 门静脉血流受阻也就越明显、门静脉压力也就越高<sup>[29]</sup>, 而无创超声检查则可以很好地反映门静脉的宽度及血流速度等情况。如前文所述, 门静脉宽度是另一项高级别肝纤维化的独立预测指标, 与以往的研究结果一致<sup>[30]</sup>。

综上所述, ICG15 与门静脉宽度均可有效地预测高级别肝纤维化。在此基础之上, 综合预测模型在 ROC 曲线分析中的 AUC、敏感度和特异度均高于独立指标, 说明联合 ICG15 与门静脉宽度的综合预测模型能对患者肝纤维化严重程度进行更为准确的预测。更可以此为基础, 获得更加真实、有效且全面的术前评估, 尽可能地将患者肝切除术后并发症的发生概率降至最低。

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