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· 专题研究 ·

预后指数在可切除胰腺导管腺癌患者术后评估中临床价值

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摘要

背景与目的: 肿瘤相关性炎症反应不仅具有促进肿瘤增殖、维持和转移作用, 还在肿瘤血管生成、适应性免疫失调以及抑制化疗反应过程中起着至关重要作用。目前已建立多项基于炎症标记物的特异度评分系统, 部分标记物已作为恶性肿瘤患者治疗反应和结果的预后评估指标。本研究旨在确定预后指数(PI)对胰腺导管腺癌(PDAC)患者远期预后评估的临床价值。

方法: 回顾性分析2011年1月—2014年12月在盘锦辽油宝石花医院接受胰腺切除的PDAC患者112例临床资料。收集术前C反应蛋白水平和白细胞计数计算PI, 比较不同PI分级(0、1、2级)患者临床病理特征与生存率的差异, 并分析影响PDAC患者的术后生存的危险因素。

结果: 112例患者中PI 0级37例、1级51例、2级24例。3组患者间基本资料差异无统计学意义(均 $P>0.05$)。临床病理特征分析结果显示, 3组患者间术前CA19-9水平、TNM分期、血管受侵方面差异有统计学意义($\chi^2=10.929、3.029、7.540$, 均 $P<0.05$), 而其他因素包括肿瘤大小、手术方式、肿瘤分化程度、神经受侵、术后并发症、术后辅助化疗等差异均无统计学意义(均 $P>0.05$)。随访时间9~81个月, 中位随访时间13个月, 随访期间患者死亡103例, 存活9例。生存分析结果显示, PI分级越高, 5年生存率越低(0级: 18.9%、1级: 3.9%、2级: 0.0%; $\chi^2=9.195$, $P=0.010$)。单因素分析结果表明, 肿瘤大小、CA19-9水平、TNM分期、肿瘤分化程度、PI、术后辅助化疗与PDAC患者术后生存明显有关($\chi^2=4.881, 8.377, 15.022, 5.349, 9.195, 4.066$, 均 $P<0.05$); 多因素分析结果显示, CA19-9 >37 IU/mL ($HR=1.639$, 95% $CI=1.073\sim2.506$, $P=0.022$)、肿瘤TNM为III期 (III vs. I: $HR=2.210$, 95% $CI=1.229\sim3.974$, $P=0.008$; II vs. I: $HR=1.925$, 95% $CI=1.081\sim3.426$, $P=0.026$) 及 PI 2 (2 vs. 0: $HR=2.083$, 95% $CI=1.190\sim3.645$, $P=0.010$; 1 vs. 0: $HR=1.764$, 95% $CI=1.101\sim2.828$, $P=0.018$) 是影响PDAC患者术后生存时间的独立危险因素。

结论: PI是PDAC患者术后预后的独立危险因素, PI分级越高, 患者预后越差, 但在将PI作为一种预后指标引入临床实践之前, 需要进行更大规模的对照试验进行评估。

关键词

胰腺肿瘤; 胰腺切除术; 预后指数; 预后

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Clinical value of prognostic index in postoperative evaluation of patients with resectable pancreatic ductal adenocarcinoma

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Abstract

Background and Aims: Cancer-related inflammation is not only associated with tumor proliferation, maintenance and dissemination, but also is critical for tumor angiogenesis, adaptive immune disorders and impaired chemotherapy response. Accordingly, a number of specific score systems have been established on the basis of inflammatory markers that have been validated as prognosticators for therapy responses and outcomes in patients with solid malignancies. This study was conducted to determine the clinical value of prognostic index (PI) for long-term results in patients with pancreatic ductal adenocarcinoma (PDAC).

Methods: The clinical data of PDAC patients who received pancreatectomy in the Panjin Liao-Oil Gem Flower Hospital from January 2011 to 2014 December were retrospectively analyzed. The PI scores were calculated via preoperative C-reactive protein levels and white blood cell counts. Among patients with different PI scores (0, 1 and 2), the differences in clinicopathologic characteristics and survival rate were compared. The risk factors for postoperative survival of PDAC patients were also determined.

Results: Of the 112 patients, 37 cases had a PI score 0, 51 cases had a score 1, and 24 cases had a score 2. There were no statistical differences in the basic data among the three groups of patients (all $P>0.05$). Analysis of clinicopathologic features showed that there were statistical differences among three groups of patients in terms of preoperative CA19-9 level, TNM stage and vascular invasion ($\chi^2=10.929, 3.029, \text{ and } 7.540$, all $P<0.05$), and no significant differences were noted in tumor size, surgical method, degree of tumor differentiation, nerve invasion, postoperative complications, and postoperative adjuvant chemotherapy (all $P>0.05$). The follow-up time was 9–81 months, with a median follow-up time of 13 months. During the follow-up period, 103 patients died, and 9 patients survived. The results of survival analysis showed that the 5-year survival rate was decreased with the elevation of PI score (score 0: 18.9%, score 1: 3.9% and score 2: 0.0%; $\chi^2=9.195, P=0.010$). Univariate analysis showed that tumor size, CA19-9 level, TNM stage, degree of tumor differentiation, PI, and postoperative adjuvant chemotherapy were significantly related to the 5-year survival rate of PDAC patients ($\chi^2=4.881, 8.377, 15.022, 5.349, 9.195, \text{ and } 4.066$, all $P<0.05$). Multivariate analysis showed that CA19-9 >37 IU/mL ($HR=1.639, 95\% CI=1.073-2.506, P=0.022$), TNM stage III (III vs. I: $HR=2.210, 95\% CI=1.229-3.974, P=0.008$; II vs. I: $HR=1.925, 95\% CI=1.081-3.426, P=0.026$) and PI score 2 (2 vs. 0: $HR=2.083, 95\% CI=1.190-3.645, P=0.010$; 1 vs. 0: $HR=1.764, 95\% CI=1.101-2.828, P=0.018$) were independent risk factors affecting the postoperative survival of PDAC patients.

Conclusion: PI is an independent risk factor for the postoperative prognosis of PDAC patients, and those with a higher PI may have a worse prognosis. However, evaluation in larger controlled studies is needed before introduction of PI into clinical practice as a prognostic indicator.

Key words

Pancreatic Neoplasms; Pancreatectomy; Prognostic Index; Prognosis

CLC number: R735.9

胰腺导管腺癌 (pancreatic ductal adenocarcinoma, PDAC) 是一种恶性程度高、预后极差的恶性肿瘤, 大多数患者确诊时已经进展至局部晚期或合并远处转移^[1-2]。精准了解患者在最初诊断时的状况和疾病进展的实际程度是治疗的关键因素。但到目前为止, 肿瘤的生物行为特征仍主要是基于影像学对侵袭血管程度和是否合并远处转移来判定^[3-4]。

近年来研究^[5-8]表明, 炎性细胞因子从肿瘤发生到扩散的不同阶段都起了促进作用。此外,

这些炎症介质不仅影响治疗效果, 并与肿瘤的迅速恶化和预后不佳相关。预后指数 (prognostic index, PI) 是通过术前血清C-反应蛋白水平 (CRP) 和白细胞计数 (WBC) 计算出的炎症指标, 首次在晚期非小细胞肺癌患者中被提出, 结果显示它对生存状况的评估具有重要价值^[9]。然而, 目前PI在评估PDAC患者预后方面的有效性尚无确切结论。本研究的目的是评估PI作为生物学标志物在PDAC患者术后中的应用, 并充分考虑已确定的预后因素, 明确其预后评估价值。

1 资料与方法

1.1 一般资料

回顾性分析2011年1月—2014年12月在盘锦辽油宝石花医院诊疗的112例PDAC患者临床资料。其中男69例,女43例;年龄42~81岁。纳入标准:(1)均行手术切除治疗;(2)经术后病理学检查,均有至少2名病理科医师确诊为PDAC者;(3)术前无重大疾病,可耐受手术者;(4)术前影像学检查明确无远处转移者;(5)具有完整的临床病理资料;(6)随访资料完整,随访时间 ≥ 6 个月或6个月内死于复发。排除标准:(1)术前合并其它脏器存在严重基础疾病,不能耐受手术者;(2)术前合并感染性疾病或血液系统疾病者;(3)术后病理学检查切缘阳性者;(4)临床病理资料缺失者;(5)术前存在远处转移或术中发现存在腹膜转移者。所有患者均签署由医院伦理委员会批准的患者知情同意书,符合医学伦理学规定。

1.2 资料收集

患者入院后在未接受任何治疗方式前,抽取空腹静脉血,检测血常规、CRP及肿瘤学标记物等。将性别、年龄、术前基础疾病、肿瘤大小、是否术前胆道引流、CA19-9水平、手术方式、TNM分期、肿瘤分化程度、血管受侵、神经受侵、术后辅助化疗等临床病理因素纳入本研究中进行分析。

所有患者根据肿瘤位置,由同一组医师行胰十二指肠切除术70例(62.5%)或胰远端切除术42例(37.5%)伴区域淋巴结清扫。根据《美国癌症联合委员会(AJCC)肿瘤分期手册》第8版对切除标本的病理特征进行分类^[10]。

1.3 随访

通过门诊和入院方式完成患者术后随访,以完成手术治疗为随访起点,终止随访为临床死亡或截止至2020年5月31日。入组患者术后每3个月复查血常规、肝肾功能、肿瘤标志物,并行胸部和腹部CT扫描,若病情需要,可将检查日期提前或增加增强磁共振成像。所有符合治疗条件的患者术后第6周开始化疗(GS方案),具体方案基于早前研究^[11]。

1.4 统计学处理

应用SPSS 18.0统计软件进行比较分析,计数资料用 $n(\%)$ 表示,组间比较采用 χ^2 检验。影响预后的单因素分析采用Kaplan-Meier法,组间生存

率比较用Log-rank检验,采用Cox回归模型对影响PDAC患者的术后生存进行多因素分析,并计算风险比(HR)及其对应的95%可信区间(CI)。以双侧 $P < 0.05$ 为差异有统计学意义。

2 结果

2.1 依据PI对PDAC患者分组

本研究分组基于早前研究^[9]结果,依据WBC和CRP进行分级,若两项指标均在正常范围内为0级,其中一项升高为1级,同时升高为2级,PI 0、1、2级患者分别为37、51、24例(表1)。

表1 依据术前CRP和WBC计数组成的PI分组
Table 1 Patient groups according to PI score combining preoperative CRP and WBC count

PI	n (%)	WBC ($\times 10^9$)	CRP (mg/L)
0	37 (33.0)	≤ 11	≤ 10
1	51 (45.5)	≤ 11 > 11	> 10 ≤ 10
2	24 (21.5)	> 11	> 10

2.2 与预后指数相关患者的肿瘤特征

将纳入本研究的3组患者基本资料进行对比,组间基本资料无统计学差异(均 $P > 0.05$),表明本研究各组间患者具有可比性(表2)。对3组患者围手术期各项临床病理特征进一步分析,结果显示,3组患者间术前CA19-9水平、TNM分期、血管受侵等因素差异有统计学意义($\chi^2 = 10.929$, 3.029, 7.540; $P < 0.05$),而与肿瘤大小、手术方式、肿瘤分化程度、神经受侵、术后并发症、术后辅助化疗等临床病理因素差异无统计学意义(均 $P > 0.05$)(表3)。

表2 各组患者基线资料比较[n(%)]
Table 2 Comparison of baseline data among the three groups [n(%)]

资料	n	PI 0 (n=37)	PI 1 (n=51)	PI 2 (n=24)	χ^2	P
性别						
男	69	21(56.8)	32(62.7)	16(76.7)	0.656	0.720
女	43	16(43.2)	19(37.3)	8(33.3)		
年龄(岁)						
< 70	70	23(62.2)	30(58.8)	17(70.8)	1.007	0.604
≥ 70	42	14(37.8)	21(41.2)	7(29.2)		
术前基础疾病						
有	74	24(64.9)	35(68.6)	15(62.5)	0.309	0.857
无	38	13(35.1)	16(31.4)	9(37.5)		

表3 各组临床病理特征比较 [n (%)]

Table 3 Comparison of clinicopathologic features among the three groups [n (%)]

因素	n	PI 0 (n=37)	PI 1 (n=51)	PI 2 (n=24)	χ^2	P
肿瘤大小 (cm)						
< 3	75	19 (51.4)	37 (72.5)	15 (62.5)	4.163	0.125
≥ 3	37	18 (48.6)	14 (27.5)	9 (37.5)		
术前胆道引流						
有	39	15 (40.5)	19 (37.3)	5 (20.8)	2.735	0.255
无	73	22 (59.5)	32 (62.7)	19 (79.2)		
CA19-9 (IU/mL)						
≤ 37	54	25 (67.6)	23 (45.1)	6 (25.0)	10.929	0.004
> 37	58	12 (32.4)	28 (54.9)	18 (75.0)		
手术方式						
胰腺十二指肠切除术	70	20 (54.1)	36 (70.6)	14 (58.3)	2.727	0.256
胰体尾切除术	42	17 (45.9)	15 (29.4)	10 (41.7)		
TNM 分期						
I	28	12 (32.4)	10 (19.6)	6 (25.0)	3.029	<0.001
II	48	12 (32.4)	25 (49.0)	11 (45.8)		
III	36	13 (35.2)	16 (31.4)	7 (29.2)		
肿瘤分化程度						
中低分化	77	26 (70.3)	31 (60.8)	20 (83.3)	3.922	0.141
高分化	35	11 (29.7)	20 (39.2)	4 (16.7)		
血管受侵						
有	44	14 (37.8)	15 (29.4)	15 (62.5)	7.540	0.023
无	68	23 (62.2)	36 (70.6)	9 (37.5)		
神经受侵						
有	33	6 (16.2)	17 (33.3)	10 (41.7)	5.212	0.074
无	79	31 (83.8)	34 (66.7)	14 (58.3)		
术后并发症						
有	17	4 (10.8)	8 (15.7)	5 (20.8)	1.155	0.561
无	95	33 (89.2)	43 (84.3)	19 (79.2)		
术后辅助化疗						
有	77	22 (59.5)	35 (68.6)	20 (83.3)	3.863	0.145
无	35	15 (40.5)	16 (31.4)	4 (16.7)		

2.3 PI 与 PDAC 患者术后生存的关系

随访时间9~81个月, 中位随访时间23个月, 随访期间患者死亡103例, 存活9例, 无失访病例。3组患者5年生存率比较, PI 分级越高, 生存率越低, 18.9% vs. 3.9% vs. 0.0% ($\chi^2=9.195$, $P=0.010$) (图1)。

2.4 影响 PDAC 患者术后生存的单因素和多因素分析

单因素分析结果表明, 肿瘤大小、CA19-9水平、TNM分期、肿瘤分化程度、PI、术后辅助化疗与PDAC患者术后生存有关 ($\chi^2=4.881$ 、8.377、15.022、5.349、9.195、4.066, 均 $P<0.05$) (表4)。多因素分析结果显示, CA19-9>37 IU/mL ($HR=1.639$, 95% $CI=1.073\sim 2.506$, $P=0.022$)、TNM III期 (III vs. I; $HR=2.210$, 95% $CI=1.229\sim 3.974$, $P=0.008$; II vs. I: $HR=1.925$, 95% $CI=1.081\sim 3.426$, $P=0.026$) 及PI 2 (2 vs. 0; $HR=2.083$,

95% $CI=1.190\sim 3.645$, $P=0.010$; 1 vs. 0: $HR=1.764$, 95% $CI=1.101\sim 2.828$, $P=0.018$) 是影响PDAC患者术后生存时间的独立危险因素 (表5)。

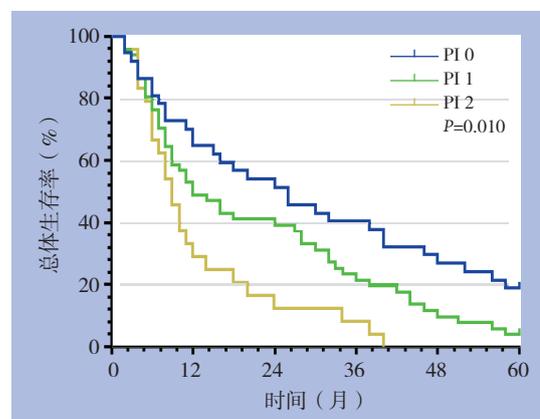


图1 不同PI 分级PDAC 患者的术后生存曲线比较
Figure 1 Comparison of postoperative survival curves of PDAC patients in different PI scores

表4 影响PDAC患者术后5年生存率的单因素分析

Table 4 Univariable analysis on influencing factors of the 5-year postoperative survival rate of PDAC patients

因素	n	5年生存率(%)	χ^2	P	因素	n	5年生存率(%)	χ^2	P
性别					TNM分期				
男	69	5.8	0.010	0.975	I	28	25.0	15.022	0.001
女	43	7.0			II	48	4.2		
年龄(岁)					III	36	0.0		
<70	70	8.6	0.008	0.928	肿瘤分化程度			5.349	0.021
≥70	42	7.1			中低分化	71	2.8		
术前基础疾病					高分化	41	17.1		
有	74	4.1	3.226	0.072	血管受侵			0.543	0.461
无	38	15.8			有	44	4.5		
肿瘤大小(cm)					无	68	10.3		
<3	67	13.4	4.881	0.027	神经受侵			0.013	0.908
≥3	45	0.0			有	33	9.1		
术前胆道引流					无	79	7.6		
有	39	7.7	0.071	0.789	PI			9.195	0.010
无	73	8.2			0	37	18.9		
CA19-9(IU/mL)					1	51	3.9		
≤37	54	16.7	8.377	0.004	2	24	0.0		
>37	58	0.0			术后并发症				0.126
手术方式					有	17	5.9		
胰腺十二指肠切除术	70	4.3	2.328	0.127	无	95	8.4		
胰体尾切除术	42	14.3			术后辅助化疗				4.066
					有	71	12.7		
					无	41	0.0		

表5 影响PDAC患者术后5年生存率的多因素分析

Table 5 Multivariable analysis of influencing factors for the 5-year postoperative survival rate of PDAC patients

因素	β	S.E	Wald χ^2	HR (95% CI)	P
肿瘤大小(>3 cm vs. ≤3 cm)	0.182	0.216	0.710	1.200 (0.786~1.832)	0.399
CA19-9 (≥37 IU/mL vs. <37 IU/mL)	0.494	0.216	5.214	1.639 (1.073~2.506)	0.022
TNM分期					
III vs. I	0.793	0.299	7.019	2.210 (1.229~3.974)	0.008
II vs. I	0.655	0.294	4.953	1.925 (1.081~3.426)	0.026
分化程度(中低分化 vs. 高分化)	0.367	0.2257	2.660	1.444 (0.929~2.245)	0.103
PI					
2 vs. 0	0.734	0.286	6.601	2.083 (1.190~3.645)	0.010
1 vs. 0	0.568	0.241	5.562	1.764 (1.101~2.828)	0.018
术后辅助化疗(有 vs. 无)	0.282	0.219	1.649	1.325 (0.862~2.037)	0.119

3 讨论

既往研究^[12-15]发现,血清CA19-9水平、肿瘤大小、病理分级、是否存在残余肿瘤、淋巴结转移和血管受侵袭是PDAC患者预后的危险因素。然而,从临床角度来看,除CA19-9和肿瘤大小,术前准确获取病理分期类型和分化程度等指标是十分困难的,而且这些参数的临界值在不同的研究中存在显著差异^[16-17]。基于目前无法准确的对个体患者进行高低危分层,造成对临床分期相同的肿瘤预后判断效能较差。即便CA19-9是最常用的PDAC诊疗标志物,但受限于胆道良性梗阻亦可造

成异常升高,因此只能在治疗过程中通过标志物的变化来权衡。此外,大约有20%的PDAC患者术前血清CA19-9水平是正常的^[18],这支持了对新型生物学标志物的需求。本研究探索术前应用PI对PDAC切除患者生存预后的临床意义,结果提示PI是影响术后生存的独立危险因素。

研究^[19-23]表明,与恶性肿瘤相关的炎症反应是其进展的特征性标志,而通过测量外周血细胞计数反映肿瘤相关性炎症反应,并由此对患者的预后进行评估,为临床医师制订更为针对性的治疗策略具有重要意义^[5, 22, 24-25]。本研究选定的评估指标是以CRP和WBC作为预后生物标志物的基

基础上建立的,能够准确的反映宿主的全身炎症反应。高CRP水平反映了恶性肿瘤发病率和相关死亡的风险。一项大型回顾性研究结果显示,在PDAC患者中,随访期间死亡组患者的中位CRP为4.9 mg/L,明显高于随访期间生存组患者的1.9 mg/L,提示CRP水平越高,患者的生存时间越短,并且是影响PDAC预后的独立危险因素^[26-27]。另有研究^[6, 28-29]表明,中性粒细胞淋巴细胞比率(NLR)、血小板淋巴细胞比率(PLR)和预后营养指数(PNI)等炎症指标被证实与恶性肿瘤治疗后效果和远期预后存在相关,但与PI相比,后者作为恶性肿瘤预后评估指标效果更佳。

本研究中发现预后指数与CA19-9、肿瘤TNM分期、血管受侵等因素具有明显的相关性,其中CA19-9越高、分期越高,PI分级越高,而合并血管受侵患者的PI分级高于未受侵者,这些结果反映预后指数作为PDAC切除患者标志物的实用性。因此,CRP和WBC两种指标的结合将最大程度的显示需要手术患者的实际炎症状态。相较于NLR、PLR、PNI等评分,PI的另一优势在于不需要通过相应指标的差值来获得所需参数,简单易行。

本研究对可能影响术后生存的多因素进行分析,发现CA19-9>37 IU/mL、肿瘤TNM为III期及PI 2的PDAC患者预后较差,是影响术后生存的独立危险因素。值得注意的是,由于治疗初始方案的不同,不同研究项目可能会将部分可边缘切除或局部进展性PDAC患者排除相关该分析之外,与既往认识不同的是本研究中手术方式和术后辅助化疗并非是影响PDAC患者术后生存的独立危险因素,可能是由于本研究中I期和II期患者超过60%以上,而IIa和IIb期患者同样存在较大生存差异,且I期和II期PDAC患者手术并发症相对少而轻,故今后需进一步引入亚组分析。另外,本研究仅反映单中心的诊疗经验,同时由于是回顾性的资料,不可避免存在数据选择偏移,如行胰十二指肠切除术患者比例明显高于行胰体尾切除者,但行胰体尾切除者III期和联合脏器切除比例较高,因此,需要进行更大规模的对照试验进行评估。

总之,本研究结果表明,尽管存在诸如肿瘤分期、CA19-9水平等PDAC特定的危险因素,但PI仍然是一种可靠的评估指标,即兼顾免疫、炎症、营养等肿瘤相关特征,又具有廉价、简单、易用的特点,并可在术前判断接受手术治疗PDAC患者的远期预后。

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