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血清 CEA, CA19-9, CA125, CA153 和 CYFRA21-1 检测对肺癌患者诊断的灵敏度及特异度

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[摘要] 目的: 观察血清癌胚抗原(carcinoembryonic antigen, CEA), 糖类抗原19-9(carbohydrate antigen 19-9, CA19-9), CA125, CA153及细胞角蛋白片段19(cytokeratin fragment 19, CYFRA21-1)检测对肺癌患者诊断的灵敏度及特异度。方法: 回顾性分析2016年1月至2017年6月在衡水市第二人民医院肿瘤科确诊的120例肺癌患者的临床资料, 选择同期门诊体检的50例健康者作为对照组。对比各组血清CEA, CA19-9, CA125, CA153和CYFRA21-1水平。结果: 肺癌组术前血清CEA, CA19-9, CA125, CA153和CYFRA21-1水平明显高于对照组($P<0.05$); 肺癌组术后1 d, 7 d, 1个月及3个月血清CEA, CA19-9, CA125, CA153和CYFRA21-1水平呈逐渐下降趋势($P<0.05$)。腺癌患者术前CEA, CA125, CA153水平明显高于鳞癌患者($P<0.05$), 鳞癌患者术前CA19-9, CYFRA21-1水平明显高于腺癌患者($P<0.05$)。III期患者术前血清CEA, CA19-9, CA125, CA153和CYFRA21-1水平明显高于I期+II期($P<0.05$)。有复发、转移患者术前血清CEA, CA19-9, CA125, CA153和CYFRA21-1水平显著高于无复发、转移患者($P<0.05$)。ROC曲线结果显示血清CEA, CA19-9, CA125, CA153和CYFRA21-1及5个指标联合检测对肺癌诊断的曲线下面积分别为0.729, 0.764, 0.744, 0.746, 0.838, 0.937, 灵敏度分别为70.00, 59.20, 60.80, 51.70, 70.00, 84.10, 特异度分别为58.00, 82.00, 80.00, 82.00, 88.00, 96.00。结论: 血清CEA, CA19-9, CA125, CA153和CYFRA21-1联合检测可为肺癌的早期筛查、诊断及随访提供重要价值, 联合测定又可提高诊断的灵敏度、特异度。

[关键词] 肺癌; 癌胚抗原; 糖类抗原19-9; 糖类抗原125; 糖类抗原153; 细胞角蛋白片段19; 诊断; 灵敏度; 特异度

Sensitivity and specificity of serum CEA, CA19-9, CA125, CA153 and CYFRA21-1 in diagnosis of lung cancer patients

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Abstract **Objective:** To observe the sensitivity and specificity of serum carcinoembryonic antigen (CEA), carbohydrate

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antigen 19-9 (CA19-9), carbohydrate antigen 125 (CA125), carbohydrate antigen 153 (CA153) and cytokeratin fragment 19 (CYFRA21-1) in the diagnosis of lung cancer patients. **Methods:** The clinical data of 120 patients with lung cancer diagnosed in Hengshui Second Hospital from January 2016 to June 2017 were analyzed retrospectively, and 50 healthy patients who underwent physical examination in the outpatient department during the same period were selected as the control group. The levels of CEA, CA19-9, CA125, CA153 and CYFRA21-1 in serum of each group were compared. **Results:** Serum CEA, CA19-9, CA125, CA153 and CYFRA21-1 levels in lung cancer group before operation were significantly higher than those in control group ($P<0.05$). The levels of serum CEA, CA19-9, CA125, CA153 and CYFRA21-1 in lung cancer group decreased gradually after 1 day, 7 days, 1 month and 3 months ($P<0.05$). The levels of CEA, CA125 and CA153 in patients with adenocarcinoma before operation were significantly higher than those in patients with squamous cell carcinoma ($P<0.05$), while the levels of CA19-9 and CYFRA21-1 in patients with squamous cell carcinoma before operation were significantly higher than those in patients with adenocarcinoma ($P<0.05$). Serum CEA, CA19-9, CA125, CA153 and CYFRA21-1 levels in patients with stage III were significantly higher than those in stage I + II ($P<0.05$). Serum CEA, CA19-9, CA125, CA153 and CYFRA21-1 levels in patients with recurrence and metastasis before operation were significantly higher than those in patients without recurrence and metastasis ($P<0.05$). ROC curve showed that the area under the curve of CEA, CA19-9, CA125, CA153 and CYFRA21-1 in serum and the combined detection of 5 indexes were 0.729, 0.764, 0.744, 0.746, 0.838 and 0.937, these indexes' sensitivities were 70.00, 59.20, 60.80, 51.70, 70.00 and 84.10, and their specificities were 58.00, 82.00, 80.00, 82.00, 88.00 and 96.00. **Conclusion:** Combined detection of serum CEA, CA19-9, CA125, CA153 and CYFRA21-1 can provide important value for early screening, diagnosis and follow-up of lung cancer, and can improve the sensitivity and specificity of diagnosis.

Keywords 肺癌; 胚胎抗原; 糖类抗原 19-9; 糖类抗原 125; 糖类抗原 153; 细胞角蛋白片段 19; 诊断; 敏感性; 特异性

肺癌的发病隐匿，缺乏特异性表现。调查研究^[1]报道，大部分肺癌患者确诊时已处于局部晚期或有远处转移，失去手术治疗机会。尽早明确诊断并及时进行相关治疗对于肺癌患者的预后改善有重要作用。肿瘤标志物是可反映肿瘤发生及生长的物质，主要是肿瘤发生发展中由肿瘤细胞生成并分泌，或宿主对肿瘤反应性释放至血液中，其可辅助肿瘤诊断、分类，并有利于疗效和预后评价^[2]。其中血清肿瘤标志物的检测具有取材方便、创伤小、重复性好等特点，现已广泛用于肿瘤的筛查。目前已有研究报道癌胚抗原(carcinoembryonic antigen, CEA)、糖类抗原 19-9(carbohydrate antigen 19-9, CA19-9)、糖类抗原 125(carbohydrate antigen 125, CA125)、糖类抗原 153(carbohydrate antigen 153, CA153)、细胞角蛋白片段19(cytokeratin fragment 19, CYFRA21-1)在肺癌诊断、疗效评价方面起到了一定作用^[3]。又有研究^[4]发现：单个肿瘤标志物检测可能存在阳性率低、特异性差等不足，因此联合多个肿瘤标志物检测更有利于肿瘤的早期诊断。通过本研究对衡水市第二人民医院120例肺癌患者的围手术期血清

CEA, CA19-9, CA125, CA153和CYFRA21-1水平进行动态监测，分析其在肺癌的诊断中的价值。

1 对象与方法

1.1 对象

回顾性分析2016年1月至2017年6月在衡水市第二人民医院肿瘤科确诊的120例肺癌患者的临床资料。纳入标准：符合肺癌的临床诊断标准^[5]，经临床症状、实验室检查、影像学、CT、ECT等证实，并经支气管镜活检确诊为肺癌的患者；有手术适应证，均在衡水市第二人民医院接受手术治疗的患者；知情同意的患者；临床资料完整的患者。排除标准：近期接受放化疗者；患其他恶性肿瘤者；合并肺部急性感染、肺结核等肺部疾病者。120例肺癌患者中男75例，女45例；年龄31~72(56.91 ± 4.96)岁；其中腺癌36例，鳞癌60例；TNM分期I期+II期46例，III期74例。选择同期门诊体检的50例健康者作为对照组，男29例，女21例；年龄30~70(55.48 ± 4.75)岁。肺癌组与对照组性别、年龄比较差异无统计学意义($P>0.05$)。

1.2 方法

对照组于体检当天采集静脉血, 肺癌患者于术前、术后1 d、7 d、1个月及3个月时采集空腹静脉血, 常规分离血清。取全自动化学发光免疫分析仪测定血清CEA, CA19-9, CA125, CA153和CYFRA21-1水平。血清CEA, CA19-9, CA125, CA153和CYFRA21-1的正常参考值分别为: 0~10 ng/mL, 0~37 U/mL, 0~21 U/mL, 0~30 U/mL, 0~3 ng/mL。

肺癌患者均以电话、门诊等方式进行1年随访, 以入组日期即为随访起始日期, 至随访结束、失访或者发生复发、转移为截止日期。统计肺癌患者发生复发和转移情况。

1.3 统计学处理

采用SPSS 18.0软件进行数据分析。计量资料用均数±标准差($\bar{x} \pm s$)表示, 选用t检验; 计数资料用例(%)表示, 用 χ^2 检验比较。绘制受试者工作特征(receiver operating characters, ROC)曲线分析血清指标对肺癌的诊断效能。 $P < 0.05$ 为差异有统计学意义。

2 结果

2.1 对照组与肺癌组血清CEA, CA19-9, CA125, CA153和CYFRA21-1水平比较

肺癌组术前血清CEA, CA19-9, CA125, CA153和CYFRA21-1水平明显高于对照组, 比较有统计学意义($P < 0.05$); 肺癌组术后1 d, 7 d, 1个月及3个月血清CEA, CA19-9, CA125, CA153和CYFRA21-1水平呈逐渐下降趋势($P < 0.05$), 且术

后7 d、1个月及3个月大部分肺癌患者血清CEA, CA19-9, CA125, CA153和CYFRA21-1水平在正常参考范围内(表1)。

2.2 不同病理类型患者术前血清CEA, CA19-9, CA125, CA153和CYFRA21-1水平比较

腺癌患者术前CEA, CA125, CA153水平明显高于鳞癌患者($P < 0.05$), 鳞癌患者术前CA19-9, CYFRA21-1水平明显高于腺癌患者($P < 0.05$, 表2)。

2.3 不同临床分期患者术前血清CEA, CA19-9, CA125, CA153和CYFRA21-1水平比较

III期患者术前血清CEA, CA19-9, CA125, CA153和CYFRA21-1水平明显高于I期+II期, 比较有统计学意义($P < 0.05$, 表3)。

2.4 有无复发、转移患者术前血清CEA, CA19-9, CA125, CA153和CYFRA21-1水平比较

有复发、转移患者术前血清CEA, CA19-9, CA125, CA153和CYFRA21-1水平显著高于无复发、转移患者, 比较有统计学意义($P < 0.05$, 表4)。

2.5 血清CEA, CA19-9, CA125, CA153和CYFRA21-1水平对肺癌的诊断效能分析

ROC曲线结果显示血清CEA, CA19-9, CA125, CA153和CYFRA21-1、及5个指标联合检测对肺癌诊断的曲线下面积分别为0.729, 0.764, 0.744, 0.746, 0.838, 0.937, 灵敏度分别为70.00, 59.20, 60.80, 51.70, 70.00, 84.10, 特异度分别为58.00, 82.00, 80.00, 82.00, 88.00, 96.00(表5)。

表1 对照组与肺癌组血清CEA, CA19-9, CA125, CA153和CYFRA21-1水平比较($\bar{x} \pm s$)

Table 1 Comparison of serum CEA, CA19-9, CA125, CA153 and CYFRA21-1 levels between control group and lung cancer group ($\bar{x} \pm s$)

组别	n	时间	CEA/(ng·mL ⁻¹)	CA19-9/(U·mL ⁻¹)	CA125/(U·mL ⁻¹)	CA153/(U·mL ⁻¹)	CYFRA21-1/(ng·mL ⁻¹)
对照组	50	体检时	3.51 ± 0.39	16.93 ± 2.41	18.19 ± 2.35	8.04 ± 1.03	1.39 ± 0.11
肺癌组	120	术前	27.96 ± 3.76*	90.14 ± 10.65*	60.33 ± 7.88*	63.27 ± 8.96*	6.99 ± 0.87*
		术后1 d	19.75 ± 2.51*#	68.43 ± 7.96*#	49.05 ± 5.43*	45.71 ± 6.84*	5.36 ± 0.59*#
		术后7 d	10.54 ± 1.03*#&	41.05 ± 5.04*#&	38.04 ± 3.03*#&	29.16 ± 3.13*#&	3.27 ± 0.38*#&
		术后1个月	5.44 ± 0.55*#& §	22.76 ± 2.77*#& §	23.91 ± 2.54*#& §	20.54 ± 2.75*#& §	2.91 ± 0.31*#& §
		术后3个月	3.71 ± 0.44*#& § ☆	18.54 ± 2.15*#& § ☆	19.32 ± 1.49*#& § ☆	10.33 ± 1.04*#& § ☆	1.45 ± 0.16*#& § ☆

与对照组比较, * $P < 0.05$; 与术前比较, # $P < 0.05$; 与术后1 d比较, *# $P < 0.05$; 与术后7 d比较, § $P < 0.05$; 与术后1个月比较, ☆ $P < 0.05$ 。

Compared with the control group, * $P < 0.05$; Compared with preoperative, # $P < 0.05$; Compared with 1 day after operation, *# $P < 0.05$; Compared with 7 days after operation, § $P < 0.05$; Compared with 1 month after operation, ☆ $P < 0.05$.

表2 不同病理类型患者术前血清CEA, CA19-9, CA125, CA153和CYFRA21-1水平比较($\bar{x} \pm s$)**Table 2 Comparison of serum CEA, CA19-9, CA125, CA153 and CYFRA21-1 levels in patients with different pathological types before operation ($\bar{x} \pm s$)**

组别	n	CEA/(ng·mL ⁻¹)	CA19-9/(U·mL ⁻¹)	CA125/(U·mL ⁻¹)	CA153/(U·mL ⁻¹)	CYFRA21-1/(ng·mL ⁻¹)
腺癌	36	30.76 ± 4.04	78.66 ± 8.03	65.86 ± 9.75	71.49 ± 10.35	5.58 ± 0.52
鳞癌	60	22.48 ± 3.17	104.08 ± 14.25	49.29 ± 4.67	47.96 ± 6.44	8.87 ± 1.37
t		11.999	12.586	10.975	14.072	18.717
P		<0.001	<0.001	<0.001	<0.001	<0.001

表3 不同临床分期患者术前血清CEA, CA19-9, CA125, CA153和CYFRA21-1水平比较($\bar{x} \pm s$)**Table 3 Comparison of serum CEA, CA19-9, CA125, CA153 and CYFRA21-1 levels in patients with different clinical stages before operation ($\bar{x} \pm s$)**

组别	n	CEA/(ng·mL ⁻¹)	CA19-9/(U·mL ⁻¹)	CA125/(U·mL ⁻¹)	CA153/(U·mL ⁻¹)	CYFRA21-1/(ng·mL ⁻¹)
I期+II期	46	13.09 ± 1.04	43.18 ± 4.74	39.77 ± 4.96	31.02 ± 4.29	3.86 ± 0.32
III期	74	37.20 ± 5.45	119.33 ± 14.32	73.11 ± 9.70	83.82 ± 11.86	8.94 ± 1.21
t		29.6254	34.851	21.5987	28.999	27.835
P		<0.001	<0.001	<0.001	<0.001	<0.001

表4 有无复发、转移患者术前血清CEA, CA19-9, CA125, CA153和CYFRA21-1水平比较($\bar{x} \pm s$)**Table 4 Comparison of preoperative serum CEA, CA19-9, CA125, CA153 and CYFRA21-1 levels in patients with recurrence or metastasis ($\bar{x} \pm s$)**

组别	n	CEA/(ng·mL ⁻¹)	CA19-9/(U·mL ⁻¹)	CA125/(U·mL ⁻¹)	CA153/(U·mL ⁻¹)	CYFRA21-1/(ng·mL ⁻¹)
无复发、转移	96	4.91 ± 0.46	20.99 ± 1.99	22.55 ± 2.34	20.71 ± 2.44	2.38 ± 0.35
有复发、转移	24	40.18 ± 4.98	126.76 ± 13.28	71.44 ± 10.03	85.51 ± 11.04	9.45 ± 0.95
t		17.588	18.724	7.669	13.526	15.455
P		<0.001	<0.001	<0.001	<0.001	<0.001

表5 血清CEA, CA19-9, CA125, CA153和CYFRA21-1水平对肺癌的诊断效能分析**Table 5 Diagnostic efficacy of serum CEA, CA19-9, CA125, CA153 and CYFRA21-1 levels for lung cancer**

指标	曲线下面积	SE	P	95% CI	灵敏度/%	特异度/%
CEA	0.729	0.041	<0.001	0.649~0.810	70.00	58.00
CA19-9	0.764	0.036	<0.001	0.693~0.834	59.20	82.00
CA125	0.744	0.038	<0.001	0.670~0.818	60.80	80.00
CA153	0.746	0.039	<0.001	0.670~0.822	51.70	82.00
CYFRA21-1	0.838	0.030	<0.001	0.780~0.897	70.00	88.00
5个指标联合	0.937	0.017	<0.001	0.902~0.971	84.10	96.00

3 讨论

肺癌为常见恶性肿瘤，近年来其发生率及病死率不断上升，明显威胁患者的生命安全^[6]。目前肺癌的早期诊断有一定难度，早期患者多无典型症状，多数患者确诊时错失了最佳治疗时机，预后较差。尽早诊断对于提高肺癌患者5年生存率有重要价值。影像学诊断对于肺癌的诊疗有一定作用，但单纯影像学检查对于隐性病灶、微小转移病灶及亚临床病灶的检出有限，且在病情监测方面也有一定难度^[7]。近年来肿瘤标志物在恶性肿瘤诊断、随访观察等方面的作用已得到临床认可^[8]。但目前临床尚未发现特异性的肺癌肿瘤标志物。

CEA为广谱肿瘤标志物，其在机体正常状态下的含量较低。既往研究^[9]表明：CEA为早期诊断结直肠癌的特异性标志物，近年来研究^[10]发现：肺癌、胃癌等恶性肿瘤中血清CEA的水平也有上升。研究^[11]表明：术前血清CEA水平为非小细胞肺癌预后的独立影响因素。Shintani等^[12]研究也表明：血清CEA在恶性肿瘤鉴别诊断、疗效评价及病情监测方面有重要作用。CA19-9为糖类蛋白质肿瘤标志物，已有研究证实CA19-9在胃肠道肿瘤诊疗、预后评估中的价值。近几年有研究^[13]报道血清CA19-9对于肺癌的诊断也有一定作用。CA125为大分子多聚糖，为卵巢癌的首选标志物。CA125作为广谱肿瘤标志物，在肺癌患者血清中的水平明显增加，且和病情进展程度有一定相关性。CA153为既往乳腺癌的重要标志物，其在肺癌、胰腺癌等肿瘤中的水平也有一定程度的增加。细胞角蛋白降解时，CYFRA21-1在蛋白酶作用下可快速激活，并释放至血液循环中，引起血清CYFRA21-1水平显著上升。CYFRA21-1在肺癌中的含量丰富，以鳞癌为甚。有研究^[14]报道：对鳞癌的诊断率较高。本研究结果显示，肺癌患者术前血清CEA，CA19-9，CA125，CA153和CYFRA21-1水平显著高于健康对照组，术后1 d以上肿瘤标志物明显低于术前，但其值仍高于正常参考值，肺癌患者术后7 d、1个月及3个月时血清CEA，CA19-9，CA125，CA153和CYFRA21-1水平较术前显著下降，且多处于正常参考值范围内，提示临床通过治疗能够下调肿瘤标志物的表达。

肺癌的组织学表现较复杂，临床主要分为小细胞肺癌及非小细胞肺癌两大类，非小细胞肺癌为肺癌的主要类型，以腺癌及鳞癌最为常见。本研究数据显示，不同病理类型患者组间术前血清CEA，CA19-9，CA125，CA153和CYFRA21-1水

平有显著差异，提示血清肿瘤标志物对于肺癌病理类型的鉴别有重要价值，与国内研究报道结果相符。肺癌治疗及预后与临床分期有紧密关系，既往研究^[15]证实，肿瘤标志物水平显著上升提示肿瘤预后较差或进展至晚期。本研究中III+IV期肺癌患者血清CEA，CA19-9，CA125，CA153和CYFRA21-1水平明显高于I+II期，提示以上肿瘤标志物对于肺癌临床分期有一定价值。

手术治疗肺癌的效果显著，虽可延长患者的生存时间，但是治疗过程中缺乏针对性，临床应加强观察肺癌患者的手术疗效及术后是否发生肿瘤的转移和复发等情况。有研究^[17]报道：肿瘤标志物水平的变化与肿瘤病情呈明显相关，为复发及转移的重要信号，且较影像学检查敏感。Fiala等^[18]研究也表明：肿瘤标志物水平和肿瘤复发、转移的变化存在明显的一致性，可对疾病转归起到监视作用，从而指导临床治疗。本研究结果显示：术后复发或转移患者术前血清CEA，CA19-9，CA125，CA153和CYFRA21-1水平显著高于术后无复发或转移患者，提示CEA，CA19-9，CA125，CA153和CYFRA21-1水平能够反映病情情况，对于预测术后复发有较高价值。尽管以上肿瘤标志物均有各自的特点，但其均为非器官特异性，有一定局限性，因此单一肿瘤标志物检测对肺癌的早期诊断价值有限，多个肿瘤标志物联合检测能够尽可能的协调互补，为肺癌的临床诊断提供重要依据。本研究结果显示：血清CEA，CA19-9，CA125，CA153和CYFRA21-1联合检测的曲线下诊断面积较单独检测高，且联合检测的灵敏度及特异度也有提高，表明多个肿瘤标志物联合检测可提高肺癌诊断的准确性。

综上所述，血清CEA，CA19-9，CA125，CA153和CYFRA21-1联合检测可为肺癌的早期筛查、诊断及随访提供重要价值，联合测定可提高诊断的灵敏度、特异度。

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