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血清 TgAb 水平在分化型甲状腺癌术后转移复发中的预测价值

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摘要 目的:探讨完全切除甲状腺组织后血清甲状腺球蛋白(TG)阴性时,血清抗甲状腺球蛋白抗体(TgAb)对分化型甲状腺癌(DTC)术后复发/转移的预测价值。**方法:**选择2013年4月-2015年4月我院收治的57例完全切除甲状腺组织,TG阴性且TgAb阳性的DTC患者临床病历资料,并将其分为复发/转移组(20例)和无复发/转移组(37例)。采用放射免疫分析法测定并比较两组患者的血清TG、TgAb水平,分析TgAb对DTC复发/转移诊断的灵敏度、特异度、阳性预测值以及阴性预测值,采用Logistic回归分析DTC复发/转移的独立危险因素。**结果:**复发/转移组的血清TgAb水平为72~3850 IU/mL,高于无复发/转移组的18~3638 IU/mL,差异有统计学意义($P<0.05$)。其中TgAb对DTC复发/转移诊断的灵敏度为85.71%,特异度为83.33%,阳性预测值为75.00%,阴性预测值为90.91%。经Logistic回归分析发现,TgAb水平为 $100\leq \text{TgAb}<204$ IU/mL、 $204\leq \text{TgAb}\leq 1000$ IU/mL、 >1000 IU/mL是DTC复发/转移的独立危险因素($\text{OR}=1.267, 2.853, 6.791, P<0.05$)。**结论:**TgAb可作为评估完全切除甲状腺组织、TG阴性且TgAb阳性的DTC患者复发/转移的重要指标,其值越高,复发/转移发生的可能性越大。

关键词:血清 TgAb; 分化型甲状腺癌; 转移/复发; 预测价值

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Predictive Value of Serum TgAb in Recurrence and Metastasis in Patients with Differentiated Thyroid Carcinoma after Operation

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ABSTRACT Objective: To explore the predictive value of serum thyroglobulin autoantibody (TgAb) for recurrence / metastasis in of thyroglobulin (TG)-negative and TgAb-positive patients with differentiated thyroid carcinoma(DTC) after thyroid ablation. **Methods:** The clinical data of 57 patients with DTC, undergoing complete resection of thyroid tissue, TG negative and TgAb positive, who were reviewed in Liaocheng People's Hospital during April 2013 to April 2015, were selected and divided into recurrence/metastasis group ($n=20$) and no recurrence/metastasis group ($n=37$). The TG and TgAb levels in the two groups were detected and compared by the electrochemical luminescence method, the sensitivity, specificity, positive predictive value and negative predictive value of TgAb in the diagnosis of DTC recurrence / metastasis were analyzed; the independent risk factors of DTC recurrence / metastasis were analyzed by Logistic regression. **Results:** The TgAb levels (72~3850 IU/mL) in the recurrence/metastasis group was higher than that (18~3638 IU/mL) in the no recurrence/metastasis group, the difference was statistically significant ($P<0.05$). The sensitivity, specificity, positive predictive value, negative predictive value of TgAb in the diagnosis of recurrence/metastasis of DTC were 85.71%, 83.33%, 75.00%, 90.91%, respectively. Logistic Regression analysis showed that the $100\leq \text{TgAb}<204$ IU/mL, $204\leq \text{TgAb}\leq 1000$ IU/mL, and >1000 IU/mL levels of TgAb were the independent risk factors of recurrence/metastasis of DTC ($\text{OR}=1.267, 2.853, 6.791, P<0.05$). **Conclusion:** TgAb can be used as evaluation of an important index of the recurrence/metastasis of patients with DTC when serum thyroglobulin (TG) was negative and TgAb was positive after thyroid ablation. The higher the TgAb levels, the more probability of the recurrence/metastasis.

Key words: Serum TgAb; Differentiate thyroid carcinoma; Recurrence/metastasis; Predictive value

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前言

甲状腺结节属于内分泌系统常见的临床疾病,流行病学资

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料显示^[1],甲状腺结节的检出率为5%,随着影像学技术的发展,甲状腺结节的检出率逐渐升高,已经超过50%,但是对于甲状腺结节的良恶性诊断依然是临床棘手的问题。目前临床上鉴别甲状腺结节的良恶性的主要手段是影像学检查、穿刺活检、同位素检测结合医生的临床经验^[2],而实验室指标检查与甲状腺结节的联系尚未建立^[3]。甲状腺结节通过触诊的诊断率约为5%,超声诊断率约为20~76%,甲状腺结节中有5~15%的类型

为恶性,即甲状腺癌^[4]。甲状腺癌是临床常见的一种头颈部恶性肿瘤,其中分化型甲状腺癌(Differentiate thyroid carcinoma, DTC)约占其总数的90%,严重影响患者的健康和生命质量^[5]。DTC手术后容易发生复发和转移,而早期诊断可以减少复发/转移的可能性。当完全切除DTC患者残留的甲状腺组织后,血清甲状腺球蛋白(thyroglobulin, TG)可作为预测DTC复发/转移的重要指标^[6],血清抗甲状腺球蛋白抗体(thyroglobulin autoantibody, TgAb)常用于诊断甲状腺疾病,但是有研究显示^[7]当患者血清TgAb呈阳性表达, TG检测可能会受到不同程度干扰,继而影响对DTC复发/转移诊断的准确性,因此DTC术后检测TgAb水平可以用于评估TG诊断的准确性^[8]。据有关文献报道, TgAb阳性患者中同样有大约20%~30%的DTC患者出现复发/转移^[9]。本研究拟通过检测TgAb水平来预测残留甲状腺组织完全切除、TG阴性且TgAb阳性DTC患者发生复发/转移的可能性,旨在探讨TgAb对DTC术后复发/转移的预测价值。

1 资料与方法

1.1 一般资料

收集2013年4月-2015年4月来我院进行复查的DTC患者为本研究对象,并行清灶治疗,纳入标准:①经病理组织学检查证实为DTC的患者;②残留的甲状腺组织已经完全被切除;③经电化学发光法检测TG阴性且TgAb阳性的患者;④符合医学伦理学要求;⑤患者及家属知情同意,并签署知情同意书。排除标准:①甲状腺床区存在未完全切除的甲状腺组织;②TG阳性和/或TgAb阴性的患者;③TG和TgAb经其它检测方法得到。

符合纳入标准的患者共57例,根据DTC患者是否出现复发/转移情况将其分为两组,复发/转移组20例,其中男8例,女12例;年龄22~79岁,平均(45.7±11.4)岁;滤泡型癌8例,乳头状癌10例,混合型癌2例。无复发/转移组37例,其中男13例,女24例;年龄18~80岁,平均(47.5±10.1)岁;滤泡型癌12例,乳头状癌20例,混合型癌5例。两组患者的性别、年龄、病理类型比较,差异无统计学意义($P>0.05$),具有可比性。

1.2 方法

术后12个月后,所有患者空腹抽取静脉血3 mL,转速为4000 r/min,离心5 min,吸取上清液,存于-80℃冰箱中。TG和TgAb水平均采用放射免疫分析法测定,使用的试剂盒由武汉博士德生物工程有限公司提供,检测仪器室由科大创新股份有限公司中佳分公司提供的GC-1200型的 γ 放射免疫计数器,严格按照说明书上操作,为了保证试验的准确性,取每个样本检测3次的平均值。

1.3 诊断标准

经¹³¹I-全身显像(WBS)、颈部超声、胸部X线或者CT扫描等手段发现DTC患者手术后有新的病灶出现作为诊断DTC复发/转移的"金标准"。TG和TgAb测定的范围分为在0.1~1000 μ g/L和10~4000 IU/L之间。TG阳性诊断标准^[10]: TSH在被抑制的情况下且TG>1 μ g/L,或者TSH在刺激的情况下且TG>2 μ g/L; TgAb阳性诊断标准:手术完全切除残留的甲状腺组织且TG呈阴性的DTC患者,如果能检测出TgAb水平;以TgAb水平=204 IU/mL作为临界点,当TgAb $\geq$ 204 IU/mL时, DTC发生复发/转移,计为阳性, TgAb<204 IU/mL时, DTC未发生复发/转移,计为阴性。

1.4 统计学处理

采用SPSS19.0软件进行数据的录入及统计分析,定量资料的描述采用($\bar{x} \pm s$)表示,两独立样本的比较采用独立样本的t检验,定性资料的描述采用率(%),比较采用 χ^2 检验,影响因素的分析采用Logistic回归分析, $P<0.05$ 表示差异有统计学意义。

2 结果

2.1 两组患者的血清TgAb水平比较

复发/转移组的血清TgAb水平为72~3850 IU/mL,中位数为1578 IU/mL,无复发/转移组的血清TgAb水平为18~3638 IU/mL,中位数为139 IU/mL。复发/转移组的血清TgAb水平高于无复发/转移组,差异有统计学意义($P<0.05$)。

2.2 TgAb指标对DTC复发/转移的判断情况比较

TgAb作为判断指标判断DTC复发/转移的情况见表1。其中TgAb对DTC复发/转移诊断的灵敏度为85.71%,特异度为83.33%,阳性预测值为75.00%,阴性预测值为90.91%。

表1 TgAb指标对DTC复发/转移的判断情况

Table 1 The judgment of TgAb index on the recurrence and metastasis of DTC

TgAb indexes	Gold standard		Totals
	+	-	
+	18	6	24
-	3	30	33
Total	21	36	57

2.3 TgAb与复发、转移的相关性分析

将TgAb划分为 $10 \leq \text{TgAb} < 100$ IU/mL、 $100 \leq \text{TgAb} < 204$ IU/mL、 $204 \leq \text{TgAb} \leq 1000$ IU/mL以及 >1000 IU/mL 4个等级,并将其作为自变量纳入回归模型,经Logistic回归分析发现, TgAb水平为 $100 \leq \text{TgAb} < 204$ IU/mL、 $204 \leq \text{TgAb} \leq 1000$ IU/mL、 >1000 IU/mL是DTC复发/转移的独立危险因素

(OR=1.267, 2.853, 6.791, $P<0.05$)。见表2。

3 讨论

目前手术切除甲状腺是治疗DTC的首选手段,手术后联合辅助性的放射性碘治疗可明显改善患者的预后,但是研究证实,术后仍然有10%~30%的DTC患者发生复发和转移^[11]。早

表 2 Logistic 回归分析
Table 2 Logistic regression analysis

TgAb(IU/mL)	β	SE(β)	Wald value	P value	OR	95%CI	
						Lower limit	Upper limit
100 $\leq$ TgAb<204	0.536	0.281	6.735	0.011	1.267	1.038	2.125
204 $\leq$ TgAb $\leq$ 1000	0.820	0.334	9.562	0.001	2.853	2.087	5.176
>1000	0.985	0.572	10.173	0.001	6.791	4.285	12.087

期预测和诊断 DTC 的复发 / 转移, 可以明显促进患者手术的预后恢复, 提高患者生活质量, 而 TG 是临床上用于评价 DTC 患者复发 / 转移的敏感和特性的指标^[12]。TG 是 TgAb 自身的不完全 '隐蔽抗原', 有研究证实对 DTC 患者的 TG 进行检查可能会受到 TgAb 的干扰, 从而影响 TG 对 DTC 复发 / 转移的诊断^[13,14]。也有临床报道显示当 TgAb 呈阳性表达且 TG 阴性时, 由于 TG 受到 TgAb 的干扰, 将 TG 作为 DTC 患者的肿瘤标志物会降低其诊断的敏感性^[15]。在 DTC 患者中约 30% 的患者的血清 TgAb 呈阳性, 并且在这些 TgAb 阳性患者中, 又大约有 25% 左右的患者被证实为存在 DTC 的复发 / 转移^[16,17]。因此是否可以将 TgAb 作为预测 DTC 患者发生复发 / 转移的肿瘤标志物, 目前相关的研究尚未达成一致意见^[18,19]。不过有学者指出当完全切除 DTC 患者残留的甲状腺组织, 并且 TG 阴性 TgAb 阳性时, 监测 TgAb 水平的变化可以较好的评估 DTC 是否发生复发 / 转移^[20,21]。

本研究对 57 例完全切除残留甲状腺组织, TG 阴性且 TgAb 阳性的 DTC 患者进行研究, 旨在探讨 TgAb 对 DTC 复发 / 转移的预测价值。本研究结果显示, 复发 / 转移组的血清 TgAb 水平为 72~3850 IU/mL, 而无复发 / 转移组的血清 TgAb 水平为 18~3638 IU/mL, 复发 / 转移组的血清 TgAb 水平明显高于无复发 / 转移组, 差异有统计学意义 ($P < 0.05$)。提示 TgAb 可作为评估 DTC 发生复发 / 转移的肿瘤标志物, 分析出现这种现象的主要原因是 TgAb 是甲状腺滤泡中的 TG 进入血液循环后产生的一种抗体, 主要成为 IgG, 其具有高度的免疫特异性, 不仅可以与 TG 结合, 而且还可以与 K 细胞结合, 通过 Fc 受体与抗体结合导致的自然杀伤细胞的活化, 从而攻击靶细胞, 加速甲状腺细胞的损伤进程, TgAb 主要由 B 淋巴细胞分泌, 而后者主要分布于甲状腺内, 大量的 TgAb 在甲状腺肿积累, 在增加 TG 分解的同时, 还可以其他蛋白水解, 最终对机体造成严重损伤。此外, TG 阴性 TgAb 阳性的 DTC 患者是否发生复发 / 转移, 与有关研究结果一致^[22]。当采用 TgAb 作为肿瘤标志物诊断 DTC 发生复发 / 转移时, 其临界值尚存在争议^[23]。有临床研究者将 TgAb=204 IU/mL 作为诊断 DTC 是否复发 / 转移的临界值, 具有较高的诊断价值^[24,25]。鉴于此, 本研究初步采用 204 IU/mL 作为本研究的临界值, 以判断其对 DTC 复发 / 转移的诊断价值。结果显示, 其中 TgAb 对 DTC 复发 / 转移诊断的灵敏度 85.71%, 特异度 83.33%, 阳性预测值 75.00%, 阴性预测值 90.91%。提示采用 TgAb 作为预测 DTC 发生复发 / 转移的指标, 具有重要的临床价值。有研究表明, DTC 患者的血清 TgAb 水平越高, 其发生复发 / 转移的可能性也越大^[26,27]。本研究结果显示, TgAb 是 DTC 患者发生复发 / 转移的独立危险因素, 并且 100 $\leq$ TgAb<204 IU/mL 组, 204 $\leq$ TgAb $\leq$ 1000 I-

U/mL 组, >1000 IU/mL 组的 DTC 患者发生复发 / 转移的可能性分别是 10 $\leq$ TgAb<100 IU/mL 组的 1.267, 2.853, 6.791 倍, 差异有统计学意义。提示随着 TgAb 水平的升高, DTC 发生复发 / 转移的可能性越大, 与有关研究结果一致^[28]。因此, 在 DTC 患者手术后的随访过程中, 应对患者的血清 TgAb 水平进行常规性的检测, 一旦 TgAb 水平超过 204 IU/mL 时, 有必要进行影像学检查, 以便早期发现并及时治疗, 并且当 TgAb 水平远高于 204 IU/mL 时, 进行相关的影像学检查和制定正确的诊疗方案, 可以提高患者的生存率^[29,30]。

综上所述, 检测患者的血清 TgAb 水平对预测 DTC 是否发生复发 / 转移具有重要的价值, 并且随着 TgAb 水平的升高, DTC 发生复发 / 转移的可能性增大, 因此临床应对 TgAb 进行常规性的检测并结合患者的影像学资料, 以早期及时发现并治疗 DTC 的复发 / 转移。

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