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· 文献综述 ·

## 甲状腺超声影像报告与数据系统的应用和研究进展

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### 摘要

高分辨率超声在甲状腺结节良恶性鉴别上敏感性高、特异性强, 且具有高效、经济、无创的优势, 是甲状腺疾病定性、定量、定位诊断的首选检查方法和细针穿刺适应证的参考依据。为更好地评估结节良恶性, 规范甲状腺结节超声应用与管理, 甲状腺超声影像报告和数据系统 (TIRADS) 应运而生, 现已历经 10 年发展。TIRADS 通过对甲状腺结节的分级管理, 不仅改变了学界对甲状腺结节非“良”即“恶”的传统认识, 也将成为推进甲状腺疾病规范化、精准化、个体化诊疗的重要手段。

### 关键词

甲状腺结节 / 影像诊断; 超声检查; 综述文献  
中图分类号: R653.2

## Application of thyroid imaging reporting and data system and its research progress

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### Abstract

High-resolution ultrasound shows high sensitivity and excellent specificity to identify the nature of the thyroid nodules with advantages of being efficient, economical and noninvasive. Thus, it is the first-choice method for qualitative, quantitative, and locational diagnosis of thyroid nodules and the reference to the indications for fine needle aspiration. For effectively ascertaining the benign or malignant nature of the thyroid nodules and standardizing the application and management of thyroid nodule ultrasound, thyroid imaging reporting and data system (TIRADS) has emerged and developed over ten years to date. TIRADS not only changes the traditional understanding of thyroid nodules of the professional world as either being benign or malignant through the grading management, but also will become an important means of propelling the standardization, precision, and individualized diagnosis and treatment of thyroid diseases.

### Key words

Thyroid Nodule/diag image; Ultrasonography; Review  
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超声是甲状腺结节的首选检查方法。为了更好地鉴别良恶性,优化结节管理,2009年甲状腺影像报告和数据系统(thyroid imaging reporting and data system, TIRADS)被首次提出。历经十年发展, TIRADS不断更新迭代,临床应用日趋广泛。对于外科医生,无论是阅读超声报告或是亲自超声检查,分析、领悟并掌握TIRADS内涵,有助于有效解读报告并进行准确诊断评估,从而制定合理诊疗策略。本文从TIRADS的发展史及其特点、诊断效能及相关影响因素、临床应用现况和临床研究热点方面进行综述。

## 1 TIRADS 发展历程及其特点

甲状腺超声检查起步较晚,应用管理不尽规范。2009年, Horvath等<sup>[1-2]</sup>先后提出了TIRADS概念。此后,各国学者对TIRADS进行多次改良、简化、更新,如韩国Kwak版、法国Russ版,均取得较为广泛的临床应用<sup>[3-4]</sup>;各国学术组织也制订了相应的甲状腺超声风险分层和管理体系,如2009年美国甲状腺协会(ATA)、2010年美国临床内分泌医师协会/美国内分泌协会/欧洲甲状腺协会(AACE/ACE/ETA)、2011年韩国甲状腺放射学会(KSThR)等<sup>[5-7]</sup>。

值得关注的是,领衔制定BIRADS的美国放射学会(ACR)于2015年和2017年分别发表“甲状腺超声报告词典”和“ACR甲状腺影像报告和数据系统”两部白皮书<sup>[8-9]</sup>。ACR-TIRADS评估5类超声征象并采用积分制,将结节分为TR1~TR5,并结合大小给出FNA、随访或无需随访的明确建议,简便实用,可操作性强。此后,各版TIRADS相继更新或创建,2016年韩国更新Ks-TIRADS、法国出台French-TIRADS、2017年ETA创建EU-TIRADS<sup>[10-12]</sup>。在国内,2017年中国医师协会超声医师分会和中华医学超声杂志编委会浅表器官学组也相继制定了相应的甲状腺超声危险分层和管理体系<sup>[13-14]</sup>。

简而言之, TIRADS的发展趋势具有3个特点:(1)简单实用化。Horvath和Park版涉及超声征象及疾病模型多达10余种,直到Kwak将其简化为5项可疑征象,才开始被临床所接受。后续各版本可疑征象都不超过5个。(2)规范明确化。最初术

语、报告、诊疗建议均相对杂乱含糊,后逐渐注重超声术语的明确定义、检查报告的规范书写、诊疗建议的具体参考。(3)定量积分化。最初仅对结节性质进行主观描述,后逐渐对结节性质进行分级、赋值,从而对恶性风险有了客观量化。

## 2 诊断效能及相关影响因素

### 2.1 诊断效能的评价指标

诊断效能的评价指标包括两类:一是对良恶性结节鉴别的敏感度、特异度、准确度、阳性预测值、阴性预测值;二是指根据TIRADS分级推荐活检的准确性,包括活检恶性率(活检中恶性结节数/活检结节总数)、不必要活检率(活检中良性结节数/结节总数)。各版本TIRADS的诊断效能不一(表1)。Ha等<sup>[15]</sup>对比研究了7个版本的TIRADS,结果显示:ACR-TIRADS、French-TIRADS、AACE/ACE/AME的特异度、准确度、阳性预测值较高,但敏感度、阴性预测值较低,活检恶性率较高,不必要活检率较低;Ks-TIRADS、NCCN、ATA反之,可以看出其相对较为激进。

### 2.2 诊断效能的影响因素

(1)大小:微小结节超声评估假阳性率较高,即便是经验丰富的医生评估<5 mm的结节,假阳性率仍可高达68.2%<sup>[23]</sup>。(2)位置:位于峡部、锥状叶及腺叶两极的结节,因周围正常组织少,回声强度的判断有一定困难,从而较易导致假阴性结果<sup>[11]</sup>。(3)合并其它病变:当存在桥本及亚急性甲状腺炎等弥漫性病变时,腺体背景回声紊乱,易导致可疑征象的误判,从而降低TIRADS诊断效能<sup>[11]</sup>。(4)病理类型:目前所有的风险分层都主要是针对经典型PTC。但对于FVPTC及FTC,更多的表现为无钙化、边界规则、纵横比<1、等/高回声等良性征象,因而更易误判为低到中度可疑<sup>[24]</sup>。对于MTC,约1/3超声表现为良性征象,可被分类为中度可疑<sup>[25]</sup>,只有大小达到较高标准方推荐活检,因此可能延误MTC的早期诊断及治疗。(5)TIRADS不能分类结节:导致无法分类的原因主要有:本身缺乏相应类别或超声特征无法判别以致无法分类,如钙化密集及后方声影导致结节成分、回声、边缘等不能确定。Ha等<sup>[15]</sup>研究表明,

应用ATA超声模型时,约有5%的结节不能进行分类,但其恶性率可达19%。当将不能分类的结节归入中等可疑风险时,该模型的敏感性可有所提高(89.6% vs. 93.8%)。(6) 观察者偏倚:超声诊断

效能易受到医生经验的影响,较易误判的超声特征有边缘、成分、回声等。研究指出,随着诊疗经验的增加,观察者偏倚减小,TIRADS诊断效能也相应有所提高<sup>[23]</sup>。

表 1 10 个版本甲状腺超声体系的诊断效能比较

Table 1 Comparison of diagnostic efficacy of ten versions of thyroid ultrasound system

版本	年份	诊断依据	研究类型	样本量			良恶性鉴别诊断效能的评估指标 (%)					活检建议是否合理的评估指标 (%) <sup>1)</sup>		
				总数 (个)	良性 (%)	恶性 (%)	敏感度	特异度	阴性预测值	阳性预测值	准确度	总数 / 个	活检恶性性率	不必要活检率
Horvath-TIRADS <sup>[1,16]</sup>	2009	病理 + 细胞 + 随访	前瞻性	502	45.8	54.2	99.6	74.4	99.4	82.1	93.8	—	—	—
Kwak-TIRADS <sup>[17-18]</sup>	2011	细胞学	回顾性	1 293	82.0	18.1	97.4	29.3	98.1	23.3	41.6	—	—	—
Russ-TIRADS <sup>[4]</sup>	2013	细胞学	前瞻性	991	93.3	6.7	98.5	44.7	99.8	99.7	48.3	—	—	—
NCCN <sup>[15,19]</sup>	2014	病理 + 细胞 + 随访	回顾性	2 000	78.3	22.7	92.5	30.2	93.2	28.0	44.4	1499	28.0	54.0
ATA <sup>[15,20]</sup>	2015	病理 + 细胞 + 随访	回顾性	2 000	78.3	22.7	89.6	32.2	91.6	28.3	46.0	1440	28.3	51.7
AACE/ACE/AME <sup>[15,21]</sup>	2016	病理 + 细胞 + 随访	回顾性	2 000	78.3	22.7	80.4	58.8	91.0	36.0	63.1	1014	36.0	32.5
Ks-TIRADS <sup>[10,15]</sup>	2016	病理 + 细胞 + 随访	回顾性	2 000	78.3	22.7	94.5	26.4	94.2	27.4	41.9	1567	27.4	56.9
French-TIRADS <sup>[11,15]</sup>	2016	病理 + 细胞 + 随访	回顾性	2 000	78.3	22.7	72.7	62.4	88.6	36.2	64.7	912	36.2	29.1
ACR-TIRADS <sup>[9,15]</sup>	2017	病理 + 细胞 + 随访	回顾性	2 000	78.3	22.7	74.7	67.3	90.1	40.2	50.9	844	40.2	25.3
EU-TIRADS <sup>[22]</sup>	2017	病理	回顾性	75	82.7	17.3	92.0	64.0	98.0	35.0	69.0	—	—	—

注: 1) 活检恶性率 = 活检中恶性结节数 / 活检结节总数, 不必要活检率 = 活检中良性结节数 / 结节总数

Note: 1) Biopsy malignancy rate = number of biopsy-proven malignant nodules/total number evaluated nodules, and unnecessary biopsy rate = number of biopsy-proven benign nodules/ total number evaluated nodules

### 3 临床应用现状

TIRADS的临床应用价值主要体现在4个方面: 第一, 对于暂无条件开展FNA的基层医院, 应用TIRADS对结节进行恶性风险分层管理, 将使诊疗更加合理化、精准化。按照TIRADS相关标准严格进行分级, 客观评价恶性风险, 减少诊断性手术。第二, 作为FNA适应证的参考标准, 将有利于减少不必要的有创检查及诊断手术。与个人经验相比, 使用ACR-TIRADS后推荐活检减少高达41%, 并且这部分结节大部分为良性<sup>[26]</sup>。第三, 对于FNA结果I-IV类的结节, 联合TIRADS将有助于更加科学合理地制定进一步的诊疗策略, 减少重复穿刺及漏诊, 合理调整随访方案。已有研究<sup>[27]</sup>将TIRADS与细胞学诊断系统结合, 创建了新的分级系统, 如“CU”系统(Cytology-Ultrasonography)。Yoon等<sup>[28]</sup>报道显示, 当细胞学无法诊断而TIRADS分级为3、4a类结节, 其恶性率相对较低(1.6%、3%), 建议连续超声监测而非重复FNA。此外, 使用TIRADS结构化报告模板, 不仅便于动态评估和同行沟通, 还有助于提高临床效率。结构化报告模板对每个结节的征象描述

完整率达96%~100%, 报告时间不超过20 s, 仅有6%无诊疗建议, 而未使用模板时则高达34%<sup>[29-30]</sup>。

但由于目前国内外均缺乏甲状腺超声检查、诊断、管理的统一标准, 在此基础之上的TIRADS应用也较为混乱, 尤其是外科医生超声理论知识和实践经验相对不足, 更应注重以下几个亟待解决的问题: 首先, 超声描述术语不标准、征象指标不统一, 报告结构不尽相同、诊疗建议尚不规范。其次, TIRADS应用与否的观念尚未达成共识, 超声科、外科、内科、核医学科等多学科间的沟通有所受限。再者, 国内医院使用多个版本TIRADS, 不同医院掌握的分类方法和处理原则有所差异, 尚无通用标准。所以当患者携带超声报告单上提示TIRADS分级但没有准确标明版本时, 其参考价值仍有待商榷。

随着TIRADS相关循证医学证据积累, 临床应用逐渐增多, 学界关注度日趋增高。近期中华医学会超声分会浅表器官学组发起的一项调查显示, 89%的超声科医生、92%的内外科等临床科室医生、95%的放射科医生, 均支持建立中国版的C-TIRADS。鉴于目前国内使用的TIRADS版本均为国外学者创建, 并不一定完全适用于中国国

情,因此C-TIRADS的创建将可能有助于更为有效地改善目前的混乱局面。

## 4 临床研究热点

### 4.1 联合诊断以提高诊断效能

TIRADS结合细胞学结果、分子检测结果、临床信息等,或将进一步提高特异性和准确性。例如,加入年龄和性别因素后,ACR-TIRADS及AAACE/ACE/AME的AUC显著提高( $P<0.001$ )<sup>[31]</sup>;TSH、TgAb水平等也被证实能提高超声诊断的准确性<sup>[32-33]</sup>。Ianni等<sup>[34]</sup>结合临床(clinical, C)、超声(ultrasonographic, U)和细胞学(thyroid cytology, T)建立了“CUT”评分系统。同样地,Zhang等<sup>[35]</sup>结合病史、性别年龄、体格检查、甲功等7项临床信息创建综合风险分层系统,使Kwak-TIRADS的特异度(90.3% vs. 68.2%)、准确度(89.3% vs. 74.9%)及阳性预测值(77.3% vs. 52.5%)均有所提高。

### 4.2 影像“偶发结节”的管理

2015年ACR出台了《影像偶发甲状腺结节管理白皮书》,对CT、MRI、核素、超声检查中发现的偶发结节的管理作出了一定的指导<sup>[36]</sup>。由于<sup>18</sup>FDG的摄取可能标志着低分化DTC和ATC,PET偶发结节容易引起患者的恐慌和医生过度处理<sup>[37]</sup>。2015版ATA指南建议局部摄取<sup>18</sup>FDG>1 cm时应行FNA,但此类结节恶性率差异大,因此该推荐并未得到充分支持<sup>[20]</sup>。学者<sup>[38]</sup>报道TIRADS结合PET检查,对偶发结节性质判断的特异度和阳性预测值提高,但敏感度及阴性预测值降低。TIRADS对PET偶发结节的评估价值还有待进一步验证。

### 4.3 多模态超声技术联合应用

TIRADS与超声实时弹性成像或超声造影联合,可提高结节良恶性鉴别诊断的敏感性、特异性和准确性,特别是4类结节(Kwak版);与声脉冲辐射力成像联合,可提高甲状腺微小癌的诊断水平;与剪切波弹性成像联合,诊断甲状腺微小癌的准确性(89.16%)高于TIRADS(87.00%)、剪切波弹性成像(54.49%)的单独应用<sup>[39]</sup>。但也有部分研究显示不同结果,多模态超声技术是否可作为TIRADS分级的辅助诊断技术还需深入研究。

### 4.4 医学人工智能技术的应用

随着现代科技的发展,更多先进手段与医学

结合,涌现出网页版、手机APP版等多种TIRADS的灵活应用形式。计算机辅助诊断技术(CAD)凭借其自动、高效、客观以及准确的图像分析性能为解决普通超声检查的局限性找到了新的方案,虽处于半自动阶段,但已实现CAD诊断软件系统的商业转化。安克甲状腺侦®是全球唯一通过美国FDA及欧盟CE Mark认证的甲状腺超声CAD软件,已在我国、巴西、澳大利亚等开展相关业务及推广<sup>[40]</sup>。同时,神经卷积网络、深度学习等更加高级、复杂的算法也已成为研究热点。

综上所述,TIRADS通过恶性风险分层管理,对甲状腺结节的诊断和治疗有一定提示指导作用。历经10年发展,整个体系从复杂到简单,可操作性提高,临床应用日趋广泛,科学研究兼具机遇与挑战。甲状腺疾病的术前评估、术中决策与术后随访多个环节均需要超声技术的支持,甲状腺外科医师通过对TIRADS的理论学习与临床应用,将更好地规范掌握甲状腺超声技术,从而提高超声诊断效能。目前,国内外TIRADS版本众多,亟待更多前瞻性、大样本研究验证,以期加强行业使用规范,助力甲状腺结节的精准诊疗。

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