

论著·临床研究

现场快速评估法辅助超声引导下甲状腺细针穿刺的研究

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[摘要] 目的 · 探索现场快速评估法 (rapid on-side evaluation, ROSE) 辅助超声引导下甲状腺细针穿刺 (ultrasound-guided fine needle aspiration cytology, US-FNAC) 的临床效果。方法 · 回顾性分析 2019 年 1 月—2022 年 12 月于上海市浦东新区公利医院确诊的甲状腺结节患者资料 ($n=874$)。根据细胞学检测方法分为 ROSE+液基薄层细胞学检测 (thinprep cytologic test, TCT) 组 ($n=469$) 和现场细胞涂片 (cell smear, CS)+TCT 组 ($n=405$)。ROSE+TCT 组中, ROSE 的组织细胞采样采用迪夫快速染色检测, 穿刺直至标本满意; CS+TCT 组采用苏木精-伊红染色 (hematoxylin-eosin staining, H-E 染色) + 巴氏液基细胞学染色检测。根据 Bethesda 报告系统 (The Bethesda System for Reporting Thyroid Cytopathology, TBSRTC) 细胞学分类标准进行细胞学诊断, 比较 2 种方法的样本细胞不满意度和临床效果。结果 · ROSE+TCT 组与 CS+TCT 组的标本不满意度分别为 2.4% 和 14.1%, 差异具有统计学意义 ($P=0.000$)。ROSE+TCT 组的涂片细胞集中、结构清楚、易于观察。将 ROSE+TCT 组细胞学诊断结果为Ⅲ级及以上的样本制作成细胞蜡块, 以提高后续诊断效率。CS+TCT 组细胞涂片因细胞数少未能制作成细胞蜡块。ROSE+TCT 组的穿刺次数与 CS+TCT 组的差异有统计学意义 ($P=0.011$)。结论 · 现场快速评估法辅助超声引导下甲状腺细针穿刺可现场评估标本的有效细胞数量, 现场反馈穿刺医师, 可满足病理医师实现准确诊断的细胞采集数量要求, 减少穿刺次数和治疗时间, 为临床医师的诊断和后续检查起到较好的辅助作用。

[关键词] 甲状腺结节; 现场快速评估法; 超声引导; 细针穿刺; 细胞量

[DOI] 10.3969/j.issn.1674-8115.2023.08.011 **[中图分类号]** R581.3 **[文献标志码]** A

Study on ultrasound-guided thyroid fine needle puncture assisted by rapid on-side evaluation

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[Abstract] Objective · To explore the clinical effect of ultrasound-guided fine needle aspiration cytology assisted by rapid on-side evaluation (ROSE). Methods · The data of patients with thyroid nodules diagnosed in Gongli Hospital of Shanghai Pudong New Area from January 2019 to December 2022 were retrospectively analyzed ($n=874$). According to cytological detection methods, they were divided into ROSE+thinprep cytologic test (TCT) group ($n=469$) and cell smear (CS)+TCT group ($n=405$). In the ROSE+TCT group, the tissue and cell samples of ROSE were detected by Diff-Quik staining and continue puncturing until the specimen was satisfied. In the CS+TCT group, the tissue and cell samples were detected by hematoxylin-eosin staining (H-E staining) + Pap staining. Cytologic diagnosis was made according to The Bethesda System for Reporting Thyroid Cytopathology (TBSRTC) cytologic classification criteria, and the cell dissatisfaction rates and clinical outcomes of the 2 methods were compared. Results · The dissatisfaction rates of the ROSE+TCT group and CS+TCT group were 2.4% and 14.1%, respectively, with statistical significance ($P=0.000$). The smear cells of the ROSE+TCT group were concentrated, and the structure was clear and easy to observe. The samples with a cytologic diagnosis of grade III and above were prepared as cell wax blocks to improve the efficiency of subsequent diagnosis. The cells of the CS+TCT group could not produce wax blocks due to the small numbers of cells. The puncture times of the ROSE+TCT group were significantly different from that of the CS+TCT group ($P=0.011$). Conclusion · The

[基金项目] 上海市浦东新区卫生系统重要薄弱学科建设项目 (PWZbr2022-18); 2022 年浦东新区卫健委重点专科建设项目 (PWZzk2022-05)。

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[Funding Information] Shanghai Pudong New Area Health System Key Weak Discipline Construction Project (PWZbr2022-18); Key Specialty Construction Project of Pudong New Area Health Commission in 2022 (PWZzk2022-05).

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[网络首发] <https://link.cnki.net/urlid/31.2045.R.20230824.1700.002> (2023-08-25 10:34:20)。



ultrasound-guided thyroid fine needle aspiration assisted by rapid on-site assessment method can assess the effective number of cells in the specimen on the spot, give feedback to the puncturing doctors on the spot, meet the diagnostic accuracy requirements of pathologists by collecting a sufficient number of cells, reduce the number of punctures and treatment time, and play a good auxiliary role in the diagnosis and follow-up examination of clinicians.

[Key words] thyroid nodule; rapid on-site evaluation (ROSE); ultrasonic guidance; fine needle aspiration; cell mass

甲状腺结节 (thyroid nodule, TN) 是甲状腺滤泡细胞局部异常生长导致的甲状腺区域内异常肿块, 是临床常见的内分泌疾病和外科疾病^[1]。甲状腺结节的发生主要与甲状腺退行性病变、自身免疫、炎症反应相关, 表现为甲状腺肿大、吞咽困难等症状^[2]。近年来, 随着社会环境的变化、人类饮食习惯的改变以及工作压力的增强, 甲状腺结节的患病率呈逐年上升趋势^[3]。甲状腺结节大多为良性结节, 但有5%~15%为恶性结节^[4]。甲状腺结节起病隐匿, 临床症状不典型, 容易出现误诊和漏诊, 因此恶性甲状腺结节的性质确认尤为重要^[5]。超声引导下甲状腺结节细针穿刺活检 (ultrasound-guided fine needle aspiration cytology, US-FNAC) 是目前诊断甲状腺结节的主要方法, 具有高效、微创、安全等优点^[6]; 液基薄层细胞学检测 (thinprep cytologic test, TCT) 的杂质少, 涂片质量高, 在一定程度上解决了血液和杂质的干扰。然而, 由于穿刺技术欠佳、结节病变部位过小、钙化或囊性变等原因, 会导致US-FNAC取样可诊断的细胞不足而造成后续病理医师阅片存在困难甚至漏诊等问题^[7-8]。为解决上述问题, 本研究在常规US-FNAC以及现场细胞涂片 (cell smear, CS)+TCT的基础上, 增加了现场快速评估法 (rapid on-site evaluation, ROSE), 现场辅助穿刺医师确认穿刺路径, 以期提高样本有效细胞数量, 降低细胞不满意率, 为甲状腺结节的诊断提供有效帮助。

1 对象与方法

1.1 研究对象

回顾性纳入2018年1月—2022年7月于上海市浦东新区公利医院就诊的全部甲状腺结节患者资料。纳入标准: ①符合《甲状腺结节和分化型甲状腺癌诊治指南》^[9]甲状腺结节的诊断标准。②临床资料完整。③具备甲状腺细针穿刺术的指征。④均行US-FNAC取样和TCT。排除标准: ①其他慢性基础疾病未得到控制者。②临床资料不全者。③存在其他肿瘤疾病

者。④存在亚急性甲状腺炎等其他甲状腺疾病者。根据细胞学检测方法分为ROSE+TCT组和CS+TCT组。

1.2 方法

1.2.1 US-FNAC 根据《甲状腺结节与分化型甲状腺癌诊治指南》^[9]为标准, 行US-FNAC活检, 由本院一位高年资医师行穿刺术和一位高年资培训合格的技师行涂片及快速染色, 还有一名高年资细胞医师现场阅片评估。

(1) 超声定位及引导。患者取仰卧位, 垫高肩部, 下颌垂直于检查床, 充分暴露患者颈部; 采用荷兰飞利浦EPIQ5全身应用彩色多普勒超声诊断系统彩超机, 将探头频率调至5~12 MHz后行常规扫描甲状腺结节, 对病变结节进行体表定位; 采用同一超声诊断仪(探头频率为5~12 MHz), 再次对甲状腺峡部及双侧甲状腺腺叶及颈部淋巴结进行扫描, 确定最佳的穿刺点及穿刺路径。

(2) FNAC取样及活检。穿刺部位常规消毒, 采用一次性22G穿刺针, 操作医师用手固定结节, 握穿刺针, 沿探头扫描的平面斜角30°~60°刺入病变区域, 避开血管、神经、钙化及囊腔等组织, 旋转针头从不同角度反复提插穿刺针3~6次, 吸取组织后迅速退出。涂片送检, CS+TCT制片进行细胞学检查。

1.2.2 ROSE US-FNAC同时行迪夫快速染色。将样品置于迪夫快速染色液(Diff-Quik)的固定液内固定1 min, 用纯净水洗去多余的固定液; 在迪夫快速染色液I(Diff-Quik I)染色1 min, 用纯净水洗去多余的染液; 迪夫快速染色液II(Diff-Quik II)染色1 min, 用纯净水洗去多余的染液; 吹干涂片, 用中性树胶封片。在奥林巴斯光学显微镜(×100)视野下观察。标本满意则穿刺结束, 标本不满意则根据反馈和穿刺经验调整进针路径再次穿刺直至样本满意为止, 穿刺结束嘱患者无菌纱布压迫10 min防止出血。

1.2.3 TCT制片 将US-FNAC所得样本的做TCT液基细胞制片。将含有穿刺细胞的TCT保存液震荡10 min, 一半转移至离心管666×g离心5 min, 弃上



清液，加入2 mL缓冲液再次震荡混匀，后用LBP液基细胞沉降式自动制片仪制片，巴氏染色。

1.2.4 蜡块制作 根据ROSE下的细胞学诊断，Bethesda报告系统(The Bethesda System for Reporting Thyroid Cytopathology, TBSRTC)细胞学分类标准^[10]Ⅲ级及以上均做细胞蜡块，剩余部分置于TCT保存液。行666×g离心10 min，弃上清液，加琼脂浆，震荡，离心待凉，取出，剔除多余琼脂，切成3片，常规脱水，包埋，切片，苏木精-伊红染色(hematoxylin-eosin staining, H-E染色)，制成的蜡块待用。

1.3 观察指标

1.3.1 标本不满意度 比较2组的标本不满意率，标准如下：①每张玻片的滤泡上皮细胞达到6簇，或散在单个的滤泡上皮不少于10个及细小的甲状腺碎片，保留着病变的结构形式，视为标本满意。②细胞团少于6簇，内含大量的胶质、B超没有可疑征象的囊性成分，大量的淋巴细胞或核异型性的滤泡上皮细胞，视为标本不满意。

1.3.2 细胞学诊断结果 根据TBSRTC细胞学分类标准^[10]，可分为6级：①I级为细胞不足或无法诊断。②II级为良性。③III级为意义不明确的非典型性病变或意义不明确的滤泡性病变。④IV级为滤泡性肿瘤或可疑滤泡性肿瘤。⑤V级为可疑恶性肿瘤。⑥VI级为恶性。并将良性（II级）和恶性（VI级）归为有确定意义的细胞学诊断结果，III~V级归为不确定的细胞学诊断结果。以病理学结果为金标准，比较2组患者的细胞学活检结果与病理学结果的一致性。

1.4 统计学分析

采用SPSS 20.0软件进行统计分析。定量数据用 $\bar{x}\pm s$ 表示，组间比较采用t检验；定性资料用频数（百分率）表示，组间比较采用 χ^2 检验。 $P<0.05$ 表示差异有统计学意义。

2 结果

2.1 患者一般资料

共纳入患者874例，其中ROSE+TCT组469例（年龄范围为19~89岁），CS+TCT组405例（年龄范围为21~87岁）。2组甲状腺结节患者的一般资料比较

结果如表1所示。2组患者的性别、年龄、穿刺部位比较差异无统计学意义（均 $P>0.05$ ）。

表1 2组甲状腺结节患者的一般资料

Tab 1 General data of the 2 groups of patients with thyroid nodules

Item	ROSE+TCT (n=469)	CS+TCT (n=405)	P value
Gender/[n(%)]			0.892
Male	126 (26.9)	113 (27.9)	
Female	343 (73.1)	292 (72.1)	
Age/year	42.1±4.0	43.2±3.4	0.358
Thyroid puncture site/[n(%)]			0.781
Left thyroid lobe	276 (58.9)	225 (55.6)	
Right thyroid lobe	193 (41.1)	180 (44.4)	

2.2 2组患者的细胞满意度比较

如表2所示，ROSE+TCT组共487个甲状腺结节，CS+TCT组共427个甲状腺结节，2组患者穿刺次数差异有统计学意义($P=0.011$)。ROSE+TCT组标本不满意度为2.4% (12/487)，CS+TCT组标本不满意度为14.1% (60/427)，差异有统计学意义($P=0.000$)。

表2 2组患者的穿刺情况和细胞不满意度

Tab 2 Puncture and cell unsatisfaction in the 2 groups of patients

Group	ROSE+TCT (n=469)	CS+TCT (n=405)	P value
Number of punctures/n	487	427	-
Number of punctures per person/n	1.01±0.11	1.32±0.76	0.011
Number of unsatisfactory specimen/[n(%)]	12 (2.4)	60 (14.1)	0.000

2.3 2组细胞学诊断结果比较

2组细胞学诊断结果如表3所示。ROSE+TCT组中，良性结节459例，恶性结节10例，其中9例未在本院做手术，未得到病理学诊断结果，1例术后病理学诊断结果与细胞学诊断结果一致。CS+TCT组中，良性结节404例，恶性结节1例，该例患者未在本院做手术，未得到病理学结果。

表3 2组患者的细胞学诊断结果[n(%)]

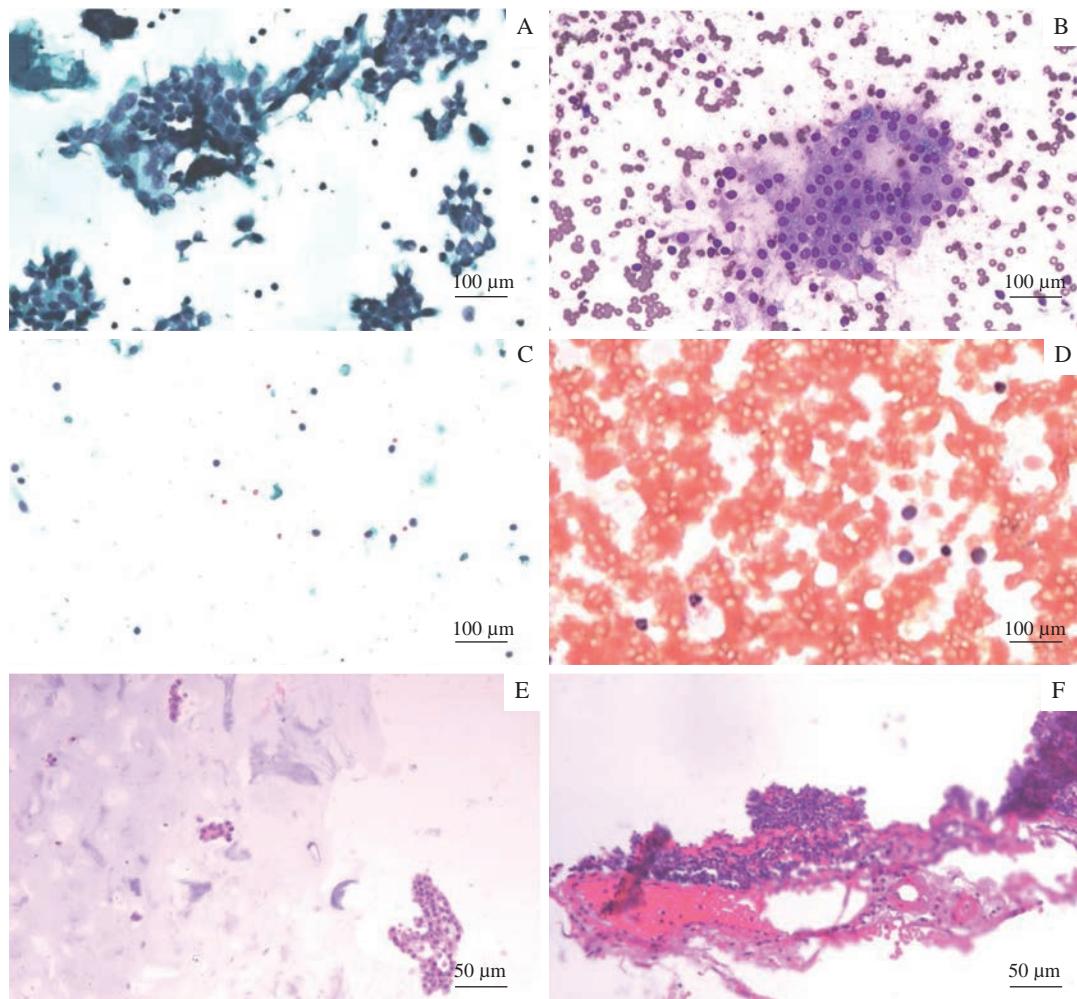
Tab 3 Cytologic diagnostic in the 2 groups of patients [n(%)]

TBSRTC classification	ROSE+TCT (n=469)	CS+TCT (n=405)
I	8 (1.7)	94 (23.2)
II	254 (54.2)	199 (49.1)
III	129 (27.5)	72 (17.8)
IV	68 (14.5)	39 (9.6)
V	9 (1.9)	1 (0.2)
VI	1 (0.2)	0 (0.0)



2.4 2种方法的细胞学检查结果

对2组患者均进行CS+TCT、ROSE+TCT+现场迪夫快速染色，并对ROSE+TCT组细胞学诊断结果



Note: A/B. TCT smear (A) and Diff-Quik staining smear (B) by ROSE ($\times 100$). C. TCT smear ($\times 100$). D. CS smear ($\times 100$). E/F. Cell wax block (E) and H-E staining (F) by ROSE ($\times 200$).

图1 2种方法的细胞学检查结果

Fig 1 Cytology results of two methods

3 讨论

甲状腺结节为临床常见的内分泌肿瘤疾病，近年来发病率呈明显上升趋势^[11-13]。甲状腺结节可分为良性和恶性，术后病理学是诊断该疾病的金标准。结节如果为良性，手术则可能存在过度治疗；如果结节为恶性，则需尽快手术，因此术前诊断的准确性至关重要^[14]。超声是临床诊断甲状腺结节的主要方法，具有较高的检出率及良、恶性诊断价值，但甲状腺结节的超声表现存在交叉重叠、缺乏典型的超声表现特

征，因而难以对其性质进行鉴别，不能很好地满足术前诊断的需求^[14]。FNAC活检是目前甲状腺结节细胞学检查的常规方法，通过抽出病变部位细胞，供细胞学涂片与切片检查。FNAC对组织器官创伤小，可获得较满意的细胞学标本^[15]。超声引导的细针穿刺活检术是甲状腺结节目前重要的诊断手段，具有微创、便捷、经济、敏感度及特异度高等优点^[16-18]。但是，超声引导的细针穿刺活检也会有漏诊，原因包括穿刺技术欠佳、结节大小、结节钙化或囊性变等不易穿到等^[19]。此外，传统制片存在细胞分布不均匀、



固定不及时、血性样本、囊性液及杂质等等干扰，导致甲状腺细胞被大量覆盖，造成病理医生阅片困难甚至漏诊^[16]。TCT涂片在显微镜下具有背景清晰、细胞集中、易于观察等特点，其良、恶性诊断符合率均高于传统涂片^[16]。在甲状腺细针穿刺样本的应用中，TCT比传统涂片在染色、诊断方面都有突破性的改进。但TCT依然存在一定的不足，主要原因因为穿刺标本内的有效细胞数量不足，未能达到诊断要求。

ROSE辅助超声引导下甲状腺细针穿刺的研究报道尚不多见。本研究实施ROSE，现场对提取组织行迪夫快速染色评估，结果表明实施ROSE可现场反馈穿刺医师，减少穿刺次数（表2），减少患者二次穿刺的痛苦和等待时间，提高诊断准确率；与陈杰桓等^[20]的研究结果一致。本研究对细胞学诊断Ⅲ级及以上的样本制作细胞蜡块，使甲状腺穿刺的细胞呈现集中、数量多、结构清楚、易于观察（图1），大大降低病理医师的工作量并提高了诊断效率，受到病理医师的欢迎。但是，由于本研究的患者被诊断为恶性后就转投其他三甲医院进行手术，因此未能得到病理学结果，无法比较诊断效能。

综上，ROSE辅助的超声引导下甲状腺细针穿刺可确保涂片的细胞数量充足，有效提高了标本满意度，而且对细胞学分类Ⅲ级及以上者制作蜡块切片，有利于病理医师准确诊断，便于后续开展免疫组化和苏氨酸特异性激酶（serine-threonine protein kinase, BRAF）、V600及端粒酶反转录酶（telomerase reverse transcriptase, TERT）启动子突变

的检测，为临床病患的个体化治疗提供依据，值得普遍推广。但本研究亦存在不足，如样本分流后细胞数量变少，对蜡块制作有一定的难度，今后将进一步优化。

利益冲突声明/Conflict of Interests

所有作者声明不存在利益冲突。

All authors disclose no relevant conflict of interests.

伦理批准和知情同意/Ethics Approval and Patient Consent

本研究涉及的所有操作均已通过上海市浦东新区公利医院伦理委员会的审核批准（批准号：GLYYIs2023-022）。所有实验过程均遵照《赫尔辛基宣言》的条例进行。

All the experiments involved in this study were approved by the Ethics Committee of Gongli Hospital of Shanghai Pudong New Area (Document No:GLYYIs2023-022), and all experimental protocols were carried out by following the guidelines of the Declaration of Helsinki.

作者贡献/Authors' Contributions

贺玉洁参与试验设计，研究实施及论文撰写；任宏政参与试验设计及修改；施超、丁珺、张翘楚、姚勇强、张至立、樊琳蕊参与研究实施及数据整理。所有作者均阅读并同意了最终稿件的提交。The study was designed by HE Yujie. The manuscript was drafted and revised by HE Yujie and REN Hongzheng. The research implementation and data analysis were carried out by SHI Chao, DING Jun, ZHANG Qiaochu, YAO Yongqiang, ZHANG Zhili, and FAN Lingrui. All the authors have read the last version of paper and consented for submission.

- Received: 2023-06-19
- Accepted: 2023-07-17
- Published online: 2023-08-25

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[本文编辑] 张慧俊