·论著·

^{131}I治疗分化型甲状腺癌术后单发颈部淋巴结转移灶的疗效及影响因素分析

阮 毅，袁 辉，郑 峰，陈雪华，徐 诚

中南大学湘雅医学院附属常德医院（常德市第一人民医院）核医学科，湖南 常德 415000

［摘要］ **背景与目的：**分化型甲状腺癌（differentiated thyroid cancer，DTC）术后颈部淋巴结转移（cervical lymph node metastasis，LNM）是影响患者预后的重要因素。对于拒绝再次手术的患者，^{131}I治疗是关键的替代方案。然而既往研究多基于影像学诊断，可能高估疗效。本研究旨在严格纳入经细胞学检查证实的单发LNM患者，真实评估^{131}I治疗在此类患者中的疗效，并分析其影响因素。**方法：**本研究为一项单中心回顾性队列研究，收集2019年1月—2023年1月中南大学湘雅医学院附属常德医院（常德市第一人民医院）收治的DTC术后经细针抽吸细胞学检查证实为单发LNM且拒绝再次手术的107例患者的临床资料，本研究获得中南大学湘雅医学院附属常德医院（常德市第一人民医院）伦理委员会批准（批件号：2025-079-02，2025-080-01）。所有患者停用左甲状腺素钠片及低碘准备后，接受单次固定剂量（5.55 GBq）^{131}I治疗。治疗后第3天进行^{131}I全身扫描（whole-body scan，WBS）及单光子发射型计算机断层扫描/计算机断层扫描（single photon emission computed tomography/computed tomography，SPECT/CT），根据转移淋巴结是否摄碘，将患者分为摄碘阳性组（n=64）与摄碘阴性组（n=43），并于治疗后随访12个月，主要随访指标包括抑制状态血清甲状腺球蛋白（thyroglobulin，Tg）及转移淋巴结大小（通过高分辨率超声及薄层CT测量），依据《^{131}I治疗分化型甲状腺癌指南（2021版）》将疗效分为疗效满意（excellent response，ER）、疗效不确切（indeterminate response，IDR）、生化疗效不佳（biochemical incomplete response，BIR）和结构性疗效不佳（structural incomplete response，SIR）。采用SPSS 26.0软件，主要比较组间血清Tg水平及淋巴结大小变化率，计量资料以M（Q1，Q3）表示，组间比较采用Mann-Whitney U检验，计数资料以n（%）表示，组间比较采用χ^2检验，多因素分析采用二元logistic回归模型。**结果：**治疗后1年，总有效率为36.4%。摄碘阳性组有效率（51.6%，33/64）显著高于摄碘阴性组（14.0%，6/43）（χ^2=16.25，P<0.001）。在抑制状态血清Tg方面，治疗后12个月，摄碘阳性组血清Tg水平中位下降率达85.2%，显著高于摄碘阴性组的12.5%，差异有统计学意义（P<0.001）。在淋巴结大小变化方面，治疗后12个月，摄碘阳性组的缩小程度（中位缩小47.8%）显著优于摄碘阴性组（中位缩小5.3%），差异有统计学意义（P<0.001）。多因素分析显示，淋巴结摄碘情况是影响疗效的独立因素［比值比（odds ratio，OR）=3.27，95% CI：1.09~9.79，P=0.034］。**结论：**对于拒绝再次手术的DTC术后单发LNM患者，^{131}I治疗是一种有效的替代方案，尤其对摄碘阳性病灶效果显著。淋巴结摄碘能力是预测疗效的关键指标。

［关键词］ 分化型甲状腺癌；^{131}I；淋巴结转移；疗效及影响因素；摄碘阳性

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Efficacy of adjuvant ^{131}I therapy for postoperative solitary cervical lymph node metastasis in differentiated thyroid cancer and its influencing factors RUAN Yi, YUAN Hui, ZHENG Feng, CHEN Xuehua, XU Cheng

［Department of Nuclear Medicine, Changde Hospital, Xiangya School of Medicine, Central South University (The First People's Hospital of Changde City), Changde 415000, Hunan Province, China］

Correspondence to: XU Cheng E-mail: 56181527@qq.com

［**Abstract**］ **Background and purpose:** Cervical lymph node metastasis (LNM) following surgery for differentiated thyroid cancer (DTC) is a significant prognostic factor. For patients who decline reoperation, radioiodine (^{131}I) therapy serves as a crucial alternative. However, previous studies, often based on imaging diagnosis alone, may overestimate its efficacy. This study aimed to strictly enroll patients with cytologically confirmed solitary LNM to accurately evaluate the efficacy of ^{131}I therapy in this specific population and to identify factors. **Methods:** This was a single-center retrospective cohort study that analyzed 107 DTC patients with postoperative, solitary cervical LNM who declined secondary surgery and were treated at Changde Hospital, Xiangya School of Medicine, Central South University (The First People's Hospital of Changde City) from January 2019 to January 2023. This study was approved by the Ethics Committee of Changde Hospital, Xiangya School of Medicine, Central South University (The First People's Hospital of Changde City) (approval number: 2025-079-02, 2025-080-01). All patients received a single oral dose of 5.55 GBq ^{131}I after thyroid hormone withdrawal and a low-iodine diet. Post-therapy ^{131}I whole-body scan (WBS) and single-photon emission computed tomography/computed tomography (SPECT/CT) were performed on day 3. Patients were categorized into a radioiodine-avid group (n=64) and a non-avid group (n=43) based on whether the metastatic lymph node showed ^{131}I uptake. All patients were followed up for 12 months. Primary follow-up parameters included stimulated serum thyroglobulin (Tg) levels and the short-axis diameter of the metastatic lymph node (measured via high-resolution ultrasound and thin-slice contrast-enhanced CT, independently verified by two physicians). Therapeutic response was assessed at 12 months according to the "Guideline for radioiodine therapy of differentiated thyroid cancer (2021 edition)" and classified as excellent response (ER), indeterminate response (IDR), biochemical incomplete response (BIR), or structural incomplete response (SIR). The effective rate was defined as the sum of ER and IDR. Secondary analysis focused on the percentage change in serum Tg and lymph node short-axis diameter. SPSS 26.0 was used for statistical analysis. Continuous variables were presented as median (IQR) and compared using the Mann-Whitney U test. Categorical variables were presented as n (%) and compared using the χ^2 test. Multivariate analysis was performed using binary logistic regression. **Results:** At 1 year post-therapy, the overall effective rate was 36.4% (39/107). The effective rate in the avid group (51.6%, 33/64) was significantly higher than that in the non-avid group (14.0%, 6/43) (χ^2=16.25, P<0.001). Regarding serum Tg changes, the median ΔTg% at 12 months was 85.2% in the avid group, significantly greater than 12.5% in the non-avid group (P<0.001). For lymph node size reduction, the median ΔShortAxis% at 12 months was -47.8% in the avid group, also significantly superior to -5.3% in the non-avid group (P<0.001). Confirmed that radioiodine avidity was an independent predictor of treatment efficacy［odds ratio (OR)=3.27, 95% CI: 1.09-9.79, P=0.034］. **Conclusion:** For patients with postoperative solitary cervical LNM who refuse surgery, ^{131}I therapy is an effective alternative, particularly for radioiodine-avid metastases. Avidity of the metastatic lymph node is the strongest independent predictor of treatment success, highlighting the importance of post-therapy SPECT/CT in guiding personalized management.

［**Key words**］ Differentiated thyroid cancer; ^{131}I; Lymph node metastasis; efficacy and influencing factors; Radioiodine avidity

甲状腺癌（thyroid carcinoma，TC）是全球发病率增长较快的恶性肿瘤之一，其中分化型甲状腺癌（differentiated thyroid cancer，DTC）占比超过90%[1]，DTC术后颈部淋巴结转移（lymph node metastasis，LNM）发生率高达35%[2]，是导致疾病复发和患者预后不良的主要危险因素[3-5]。目前手术治疗仍是LNM的首选治疗方式，但再次手术存在局部损伤风险增加、影响生活质量等问题。因此临床实践中存在一部分患者因担心手术风险、并发症或个人意愿等原因明确拒绝再次手术，对于这一特定人群，^{131}I治疗成为关键的替代选择[6-8]。既往研究[9-10]多以影像学与血清甲状腺球蛋白（thyroglobulin，Tg）来诊断淋巴结转移，尤以^{131}I全身扫描（whole-body scan，WBS）摄碘阳性为主，其存在高估^{131}I整体疗效的问题。因此，本研究旨在严格纳入因拒绝手术而选择^{131}I治疗且经细针抽吸细胞学检查证实为单发LNM的DTC患者，通过分析其治疗反应，更真实地评估^{131}I在此临床情境下的疗效价值，并探讨其影响因素。

1 资料和方法

1.1 研究对象

回顾性分析2019年1月—2023年1月中南大学湘雅医学院附属常德医院（常德市第一人民医院）核医学科收治的DTC患者的临床资料。纳入标准：① 高分辨率超声及薄层增强计算机断层扫描（computed tomography，CT）仔细筛查颈部淋巴结区域（包括锁骨区，归为颈部Ⅴ区），确认仅为单发淋巴结，且经细胞学检查证实为DTC转移；② 患者明确拒绝再次手术。排除标准：① 抗甲状腺球蛋白抗体（anti-thyroglobulin

antibody，anti-TGAb）阳性（>115 IU/mL）；②存在远处转移；③合并其他恶性肿瘤；④孕期、哺乳期妇女。本研究获得中南大学湘雅医学院附属常德医院（常德市第一人民医院）伦理委员会批准（批件号：2025-079-02，2025-080-01），豁免知情同意。

1.2 ^{131}I治疗和显像

患者行TC根治术（中央区及侧颈淋巴结清扫），禁碘4周，停服左甲状腺素钠片3~4周，使血清促甲状腺激素（thyroid-stimulating hormone，TSH）>30 μIU/mL，根据《^{131}I治疗分化型甲状腺癌指南（2021版）》[11]对明确为LNM的患者推荐^{131}I治疗剂量为3.70~5.55 GBq（100~150 mCi），本研究为排除不同剂量的影响仅纳入最大150 mCi的患者进行研究。

治疗后第3天进行WBS及单光子发射型计算机断层扫描/CT（single photon emission computed tomography/CT，SPECT/CT），显像设备为德国Siemens公司Symbia T16。WBS采集设置为Matrix size：1024×256；Scan Speed：5 cm/min。随后进行颈部断层显像，Matrix size：64×64；ZOOM：1.0；Degrees of Rotation：180°，40 s/帧，共60帧。CT扫描参数为管电压130 kV，管电流250 mA，层厚3 mm。CT定位到已穿刺活检的淋巴结，记录淋巴结摄碘情况，由2名高年资核医学科医师独立判读，诊断意见一致时，诊断成立；若意见不一致，则需请上级医师会诊，并以会诊结果为最终诊断。^{131}I治疗后WBS发现甲状腺床外有碘浓聚病灶，SPECT/CT证实淋巴结摄碘的，定义为淋巴结摄碘阳性；反之，定义为淋巴结摄碘阴性（图1）。随访中将高分辨率超声和颈部薄层CT（层厚1~2 mm）进行测量与交叉验证，每次测量均由2位不低于5年经验的核医学科医师独立进行，若两次测量结果差异>0.5 mm，则通过协商达成一致或由第3位高年资医师裁定。

1.3 随访和疗效评价

收集随访资料，包括抑制状态下血清Tg、Tg-Ab水平及颈部超声、薄层增强CT等检查。疗效评价根据《^{131}I治疗分化型甲状腺癌指南（2021版）》[11]标准分为4类：疗效满意（excellent response，ER）、疗效不确切（indeterminate response，IDR）、生化疗效不佳（biochemical incomplete response，BIR）和结构性疗效不佳（structural incomplete response，SIR），有效率为ER与IDR之和。为更科学地评估疗效，主要分析指标为各随访时间点血清Tg水平及转移淋巴结大小相较于基线的变化率（%）。

1.4 统计学处理

采用SPSS 26.0软件，所有数据通过Kolmogorow-Smironov检验进行正态分布检验，对于符合或接近正态分布的定量数据，采用t检验或秩和检验进行组间比较，数据以$\bar{x}\pm s$表示；非正态分布的数据以M（Q1，Q3）表示，组间比较采用Mann-Whitney U检验；计数资料以n（%）表示，采用χ^2检验。重点比较摄碘阳性组与阴性组之间血清Tg水平变化率（ΔTg%）和淋巴结大小变化率（ΔSize%）的差异。多因素分析采用logistic回归。P<0.05为差异有统计学意义。

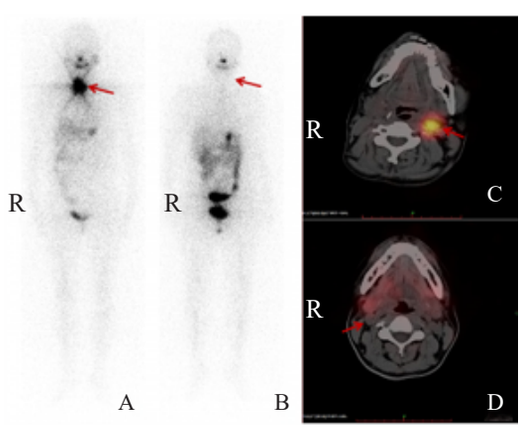

图1 ^{131}I治疗后淋巴结摄碘图示

Fig. 1 Lymph node radioiodine uptake on post-therapy ^{131}I scan

A: Post-therapy ^{131}I-WBS shows focal radioactive concentration in the neck (as shown by red arrow); B: Post-therapy ^{131}I-WBS reveals no abnormal radioactive uptake in the neck (as shown by red arrow); C: SPECT/CT fusion imaging demonstrates iodine-avid lymph nodes (as shown by red arrow); D: SPECT/CT fusion imaging shows no evidence of iodine-avid lymph nodes (as shown by red arrow).

2 结　果

2.1 基线资料比较

最终107例患者纳入本研究，患者纳入和排除流程图见图2。其中男性26例（24.3%），女性81例（75.7%）；年龄<55岁的87例（81.3%），≥55岁的20例（18.7%）。参考美国癌症联合会（American Joint Committee on Cance，AJCC）第8版指南TNM分期，Ⅰ期59例，Ⅱ期28例，Ⅲ期13例，Ⅳ期7例；摄碘阳性64例（59.8%），摄碘阴性43例（40.2%）。两组患者抑制状态、刺激状态血清Tg差异有统计学意义（P<0.05），年龄、性别、肿瘤分期等基线资料差异无统计学意义（P>0.05），患者一般临床资料见表1。

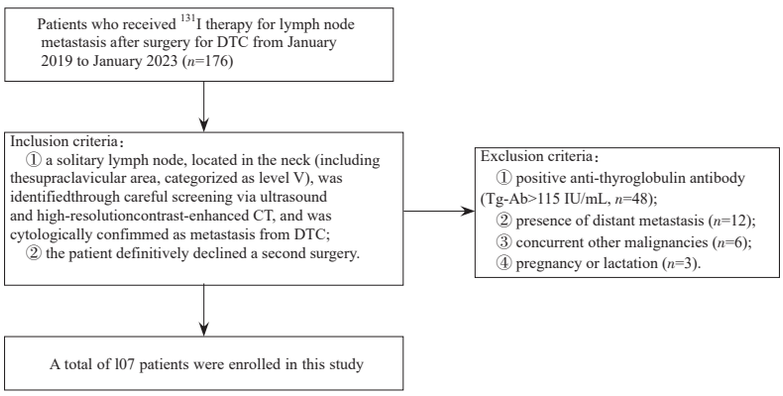

图2 患者纳入和排除流程图

Fig. 2 Flowchart of patients inclusion and exclusion

表1 107例DTC患者的基线资料

Tab. 1 Baseline characteristics of the 107 patients with DTC

Characteristic	Non-avid group	Avid group	χ^2	*P* value
Gender *n* (%)				
Female	11 (42.3)	15 (57.7)	0.06	0.802
Male	32 (39.5)	49 (60.5)		
Age/year *n* (%)				
<55	36 (41.4)	51 (58.6)	0.27	0.600
≥55	7 (35.0)	13 (65.0)		
TNM *n* (%)				
Ⅰ	21 (35.6)	38 (64.4)	0.12	0.861
Ⅱ	15 (53.6)	13 (46.4)		
Ⅲ	5 (38.5)	8 (61.5)		
Ⅳ	3 (42.9)	4 (57.1)		
Dynamic risk stratification *n* (%)				
Low risk	2 (40.0)	3 (60.0)	1.14	0.580
Intermediate risk	32 (45.1)	39 (54.9)		
High risk	9 （28.1)	23 (71.9)		
Lymph node level *n* (%)				
Ⅰ	1 (50.0)	1 (50.0)	4.96	0.410
Ⅱ	5 (27.8)	13 (72.2)		
Ⅲ	16 (45.7)	19 (54.3)		
Ⅳ	12 (54.5)	10 (45.5)		
Ⅴ	4 (30.8)	9 (69.2)		
Ⅵ	5 (29.4)	12 (70.6)		
Ns-Tg/(ng·mL^{-1}) M (Q1, Q3)	4.37 (0.32, 10.17)	0.37 (0.14, 2.32)	1.98	0.011
Ns-Tg-Ab/(U·mL^{-1}) M (Q1, Q3)	20.06 (17.21, 31.83)	19.11 (14.55, 99.23)	0.35	0.722
Ns-TSH/(U·mL^{-1}) M (Q1, Q3)	0.24 (0.07, 0.89)	0.28 (0.04, 0.97)	-1.62	0.103
sTg/(ng·mL^{-1}) M (Q1, Q3)	38.27 (11.48, 87.68)	6.58 (0.96, 25.88)	3.29	0.000
Tg-Ab/(U·mL^{-1}) M (Q1, Q3)	19.15 (15.00, 26.30)	21.50 (16.68, 71.15)	0.64	0.520
TSH/(U·mL^{-1}) M (Q1, Q3)	100.00 (91.38, 100.23)	100.00 (80.95, 100.15)	1.56	0.120
Short axis baseline/mm M (Q1, Q3)	5.45 (3.72, 7.14)	4.72 (3.93, 5.64)	1.70	0.090

2.2 治疗后血清Tg水平及淋巴结大小的变化率比较

摄碘阳性组血清Tg水平下降及淋巴结缩小的程度均显著大于摄碘阴性组。以治疗后12个月为例，摄碘阳性组血清Tg水平中位下降率达85.2%，而摄碘阴性组中位下降率仅为12.5%，组间差异显著（*P*<0.001）；淋巴结短径的变化率同样显示，摄碘阳性组的缩小程度（中位缩小47.8%）显著优于摄碘阴性组（中位缩小5.3%）差异有统计学意义（*P*<0.001，表2、3）。

表2 两组患者治疗后血清Tg水平相较于基线的变化率比较

Tab. 2 Comparison of the percentage change in serum Tg levels from baseline between the two groups

［M (Q1, Q3), %］

Group	ΔTg% (1 month)	ΔTg% (3 months)	ΔTg% (6 months)	ΔTg% (12 months)
Avid group (*n*=64)	-65.5 (-78.2, -50.1)	-78.3 (-85.6, -65.4)	-82.7 (-90.5, -70.2)	-85.2 (-92.1, -75.8)
Non-avid group (*n*=43)	-10.5 (-25.3, +5.8)	-8.7 (-20.1, +10.3)	-11.4 (-23.5, +8.9)	-12.5 (-28.3, +15.6)
P value	0.007	0.003	<0.001	<0.001

ΔTg%=［(Tg at follow-up—baseline Tg)/baseline Tg］×100%, where a negative value indicates a decrease. The Mann-Whitney U test was used for intergroup comparisons.

表3 两组患者治疗后转移淋巴结短径相较于基线的变化率比较

Tab. 3 Comparison of the percentage change in short-axis diameter of metastatic lymph nodes from baseline between the two groups

［M (Q1, Q3), %］

Group	Δshort axis% (3 months)	Δshort axis% (6 months)	Δshort axis% (12 months)
Avid group (*n*=64)	-25.4 (-35.6, -15.8)	-38.9 (-50.2, -28.7)	-47.8 (-60.5, -35.1)
Non-avid group (*n*=43)	-3.5 (-8.9, +2.1)	-4.1 (-10.5, +5.8)	-5.3 (-12.4, +10.2)
P value	0.036	<0.001	<0.001

Δshort axis%=［(short diameter at follow-up—baseline short diameter)/baseline short diameter］×100%, where a negative value indicates a reduction. The Mann-Whitney U test was used for intergroup comparisons.

2.3 疗效评价与多因素分析

治疗后1年，两组患者均无明确不良反应发生，总有效率为36.4%。摄碘阳性组有效率（51.6%）显著高于摄碘阴性组（14.0%）（*P*<0.001）。多因素logistic回归分析显示，淋巴结摄碘阳性是疗效佳的独立预测因素［比值比（odds ratio，OR）=3.27，95% CI：1.09~9.79，*P*=0.034，表4、5］。

表4 治疗后1年疗效评估

Tab. 4 Therapeutic response at 1-year follow-up

［*n* (%)］

Group	ER	IDR	BIR	SIR	ER+IDR
Avid group (*n*=64)	25 (39.1)	8 (12.5)	5 (7.8)	26 (40.6)	33 (51.6)
Non-avid group (*n*=43)	2 (4.7)	4 (9.3)	2 (4.7)	35 (81.4)	6 (14.0)
P value	0.024	0.013	0.064	0.051	<0.001

表5 ^{131}I治疗效果多因素logistic回归分析

Tab. 5 Multivariate logistic regression analysis of radioiodine therapeutic efficacy

Variables	β	*SE*	Wald χ^2	*P* value	OR (95% CI)
TNM			2.18	0.516	
Ⅰ	-	-	-	-	1.00 (reference)
Ⅱ	-0.32	0.52	0.38	0.539	0.73 (0.26-2.02)
Ⅲ	0.41	0.68	0.36	0.547	1.51 (0.40-5.72)
Ⅳ	-0.58	0.91	0.41	0.524	0.56 (0.09-3.34)
Dynamic Risk Stratification			3.05	0.217	
Low risk	-	-	-	-	1.00 (reference)
Intermediate risk	0.70	0.85	0.68	0.410	2.01 (0.38-10.61)
High risk	1.22	0.89	1.88	0.170	3.39 (0.59-19.42)
Radioiodine avidity					
Avidity *vs* non-avid	1.18	0.56	4.52	0.034	3.27 (1.09-9.79)
Short axis/mm	0.28	0.14	3.72	0.055	1.32 (0.99-1.75)
Tg/(ng·mL^{-1})	1.57	0.83	2.78	0.059	4.81 (0.94-24.62)
Constant	-1.80	0.81	4.94	0.026	0.17

3 讨 论

本研究聚焦于DTC术后单发LNM且明确拒绝再次手术这一特殊临床人群，尽管手术是第一推荐方案，但尊重患者意愿并为其寻求有效替代疗法具有重要的现实意义。本研究通过细胞学检查确诊入组，避免了仅纳入摄碘阳性患者导致的选择偏倚，客观揭示了^{131}I在该群体中的总体有效率为36.4%。这一结果低于部分既往研究（76.4%~88.07%）报道[12-13]，其根本原因在于本研究纳入了高达40.2%的摄碘阴性病例，而这部分患者在以往研究中往往被排除在以“摄碘病灶”为起点的疗效分析之外，提示忽略肿瘤功能异质性可能高估^{131}I的整体疗效。

本研究的关键发现是证实了病灶摄碘情况是决定疗效的核心。摄碘阳性组有效率高达51.6%，且血清Tg下降率和淋巴结缩小率均显著更优，这与^{131}I通过钠碘同向转运体（sodium-iodide symporter，NIS）靶向杀伤肿瘤细胞的机制完全吻合[14]。多因素分析进一步证实，摄碘阳性是疗效佳的独立预测因子（OR=3.27）。这一结论具有重要的临床指导价值，^{131}I治疗后的SPECT/CT功能成像不仅是疗效评估工具，更是实施精准医疗的关键预判指标，与Spanu等[15]的研究相符。2015版及2025版美国甲状腺协会（American Thyroid Association，ATA）指南[3-4]均强调，对于持续性DTC，治疗决策应基于病灶的摄碘状态。对于淋巴结摄碘阳性的患者，本研究在^{131}I治疗后6个月进行系统性评估（包括血清Tg、颈部影像学等），根据2015年ATA指南及《^{131}I治疗分化型甲状腺癌指南（2021版）》[3, 9]：若评估显示ER或IDR，对于低危患者，治疗后抑制状态血清性Tg水平降至无法检测（如<0.1 ng/mL）或处于较低水平（如<1 ng/mL）且保持稳定，同时颈部影像学检查未见明确的结构性病变进展，则表明治疗反应良好，首选TSH抑制治疗和定期随访，而非立即再次进行碘治疗；若进展为SIR，则转向再次^{131}I治疗、手术或局部消融等。但摄碘阳性不代表均需重复碘治疗，而是基于个体化反应策略。本研究的结果为来自中国人群的DTC术后LNM患者^{131}I治疗提供了有力证据，明确将SPECT/CT界定为筛选^{131}I治疗优势人群的有效手段。

摄碘功能的缺失往往与甲状腺细胞分化程度丢失相关，可能与*BRAF* V600E等基因突变介导的NIS表达抑制有关[16]。本研究中摄碘阴性组仍显示14.0%的有效率，其原因可能在于TSH抑制治疗对部分微小病灶或分化程度尚可的肿瘤细胞产生了控制作用。然而，该组绝大多数（81.4%）患者最终表现为SIR，表明对于已失分化、不摄碘的肿瘤细胞，^{131}I治疗效果极其有限，继续盲目追加^{131}I治疗不仅无效，还会带来不必要的辐射暴露和经济负担。因此，一旦确诊摄碘阴性LNM，临床决策应果断地转向其他治疗模式，如再次手术切除、局部消融治疗等[5]。对于无法手术或消融治疗者，应密切监测，并考虑行^{18}F-FDG正电子发射计算机体层成像（positron emission tomography and computed tomography，PET/CT）评估其代谢活性，为后续可能需要的分子靶向治疗提供依据[4, 11]。

本研究的局限性在于其为单中心回顾性设计，样本量有限，且随访时间较短（12个月），虽收集了部分患者2年的随访数据，但因后续治疗策略分化（如部分患者因淋巴结增大接受再次手术、二次碘治疗等），未纳入统计学分析。对于治疗后残存的淋巴结，且血清Tg稳定者，本研究缺少治疗后病理学检查结果，无法明确其最终治疗后性质。未来需进一步验证本研究结论，探讨多次^{131}I治疗效果，并探索影响摄碘功能的深层次分子机制，以开发逆转摄碘能力的协同策略。

对于拒绝再次手术的DTC术后单发LNM患者，^{131}I治疗是一种合理的替代选择，尤其对摄碘阳性病灶具有确切的疗效。淋巴结摄碘能力是预测疗效的最关键因素。临床应基于SPECT/CT结果，实施个体化治疗和管理。

第一作者：

阮毅（ORCID: 0009-0009-6271-7289），硕士，主治医师。

通信作者：

徐诚（ORCID: 0009-0000-8433-2499），学士，副主任医师，中南大学湘雅医学院附属常德医院（常德市第一人民医院）核医学科科研主任，E-mail: 56181527@qq.com。

作者贡献声明：

阮毅：研究设计，数据分析，论文撰写；袁辉，郑峰：数据采集与整理；陈雪华：论文修改，临床数据审核；徐诚：论文审阅与修订。

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