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重组人促甲状腺激素临床应用中国专家共识（2025年版）

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［**摘要**］ 重组人促甲状腺激素（recombinant human thyroid-stimulating hormone, rhTSH）可应用于分化型甲状腺癌（differentiated thyroid cancer, DTC）手术后随访、^{131}I 治疗前准备和^{131}I 治疗后随访。该药物自 1998 年由美国食品药品监督管理局（Food and Drug Administration, FDA）批准上市以来，在欧美等国家已临床应用近 30 年。2024 年 4 月，中国首个自主研发的创新型 rhTSH 药物获批上市。国内专家基于临床经验，整合国内外证据，组织研讨并形成 rhTSH 临床应用中国专家共识，并根据现有证据作相应推荐，旨在规范 rhTSH 的临床应用场景。

［**关键词**］ 重组人促甲状腺激素；分化型甲状腺癌；临床应用；专家共识
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Chinese expert consensus on the clinical application of recombinant human thyroid-stimulating hormone (2025 edition)

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［**Abstract**］ The recombinant human thyroid-stimulating hormone (rhTSH) can be used for differentiated thyroid cancer (DTC) preparation before ^{131}I therapy, and follow-up. Since its approval by the American Food and Drug Administration (FDA) in 1998, rhTSH has been clinically used in European countries, the United States, and other countries for nearly 30 years. In April 2024, the first independently developed rhTSH agent in China was approved. Based on clinical experience and integrating evidence from domestic and international studies, an expert consensus on the application of rhTSH has been developed following thorough consultations among experts. The consensus offers evidence-based recommendations designed to guide the appropriate use of rhTSH in clinical practice.

［**Key Words**］ recombinant human thyroid-stimulating hormone; differentiated thyroid cancer; clinical application; expert consensus

促甲状腺激素（thyroid-stimulating hormone, TSH）是一种相对分子量约为30 000的糖蛋白，由2种亚基组成，即α亚基及β亚基，其中β亚基具有TSH特异的免疫原性和生物学活性。内源性TSH由垂体前叶特异性嗜碱细胞生成并分泌，主要功能是促进甲状腺激素的生成和分泌，同时具有促进甲状腺细胞增殖的效应[1]。分化型甲状腺癌（differentiated thyroid cancer, DTC）细胞保留了部分正常甲状腺滤泡上皮细胞的特征，多数仍表达TSH受体（TSH receptor, TSHR）。TSH可以与DTC细胞膜上的TSHR结合，促进碘处理相关蛋白的表达上调，包括钠碘同向转运体（sodium iodide symporter, NIS）、甲状腺球蛋白（thyroglobulin, Tg）、甲状腺过氧化物酶

（thyroid peroxidase, TPO）等，同时可促进 DTC 细胞增殖[2]。

重组人促甲状腺激素（recombinant human thyroid-stimulating hormone, rhTSH）是通过重组脱氧核糖核酸（deoxyribonucleic acid, DNA）技术产生的异二聚体糖蛋白，由 2 个非共价连接的亚基（α 亚基及 β 亚基）组成。α 亚基含有 2 个 N 连接糖基化位点，由 92 个氨基酸残基组成；β 亚基含有 1 个 N 连接糖基化位点，由 118 个氨基酸残基组成。rhTSH 也可与正常甲状腺细胞和 DTC 细胞上的 TSHR 结合并发挥与 TSH 类似的生物学功能[3]。

本共识由核医学科、甲状腺及头颈外科等领域共 43 位专家（附录 1，*https://c-jcm.com/article/doi/10.12025/j.issn.1008-6358.2025.20260158*）参与制订，专家意见一致率≥75% 作为达成共识的标准，共形成 8 条意见。

1 rhTSH 的研发、生物学特征及临床应用

rhTSH 最早于 1993 年由美国健赞公司（Genzyme Corporation）利用重组 DNA 技术开发并生产（thyrotropin alfa）。Thyrotropin alfa 氨基酸序列与垂体内源性 TSH 一致。rhTSH 与内源性 TSH 的区别主要在于氨基酸残基糖基化的类型与数量。因 N-乙酰氨基葡萄糖（N-acetylglucosamin, GlcNAc）和甘露糖残基的含量较高，thyrotropin alfa 的糖基化水平高于内源性 TSH；由于无 N-乙酰半乳糖胺（N-acetylgalactosamine, GalNAc）残基，thyrotropin alfa 无硫酸化修饰；同时，thyrotropin alfa 末端的唾液酸化饱和度高于内源性 TSH[3]，但其半衰期较内源性 TSH 长 10 倍以上[4]。国内 2024 年 4 月获批应用于临床的第 1 款 rhTSH 药物（人促甲状腺素注射液，研发代码 SNA001）的氨基酸序列与内源性 TSH 一致，且其药代动力学特征与 thyrotropin alfa 高度一致[5]。

美国食品药品监督管理局（Food and Drug Administration, FDA）与欧洲药品管理局（European Medicines Agency, EMA）分别于 1998 年与 2001 年正式批准 rhTSH（thyrotropin alfa）应用于 DTC 患者甲状腺全切除术后随访中血清甲状腺球蛋白的检测[伴或不伴诊断性全身显像（diagnostic whole body scan, DxWBS）]。随后，EMA 与 FDA 又分别于 2005 年和 2007年批准 rhTSH（thyrotropin alfa）用于无远处转移的 DTC 患者在甲状腺全切除或近全切除术后^{131}I 清除残余甲状腺组织的辅助治疗。中国国家药品监督管理局（National Medical Products Administration, NMPA）于 2024 年 4 月正式批准人促甲状腺素注射液用于无远处转移的 DTC 患者在甲状腺全切除或近全切除术后^{131}I 清除残余甲状腺组织的辅助治疗。

DTC 患者^{131}I 治疗前使用 rhTSH 方法：肌肉注射，1 支（0.9 mg）/d，连续 2 d。满足 TSH＞30 mIU/L 可进行^{131}I 治疗，或给予口服诊断剂量^{131}I 行治疗前 DxWBS。

DTC 患者在术后或^{131}I 治疗后开展刺激性甲状腺球蛋白（stimulated thyroglobulin, sTg；即 TSH 水平＞30 mIU/L 时测定的 Tg）检测及 DxWBS 使用 rhTSH 方法：肌肉注射，1 支（0.9 mg）/d，连续 2 d。第 5 天检测 sTg，和（或）第 3 天给予口服小剂量^{131}I 后行 DxWBS。

2 rhTSH 在 DTC ^{131}I 治疗中的应用

^{131}I 治疗是 DTC 患者全切除或近全切除术后综合治疗的主要措施之一，治疗目的：（1）清除手术后残留的甲状腺组织（清甲治疗）；（2）清除手术后影像学检查无法证实的可能存在的微小转移或残留病灶（辅助治疗）；（3）清除已证实的无法手术切除的局部或远处转移灶（清灶治疗）。

2.1 *清甲治疗* 循证医学证据表明，使用 rhTSH 与停服甲状腺激素（thyroid hormone withdrawal, THW）后^{131}I 清甲治疗的疗效相当，且患者的远期复发率差异无统计学意义。但 THW 须持续 2～4 周，导致患者体内甲状腺激素水平降低及甲状腺功能减退（简称甲减）症状，影响其生活质量与工作[6-11]。使用 rhTSH 则无需 THW，肌肉注射 2 次后，患者 TSH 能提升至 30 mIU/L 及以上，缩短了患者清甲治疗准备时间，同时避免甲减对生活质量的影响[9-13]。

国内外权威指南[14-19]均推荐将 rhTSH 用于

DTC ^{131}I 清甲治疗前准备。2023 年由英国甲状腺协会（British Thyroid Association, BTA）等多学会发布的指南强烈推荐，对于 $T_{1\sim3}$、$N_0/N_1/N_x$、M_0 并 R0 切除的 DTC 患者，在清甲前准备时使用 rhTSH[14]。2023 年，由中华医学会内分泌学分会、中华医学会外科学分会甲状腺及代谢外科学组、中国抗癌协会头颈肿瘤专业委员会、中华医学会核医学分会、中国抗癌协会甲状腺癌专业委员会、中国医师协会外科医师分会甲状腺外科医师委员会、中华医学会超声医学分会联合修订的《甲状腺结节和分化型甲状腺癌诊治指南（第二版）》[15]也强推荐，对于低、中危 DTC 患者，使用 rhTSH 用于^{131}I 治疗前准备。2022 版欧洲甲状腺协会（European Thyroid Association，ETA）共识推荐，将 rhTSH 作为^{131}I 治疗前的优选准备方案[16]，充分肯定 rhTSH 的临床诊疗价值。2025 版美国甲状腺学会（American Thyroid Association, ATA）成人 DTC 患者管理指南[20]则明确指出，进行^{131}I 清甲治疗前准备时，rhTSH 优于 THW（强推荐，高确定性证据）。因此，rhTSH 可作为优选方案，用于 DTC 患者^{131}I 清甲治疗前准备。

推荐意见 1：DTC 患者全切除或近全切除术后^{131}I 清甲治疗前准备，推荐使用 rhTSH。

2.2　*辅助治疗*　^{131}I 辅助治疗的目的是清除中、高危 DTC 患者术后可能存在的微小残留病灶，从而延长疾病特异性生存期（disease-specific survival, DSS）和降低复发率[21]。

多项回顾性临床研究[22-24]结果显示，对于^{131}I 辅助治疗，使用 rhTSH 与 THW 进行治疗前准备时的初始治疗疗效及患者远期预后均相当。一项纳入 586 例中危和高危复发风险 DTC 患者的回顾性临床研究[25]发现，rhTSH 组患者的术后首次^{131}I 治疗疗效满意（excellent response, ER）率优于 THW 组（39.4% vs 30%, P=0.03）。2024 年一项荟萃分析[26]结果显示，对于中危和高危复发风险 DTC 患者（包括远处转移患者），rhTSH 是一种^{131}I 治疗前准备的实用性选择。2020 年，来自欧洲的一个多学科专家小组建议，将 rhTSH 作为低中复发风险患者^{131}I 治疗前准备的优选[27]。^{131}I 清甲治疗与辅助治疗常有重叠，且难于区分。清甲治疗的同时有辅助治疗的作用，辅助治疗本身也有清甲作用。2025 版 ATA 成人 DTC 患者管理指南[20]推荐，在进行^{131}I 辅助治疗前准备时，使用 rhTSH 优于 THW（强推荐，高确定性证据）。

推荐意见 2：DTC 患者全切除或近全切除术后^{131}I 辅助治疗前准备，推荐使用 rhTSH。

2.3　*清灶治疗*　2010 年 EMA 更新了 thyrotropin alfa 适应证：没有远处转移证据的全切除或近全切除术后分化良好的甲状腺癌。因此，rhTSH 可用于局部晚期肿瘤（TNM T_4 期）或局部淋巴结转移（TNM N_{1a}/N_{1b} 期）患者^{131}I 辅助治疗前准备[28]。

TSH 抑制治疗的理论基础是 TSH 对 DTC 细胞有促增殖作用。有研究对比了^{131}I 治疗前使用 rhTSH 与 THW 后血清 TSH 水平的曲线下面积（area under the curve，AUC），发现 THW 组血清 TSH 的 AUC 是 rhTSH 组的 4.6 倍[29]。由于促使 TSH 上升过程缓慢、耗时较长，THW 促使 DTC 转移并导致其增长的风险增高[30]。另有研究[31-33]显示，血管内皮生长因子（vascular endothelial growth factor, VEGF）对 DTC 转移的发生发展有促进作用，且 DTC 患者血清 VEGF 水平与 TSH 正相关，但短期使用 rhTSH 不会提高转移性 DTC 患者血清中的 VEGF 水平。

2022 年，美国核医学和分子影像学会和欧洲核医学协会（Society of Nuclear Medicine and Molecular Imaging/European Association of Nuclear Medicine, SNMMI/EANM）DTC 核医学评估和治疗指南[34]建议，在有转移灶的情况下，根据个体化选择，可以在适应证外应用 rhTSH。2023 年，由 BTA 等学会发布的指南[14]也推荐，可在^{131}I 清灶治疗前使用 rhTSH 进行准备。2025 版 ATA 成人 DTC 患者管理指南[20]推荐，对于远处转移的 DTC 患者，在进行清灶治疗前准备时，可选用 THW 或 rhTSH（有条件推荐，低确定性证据）。

大量临床证据[22-25, 35-50]提示，rhTSH 用于^{131}I 清灶治疗前准备安全有效，是 THW 的良好替代方案。一项纳入 10 项临床研究共 1 929 例患者的荟萃分析[51]表明，rhTSH（n＝953）与 THW（n＝976）预处理对^{131}I 治疗转移性 DTC 的有效性差异无统计学意义。^{131}I 清灶治疗前准备方案应根据患

者的个体情况选择，并尽量减少不良反应[26, 51]。^{131}I 清灶治疗前使用 rhTSH 或 THW 对^{131}I 治疗疗效及患者远期预后的影响是否存在差异，还需要更多高质量临床研究确定。

推荐意见 3：DTC 患者全切除或近全切除术后^{131}I 清灶治疗前准备，可考虑使用 rhTSH。

3 rhTSH 在 DTC 术后、^{131}I 治疗后评估及随访中的应用

对于全切除或近全切除术后的 DTC 患者，需经过系统的术后动态评估，以决策是否进行^{131}I 治疗、进入随访或给予其他治疗。

3.1 rhTSH 在 DTC 术后评估及随访中的应用 国内外权威指南[14, 16-17, 52-54]指出，DTC 患者术后均应进行 TNM 分期及初始复发风险度分层，并可在术后随访过程中根据临床实际情况进行动态评估，主要评估血清学指标[如 Tg、sTg、甲状腺球蛋白抗体（thyroglobulin antibody, TgAb）、TSH]及影像学检查（如颈部超声、DxWBS、CT、MRI、^{18}F-FDG PET/CT）结果[14, 16]。DTC 患者术后疗效包括 ER、生化疗效不佳（biochemically incomplete response, BIR）、结构性疗效不佳（structurally incomplete response, SIR）、疗效不确切（indeterminate response, IDR）等[15]。TSH 刺激可使残留甲状腺组织和（或）转移灶分泌较高水平的 Tg，进而提高对结构性复发及转移的预测效能。因此，对于有中/高复发风险、疗效不确切、BIR、SIR 的 DTC 患者，随访 sTg 较抑制性 Tg 更有助于监测病情[15]。

2025 版 ATA 成人 DTC 患者管理指南[20]强烈建议，在行甲状腺全切除术后 6～12 周，行血清 sTg 水平测定。虽然使用 rhTSH 后 sTg 的升高幅度通常低于 THW，但两者均可很好地预测疾病状态[19, 52-55]。对于 THW 所致的 sTg＞10 ng/mL 或应用 rhTSH 所致的 sTg ＞5 ng/mL（rhTSH 第 2 次注射后约 72 h），Tg 或 TgAb 水平持续升高，且颈部、胸部影像学及^{18}F-FDG PET/CT 阴性的患者，可行^{131}I 经验性治疗[20]。2025 版 ATA 指南[20]指出，在^{131}I 治疗前可行 DxWBS，以帮助指导制订治疗计划。DxWBS 可用于 DTC 术后探查甲状腺残留、可疑复发/转移灶、病灶摄碘能力及肿瘤负荷，预测^{131}I 治疗疗效及可能的不良反应[52, 56]。研究[57-58]显示，采用 rhTSH 或 THW 后的 DxWBS 结果一致率为 83%～88.2%。与 THW 相比，rhTSH 显著缩短 sTg 检测及 DxWBS 等待时间，且无甲减相关不良反应；但是，由于 rhTSH 刺激时间相对较短，sTg 的峰值水平（一般出现在 rhTSH 第 2 次注射后约 72 h）可能低于传统的 THW[4]。

sTg 测定及 DxWBS 在 DTC 术后动态评估中具有重要临床价值。多个指南[14, 19, 52]指出，进行 sTg 检测和 DxWBS，需要 TSH＞30 mIU/L 以提高检出甲状腺癌复发、转移的灵敏度时，rhTSH 及 THW 均可选用。但是，目前 sTg 测定及 DxWBS 检查时间点尚未达成共识。

推荐意见 4：DTC 患者全切除或近全切除术后评估及随访过程中 sTg 检测前，推荐使用 rhTSH 或 THW。

推荐意见 5：DTC 患者全切除或近全切除术后评估及随访过程中 DxWBS 辅助诊断前，推荐使用 rhTSH 或 THW。

3.2 rhTSH 在^{131}I 治疗后评估及随访中的应用 DTC 患者^{131}I 治疗后 6～12 个月，应依据疗效反应评估体系进行疗效评估，依据血清学指标（如 sTg）及影像学检查（如 DxWBS）结果制定后续治疗及随访方案，并根据随访结果进行动态评估[17]。

对于中、高危患者，^{131}I 治疗后 6～12 个月可考虑行 DxWBS[52]；对于接受清灶治疗的患者，治疗后 6～12 个月行 DxWBS 有助于实时评价病灶的摄碘功能，进而评估是否再次行^{131}I 治疗[17, 52]。在^{131}I 治疗后行疗效评估时及随访过程中，需 sTg 检测（如抑制性 Tg 水平较低不能反映疾病真实情况或抑制性 Tg 短期内升高）及 DxWBS 时，可应用 rhTSH 或 THW 使 TSH＞30 mIU/L。应用 rhTSH 后，同时进行 sTg 检测和 DxWBS 检查，可使残留甲状腺组织/颈部病灶的检出率达 93%、远处转移灶的检出率达 100%[55]。使用 rhTSH 可缩短患者准备时间，同时避免甲减对患者生活质量的影响。因此，在^{131}I 治疗后疗效评估时及随访过程中，rhTSH 也可作为一种选择。但是，由于 rhTSH 刺激时间相对较短，sTg 的升高水平可能

低于 THW。

推荐意见 6：DTC 患者^{131}I 治疗后评估及随访过程中 sTg 检测前，推荐使用 rhTSH 或 THW。

推荐意见 7：DTC 患者^{131}I 治疗后评估及随访过程中 DxWBS 辅助诊断前，推荐使用 rhTSH 或 THW。

4　rhTSH 在特殊 DTC 患者中的应用

对于某些特殊患者，如垂体功能不良、肥胖患者及部分老年患者等，即使 THW 持续 4 周，体内 TSH 也难以高于 30 mIU/L；对于合并严重基础疾病（如中枢神经系统或呼吸系统功能障碍、充血性心力衰竭、冠状动脉疾病）或精神疾病的患者，THW 持续 2～4 周则可能导致严重并发症；此外，THW 后的甲减状态会一定程度影响患者的生活质量，导致^{131}I 治疗延迟等。DTC 患者术后 THW 持续 2～4 周，体内 TSH 仍无法高于 30 mIU/L，且患者不愿继续 THW 或有明显甲减症状时, 可使用 rhTSH。对于这些特殊人群，rhTSH 是^{131}I 治疗前准备的优选方案[14-17]。

对于儿童及青少年 DTC 患者，一般认为血清 TSH＞30 mIU/L，可取得较好的^{131}I 治疗效果。尽管应用 rhTSH 者较少，但有研究[59-65]表明，儿童应用 rhTSH 安全有效，且中远期预后与 THW 相当。

2015 版 ATA 指南[66]指出，对于无法产生足够内源性 TSH 或无法耐受严重甲减的患者，可考虑使用 rhTSH（推荐级别 A）。其他国内外权威指南[67-71]作了相似推荐。

对于放射性碘难治性 DTC 患者，在进行小分子靶向药物再分化等治疗后病灶摄碘功能评估时，或行 DxWBS 和^{131}I 治疗前，使用 rhTSH 可能更具优势[72]。

推荐意见 8：特殊 DTC 人群（如无法产生足够内源性 TSH 或无法耐受严重甲减的患者）^{131}I 治疗前准备，推荐使用 rhTSH。

5　rhTSH 的安全性及药物经济学

总体而言，rhTSH 的安全性较好。日本一项大型上市后长期监测研究[73]发现，使用 rhTSH 后，5.8% 的患者（336/5 822）发生药物不良反应，其中最常见的是恶心（发生率为 3.2%），而严重不良反应的发生率仅为 0.2%。国产首个 rhTSH 药物Ⅲ期临床试验（TRESON-01）[8]显示相关不良反应主要为胃肠道症状，如恶心（8.4%）、腹泻（1.9%）、呕吐（1.9%），且所有不良事件和不良反应轻微且短暂。与 THW 相比，rhTSH 使用后，患者未出现血脂异常。与 THW 相比，rhTSH 的使用在不影响残留甲状腺组织对^{131}I 的摄取和^{131}I 作用时间的同时，能缩短^{131}I 在 DTC 患者体内的生物半衰期[8, 74-76]，原因可能在于注射 rhTSH 能避免甲减对肾功能的影响[77-78]。血液中^{131}I 水平的增高，会增加造血系统[79]和其他表达 NIS 器官的受损风险[80]。一项前瞻性临床研究[79]发现，与 THW 相比，^{131}I 治疗前准备应用 rhTSH 的患者发生急性涎腺炎（30% vs 58.3%）、血小板减少症或中性粒细胞减少症（7% vs 21.4%）的比例均降低。rhTSH 使用后唾液腺炎发生率也较 THW 使用后低[81-82]。美国头颈学会发布的多学科共识声明[83]指出，^{131}I 治疗前准备应用 rhTSH 较 THW 有助于降低唾液腺和泪腺并发症风险。THW 所致的甲减症状主要包括体质量增加、疲劳、畏寒、苍白、皮肤干燥、毛发粗糙和便秘等，会影响患者的生活质量。前瞻性临床研究[6, 11, 59, 84-85]表明，rhTSH 组患者简明健康调查量表（short form-36, SF-36）、Billewicz 评分或慢性病治疗功能评估（functional assessment of chronic illness therapy, FACIT）-TOI 量表评估的短期生活质量优于 THW 组，而 3 个月后两组患者生活质量差异无统计学意义。

药物经济学角度，使用 rhTSH 较 THW 需支付额外费用。但是，与采用 rhTSH 患者相比，采用 THW 的患者病假天数更多[86-87]、住院天数更长[88-89]。来自德国、加拿大和西班牙等的药物经济学报告[90-92]显示，rhTSH 具有高成本效益比，药品费用成本能够被其节约的其他间接成本抵消。

6　小　结

大量的临床研究证据显示，DTC 患者接受^{131}I 治疗前，使用 rhTSH 与 THW 的诊疗效果相仿，且安全性好，不良反应轻微可控。与接受 THW 的患者相比，接受 rhTSH 的患者^{131}I 治疗不

良反应发生率更低，无甲减症状、生活质量明显提升。rhTSH在保证诊治效果的同时，可缩短诊疗所需准备时间、降低诊疗过程对患者生活和工作的影响。

本共识对rhTSH的推荐总结

推荐意见1：DTC患者全切除或近全切除术后^{131}I清甲治疗前准备，推荐使用rhTSH。

推荐意见2：DTC患者全切除或近全切除术后^{131}I辅助治疗前准备，推荐使用rhTSH。

推荐意见3：DTC患者全切除或近全切除术后^{131}I清灶治疗前准备，可考虑使用rhTSH。

推荐意见4：DTC患者全切除或近全切除术后评估及随访过程中sTg检测前，推荐使用rhTSH或THW。

推荐意见5：DTC患者全切除或近全切除术后评估及随访过程中DxWBS辅助诊断前，推荐使用rhTSH或THW。

推荐意见6：DTC患者^{131}I治疗后评估及随访过程中sTg检测前，推荐使用rhTSH或THW。

推荐意见7：DTC患者^{131}I治疗后评估及随访过程中DxWBS辅助诊断前，推荐使用rhTSH或THW。

推荐意见8：特殊DTC人群（如无法产生足够内源性TSH或无法耐受严重甲减的患者等）^{131}I治疗前准备，推荐使用rhTSH。

伦理声明 本共识是基于现有最佳证据和专家临床经验形成的指导性意见，旨在为相关疾病的诊断、治疗与管理提供参考。医学实践具有复杂性和个体差异性，本共识不能替代临床医生的独立判断。在实际应用中，医师应结合患者的具体病情、意愿、医疗资源可获得性，以及自身的专业知识，制定最适宜的个体化诊疗方案。本共识的内容不作为任何医疗纠纷或法律诉讼的依据，共识制定者及发布方不承担因应用本共识内容而产生的任何直接或间接法律责任。

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