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世界中医药学会联合会

World Federation of Chinese Medicine Societies

SCM NP-2023-177

国际中医临床实践指南 桥本甲状腺炎

International clinical practice guidelines of Chinese Medicine
Hashimotos thyroiditis

世界中联国际组织标准

International Standard of WFCMS

20--发布实施

Issued & implemented on , 20

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本文件的起草程序遵守世界中医药学会联合会发布的 SCM1.1-2021《标准化工作导则第1部分：标准制修订与发布》相关规定。

引　言

桥本甲状腺炎又称慢性淋巴细胞性甲状腺炎，属于自身免疫性甲状腺炎，1912年由日本学者 Hashimoto首先报道[1]。桥本甲状腺炎的患病率在不同国家和地区存在差异，其患病率受地理区域和环境因素的影响，非洲为14.2%，大洋洲为11.0%，南美洲和欧洲为8.0%，北美洲为7.8%，亚洲为5.8%[2]。女性发病率是男性发病率的15～20 倍[3]，30～50 岁的女性是高发人群[4]。发病机制尚不明确。现代医学以随访为主，无特殊治疗方式，如继发甲状腺毒症、继发甲状腺功能减退症，需进行抗甲状腺药物或激素补充治疗。

中医学对桥本甲状腺炎领域临床研究较多，但中西医结合诊治方面存在诸多争议点，且尚未建立系统的指南。2008年中华医学会内分泌学分会发布的《中国甲状腺疾病诊治指南-甲状腺炎》，目前多项科学证据有待更新。2021年，北京中西医结合学会甲状腺病专业委员会发布的《桥本甲状腺炎中西医结合诊疗北京专家共识（2021，北京）》《桥本氏甲状腺炎中西医结合质量控制指标体系北京专家共识（2021版）》，对桥本甲状腺炎患者所处疾病阶段未进行具体阐述，且多以共识为主，缺乏高质量的循证证据支持，难以满足目前临床需求。因此，亟需在新的临床实践和研究基础上，制定桥本甲状腺炎诊疗规范指南，以更好地指导临床规范诊疗。

本文件在既往指南的基础上，在筛选高质量研究成果并广泛征求专家意见基础上，形成一系列疗效确切、安全性高且便于推广的中医药治疗推荐方案。同时，本文件在研制过程中，注重与国际中医学术团体的密切交流与合作，内容设计着力提升国际普适性和实用性，确保其在临床实践中的可操作性。本文件的制定遵循国际循证指南制定规范，并在相关法律法规和技术指导文件框架下完成。选择本文件所推荐或建议的诊疗措施时，应确保其符合并遵守所在国家或地区的相关法律法规。

请注意：在临床实践中，应在西医治疗基础上，运用本指南所推荐的中医治疗方法，各阶段西医治疗参见附录 C。

国际中医临床实践指南 桥本甲状腺炎

1 范围

本文件规范了成年桥本甲状腺炎患者（除外妊娠期、哺乳期患者）的临床表现、诊断及中医治疗方案等内容。

本文件适用于开展桥本甲状腺炎诊疗的医疗机构，以及相关中医医师和中西医结合医师使用。

2 规范性引用文件

下列文件对本文件的应用是必不可少的。凡是注日期的引用文件，仅注日期的版本适用于本文件。凡是不注日期的引用文件，其最新版本（包括所有的修改单）适用于本文件。

GB/T 21709.1-2008 针灸技术操作规范 第 1 部分：艾灸

GB/T 21709.9-2008 针灸技术操作规范 第 9 部分：穴位贴敷

GB/T 21709.20-2009 针灸技术操作规范 第 20 部分：毫针基本刺法

GB/T 33414-2016 穴位贴敷用药规范

中华医学会内分泌学分会.中国甲状腺疾病诊治指南—甲状腺炎[J].中华内科杂志,2008,47(09) : 784-788.

中华医学会内分泌学分会,中国医师协会内分泌代谢科医师分会,中华医学会核医学分会,等.中国甲状腺功能亢进症和其他原因所致甲状腺毒症诊治指南[J]. 国际内分泌代谢杂志,2022,42(5):401-450.

中华医学会内分泌学分会,中国医师协会内分泌代谢科医师分会,中华医学会核医学分会,等. 中国甲状腺功能亢进症和其他原因所致甲状腺毒症诊治指南[J]. 国际内分泌代谢杂志,2022,42(5):401-450.

北京中西医结合学会甲状腺病专业委员会.桥本甲状腺炎中西医结合诊疗北京专家共识(2021，北京)[J].中国医药导报,2022,19(34):4-7.

北京中西医结合学会甲状腺病专业委员会.桥本氏甲状腺炎中西医结合质量控制指标体系北京专家共识(2021 版)[J].中日友好医院学报,2021,35(06):323-327.

3 术语和定义

下列术语和定义适用于本文件

3.1

桥本甲状腺炎

慢性淋巴细胞性甲状腺炎

以甲状腺弥漫性肿大、质地韧硬、表面结节状，伴甲状腺过氧化物酶抗体、甲状腺球蛋白抗体升高为主要临床特征，淋巴细胞浸润甲状腺为主要病理特征的自身免疫性甲状腺炎。

注：中医认为，桥本甲状腺炎多归属于瘿肿、气瘿、瘿病、虚劳、瘿瘤等范畴，其中以瘿肿、气瘿最为多见。

3.2

瘿肿

以颈前漫肿，质地韧硬，颈前喉间可触及结节等为临床特征的瘿病。

注：西医的桥本甲状腺炎、慢性淋巴细胞性甲状腺炎等疾病可参考本病进行辨证施治。

4　临床表现

本病临床表现不典型，起病隐匿，进展缓慢，病程较长，主要表现为甲状腺弥漫性肿大，多呈无痛性、对称性，质地偏韧硬，与周围组织无粘连，随吞咽上下活动，病程长者可扪及结节。早期临床表现往往并不典型，部分患者可伴有咽部不适或轻度吞咽困难、颈部压迫感、局部疼痛与触痛、乏力、失眠等症状。继发甲状腺毒症时，临床表现可见心悸、多汗、食欲亢进等；继发甲状腺功能减退症时，临床表现可见乏力、困倦、心动过缓、怕冷、黏液性水肿、便秘等。

5　诊断

5.1西医诊断

本病西医诊断、辅助检查及鉴别诊断参见附录B。

5.2 中医诊断

5.2.1 诊断原则

本病以甲状腺功能水平为依据，对桥本甲状腺炎（甲状腺功能正常阶段）、桥本甲状腺炎继发甲状腺毒症、桥本甲状腺炎继发甲状腺功能减退症，分别进行中医辨证分型。

5.2.2 辨证分型

5.2.2.1 桥本甲状腺炎

5.2.2.1.1 肝郁气滞证

主症：颈部多无明显肿大，可有颈前肿胀感或咽部异物感，无痛，情绪抑郁，善太息；
次症：胸胁或脘腹胀满，得太息则舒，食欲不振，妇女可有乳房胀痛，月经不调；
舌脉：舌质淡红，舌苔薄白，脉弦。

5.2.2.1.2 肝郁化热证

主症：颈前弥漫性肿大，可伴肿胀、疼痛，或咽部异物感，心烦易怒，口苦咽干；
次症：胁肋灼痛，寐少、梦多，大便秘结，小便黄赤；
舌脉：舌质红，苔黄，脉弦数。

5.2.2.1.3 肝郁痰凝证

主症：颈前肿大，局部闷胀不适，咽部异物感，似有痰梗，吞咽不下，咳咯不出，随情绪波动而增减；
次症：情绪急躁或抑郁，胸胁或少腹闷胀，善太息；
舌脉：舌淡或暗、苔白或腻，脉弦滑。

5.2.2.1.4 肝郁脾虚证

主症：颈部弥漫性肿大，情志抑郁，喜太息，体倦乏力；
次症：胸胁胀痛，或食少腹胀，便溏不爽，或腹痛欲泻，泻后痛减；
舌脉：舌质淡，苔白，脉弦细或缓弱。

5.2.2.2 桥本甲状腺炎继发甲状腺毒症

5.2.2.2.1 肝郁化火证

主症：颈前弥漫性肿大，可有颈部肿胀、疼痛，或咽部异物感，急躁易怒，汗出增多，食欲亢进；

次症：怕热，耳暴鸣，口干，口苦，大便质干，小便黄赤；

舌脉：舌质红，苔黄，脉弦数。

5.2.2.2.2 心肝热盛证

主症：颈前弥漫性肿大，按之震颤，可有疼痛，焦虑、易怒，身热多汗，心慌，手抖，不寐，多梦；

次症：面红目赤，头痛，口干，口苦，多食易饥，身体消瘦；

舌脉：舌红、苔黄，脉弦数有力。

5.2.2.2.3 阴虚火旺证

主症：颈前弥漫性肿大，五心烦热，急躁易怒，怕热，汗出，多食易饥，手指震颤；

次症：面部烘热，潮热，盗汗，失眠多梦，口燥咽干，溲赤，便秘；

舌脉：舌红瘦，少苔或无，脉细数。

5.2.2.2.4 气阴两虚证

主症：颈前弥漫性肿大，神疲乏力，气促多汗，手抖，五心烦热，心悸怔忡；

次症：健忘失眠，烦渴欲饮，纳少，形体消瘦，溲赤，便秘或便溏；

舌脉：舌红，少苔，脉细或虚数。

5.2.2.3 桥本甲状腺炎继发甲状腺功能减退症

5.2.2.3.1 痰结血瘀证

主症：颈前肿块质韧或硬，有结节感，咽喉阻塞感，胸闷脘痞，胀痛或刺痛，头身困重，疲乏嗜睡；

次症：头晕耳鸣，表情淡漠，肌肤麻木或甲错，痰多，或形体肥胖，腹胀，便溏；

舌脉：舌暗胖或有瘀斑、瘀点，苔滑腻，脉沉迟或弦涩。

5.2.2.3.2 肝郁脾虚证

主症：颈前弥漫性肿大，质软或韧，可有异物感，情志抑郁，四肢倦怠，语声低微，懒言、少动；

次症：胸闷嗳气，喜太息，或腹胀，食欲不振，纳呆，便溏不爽；

舌脉：舌淡胖，边有齿痕，苔白，脉弦细或缓弱。

5.2.2.3.3 脾肾阳虚证

主症：颈前漫肿或不肿，质地韧或硬，面浮肢肿、畏寒怕冷、倦怠乏力、腹胀纳呆；

次症：记忆力减退、毛发稀疏，下肢浮肿、男子阳痿，女子月经量少或闭经，大便排出困难或五更泻，小便清长；

舌脉：舌淡胖，苔白滑，脉沉细或沉迟无力。

5.2.2.3.4 心肾阳虚证

主症：颈前漫肿或不肿，质地韧或硬，形寒肢冷，面㿠虚浮，下肢水肿，心悸气促，嗜睡息短，肢软乏力；

次症：头晕目眩，耳鸣重听，胸闷胸痛，唇甲青紫，小便不利；

舌脉：舌质淡或暗，舌苔白滑，脉沉迟而弱。

6　治疗

6.1 治疗原则

6.1.1 西医辨病，中医辨证，病证结合

结合患者临床症状及辅助检查结果明确西医诊断，在此基础上，谨守“西医辨病，中医辨证，病证结合”的原则，进行分阶段辨证论治（共识建议）。

6.1.2 分段论治，中西协同，优势互补

中西医结合治疗的目的在于优势互补，增强疗效的同时，弥补各疗法的薄弱方面。现代医学在调控甲状腺功能等方面优势明显，而中医学在改善临床症状、降低甲状腺相关抗体滴度、辅助抗甲状腺药物或左甲状腺素(L-T4)减量、提升生活质量等方面效果更好。中西医结合治疗对于桥本甲状腺炎早期患者，若症状及中医证候不明显者，可在干预生活方式的基础上定期随访；若症状或中医证候明显者，则应在正确辨证的前提下增加中医治疗；对于临床症状明显、甲状腺功能异常的患者，可在干预生活方式的基础上进行中西医结合治疗（共识建议）。

6.2 辩证论治

6.2.1 桥本甲状腺炎

6.2.1.1 肝郁气滞证

治则治法：疏肝解郁；

推荐方药：柴胡疏肝散加减（药物组成：柴胡、川芎、香附、陈皮、白芍、枳壳、甘草等）（证据级别：C，强推荐）。

6.2.1.2 肝郁化热证

治则治法：疏肝清热。

推荐方药：清肝散结消瘿方（药物组成：夏枯草、柴胡、合欢花、牡丹皮、白芍、黄芩、赤芍、桔梗、猫爪草、生牡蛎、珍珠母、黄芪）（证据级别：B，强推荐）。

6.2.1.3 肝郁痰凝证

治则治法：疏肝散结；

推荐方药：四逆散合半夏厚朴汤加减（药物组成：柴胡、白芍、赤芍、枳实、半夏、紫苏叶、茯苓、炙甘草、生姜、乌梅等）（证据级别：B，强推荐）。

6.2.1.4 肝郁脾虚证

治则治法：疏肝健脾；

推荐方药：小柴胡汤合当归芍药散加减(药物组成：柴胡、黄芩、人参、半夏、生姜、当归、白芍、白术、茯苓、泽泻、川芎等）（证据级别：C，强推荐）。

6.2.2 桥本甲状腺炎继发甲状腺毒症

6.2.2.1肝郁化火证

治则治法：清肝泻火；

推荐方药：丹栀逍遥散加减（药物组成：柴胡、茯苓、白芍、白术、当归、栀子、牡丹皮、甘草、生姜、薄荷等）（证据级别：C，强推荐）。

6.2.2.2心肝热盛证

治则治法：清心泻肝；

推荐方药：栀子清肝汤加减（药物组成：柴胡、栀子、牡丹皮、茯苓、川芎、白芍、当归、牛蒡子、甘草等）（证据级别：B，强推荐）。

6.2.2.3阴虚火旺证

治则治法：滋阴清热；

推荐方药：当归六黄汤加减（药物组成：当归、生地黄、黄芩、黄连、黄柏、熟地黄、黄芪等）（证据级别：B，强推荐）。

6.2.2.4气阴两虚证

治则治法：益气养阴；

推荐方药：天王补心丹合补中益气汤加减（药物组成：党参、茯苓、玄参、丹参、桔梗、远志、当归、柏子仁、酸枣仁、生地黄、黄芪、白术、陈皮、升麻、柴胡、甘草、当归等）（证据级别：C，强推荐）。

6.2.3 桥本甲状腺炎继发甲状腺功能减退症

6.2.3.1痰结血瘀证

治则治法：理气活血，化痰消瘿；

推荐方药：解郁通络消瘿汤（柴胡、白芍、茯苓、玄参、当归、白术、郁金、法半夏、陈皮、浙贝母、山慈菇、连翘、鸡血藤、莪术、炙甘草）（证据级别：C，强推荐）；或化痰祛瘀消瘿汤（半夏、当归、厚朴、茯苓、赤芍、川芎、僵蚕、柴胡、黄芩、人参、丹参、鸡血藤、炙甘草等）（证据级别：C，强推荐）；或消瘿散结方（夏枯草、仙鹤草、猫爪草、生甘草、三棱、莪术、仙灵脾）（证据级别：C，强推荐）。

6.2.3.2肝郁脾虚证

治则治法：疏肝健脾；

推荐方药：柴胡疏肝散或逍遥散加减(药物组成：柴胡、白芍、枳实、陈皮、川芎、香附、甘草或柴胡、当归、白芍、白术、茯苓、炙甘草、生姜等）（证据级别：C，强推荐）。

6.2.3.3脾肾阳虚证

治则治法：温补脾肾；

推荐方药：参苓白术散合金匮肾气丸加减（药物组成：人参、炙甘草、白术、熟地黄、山药、山茱萸、泽泻、茯苓、牡丹皮、桂枝、附子等）（证据级别：C，强推荐）。

6.2.3.4心肾阳虚证

治则治法：温补心肾；

推荐方药：真武汤加减（药物组成：茯苓、白术、白芍、炙甘草、生姜、附子等）（证据级别：C，强推荐）。

6.3 中成药

6.3.1 桥本甲状腺炎

在生活方式干预的基础上，推荐使用百令胶囊（证据级别：D，弱推荐）或逍遥丸（证据级别：D，弱推荐）降低TPOAb抗体滴度。

6.3.2 桥本甲状腺炎继发甲状腺功能减退症

在生活方式干预的基础上，推荐使用百令胶囊（证据级别：D，弱推荐）；或夏枯草制剂（证据级别：D，弱推荐）；或金水宝胶囊（证据级别：C，弱推荐），以上三种中成药均可联合左甲状腺素，以降低 TPOAb 抗体滴度，改善甲状腺功能；脾肾阳虚证推荐使用右归丸（证据级别：D，弱推荐）联合左甲状腺素，以降低 TPOAb 抗体滴度，改善临床症状。

6.4 其他治法

6.4.1 中药外敷

6.4.1.1 桥本甲状腺炎伴有甲状腺肿者，可予颈部甲状腺区域敷贴治疗，针对以下情况可使用推荐药方：

a）桥本甲状腺炎气郁痰阻证：消瘿散结方（夏枯草、连翘、姜半夏、陈皮、土贝母、三棱、莪术、牡丹皮、乳香、没药、丹参、赤芍、白芍、生牡蛎、水蛭、郁金、芒硝）（证据级别：C，强推荐）。

b）桥本甲状腺炎继发甲状腺功能减退症：消瘿方（黄芪、夏枯草、猫爪草、柴胡、香附、莪术、丁香、冰片）（证据级别：C，强推荐）；或消瘿膏（黄芪、柴胡、黄芩、夏枯草、郁金、山慈菇、红花、天葵子、川芎、赤芍、当归、肉桂、菊花、金银花、杜仲、莪术、半夏、川楝子、浙贝、芒硝）（证据级别：C，强推荐），以上两种种中成药均可联合左甲状腺素。

6.4.1.2 外敷药制备可将诸药研磨成粉，根据情况可加入助透剂、巴布剂、赋形剂等，将药粉调成糊状，制成膏剂。赋形剂、助透剂功效与特点可参见 GB/T 33414-2016[5]，制作、使用、贮藏原则应符合 GB/T 33414-2016 规定。

注 1：助透剂是能够增加药物透皮速度或增加药物透皮量的物质。

注 2：巴布剂是以水溶性高分子材料或亲水性物质为基质，与药物制成的外用贴敷剂；

注 3：赋形剂是赋予药物以适当的形态和体积的物质。

6.4.1.3 使用中药外敷疗法应注意，凡用溶剂调敷药物时，需随调配随敷用，以防挥发；对于残留在皮肤上的药膏，不宜用刺激性物质擦洗；贴敷药物后注意局部防水；贴敷后若出现范围较大、程度较重的皮肤红斑、水泡、瘙痒现象，应立即停药，进行对症处理；出现全身性皮肤过敏症状者，应及时到医院就诊。贴敷部位有创伤、溃疡者禁用；对药物或敷料成分过敏者禁用等。详细注意事项与禁忌证应符合 GB/T 21709.9-2008 的要求。

6.4.2 针刺

6.4.2.1 桥本甲状腺炎继发甲状腺功能减退症可依据证候予针刺疗法联合左甲状腺素治疗。临床应用时可适当配合电针（疏波）。

a）手阳明经透刺取穴：三间、合谷、曲池、臂臑、肩髃、人迎、足三里（证据级别：B，强推荐）。

患者卧位，穴位局部常规消毒，三间透合谷，曲池透臂臑，臂臑透肩髃，肩髃斜刺，人迎、足三里直刺。每周 2～3 次。

b）肝郁肾虚证取穴：关元、太溪、悬钟、太冲、合谷、三阴交、内关、丰隆、人迎、扶突。除关元外，余穴位均取双侧（证据级别：C，强推荐）。

患者取仰卧位，对针灸部位进行常规消毒，直刺或斜刺进针，针刺得气后，使用平补平泻，使局部有酸麻重胀感，每次留针 30 min，隔日 1 次。

c）脾肾阳虚证温针灸推荐取穴：脾俞（双侧）、肾俞（双侧）、命门、丰隆（双侧）、太冲（双侧）（证据级别：C，强推荐）。

患者取俯卧位，针刺得气后，行温灸治疗，用艾绒或艾条套入针柄并点燃尾底部，每次艾灸 2 壮；温灸过程中，艾炷燃烧时，若患者灼烫难忍，可将硬纸薄片裁剪至适宜大小，并放置在对应穴位，以减弱火力，避免皮肤烫伤。

注：温针灸：毫针留针时在针柄上置以艾绒（艾团或艾条段）施灸，是针刺与艾灸结合应用的方法。

6.4.2.2 使用针刺疗法应注意，行针时，提插幅度和捻转角度的大小、频率的快慢、时间的长短等，应根据患者的具体情况和术者所要达到的目的而灵活掌握；体质虚弱，气血亏损者其针感不宜过重，应尽量采取卧位行针；饥饿、饱食、醉酒、大怒、大惊、过度疲劳、精神紧张者，不宜立即进行针刺；皮肤有感染、溃疡、瘢痕或肿瘤部位，不应在患部直接针刺，有凝血机制障碍的患者，应禁用针刺等。详细注意事项与禁忌证应符合 GB/T 21709.20-2009 中的规定。

6.5 生活方式

6.5.1 饮食有节，营养均衡

适量补充热量和营养，如维生素、蛋白质、微量元素等，保证营养均衡。关于碘摄入，建议根据尿碘浓度水平评估，制订个体化方案；平素饮食有所节制，避免过食或偏嗜，避免食用高碘食物，富碘类药物根据临床需求谨慎使用（共识建议）。

6.5.2 调畅情志，心理健康

情志对甲状腺病的影响尤为突出。保持精神愉悦，心胸开朗，及时疏解不良情绪；积极沟通和社交，适应周围生活环境变化是防治HT的重要方式（共识建议）。

6.5.3 起居有常，不妄作为

顺应四时变化，培养良好的生活习惯，注意劳逸结合，五脏六腑调和，机体内环境稳定，疾病乃愈（共识建议）。

6.5.4 适度运动，增强体质

积极锻炼身体，避免过度劳累，增强抗病能力，激发正气，中医所谓“正气存内，邪不可干”（共识建议）。

6.5.5 早期发现，适时干预

本病发病慢，病程长，具有一定隐匿性。注意定期体检甲状腺，有相关家族遗传史者更应重视；一旦发现应定期复查，适时合理治疗（共识建议）。

7 结局指标

关键结局指标可参见附录 D 。

附录 A
（资料性）
编制方法

A.1 指南的编制依据和原则

本文件的起草程序依据世界中医药学会联合会发布的 《SCM1.1-2021 标准化工作指导导则 第 1 部分：标准制修订与发布》的要求进行，同时参考《GB/T 1.1-2020 标准化工作导则（第 1 部分：标准化文件的结构和起草规则）》的相关规定进行编制。

在指南制订过程中，严格遵循相关证据质量评价、证据分级及推荐意见形成的原则和标准，确保指南编制的科学性和严谨性。系统评价方法学的质量评价采用 AMSTAR2 工具；随机对照试验（Randomized Controlled Trial, RCT）的方法学质量通过 Cochrane 偏倚风险评估工具进行评价；证据质量评价和分级采用 GRADE 系统。指南的推荐意见或共识意见采用“德尔菲”法实现。

A.2 编制过程

本指南的编制严格按照规范步骤进行。

第一阶段：成立指南起草组并签署利益声明；对国内外桥本甲状腺炎中西医相关指南与临床研究进行梳理，确定指南的题目、范围和目的；规划指南研究方案并撰写申报材料。正式立项后，通过访谈权威专家及线上临床医师调研，全面收集临床实践中的关键问题，以初步构建指南问题和结局指标清单；通过德尔菲法优化指南所拟解决的临床问题和疗效评价指标重要性分级问题，最终形成指南临床问题清单。

第二阶段：依据已确定的临床问题清单，进行证据的检索、筛选、综合及评价。针对有循证医学证据支撑的临床问题，采用GRADE方法对证据质量进行评价和分级，形成证据概要表；对于证据不足的临床问题，初步形成专家共识推荐意见，并通过线上专家共识会议对推荐意见达成一致意见。

第三阶段：完成指南草案后，由编写工作组内部专家进行自评，并对草案进行修改和完善。随后，将草案上报至世界中医药学会联合会，进行公示广泛征求意见；在公示期满并经学会审查通过后，根据反馈意见进行最终修订、确认与发布。

A.3 证据评价分级与推荐规则

A.3.1 证据评价分级

本指南采用 GRADE 标准对证据体的质量进行评价，包括 5 项降低证据质量的因素：偏倚风险、不一致性、不直接性、不精确性、发表偏倚，3 项提高证据质量的因素：大效应量、剂量反应关系、混杂偏倚的影响。并将所形成的证据概要表和证据总结表存档，以确保证据过程的透明性与可追溯性。

表 1 证据质量描述

证据分级	具体描述	研究类型
高质量/A ⊕⊕⊕⊕	我们非常确信真实的效应值接近效应估计	RCT，质量升高 2 级的观察性研究
中等质量/B ⊕⊕⊕◯	对效应估计值我们有中等强度的信心：真实值有可能接近估计值，但仍存在二者大不相同的可能性	质量降低 1 级的 RCT，质量升高 1 级的观察性研究
低质量/C ⊕⊕◯◯	我们对效应估计值的确信程度有限：真实值可能与估计值大不相同	质量降低 2 级的 RCT，观察性研究
极低质量/D⊕◯◯◯	我们对效应估计值几乎没有信心：真实值很可能与估计值大不相同	质量降低 3 级的 RCT，质量降低 1 级的观察性研究，系列病例观察，个案报道

A.3.2 推荐规则

A.3.2.1推荐强度确定规则

针对推荐强度，共设立 5 个选项：“强推荐”“弱推荐”“不确定”“弱不推荐”“强不推荐”。具体规则如下：若除了“不确定”以外的任何 1 格票数超过 50%，则视为达成共识，可直接确定推荐方向及强度；若“不确定”某一侧两格总票数超过 70%，亦视为达成共识，推荐方向明确，推荐强度直接定为“弱”；其余情况视为未达成共识，共识推荐进入下一轮投票；投票轮次最多为 3 轮。

A.3.2.2 对于无临床证据的共识建议

针对无临床证据的共识建议，共设立3个选项：“建议”“不确定”“不建议”。具体规则如下：

若“不确定”以外任意一项的票数超过50%，则视为达成共识。

其余情况视为未达成共识，共识建议进入下一轮投票；投票轮次最多为 3 轮。

A.4 资金资助及利益冲突情况

本项目受财政部办公厅、国家中医药管理局“中医药传承创新发展示范试点项目”资助。本项目组成员在项目正式启动前均签署了“利益冲突声明书”，且存档。本指南制订过程中不存在利益冲突，为此不会成为本指南制订的偏倚来源，所有参与本指南制订的成员均和药品生产企业没有任何经济利益往来。

附录 B
（资料性）
桥本甲状腺炎西医诊断

桥本甲状腺炎的诊断应依据临床表现及辅助检查结果进行判断。

B.1 辅助检查

B.1.1 甲状腺功能

甲状腺功能包括血液中总甲状腺素（Total Thyroxine，TT_4），总三碘甲状腺原氨酸（Total Triiodothyronine，TT_3）、血清游离甲状腺素（Free Thyroxine，FT_4）和游离三碘甲腺原氨酸（Free Triiodthyronine，FT_3）以及促甲状腺激素（Thyroid Stimulating Hormone，TSH）。根据甲状腺破坏的程度，本病早期甲状腺功能可正常，部分患者可有一过性甲状腺毒症；发生甲状腺功能损伤时可出现甲状腺功能减退，表现为血清 TSH 增高和/或 TT_4、FT_4 降低。部分患者亦可出现甲状腺毒症与甲状腺功能减退交替的病程。

B.1.2 甲状腺自身抗体

甲状腺相关抗体 TPOAb、TgAb 滴度明显升高是本病的特征之一。在出现甲减以前，抗体阳性是临床诊断本病的主要依据。TPOAb 是诊断 HT 的最重要指标，HT 患者血清中 TPOAb 的阳性率达到 95%以上，TPOAb 的滴度与甲状腺淋巴细胞浸润的程度密切相关，直接反映炎症程度。TgAb 具有与 TPOAb 相同的诊断意义，HT 患者中 TgAb 的阳性率为 60%～80%，但其敏感性不如 TPOAb。

B.1.3 超声检查

双侧甲状腺体积增大，回声不均匀，弥漫性低回声内出现短线状强回声并形成分隔状或网格状改变，对本病的诊断具有较高的特异性。部分患者可合并甲状腺结节。早期甲状腺体积增大明显，后期由于腺体萎缩、纤维化，体积缩小，内部呈网格样改变。弥漫性低回声反映甲状腺内的淋巴细胞浸润，网格样改变反映间质的纤维化。

B.1.4 核医学检查

甲状腺摄碘率：本病早期摄碘率可以正常，后期甲状腺滤泡逐渐被破坏，摄碘率逐渐降低。

甲状腺核素显像：可显示为不规则的浓集与稀疏区，显影密度不均、边界不清，或呈“冷结节”样改变。

B.1.5 细针穿刺和细胞学检查（Fine Needle Aspiration Cytology，FNAC）

不作为常规诊断手段，如桥本甲状腺炎合并可疑恶性肿瘤、持续性甲状腺毒症，需要鉴别桥本甲状腺炎和毒性弥漫性甲状腺肿时可考虑行 FNAC。

组织病理学检查：桥本甲状腺炎病理切片可见淋巴细胞和浆细胞，甲状腺滤泡上皮细胞可表现增生、萎缩、结构破坏及间质显微组织增生等不同改变。

B.2 诊断标准

B.2.1 桥本甲状腺炎诊断标准

血清 TPOAb 和 TgAb 阳性，诊断即可成立。如 TPOAb、TgAb 单一抗体阳性，需要结

合临床表现。甲状腺弥漫性肿大，质地较韧，特别是伴有峡部锥状叶肿大，不论甲状腺功能是否改变，均应怀疑桥本甲状腺炎。伴有亚临床甲减或临床甲减可进一步支持诊断，FNAC或病理检查有确诊价值。

B.2.2 桥本甲状腺炎继发甲状腺功能异常诊断标准

在符合“B.1.1 桥本甲状腺炎诊断标准”的前提下：

桥本甲状腺炎继发甲状腺毒症的临床诊断需同时满足：血清 TSH 水平降低，和/或 FT4、FT3 水平升高。

桥本甲状腺炎继发甲状腺功能减退症的临床诊断需同时满足：血清 TSH 水平升高，和/或 FT4、TT4 水平降低。

B.3 鉴别诊断

B.3.1 亚急性甲状腺炎

发病前多有上呼吸道感染史，甲状腺区域性疼痛及肿大逐渐或突然发生，放射性疼痛及转移性疼痛为特征性表现，红细胞沉降率（Erythrocyte Sedimentation Rate，ESR）可明显升高，血清中 TT4、TT3 增高或正常，可由于炎症导致甲状腺滤泡破坏，释放出储存的甲状腺激素，出现血清甲状腺激素水平升高的同时，甲状腺摄碘率却显著降低，该现象可协助诊断，必要时可行 FNAC 鉴别。

B.3.2 弥漫性毒性甲状腺肿（Graves 病）

HT 与 Graves 病均为自身免疫性甲状腺疾病，HT 继发甲状腺毒症临床症状相对较轻，不伴或较少伴有胫前黏液水肿及突眼。摄碘率可有助于鉴别，HT 继发甲状腺毒症时甲状腺吸碘率可正常或升高，但可被 T3 抑制；Graves 病时甲状腺吸碘率明显升高，且不能被 T3 抑制。

B.3.3 单纯性甲状腺肿

甲状腺肿质软，甲状腺自身抗体多为阴性，甲功正常。

B.3.4 甲状腺恶性淋巴瘤

病理学家观察到几乎所有的恶性淋巴瘤患者的甲状腺组织都存在不同程度的 HT 表现。当 HT 患者甲状腺短期迅速增大，并伴有气管、喉部受压，发热、体重明显减轻等症状时，应行 FNAC 相鉴别。

B.3.5 甲状腺恶性肿瘤

HT 中甲状腺癌的发生率为 5%～17%，比普通人群高 3 倍。二者均可有甲状腺结节样改变，但甲状腺癌的肿块坚硬固定、与周围器官粘连，可伴随颈部淋巴结肿大或出现对周围器官的压迫症状，甲状腺超声或 FNAC 可协助鉴别。

附录 C
（资料性）
桥本甲状腺炎西医治疗

C.1 桥本甲状腺炎

本病甲状腺功能正常阶段，在生活方式干预的基础上，定期随访，一般主张每半年到 1 年随访 1 次，主要检查甲状腺功能，必要时可行甲状腺超声检查。控制碘摄入量在安全范围有助于阻止甲状腺自身免疫破坏的进展。

C.2 桥本甲状腺炎继发甲状腺毒症

一般不用抗甲状腺药物，在生活方式干预的基础上，甲状腺毒症症状明显尤其老年患者、静息心率超过 90 次/min 或合并心血管疾病，可用β受体阻滞剂（如普萘洛尔）治疗，个别症状严重不能控制者，可应用小剂量抗甲状腺药物，并根据甲状腺功能监测情况及时调整剂量或停药，以免导致甲减。一般不予 I^{131} 及手术治疗。具体药物使用方法及注意事项、不良反应可参考《中国甲状腺功能亢进症和其他原因所致甲状腺毒症诊治指南（2022)》[6]（中华内分泌代谢杂志,2022,38(8):700-748.)。

C.3 桥本甲状腺炎继发甲状腺功能减退症

可根据情况进行左甲状腺素钠片（L-T4）替代治疗。具体药物使用方法可参考《成人甲状腺功能减退症诊治指南》[7]（中华内分泌代谢杂志，2017, 33(2):167-180）。

附录 D
（资料性）
关键结局指标

D.1 TPOAb 抗体滴度改善情况；

D.2 甲状腺功能 FT3、FT4、TT3、TT4、TSH 水平恢复情况；

D.3 临床症状改善情况：

颈前压迫感、咽部异物感、倦怠乏力、情绪低落或烦躁易怒等，可采用甲状腺疾病生活质量简明量表（ThyPRO-39）或中医证候积分量表进行评定。

D.4 甲状腺肿改善情况

D.4.1 甲状腺肿大分级

不能看出肿大但能触及者为I度；既能看到肿大又能触及，但在胸锁乳突肌以内者为II度；超过胸锁乳突肌外缘者为III度。

D.4.2 甲状腺超声检查

甲状腺大小划分与体重、年龄显著相关，个体之间有较大差异。

甲状腺体积正常值：（4～6cm）（上下径）×（2～2.5cm）（左右径）×（1.5～2cm）（前后径），峡部<0.3cm。多以前后径作为判断甲状腺是否肿大的重要指标，将“双侧叶前后径＜1cm，峡部厚度＜0.2cm”定义为甲状腺缩小；将“双侧叶前后径＞2cm，峡部厚度＞0.3cm”定义为甲状腺增大。“双侧叶前后径介于 1.5～2cm，峡部厚度介于 0.2～0.3cm”依据患者个体差异判是否肿大。

附录 E
（资料性）
摘要性快速推荐表

疾病/阶段	推荐干预意见	辩证	推荐方药
桥本甲状腺炎 **甲状腺功能正常阶段**	**推荐意见 1**：在生活方式干预的基础上，定期随访，一般主张每半年到 1 年随访 1 次，主要检查甲状腺功能，必要时可行甲状腺超声检查。控制碘摄入量在安全范围有助于阻止甲状腺自身免疫破坏的进展。 **推荐意见 2**：在上述治疗基础上，进行中医辨证治疗。 **推荐中成药**：在生活方式干预的基础上，推荐使用百令胶囊（证据级别：D，弱推荐）或逍遥丸（证据级别：D，弱推荐）降低TPOAb抗体滴度。	肝郁气滞	柴胡疏肝散加减（药物组成：柴胡、川芎、香附、陈皮、白芍、枳壳、甘草等）（证据级别：C，强推荐）
		肝郁化热	清肝散结消瘿方（药物组成：夏枯草、柴胡、合欢花、牡丹皮、白芍、黄芩、赤芍、桔梗、猫爪草、生牡蛎、珍珠母、黄芪）（证据级别：B，强推荐）
		肝郁痰凝	四逆散合半夏厚朴汤加减（药物组成：柴胡、白芍、赤芍、枳实、半夏、紫苏叶、茯苓、炙甘草、生姜、乌梅等）（证据级别：B，强推荐）
		肝郁脾虚	小柴胡汤合当归芍药散加减(药物组成：柴胡、黄芩、人参、半夏、生姜、当归、白芍、白术、茯苓、泽泻、川芎等）（证据级别：C，强推荐）
桥本甲状腺炎 **继发甲状腺毒症**	**推荐意见 1**：一般不用抗甲状腺药物，在生活方式干预的基础上，甲状腺毒症症状明显尤其老年患者、静息心率超过 90 次/min 或合并心血管疾病，可用β受体阻滞剂（如普萘洛尔）治疗，个别症状严重不能控制者，可应用小剂量抗甲状腺药物，并根据甲状腺功能监测情况及时调整剂量或停药，以免导致甲减。一般不予 I^{131} 及手术治疗。具体药物使用方法及注意事项、不良反应可参考《中国甲状腺功能亢进症和其他原因所致甲状腺毒症诊治指南（2022)》[6]（中华内分泌代谢杂志，2022,38(8):700-748.）。 **推荐意见 2**：在上述治疗基础上，进行中医辨证治疗。	肝郁化火	丹栀逍遥散加减（药物组成：柴胡、茯苓、白芍、白术、当归、栀子、牡丹皮、甘草、生姜、薄荷等）（证据级别：C，强推荐）
		心肝热盛	栀子清肝汤加减（药物组成：柴胡、栀子、牡丹皮、茯苓、川芎、白芍、当归、牛蒡子、甘草等）（证据级别：B，强推荐）
		阴虚火旺	当归六黄汤加减（药物组成：当归、生地黄、黄芩、黄连、黄柏、熟地黄、黄芪等）（证据级别：B，强推荐）
		气阴两虚	天王补心丹合补中益气汤加减（药物组成：党参、茯苓、玄参、丹参、桔梗、远志、当归、柏子仁、酸枣仁、生地黄、黄芪、白术、陈皮、升麻、柴胡、甘草、当归等）（证据级别：C，强推荐）

疾病/阶段	推荐干预意见	辩证	推荐方药
桥本甲状腺炎 **继发甲状腺功能减退症**	**推荐意见 1：**可根据情况进行左甲状腺素钠片（L-T4）替代治疗。具体药物使用方法可参考《成人甲状腺功能减退症诊治指南》[7]（中华内分泌代谢杂志，2017，33(2):167-180）。 **推荐意见2：**在上述治疗基础上，进行中医辨证治疗。 **推荐中成药：**在生活方式干预的基础上，推荐使用百令胶囊（证据级别：D，弱推荐）；或夏枯草制剂（证据级别：D，弱推荐）；或金水宝胶囊（证据级别：C，弱推荐），以上三种中成药均可联合左甲状腺素，以降低 TPOAb 抗体滴度，改善甲状腺功能；脾肾阳虚证推荐使用右归丸（证据级别：D，弱推荐）联合左甲状腺素，以降低 TPOAb 抗体滴度，改善临床症状。	痰结血瘀	解郁通络消瘿汤（柴胡、白芍、茯苓、玄参、当归、白术、郁金、法半夏、陈皮、浙贝母、山慈菇、连翘、鸡血藤、莪术、炙甘草） （证据级别：C，强推荐）
			化痰祛瘀消瘿汤（半夏、当归、厚朴、茯苓、赤芍、川芎、僵蚕、柴胡、黄芩、人参、丹参、鸡血藤、炙甘草等） （证据级别：C，强推荐）
			消瘿散结方（夏枯草、仙鹤草、猫爪草、生甘草、三棱、莪术、仙灵脾） （证据级别：C，强推荐）
		肝郁脾虚	柴胡疏肝散或逍遥散加减(药物组成：柴胡、白芍、枳实、陈皮、川芎、香附、甘草或柴胡、当归、白芍、白术、茯苓、炙甘草、生姜等） （证据级别：C，强推荐）
		脾肾阳虚	参苓白术散合金匮肾气丸加减（药物组成：人参、炙甘草、白术、熟地黄、山药、山茱萸、泽泻、茯苓、牡丹皮、桂枝、附子等） （证据级别：C，强推荐）
		心肾阳虚	真武汤加减（药物组成：茯苓、白术、白芍、炙甘草、生姜、附子等） （证据级别：C，强推荐）

附录 F
资料性
缩略词对照表

缩写	全称	中文
ESR	Erythrocyte Sedimentation Rate	红细胞沉降率
FNAC	Fine Needle Aspiration Cytology	细针穿刺细胞学
FT_3	Free Triiodthyronine	游离三碘甲腺原氨酸
FT_4	Free Thyroxine	血清游离甲状腺素
GD	Graves' disease	弥漫性毒性甲状腺肿
HT	Hashimotos thyroiditis	桥本甲状腺炎
L-T4	Levothyroxine Sodium Tablets	左甲状腺素钠片
TgAb	Anti-Thyroid Globulin Antibody	甲状腺球蛋白抗体
ThyPRO-39	Thyroid-Related Patient-Reported Outcome	甲状腺疾病生活质量简明量表
TPOAb	Anti-Thyroid Peroxidase Antibody	甲状腺过氧化物酶抗体
TSH	Thyroid Stimulating Hormone	促甲状腺激素
TT_3	Total Triiodothyronine	总三碘甲状腺原氨酸
TT_4	Total Thyroxine	总甲状腺素
UIC	Urine Iodine Concentration	尿碘

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Foreword

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The drafting procedure of this document abides by the relevant provisions of SCM 1.1-2021 *Guidelines for Standardization Part 1: Standard Formulation, Revision and Publication* issued by the World Federation of Societies of Traditional Chinese Medicine.

Introduction

Hashimotos thyroiditis, also known as chronic lymphocytic thyroiditis, is an autoimmune thyroiditis first reported by Hashimoto in 1912 [1]. The prevalence of Hashimotos thyroiditis varies in different countries and regions, and is influenced by geographic regions and environmental factors, with 14.2% in Africa, 11.0% in Oceania, 8.0% in South America and Europe, 7.8% in North America, and 5.8% in Asia[2]. The incidence rate in women is 15-20 times higher than that in men[3] , and women aged 30-50 years are the most prevalent group[4]. The pathogenesis is not clear. Modern medicine is based on follow-up, with no special treatment, such as secondary thyrotoxicosis, secondary hypothyroidism, requiring antithyroid drugs or hormone supplementation.

TCM has conducted extensive clinical research on Hashimotos thyroiditis; however, there are many points of contention regarding integrated traditional Chinese and Western medicine (TCWM) diagnosis and treatment, and no systematic guidelines or standards have been established. The existing Western medicine guideline is the Guideline for the Diagnosis and Treatment of Thyroid Diseases—Thyroiditis, issued by the Endocrinology Branch of the Chinese Medical Association in 2008, which requires updates based on scientific evidence accumulated since then. In the field of TCWM, the main references include the Beijing Consensus on Integrated Traditional Chinese and Western Medicine for the Diagnosis and Treatment of Hashimotos thyroiditis (2021, Beijing) and the Beijing Expert Consensus on Quality Control Indicators for Integrated Diagnosis and Treatment of Hashimotos thyroiditis (2021 Edition). These documents do not specify the stages of disease progression and are largely consensusbased, lacking highquality evidence to meet current clinical needs. With the growing global influence of Chinese medicine, optimizing TCM treatment strategies and recommendations for Hashimotos thyroiditis to promote its international application has become a critical task requiring standardization and implementation.

On the basis of previous guidelines, this document has formed a series of recommended TCM treatment protocols with precise efficacy, high safety and easy to promote based on the screening of high-quality research results and extensive consultation with experts. Meanwhile, during the development of this document, close communication and cooperation with international Chinese medicine academic organizations were emphasized, and the content design was designed to enhance international universality and practicability and ensure its operability in clinical practice. The development of this document follows the international norms for the development of evidence-based guidelines and is accomplished under the framework of relevant laws and regulations and technical guidance documents. When selecting the diagnostic and therapeutic measures recommended or suggested in this document, it should be ensured that

they are in line with and comply with the relevant laws and regulations of the country or region in which they are located.

Please note: In clinical practice, the TCM treatments recommended in this guideline should be utilized on the basis of Western medical treatments; see ANNEX C for Western medical treatments at various stages.

International clinical practice guideline of Chinese medicine: Hashimotos thyroiditis

1 Scope

This document standardizes the clinical manifestations, diagnostic crite ria and Chinese medicine treatment options for adult hashimotos thyroiditi s patients (except those during pregnancy and lactation).

This document applies to the medical institutions that carry out the d iagnosis and treatment of Hashimotos thyroiditis, and applies to the Chine se medicine practitioners and Chinese and Western medicine practitioners who carry out the diagnosis and treatment of hashimotos thyroiditis.

2 Normative References

The following documents are indispensable for the application of this document. For dated references, only the versions cited apply. For undate d references, the latest versions (including all amendments) apply.

GB/T 21709.1-2008 Standardized Manipulations of Acupuncture and Moxibustion—Part 1: Moxibustion

GB/T 21709.9-2008 Standardized Manipulations of Acupuncture and Moxibustion—Part 9: Acupoint Paste

GB/T 21709.20-2009 Standardized Manipulations of Acupuncture and Moxibustion—Part 20: Basic Techniques of Filiform Needle

GB/T 33414-2016 Specification on Chinese Herbal Application of Acu point Paste

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Hashimotos thyroiditis (2021, Beijing). Chinese Medical Journal of Medicine, 2022, 19(34): 4-7.

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3 Terms and Definitions

The following terms and definitions apply to this document.

3.1

Hashimotos thyroiditis (HT)

Chronic lymphocytic thyroiditis

Autoimmune thyroiditis characterized by diffuse enlargement of the thyroid gland, toughness and hardness, nodularity on the surface, accompanied by elevated antibodies to thyroid peroxidase and thyroglobulin, and infiltration of lymphocytes into the thyroid gland as the main pathologic feature.

Note: In Traditional Chinese Medicine (TCM), Hashimotos thyroiditis is mostly categorized under terms such as goiter swelling, qi goiter, goiter disease, exhaustion and goiter tumors, goiter swelling and qi goiter being the most commonly seen categories.

3.2

Goiter swelling

Goiter swelling refers to the clinical manifestation of diffuse anterior neck swelling, firm texture, and palpable nodules in the anterior neck region.

Note: Western medicine conditions such as Hashimotos thyroiditis and chronic lymphocytic thyroiditis can refer to this disease for syndrome differentiation and treatment.

4 Clinical Manifestations

The clinical manifestations of this disease are atypical, with an insidious onset, slow progression, and a prolonged course. The primary symptom is diffuse thyroid enlargement, often painless, symmetric, and with a firm texture. It is not adherent to surrounding tissues and moves up and down with swallowing. In patients with a longer course, nodules may be palpated. Early clinical manifestations are often not characteristic, and some patients may have symptoms such as discomfort in the throat, mild difficulty swallowing, a sense of neck pressure, local pain and tenderness, fatigue, and insomnia. When secondary hyperthyroidism occurs, clinical manifestations may include palpitations, excessive sweating, and increased appetite. When secondary hypothyroidism develops, symptoms may include fatigue,

drowsiness, bradycardia, cold intolerance, myxedema, and constipation.

5 Diagnosis

5.1 Western medical diagnosis

The diagnosis, auxiliary examinations, and differential diagnosis of this disease in Western medicine can be found in ANNEX B.

5.2 Traditional Chinese Medicine Diagnosis

5.2.1 Diagnostic Principles

This disease is based on the level of thyroid function, and TCM diagn osis and typing is performed for Hashimotos thyroiditis (normal thyroid fu nction stage), Hashimotos thyroiditis secondary to thyrotoxicosis, and Hashi motos thyroiditis secondary to hypothyroidism, respectively.

5.2.2 Syndrome Differentiation and Classification

5.2.2.1 Hashimotos thyroiditis

5.2.2.1.1 Liver Qi Stagnation Syndrome

Primary Symptoms: No significant enlargement of the neck, but may experience anterior neck swelling or foreign body sensation in the throat, painless, emotional depression, and frequent sighing.

Secondary Symptoms: Chest, hypochondrium, or abdominal distension, which eases after sighing; poor appetite; breast distension or pain; irregular menstruation in women.

Tongue and Pulse: Palered tongue with thin white coating; wiry pulse.

5.2.2.1.2 Liver Depression and Heat Syndrome

Primary symptoms: Diffuse swelling in the anterior neck, possibly acc ompanied by swelling, pain, or a foreign body sensation in the throat; irri tability, bitterness in the mouth, and dry throat.

Secondary symptoms: Burning pain in the hypochondrium, insomnia w ith frequent dreams, constipation, and yellowishred urine.

Tongue and pulse: Red tongue with yellow coating, wiry and rapid pu lse.

5.2.2.1.3 Liver Depression and Phlegm Coagulation Syndrome

Primary symptoms: Swelling in the anterior neck, local discomfort, for eign body sensation in the throat resembling phlegm obstruction, which ca nnot be swallowed or expectorated, fluctuating with emotions.

Secondary symptoms: Irritability or depression, fullness in the chest a nd hypochondrium or lower abdomen, frequent sighing.

Tongue and pulse: Pale or dark tongue with white or greasy coating, wiry and slippery pulse.

5.2.2.1.4 Liver Stagnation and Spleen Deficiency Syndrome

Primary symptoms: Diffuse swelling in the neck, emotional depression, frequent sighing, fatigue.

Secondary symptoms: Fullness in the chest and hypochondrium, reduced appetite, abdominal distension, loose stools, or abdominal pain relieved after diarrhea.

Tongue and pulse: Pale tongue with white coating, wiry and thin or slow and weak pulse.

5.2.2.2 Hashimotos thyroiditis secondary to thyrotoxicosis

5.2.2.2.1 Liver depression transforming into fire syndrome

Primary symptoms: Diffuse swelling in the anterior neck, possibly accompanied by neck swelling and pain, or foreign body sensation in the throat, irritability, excessive sweating, and increased appetite.

Secondary symptoms: Fear of heat, tinnitus, dry mouth, bitter taste, hard stools, and yellow or reddish urine.

Tongue and pulse: Red tongue body, yellow coating, and wiry, rapid pulse.

5.2.2.2.2 Heart and Liver Heat Syndrome

Primary Symptoms: Diffuse swelling in the anterior neck, palpable tremor, possible pain, anxiety, irritability, fever, excessive sweating, palpitations, hand tremors, insomnia, vivid dreams.

Secondary Symptoms: Red face and eyes, headache, dry mouth, bitter taste, increased appetite with frequent hunger, weight loss.

Tongue and Pulse: Red tongue with yellow coating; taut, rapid, and forceful pulse.

5.2.2.2.3 Yin Deficiency Fire Exuberance Syndrome

Primary Symptoms: Diffuse swelling in the anterior neck, feverish sensation in the palms and soles, irritability, quick temper, heat intolerance, sweating, polyphagia with frequent hunger, hand tremors.

Secondary Symptoms: Facial flushing, tidal fever, night sweats, insomnia with vivid dreams, dry mouth and throat, dark urine, constipation.

Tongue and Pulse: Red and thin tongue with little or no coating; thin and rapid pulse.

5.2.2.2.4 Qi and Yin Deficiency Syndrome

Main symptoms: Diffuse swelling in the anterior neck, fatigue, shortness of breath, excessive sweating, hand tremors, irritability with a sensation of heat in the palms and soles, palpitations.

Secondary symptoms: Forgetfulness, insomnia, excessive thirst, poor appetite, emaciation, dark yellow urine, constipation or loose stools.

Tongue and pulse: Red tongue with little coating, thin or weak and ra pid pulse.

5.2.2.3 Hashimotos thyroiditis secondary to hypothyroidism

5.2.2.3.1 Phlegm-Blob and Blood Stasis Syndrome

Main Symptoms: Firm or hard mass in the front of the neck, with a nodular sensation; Sensation of obstruction in the throat; Chest tightness, epigastric distension, bloating or stabbing pain; Heaviness in the head a nd body, fatigue, and somnolence.

Secondary Symptoms: Dizziness, tinnitus, facial dullness, numbness of t he skin or the thyroid, excessive phlegm; Obesity, abdominal distension, an d loose stools.

Tongue and Pulse: Tongue: dark, swollen, or with ecchymosis or petec hiae; Coating: slippery and greasy; Pulse: deep, slow, or wiry.

5.2.2.3.2 Liver Stagnation and Spleen Deficiency Syndrome

Main Symptoms: Diffuse swelling in the anterior neck with a soft or f irm texture, possible foreign body sensation, emotional depression, limb fa tigue, low voice, reluctance to speak or move.

Secondary Symptoms: Chest tightness, belching, frequent sighing, or ab dominal distension, poor appetite, food stagnation, unformed stools.

Tongue and Pulse: Pale and swollen tongue with teeth marks on the edges, white coating; wiry-thin or moderate-weak pulse.

5.2.2.3.3 Spleen and Kidney Yang Deficiency Syndrome

Main Symptoms: Diffuse or no swelling in the anterior neck, firm or hard texture, facial puffiness, limb swelling, cold intolerance, fatigue, abdo minal distension, poor appetite.

Secondary Symptoms: Memory decline, sparse hair, lower limb edema, male impotence, female scant menstruation or amenorrhea, difficult defec ation or early morning diarrhea, clear and long urination.

Tongue and Pulse: Pale and swollen tongue with white slippery coatin g; deep-thin or deep-slow and weak pulse.

5.2.2.3.4 Heart and Kidney Yang Deficiency Syndrome

Primary Symptoms: Diffuse swelling or no swelling in the anterior ne ck, firm or hard texture, aversion to cold, cold extremities, pale and puffy complexion, lower limb edema, palpitations, shortness of breath, drowsine ss, weakness in the limbs.

Secondary Symptoms: Dizziness, tinnitus, chest tightness or pain, cyan osis of lips and nails, and dysuria.

Tongue and Pulse: Pale or dark tongue, white slippery coating, and d eep, slow, and weak pulse.

6 treatments

6.1 Principles of treatment

6.1.1 Western medicine disease differentiation, TCM syndrome differentiation, and integration of disease and syndrome

Combined with the patient's clinical symptoms and auxiliary examinati on results to clarify the Western medical diagnosis, on this basis, adhering to the principle of “Western medicine to identify the disease, Chinese me dicine to identify the evidence, and the combination of disease and eviden ce”, to carry out a phased diagnosis and treatment (consensus recommend ations).

6.1.2 Stepwise treatment, TCMWM synergy, and complementary advantages

The purpose of combining Chinese and Western medicine is to compl ement each other's strengths and enhance the efficacy of the treatment w hile making up for the weak aspects of each treatment. Modern medicine excels in regulating thyroid function, while TCM shows superior effects in improving clinical symptoms, reducing thyroidrelated antibody titers, assisti ng in dose reduction of antithyroid drugs or levothyroxine (LT4), and enh ancing quality of life. Integrated TCMWM therapy can enhance therapeutic efficacy while compensating for the limitations of each approach. for ear lystage HT patients with mild symptoms and inconspicuous TCM syndrome s, lifestyle modifications and regular followup are recommended. For patie nts with significant symptoms or obvious TCM syndromes, TCM treatment should be added based on correct syndrome differentiation. For those wi th marked clinical symptoms and abnormal thyroid function, integrated TC MWM therapy should be implemented alongside lifestyle interventions (Co nsensus Recommendation).

6.2 Dialectical treatment

6.2.1 Hashimotos thyroiditis

6.2.1.1 Liver Qi Stagnation Syndrome

Treatment Principle: Soothing liver and relieving depression.

Recommended Prescription: Chaihu Shugan Powder(ingredients: Buple urum, Chuanxiong, Cyperus, Chenpi, Baishao, Zhike, Gancao, etc.) (Evidence Level: C, Strong Recommendation).

6.2.1.2 Liver Depression and Heat Syndrome

Treatment principle and method: Soothing the liver and clearing heat.

Recommended prescription: Qinggan Sanjie Xiaoying Formula (Medicin al composition: Prunella vulgaris, Radix Bupleuri, Albizia julibrissin, Cortex

Moutan, Radix Paeoniae Alba, Scutellaria baicalensis, Radix Paeoniae Rubra, Platycodon grandiflorus, Clinopodium gracile, Ostreae Concha, Margaritifera, Astragalus membranaceus) (evidence level: B, strong recommendation).

6.2.1.3 Liver Depression and Phlegm Coagulation Syndrome

Treatment principle and method: Soothing the liver and dispersing knots.

Recommended prescription: Powder for regulating liver and spleen combined with Banxia Houpu decoction addition and subtraction(Medicinal composition: Radix Bupleuri, Radix Paeoniae Alba, Radix Paeoniae Rubra, Fructus Aurantii Immaturus, Pinellia ternata, Perilla leaf, Poria, Honeyfried Licorice, Fresh Ginger, Fructus Mume, etc.) (evidence level: B, strong recommendation).

6.2.1.4 Liver Stagnation and Spleen Deficiency Syndrome

Treatment principle and method: Soothing the liver and strengthening the spleen.

Recommended prescription: Modified Xiaochaihu Decoction combined with Danggui Shaoyao San (Medicinal composition: Radix Bupleuri, Scutellaria baicalensis, Ginseng, Pinellia ternata, Fresh Ginger, Angelica sinensis, Radix Paeoniae Alba, Atractylodes macrocephala, Poria, Alismatis Rhizoma, Ligusticum chuanxiong, etc.) (evidence level: C, strong recommendation).

6.2.2 Hashimotos thyroiditis secondary to thyrotoxicosis

6.2.2.1 Liver depression transforming into fire syndrome

Treatment principle and method: Clearing liver and purging fire.

Recommended prescription: Modified Dan Zhi Xiao Yao San (herbal composition: Bupleurum root, Poria, White Peony root, Atractylodes macrocephala, Angelica sinensis, Gardenia, Moutan Bark, Licorice, Ginger, Mint, etc.) (Evidence Level: C, Strong Recommendation).

6.2.2.2 Heart and Liver Heat Syndrome

Treatment Principle: Clearing heart and purging liver.

Recommended Formula: Modified Zhi Zi Qing Gan Decoction (Herbal ingredients: Bupleurum, Gardenia, Moutan Cortex, Poria, Ligusticum Chuanxiong, White Peony Root, Angelica Sinensis, Great Burdock Fruit, Licorice, etc.) (Evidence level: B, strong recommendation).

6.2.2.3 Yin Deficiency Fire Exuberance Syndrome

Treatment Principle: Nourishing yin and clearing heat.

Recommended Formula: Modified Danggui Liu Huang Decoction (Herbal ingredients: Angelica Sinensis, Rehmannia Root, Scutellaria Baicalensis, Coptis Chinensis, Phellodendron Amurense, Prepared Rehmannia, Astragalus R

oot, etc.) (Evidence level: B, strong recommendation).

6.2.2.4 Qi and Yin Deficiency Syndrome

Therapeutic principles and methods: Reinforcing Qi and nourishing Yin.

Recommended prescriptions: Tian Wang Bu Xin Dan combined with Buzhong yiqi decoction, modified as needed (Ingredients: Codonopsis pilosula, Poria cocos, Scrophularia ningpoensis, Salvia miltiorrhiza, Platycodon grandiflorus, Polygala tenuifolia, Angelica sinensis, Biota orientalis seeds, Ziziphus jujuba seeds, Rehmannia glutinosa, Astragalus membranaceus, Atractylodes macrocephala, Chenpi, Cimicifuga, Bupleurum, Glycyrrhiza uralensis, Angelica sinensis, etc.) (Evidence level: C, strong recommendation).

6.2.3 Hashimotos thyroiditis secondary to hypothyroidism

6.2.3.1 Phlegm-Blob and Blood Stasis Syndrome

Treatment Principle: Regulate Qi, activate blood, resolve phlegm, and eliminate goiter.

Recommended Formula: Jieyu Tongluo Xiaoying Decoction (Chaihu, Baishao, Fuling, Xuanshen, Danggui, Baizhu, Yujin, Fabanxia, Chenpi, Zhebeimu, Shancigu, Lianqiao, Jixueteng, E Zhu, Zhi Gancao) (Evidence Level: C, Strongly Recommended)

Huatan Quyu Xiaoying Decoction (Banxia, Danggui, Houpo, Fuling, Chishao, Chuanxiong, Jiangcan, Chaihu, Huangqin, Renshen, Danshen, Jixueteng, Zhi Gancao, etc.) (Evidence Level: C, Strongly Recommended)

Xiaoying Sanjie Formula (Xiakucao, Xianhecao, Maozhuacao, Sheng Gancao, Sanling, E Zhu, Xianlingpi) (Evidence Level: C, Strongly Recommended)

6.2.3.2 Liver Stagnation and Spleen Deficiency Syndrome

Principles of Treatment: Liver soothing and spleen strengthening.

Recommended Prescriptions: Chaihu Shugan Powder or Xiaoyao Powder with modifications (composition: Bupleurum root, white peony root, bitter orange, dried tangerine peel, Ligusticum wallichii, nutgrass rhizome, licorice root, or Bupleurum root, angelica root, white peony root, Atractylodes macrocephala, poria, roasted licorice root, fresh ginger, etc.) (Evidence Level: C, strong recommendation)

6.2.3.3 Spleen and Kidney Yang Deficiency Syndrome

Principles of Treatment: Warming and replenishing the spleen and kidney.

Recommended Prescriptions: Shenling Baizhu Powder combined with Jin Gui Shenqi Pill with modifications (composition: ginseng, roasted licorice root, Atractylodes macrocephala, prepared rehmannia root, Chinese yam, Asiatic cornelian cherry fruit, alisma, poria, tree peony root bark, cinnamon twig, prepared aconite root, etc.) (Evidence Level: C, strong recommenda

tion).

6.2.3.4 Heart and Kidney Yang Deficiency Syndrome

Treatment Principles: Warming and replenishing the heart and kidneys.

Recommended Formula: Modified Zhenwu Tang (Composition: Poria, Atractylodes macrocephala, White Peony Root, Roasted Licorice, Fresh Ginger, Aconite Root, etc.) (Evidence Level: C, Strong Recommendation).

6.3 Proprietary Chinese medicines

6.3.1 Hashimotos thyroiditis

On the basis of lifestyle intervention, the use of Bailing capsule (Level of Evidence: D, weak recommendation) or Xiaoyao pill (Level of Evidence: D, weak recommendation) is recommended to reduce the TPOAb antibody titer.

6.3.2 Hashimotos thyroiditis secondary to hypothyroidism

On the basis of lifestyle intervention, Bailing capsule (evidence level: D, weak recommendation) or prunella preparation (evidence level: D, weak recommendation) or Jin Shui Bao capsule (evidence level: C, weak recommendation) in combination with levothyroxine is recommended to reduce TPOAb antibody titer and improve thyroid function; Right-restoring pill (evidence level: D, weak recommendation) in combination with levothyroxine is recommended to reduce the TPOAb antibody titer and improve thyroid function in the case of spleen and kidney yang deficiency. TPOAb antibody titer and improve clinical symptoms.

6.4 Other Treatment Methods

6.4.1 External application of traditional Chinese medicine

6.4.1.1 For Hashimotos thyroiditis with goiter, compresses can be applied to the thyroid region of the neck.The following recommended prescriptions can be used for the following situations:

a) Qi Stagnation and Phlegm Obstruction Syndrome in HT: Recommended formula: Xiaoying Sanjie Decoction (Prunella vulgaris, Forsythia suspensa, Pinellia ternata [processed with ginger], Pericarpium Citri Reticulatae, Fritillaria thunbergii, Rhizoma Sparganii, Rhizoma Curcumae, Cortex Moutan, Resina Olibani, Resina Myrrha, Salvia miltiorrhiza, Radix Paeoniae Rubra, Radix Paeoniae Alba, Ostreae Concha [raw], Hirudo, Radix Curcumae, Mirabilitum) (Evidence Level: C, Strong Recommendation).

b) Hypothyroidism Secondary to HT: Recommended formulas:

Hashimotos thyroiditis with Secondary Hypothyroidism: Xiao Ying Formula (includes Astragalus membranaceus, Prunella vulgaris, Uncaria rhynchophylla, Bupleurum chinense, Cyperus rotundus, Curcuma zedoaria, Clove,

Borneol) (Evidence level: C, Strong recommendation); or Xiao Ying Paste (i ncludes Astragalus membranaceus, Bupleurum chinense, Scutellaria baicalen sis, Prunella vulgaris, Curcuma longa, Paris polyphylla, Carthamus tinctorius, Trionyx sinensis, Ligusticum wallichii, Radix Paeoniae Rubra, Angelica sine nsis, Cinnamomum cassia, Chrysanthemum indicum, Lonicera japonica, Euco mmia ulmoides, Curcuma zedoaria, Pinellia ternata, Atractylodes lancea, Sic huan pepper, Fritillaria thunbergii, Mangxiao) (Evidence level: C, Strong rec ommendation). Either of the two formulas can be combined with Levothyr oxine.

6.4.1.2 Preparation of external medicine: Grind all the drugs into powder, and according to the situation, auxiliary permeability agents, babbling agen ts, excipients, etc., may be added. The powder should be mixed into a pas te to form a topical paste. The efficacy and characteristics of excipients an d permeability agents can be referred to GB/T 33414-2016 [5], and the pr oduction, use, and storage principles should comply with the provisions of GB/T 33414-2016.

Note 1: Permeability agents: substances that increase the transdermal rate or the am ount of the drug absorbed through the skin.

Note 2: Babbling agents: external application patches made from water-soluble polym er materials or hydrophilic substances as a base combined with the drug.

Note 3: Excipients: substances that give the drug an appropriate form and volume.

6.4.2 Acupuncture

6.4.2.1 Hashimotos thyroiditis secondary to hypothyroidism can be treated with acupuncture combined with levothyroxine according to the evidence. Clinical application can be appropriately combined with electroacupuncture (sparing wave).

a）Hand-Yangming meridian through-needling:

Recommended acupoints: Sān jiān (LI3), Hé gǔ (LI4), Qū chí (LI11), Bì nào (LI14), Jiān yú (LI15), Rén yíng (ST9), Zú sān lǐ (ST36) (Evidence level: B, strong recommendation).

The patient should lie supine, and the local area of the acupoints should be disinfected routinely. LI3 and LI4 are needled through each other; LI11 is needled through LI14; LI14 is needled through LI15; LI15 is obliquely punctured, while ST9 and ST36 are perpendicularly punctured. The treatment is conducted 2–3 times a week.

b）Liver depression and kidney deficiency syndrome:

Recommended acupoints: Guān yuán (RN4), Tài xī (KI3), Xuán zhōng (GB39), Tài chōng (LR3), Hé gǔ (LI4), Sān yīn jiāo (SP6), Nèi guān (PC6), Fēng lóng (ST40), Rén yíng (ST9), Fú tū (LI18). Except for Guān yuán, all other acupoints are bilateral (Evidence level: C, strong recommendation).

The patient should lie supine, and the acupuncture area should be routinely disinfected. Needles are inserted perpendicularly or obliquely, and after

achieving deqi, a balanced reinforcing and reducing method is applied to create a localized sensation of soreness, numbness, heaviness, and distention. The needles are retained for 30 minutes, and the treatment is performed every other day.

c） Spleen-kidney yang deficiency syndrome:

Recommended therapy: Moxibustion with needle on the following acupoints: Pí shū (BL20, bilateral), Shèn shū (BL23, bilateral), Mìng mén (DU4), Fēng lóng (ST40, bilateral), and Tài chōng (LR3, bilateral) (Evidence level: C, strong recommendation).

The patient should lie prone. After achieving deqi, warm moxibustion is performed. Moxa floss or moxa sticks are placed onto the needle handles and ignited at the base. Each session involves 2 moxa cones. During moxibustion, if the patient feels excessive heat, thin hard paper can be used to shield the skin to reduce heat intensity and prevent burns.

Note: Moxibustion with needle refers to the method that combines acupuncture and moxibustion, where moxa wool (moxa ball or segment of moxa stick) is placed on the needle handle during acupuncture.

6.4.2.2 When using acupuncture therapy, attention should be paid to the specific conditions of the patient. The amplitude and angle of needle insertion, frequency, and duration should be flexibly adjusted according to the patient's condition and the practitioner's goal. For patients with weak constitutions or deficiency in Qi and blood, excessive needle sensation should be avoided, and acupuncture should be performed while the patient is lying down. Acupuncture should not be performed immediately after hunger, overeating, alcohol consumption, intense anger, surprise, excessive fatigue, or mental stress. In cases of skin infection, ulcers, scarring, or tumors, acupuncture should not be performed directly on the affected area. For patients with coagulation disorders, acupuncture is contraindicated. Detailed precautions and contraindications should comply with the provisions of GB/T 21709.20-2009.

6.5 Lifestyle

6.5.1 Moderation in diet and balanced nutrition

Adequate intake of calories and nutrients, such as vitamins, proteins, and trace elements, should be ensured to maintain nutritional balance. Regarding iodine intake, it is recommended to evaluate the levels based on urine iodine concentration (UIC) and develop individualized plans. Daily diets should be moderate, avoiding overeating or partiality to specific foods. High-iodine foods should be avoided, and iodine-rich medications should be used cautiously according to clinical needs (Consensus recommendation).

6.5.2 Emotional regulation and mental health

Emotional well-being has a significant impact on thyroid diseases. Maintaining a cheerful and open-minded attitude, promptly addressing negative emotions, engaging in positive communication and social activities, and adapting to changes in the living environment are important measures for preventing and managing HT (Consensus recommendation).

6.5.3 Regular lifestyle and appropriate actions

Aligning with seasonal changes, cultivating good living habits, maintaining a balance between work and rest, harmonizing the functions of internal organs, and stabilizing the body's internal environment are essential for disease recovery (Consensus recommendation).

6.5.4 Moderate exercise and enhanced physical fitness

Regular physical exercise is encouraged to strengthen the body, avoid overexertion, improve disease resistance, and enhance the body's vital energy. Traditional Chinese medicine holds that "When vital energy is sufficient within, pathogenic factors cannot invade" (Consensus recommendation).

6.5.5 Early detection and timely intervention

HT has a slow onset, long course, and certain insidious characteristics. Regular thyroid check-ups should be emphasized, especially for those with a family history of the condition. Once diagnosed, regular follow-ups and timely, reasonable treatments are recommended (Consensus recommendation).

7 Indicators of outcomes

The key outcome indicators can be referred to in ANNEX D.

ANNEX A
(informative)
Method of Preparation

A.1 Basis and principles for the preparation of the guidelines

The drafting procedure of this document follows the requirements outlined in the "SCM1.1-2021 Guidelines for Standardization Work - Part 1: Standard Development, Revision, and Release" issued by the World Federation of Chinese Medicine Societies, and also refers to the relevant provisions in "GB/T 1.1-2020 Guidelines for Standardization Work (Part 1: Structure and Drafting Rules of Standardized Documents)."

During the guideline development process, strict adherence was made to the principles and standards of evidence quality evaluation, evidence grading, and the formation of recommendations to ensure the scientific rigor and accuracy of the guideline. The quality evaluation of systematic review methodologies was carried out using the AMSTAR2 tool; the methodological quality of Randomized Controlled Trials (RCT) was assessed using the Cochrane risk of bias assessment tool; and evidence quality evaluation and grading were performed using the GRADE system. The guideline's recommendations or consensus opinions were formed using the "Delphi" method.

A.2 Preparation process

The preparation of this guideline was carried out in strict accordance with the standardized steps.

Stage 1: Establishing a guideline drafting group and signing a declaration of interest; combing domestic and international guidelines and clinical studies related to Hashimotos thyroiditis in Chinese and Western medicine to determine the topic, scope and purpose of the guideline; planning the guideline research program and writing the declaration materials. After the project was formally established, key issues in clinical practice were comprehensively collected through interviews with authoritative experts and online clinician research in order to initially construct a list of guideline issues and outcome indicators; the clinical issues to be addressed by the guideline and the grading of the importance of the efficacy evaluation indexes were optimized through the Delphi method to ultimately form a list of clinical issues for the guideline.

Stage 2: Based on the identified list of clinical problems, searching, screening, synthesizing and evaluating the evidence were conducted. For clinical problems supported by evidence-based medicine, the GRADE method is used to evaluate and grade the quality of evidence, and a summary table of evidence is formed; for clinical problems with insufficient evidence, expert consensus recommendations are initially formed, and the recommenda

tions are agreed upon through an online expert consensus meeting.

Stage 3: After completing the draft guideline, experts within the writi ng working group conducted self-assessment and revised and improved th e draft. Subsequently, the draft was submitted to the World Federation of Societies of Traditional Chinese Medicine (WFTCM) for publicity and exten sive consultation; after the expiration of the publicity period and review a nd approval by the Society, the final revision, confirmation and release we re made based on the feedback.

A.3 Evidence Evaluation Grading and Recommendation Rules

A.3.1 Grading of Evidence Evaluation

This guideline uses the GRADE criteria to evaluate the quality of the body of evidence, including five factors that reduce the quality of evidence: risk of bias, inconsistency, non-directness, imprecision, and publication bia s, and three factors that improve the quality of evidence: large effect sizes, dose-response relationships, and the effect of confounding bias. The resul ting Evidence Summary Sheet and Evidence Summary Sheet were also arc hived to ensure transparency and traceability of the evidence process.

Table 1 Description of quality of evidence

Grading of eviden ce	specific descriptions	Type of study
high quality/A ⊕⊕⊕⊕	We are pretty sure that the true effect value is close to the effect estimate	Observational study of RCT mass elevation grade 2
medium quality/B ⊕⊕⊕◯	We are moderately confident in the eff ect estimates: it is possible that the tr ue values are close to the estimates, b ut there is still a possibility that they are very different.	RCT with 1 level of qualit y reduction, observational study with 1 level of quali ty increase
low mass/C ⊕⊕◯◯	We have limited confidence in the esti mates of the effects: the true values m ay be quite different from the estimate s.	RCTs with quality reductio n level 2, observational stu dy

A.3.2 Recommended rules

A.3.2.1 Recommendation Strength Determination Rules

For recommendation strength, there are 5 options: “Strongly Recomme nded” “Weakly Recommended” “Unsure” “Weakly Not Recommended “ “Stro ngly do not recommend”. Specific rules are as follows: if the number of v otes in any one cell other than “uncertain” exceeds 50%, it is regarded as a consensus, and the direction and strength of the recommendation can be determined directly; if the total number of votes in the two cells on o ne side of “uncertain” exceeds 70%, it is also regarded as a consensus, an

d the direction of the recommendation is clear, and the strength of the re commendation is set directly as “strong recommendation”. If the total num ber of votes on the “uncertainty” side exceeds 70%, it is also considered t hat a consensus has been reached and the direction of recommendation is clear, and the strength of recommendation is directly designated as “wea k”; in the remaining cases, it is considered that no consensus has been re ached, and the consensus recommendation will be put into the next round of voting; the number of voting rounds shall be up to three.

A.3.2.2 For consensus recommendations without clinical evidence

For consensus recommendations without clinical evidence, three option s are created: “Recommended,” “Unsure,” and “Not Recommended.” The spe cific rules are as follows:

If more than 50% of the votes are cast for any of the options other than “not sure”, a consensus is considered to have been reached.

In the rest of the cases, it is considered that there is no consensus, a nd the consensus recommendation goes to the next round of voting; the maximum number of rounds of voting is three.

A.4 Funding and conflicts of interest

This project is funded by the General Office of the Ministry of Financ e and the State Administration of Traditional Chinese Medicine under the “Demonstration and Pilot Project of Traditional Chinese Medicine Inheritan ce and Innovation Development”.The members of the project team signed a “Declaration of Conflict of Interest” before the official launch of the proj ect, which is on file. There is no conflict of interest in the development o f this guideline, which will not be a source of bias in the development of this guideline, and all the members involved in the development of this guideline have no financial interests with drug manufacturers.

ANNEX B
(Informative)
Western medical diagnosis of Hashimotos thyroiditis

B.1 Ancillary tests

B.1.1 Thyroid function

Thyroid function includes the measurement of total thyroxine (TT4), t otal triiodothyronine (TT3), free thyroxine (FT4), free triiodothyronine (FT 3), and thyroid-stimulating hormone (TSH) in the blood. Depending on the extent of thyroid damage, the thyroid function in the early stages of this disease may be normal, and some patients may experience transient hype rthyroidism. When thyroid function is impaired, hypothyroidism may occur, characterized by elevated serum TSH and/or decreased TT4 and FT4 leve ls. Some patients may also experience an alternating course of thyrotoxico sis and hypothyroidism.

B.1.2 Thyroid autoantibodies

Significantly elevated titers of thyroid-related antibodies TPOAb and Tg Ab are one of the characteristics of the disease. Before the appearance of hypothyroidism, antibody positivity is the main basis for clinical diagnosis of the disease.TPOAb is the most important index for diagnosing HT, the p ositive rate of TPOAb in the serum of HT patients reaches more than 9 5%, and the titer of TPOAb is closely related to the degree of lymphocyte infiltration of the thyroid gland, which directly reflects the degree of infla mmation.TgAb has the same diagnostic significance as that of TPOAb, and the positivity rate of TgAb in the HT patients is 60%~80%. TgAb has the same diagnostic significance as TPOAb, and the positive rate of TgAb in patients with HT is 60%～80%, but its sensitivity is not as good as TPOA b.

B.1.3 Ultrasonography

Bilateral enlargement of the thyroid gland, uneven echogenicity, and th e appearance of short lines of strong echogenicity within diffuse hypoechoi city and the formation of segregated or grid-like changes have a high spec ificity for the diagnosis of this disease. Some patients may be combined w ith thyroid nodules. In the early stage, the thyroid gland increases signific antly in size, and in the later stage, due to atrophy and fibrosis of the gl and, it decreases in size with internal grid-like changes. Diffuse hypoechoic ity reflects lymphocytic infiltration of the thyroid gland, and grid-like chan ges reflect interstitial fibrosis.

B.1.4 Nuclear medicine examination

Thyroid iodine uptake: the iodine uptake rate can be normal in the early stage of the disease, and then the follicles of the thyroid gland are gradually destroyed, and the iodine uptake rate gradually decreases.

Thyroid nuclear imaging: it can show irregular areas of concentration and sparseness, with uneven density and unclear borders, or “cold nodule”-like changes.

B.1.5 Fine Needle Aspiration Cytology (FNAC)

FNAC is not used as a routine diagnostic tool, but may be considered if Hashimotos thyroiditis is associated with suspected malignancy, persistent thyrotoxicosis, and if it is necessary to differentiate Hashimotos thyroiditis from toxic diffuse goiter.

Histopathological examination: lymphocytes and plasma cells can be seen in pathological sections of Hashimotos thyroiditis, and thyroid follicular epithelial cells may show different changes such as hyperplasia, atrophy, structural destruction, and interstitial microorganisms hyperplasia.

B.2 Diagnostic Criteria

B.2.1 Diagnostic Criteria for Hashimotos thyroiditis

A diagnosis can be made with positive serum TPOAb and TgAb. If only one antibody (TPOAb or TgAb) is positive, clinical manifestations should be considered. A diffuse enlargement of the thyroid with a firm texture, especially when accompanied by enlargement of the isthmus or pyramidal lobe, should raise suspicion of Hashimotos thyroiditis, regardless of whether thyroid function is altered. The presence of subclinical hypothyroidism or clinical hypothyroidism further supports the diagnosis. Fine needle aspiration cytology (FNAC) or pathological examination may provide diagnostic value.

B.2.2 Diagnostic Criteria for Secondary Thyroid Dysfunction in Hashimotos thyroiditis

Under the premise of meeting the "B.1.1 Diagnostic Criteria for Hashimotos thyroiditis":

The clinical diagnosis of secondary hyperthyroidism in Hashimotos thyroiditis requires the following conditions: serum TSH level decreased, and/or FT4 and FT3 levels increased.

The clinical diagnosis of secondary hypothyroidism in Hashimotos thyroiditis requires the following conditions: serum TSH level increased, and/or FT4 and TT4 levels decreased.

B.3 Differential diagnosis

B.3.1 Subacute thyroiditis

There is a history of upper respiratory tract infection before the onset of the disease, regional pain and enlargement of the thyroid gland occurs gradually or suddenly, radiating pain and metastatic pain are the characteristic manifestations, the erythrocyte sedimentation rate (ESR) can be significantly elevated, and the serum TT4, TT3 is increased or normal, which can be attributed to inflammation leading to destruction of the thyroid follicles and release of the stored thyroid hormones. stored thyroid hormones, the presence of elevated serum thyroid hormone levels is accompanied by a significant decrease in thyroid iodine uptake rate, a phenomenon that may assist in the diagnosis and, if necessary, in the differential of FNAC.

B.3.2 Diffuse toxic goiter (Graves' disease)

Both HT and Graves' disease are autoimmune thyroid disorders, with HT secondary to thyrotoxicosis having relatively mild clinical symptoms, with no or minimal pretibial mucous edema and proptosis. Iodine uptake rate can be helpful in differentiation. In HT secondary thyrotoxicosis, the iodine uptake rate of the thyroid gland may be normal or elevated but can be suppressed by T3; in Graves' disease, the iodine uptake rate of the thyroid gland is markedly elevated and cannot be suppressed by T3.

B.3.3 Simple Goiter

The goiter is soft, thyroid autoantibodies are mostly negative, and the thyroid function is normal.

B.3.4 Malignant Lymphoma of the Thyroid Gland

Pathologists have observed varying degrees of HT manifestations in the thyroid tissue of almost all patients with malignant lymphoma. When the thyroid gland of a patient with HT enlarges rapidly over a short period of time and is accompanied by tracheal and laryngeal compression, fever, and significant weight loss, FNAC should be performed to differentiate it.

B.3.5 Thyroid malignant tumors

The incidence of thyroid cancer in HT is 5% to 17%, three times higher than in the general population. Both may have nodular changes in the thyroid gland, but thyroid cancer masses are hard and fixed, adherent to the surrounding organs, and may be accompanied by enlarged lymph nodes in the neck or symptoms of compression on the surrounding organs, and ultrasound of the thyroid gland or FNAC may assist in the differentiation.

ANNEX C
(Informative)
Western medical treatment of Hashimotos Hyroiditis

C.1 Hashimotos Hyroiditis

In the stage of normal thyroid function, the patient should be regularly followed up on the basis of lifestyle interventions, generally recommended once every six months to one year. The main examination is thyroid function, and thyroid ultrasound can be performed if necessary. Controlling iodine intake within a safe range helps prevent the progression of thyroid autoimmune damage.

C.2 Hashimotos thyroiditis secondary to thyrotoxicosis

Generally, anti-thyroid medications are not required. On the basis of lifestyle interventions, for patients with obvious symptoms of thyrotoxicosis, especially elderly patients, those with a resting heart rate exceeding 90 beats per minute, or those with concurrent cardiovascular diseases, β-blockers (such as propranolol) can be used for treatment. In cases of severe symptoms that cannot be controlled, small doses of anti-thyroid medications may be applied, and the dosage should be adjusted or stopped in a timely manner based on thyroid function monitoring to avoid inducing hypothyroidism. I^{131} therapy and surgery are generally not recommended. For specific medication usage, precautions, and adverse reactions, refer to the "Guideline for Diagnosis and Treatment of Hyperthyroidism and Other Causes of Thyrotoxicosis in China (2022)" [6] (Chinese Journal of Endocrinology and Metabolism, 2022, 38(8): 700-748).

C.3 Hashimotos thyroiditis secondary to hypothyroidism

Levothyroxine sodium tablets (L-T4) replacement therapy can be considered depending on the situation. For specific medication usage, refer to the "Guideline for Diagnosis and Treatment of Adult Hypothyroidism" [7] (Chinese Journal of Endocrinology and Metabolism, 2017, 33(2): 167-180).

ANNEX D
(Informative)
Key outcome indicators

D.1 Improvement in TPOAb antibody titers;

D.2 Recovery of thyroid function FT3, FT4, TT3, TT4, and TSH levels;

D.3 Improvement in clinical symptoms:

Pressure sensation in front of the neck, foreign body sensation in the pharynx, tiredness and fatigue, low mood or irritability, etc., which can be assessed by using the Thyroid Disease Quality of Life Concise Scale (ThyPRO-39) or Chinese Medicine Symptoms Score Scale.

D.4 Improvement of goiter

D.4.1 Enlarged thyroid grading

Those who cannot see the enlargement but can palpate it are classified as Grade I; those who can see both the enlargement and palpate it but within the sternocleidomastoid muscle are classified as Grade II; and those who exceed the outer edge of the sternocleidomastoid muscle are classified as Grade III.

D.4.2 Ultrasonography of the thyroid gland

Thyroid size delineation is significantly correlated with body weight and age and varies widely between individuals.

Normal value of thyroid volume: (4-6cm) (upper and lower diameter) × (2-2.5cm) (left and right diameter) × (1.5-2cm) (anterior and posterior diameter), isthmus <0.3cm Mostly the anterior and posterior diameter is used as an important index for determining whether or not the thyroid gland is enlarged, and “anterior and posterior diameter of the bilateral lobes is <1cm, and the isthmus thickness is <0.2cm” is defined as the thyroid size. Define “anteroposterior diameter of bilateral lobes <1cm, thickness of isthmus <0.2cm” as shrinkage of the thyroid gland; define “anteroposterior diameter of bilateral lobes >2cm, thickness of isthmus >0.3cm” as enlargement of the thyroid gland. “Bilateral lobes with anteroposterior diameters between 1.5 and 2 cm and isthmus thicknesses between 0.2 and 0.3 cm were defined as enlarged or not according to individual patient differences.

ANNEX E
(Informational)
Summary Quick Recommendation Form

Disease / Stage	Recommended Interventions	Dialectics	Recommended Remedies
Hashimotos thyroiditis Euthyroid Stage	**Recommendation 1:** On the basis of lifestyle interventions, regular follow-up is generally advocated every six months to one year, mainly to check thyroid function and, if necessary, thyroid ultrasound. Controlling iodine intake in a safe range helps to stop the progression of autoimmune destruction of the thyroid. **Recommendation 2:** On the basis of the above treatment, carry out TCM diagnosis and treatment. **Recommended proprietary Chinese medicines:** On the basis of lifestyle intervention, Bailing capsule (Level of Evidence: D, weak recommendation) or Xiaoyao pill (Level of Evidence: D, weak recommendation) is recommended to reduce TPO Ab antibody titer.	Liver Qi Stagnation Syndrome	Chaihu Shugan Powder, modified (ingredients: Bupleurum, Chuanxiong, Cyperus, Chenpi, Baishao, Zhike, Gancao, etc.) (Evidence Level: C, Strong Recommendation).
		Liver Depression and Heat Syndrome	Qinggan Sanjie Xiaoying Formula (Medicinal composition: Prunella vulgaris, Radix Bupleuri, Albizia julibrissin, Cortex Moutan, Radix Paeoniae Alba, Scutellaria baicalensis, Radix Paeoniae Rubra, Platycodon grandiflorus, Clinopodium gracile, Ostreae Concha, Margaritifera, Astragalus membranaceus) (evidence level: B, strong recommendation).
		Liver Depression and Phlegm Coagulation Syndrome	Modified Powder for regulating liver and spleen combined with Banxia Houpo Decoction (Medicinal composition: Radix Bupleuri, Radix Paeoniae Alba, Radix Paeoniae Rubra, Fructus Aurantii Immaturus, Pinellia ternata, Perilla leaf, Poria, Honeyfried Licorice, Fresh Ginger, Fructus Mume, etc.) (evidence level: B, strong recommendation).
		Liver Stagnation and Spleen Deficiency Syndrome	Modified Xiaochaihu Decoction combined with Danggui Shaoyao San (Medicinal composition: Radix Bupleuri, Scutellaria baicalensis, Ginseng, Pinellia ternata, Fresh Ginger, Angelica sinensis, Radix Paeoniae Alba, Atractylodes macrocephala, Poria, Alismatis Rhizoma, Ligusticum chuanxiong, etc.) (evidence level: C, strong recommendation).

Hashimotos thyroiditis Secondary Thyrotoxicosis	**Recommendation 1:** generally do not use antithyroid drugs, on the basis of lifestyle intervention, thyrotoxic symptoms are obvious especially in elderly patients, resting heart rate more than 90 beats/min or combined cardiovascular disease, available β-blocker (eg, propranolol) treatment, individual symptoms are serious and can not be controlled, can be applied to a small dose of antithyroid drugs, and according to the monitoring of thyroid function to adjust the dose in a timely manner or The dose should be adjusted or discontinued according to the thyroid function monitoring to avoid hypothyroidism. Generally, I 131 and surgical treatment are not recommended. Specific methods of drug use, precautions, and adverse reactions can be referred to the "Chinese Guidelines for the Diagnosis and Treatment of Hyperthyroidism and Thyrotoxicosis Due to Other Causes (2022)" [6] (Chinese Journal of Endocrinology and Metabolism, 2022, 38(8):700-748.) **Recommendation 2:** On the basis of the above treatment, Chinese medicine identification and treatment.	Liver depression transforming into fire syndrome	Modified Dan Zhi Xiao Yao San (herbal composition: Bupleurum root, Poria, White Peony root, Atractylodes macrocephala, Angelica sinensis, Gardenia, Moutan Bark, Licorice, Ginger, Mint, etc.) (Evidence Level: C, Strong Recommendation).
		Heart and Liver Heat Syndrome	Modified Zhi Zi Qing Gan Decoction (Herbal ingredients: Bupleurum, Gardenia, Moutan Cortex, Poria, Ligusticum Chuanxiong, White Peony Root, Angelica Sinensis, Great Burdock Fruit, Licorice, etc.) (Evidence level: B, strong recommendation).
		Yin Deficiency Fire Exuberance Syndrome	Modified Danggui Liu Huang Decoction (Herbal ingredients: Angelica Sinensis, Rehmannia Root, Scutellaria Baicalensis, Coptis Chinensis, Phellodendron Amurense, Prepared Rehmannia, Astragalus Root, etc.) (Evidence level: B, strong recommendation).
		Qi and Yin Deficiency Syndrome	Tian Wang Bu Xin Dan combined with Bu Zhong Yi Qi Tang, modified as needed (Ingredients: Codonopsis pilosula, Poria cocos, Scrophularia ningpoensis, Salvia miltiorrhiza, Platycodon grandiflorus, Polygala tenuifolia, Angelica sinensis, Biota orientalis seeds, Ziziphus jujuba seeds, Rehmannia glutinosa, Astragalus membranaceus, Atractylodes macrocephala, Chenpi, Cimicifuga, Bupleurum, Glycyrrhiza uralensis, Angelica sinensis, etc.) (Evidence level: C, strong recommendation).
Hashimotos thyroiditis Secondary hy	**Recommendation 1:** Levothyroxine sodium tablets (L-T4) replacement therapy can be considered depending on the situation. For specific medication usage, refer to the "Guideline for Diagnosis and Treatment o	Phlegm-Blob and Blood Stasis Syndrome	Jieyu Tongluo Xiaoying Decoction (Chaihu, Baishao, Fuling, Xuanshen, Danggui, Baizhu, Yujin, Fabanxia, Chenpi, Zhebeimu, Shancigu, Lianqiao, Jixueteng, E Zhu, Zhi Gancao) (Evidence Level: C, Strongly Recommended)

pothyroidism	f Adult Hypothyroidism" [7] (Chinese Journal of Endocrinology and Metabolism, 2017, 33(2): 167-180). **Recommendation 2:** On the basis of the above treatment, Chinese medicine identification treatment. **Recommended proprietary Chinese medicines:** n the basis of lifestyle intervention, Bailing capsule (evidence level: D, weak recommendation) or prunella preparation (evidence level: D, weak recommendation) or Jin Shui Bao capsule (evidence level: C, weak recommendation) in combination with levothyroxine is recommended to reduce TPOAb antibody titer and improve thyroid function; Right-restoring pill (evidence level: D, weak recommendation) in combination with levothyroxine is recommended to reduce the TPOAb antibody titer and improve thyroid function in the case of spleen and kidney yang deficiency. TPOAb antibody titer and improve clinical symptoms.		Huatan Quyu Xiaoying Decoction (Banxia, Danggui, Houpo, Fuling, Chishao, Chuanxiong, Jiangcan, Chaihu, Huangqin, Renshen, Danshen, Jixueteng, Zhi Gancao, etc.) (Evidence Level: C, Strongly Recommended)
			Xiaoying Sanjie Formula (Xiakucao, Xianhecao, Maozhuacao, Sheng Gancao, Sanling, E Zhu, Xianlingpi) (Evidence Level: C, Strongly Recommended)
		Liver Stagnation and Spleen Deficiency Syndrome	Chaihu Shugan Powder or Xiaoyao Powder with modifications (composition: Bupleurum root, white peony root, bitter orange, dried tangerine peel, Ligusticum wallichii, nutgrass rhizome, licorice root, or Bupleurum root, angelica root, white peony root, Atractylodes macrocephala, poria, roasted licorice root, fresh ginger, etc.) (Evidence Level: C, strong recommendation).
		Spleen and Kidney Yang Deficiency Syndrome	Shenling Baizhu Powder combined with Jin Gui Shenqi Pill with modifications (composition: ginseng, roasted licorice root, Atractylodes macrocephala, prepared rehmannia root, Chinese yam, Asiatic cornelian cherry fruit, alisma, poria, tree peony root bark, cinnamon twig, prepared aconite root, etc.) (Evidence Level: C, strong recommendation).
		Heart and Kidney Yang Deficiency Syndrome	Modified Zhenwu Tang (Composition: Poria, Atractylodes macrocephala, White Peony Root, Roasted Licorice, Fresh Ginger, Aconite Root, etc.) (Evidence Level: C, Strong Recommendation).

ANNEX F
(Informative)
Acronym Comparison Table

Abbreviation	Full name	Chinese
ESR	Erythrocyte Sedimentation Rate	红细胞沉降率
FNAC	Fine Needle Aspiration Cytology	细针穿刺细胞学
FT_3	Free Triiodthyronine	游离三碘甲腺原氨酸
FT_4	Free Thyroxine	血清游离甲状腺素
GD	Graves' disease	弥漫性毒性甲状腺肿
HT	Hashimotos thyroiditis	桥本甲状腺炎
L-T4	Levothyroxine Sodium Tablets	左甲状腺素钠片
TgAb	Anti-Thyroid Globulin Antibody	甲状腺球蛋白抗体
ThyPRO-39	Thyroid-Related Patient-Reported Outcome	甲状腺疾病生活质量简明量表
TPOAb	Anti-Thyroid Peroxidase Antibody	甲状腺过氧化物酶抗体
TSH	Thyroid Stimulating Hormone	促甲状腺激素
TT_3	Total Triiodothyronine	总三碘甲状腺原氨酸
TT_4	Total Thyroxine	总甲状腺素
UIC	Urine Iodine Concentration	尿碘

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