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世界中医药学会联合会

World Federation of Chinese Medicine Societies

SCM **-20**

慢性萎缩性胃炎浊毒蕴胃证诊断指南

Diagnostic guide for chronic atrophic gastritis syndrome of turbid toxicity and gastric accumulation

(征求意见稿)

世界中联国际组织标准

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前 言

请注意本文件的某些内容可能涉及专利。本文件的发布机构不承担识别专利的责任。

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引 言

浊毒理论是河北省中医院国医大师李佃贵教授提出的独创性学说，浊毒有广义狭义之别，广义泛指一切对身体有害的不洁物质，而狭义是指由于湿浊、谷浊久蕴化热而成的可对脏腑气血造成严重损害的黏腻秽浊之物^[1]。浊毒自外来或内生，循人体络脉由表入里，胶结作用于人体，致人体细胞、组织和器官浊变，即毒害细胞、组织和器官，使之代谢和机能失常，乃至机能衰竭^[2,3]。

慢性萎缩性胃炎（Chronic atrophic gastritis, CAG）是一种胃黏膜长期受慢性炎症影响而逐渐发生萎缩和变薄的疾病，属于胃癌前疾病的一种，通常由幽门螺杆菌感染、自身免疫反应、胃酸分泌减少等因素引起，与胃癌的发生关系密切，其发病率及检出率随年龄增长而增加，近年来其就诊人数呈逐渐上升趋势^[4,5]。李佃贵教授研究团队一直致力于 CAG 与浊毒理论的研究，提出浊毒蕴胃为 CAG 关键病机，并将这一认识应用于 CAG 的临床检查、诊断和治疗，疗效确切。CAG 浊毒蕴胃证的一般临床表现有以下几方面：

1. 胃脘胀满、痞闷或疼痛 浊毒之邪蕴结于胃腑，使得清气不升，浊气不降，阻滞中焦气机；或因浊毒之邪伤及脾胃运化之功，使水谷精微不得下行输布，郁积于内；二者均可导致胃脘饱胀、痞闷感。浊毒之邪易入血入络，伤津耗气，胃腑气血不足，致“不荣则痛”。

2. 颜面五官 浊毒蕴结，郁蒸体内，上蒸于头面，而见面色粗黄，晦浊。若浊毒为热蒸而外溢于皮肤则见皮肤油腻，浊毒上犯清窍而见咽部红肿，浊毒上犯清窍而见眼胞红肿湿烂、目眵增多，鼻头红肿溃烂、鼻涕多，耳屎多，咳吐黏稠之涎沫。

3. 舌苔 患者以黄腻苔多见，但因感浊毒的轻重不同而有所差别。浊毒轻者舌红，苔腻、薄腻、厚腻，或黄或白或黄白相间；浊毒重者舌质紫红、红绛，苔黄腻，或中根部黄腻。因感邪脏腑不同苔位亦异，如浊毒中阻者，苔中部黄腻；浊毒阻于肝胆者，苔两侧黄腻。苔色、苔质根据病情的新久而变，初感浊毒、津液未伤时见黄滑腻苔；浊毒日久伤津时则为黄燥苔。

4. 排泄物 浊毒内蕴，可见大便黏腻不爽，臭秽难闻，小便或浅黄或深黄或浓茶样。

李佃贵^[6]根据前人理论和多年的临床经验，创立浊毒理论，认为浊毒既是致病因素，又是病理产物。从浊毒论治 CAG 的基本病机以脾胃虚弱为本，气滞、浊毒、瘀血为标。内外病因均可损伤脾胃，致其失于和降，运化失司，水湿不化，湿浊、痰凝内生，郁久生热，毒为热之渐，浊为湿之甚，浊毒内蕴，伤及阴液，气血运行不畅，瘀血内生，胃失濡养，导致胃黏膜受损、萎缩、肠化、异型增生等病变。刘小发^[7]认为“心之浊毒”是 CAG 浊毒蕴胃证形成的重要因素，且互为因果，对于 CAG 经久不愈者应从“心之浊毒”论治。王绍坡^[8]认为浊毒内蕴是 CAG 向胃恶性肿瘤病理形成过程中的关键区别所在，浊毒内蕴是 CAG 发生发展的病机关键，治疗应以化浊解毒为大法。韩欣璞^[9]认为肿瘤的核心病机为阳虚毒结，而外寒易伤脾胃阳气，导致气血津液输布失常化生浊邪，浊邪进一步聚而成毒，即形成胃癌阳虚、浊化、浊变与浊毒的核心病机演变过程。以探索相关方药靶向调控胃癌微环境为切入点，提高微观辨治精准性。张泰^[10]等认为，“瘀、毒、郁”互结是 CAG 的核心病机，其中“郁”可能是促进瘀血、湿浊、湿热转为瘀毒、浊毒，进而化生热毒的病理要素。

杨倩^[11]教授发现，CAG 浊毒内蕴证与血清胃蛋白酶原（pepsinogen, PG）、胃泌素-17（Gastrin-17, G17）水平降低有关。娄莹莹^[12]等讨论慢性胃炎（CG）浊毒内蕴证与 Th1/Th2

平衡的关系,发现慢性胃炎浊毒内蕴证与 Th1/Th2 动态平衡密切相关,“浊毒”可能是介导 Th1 型细胞因子发生免疫反应的关键病理因素。张伟健^[13]等基于中医传承辅助平台分析国医大师治疗 CAG 病案处方中的证候要素,结果显示,154 例 CAG 患者中,出现频次最高的证型为肝胃不和证(31.43%),其次分别为浊毒内蕴证(28.57%)、胃阴不足证(27.14%)。在 CAG 发生发展的过程中,浊毒蕴胃的状态尤为重要。徐伟超^[14]等通过整合、分析《当代名老中医药专家脾胃病数据库(1911—2018 年)》以及《学术期刊脾胃病数据库(1989—2018 年)》数据库发现,慢性萎缩性胃炎病因以浊毒内蕴、阴虚内热、情志不畅、脉络瘀阻等为主。杨玥玮^[15]等通过生物信息学分析联合动物实验,发现 CAG 浊毒蕴胃证与调控细胞分化和增殖的 EGFR/MAPK/ERK 信号转导通路的过度激活密切相关,且原癌基因(c-myc)蛋白表达水平也有升高。许亚培^[16]等通过观察 86 例 CAG 浊毒内蕴证患者,发现 CAG 浊毒内蕴证与肿瘤特异性生长因子(TSGF)、胃癌单抗 MG7 相关抗原(MG7-Ag)关系密切。白海燕、默雪梅^[17-19]等通过临床实验发现,化浊解毒方能明显改善 CAG 浊毒内蕴证患者的临床症状、胃镜及病理情况,其机制可能与调节细胞毒素相关蛋白(CagA)、空泡细胞毒素(VacA)及尿素酶 B(UreB)水平有关。张金丽^[20]通过观察 311 例、六种不同中医证型的 CAG 患者,发现浊毒内蕴证在内镜下主要表现为隆起结节、糜烂、黏膜粗糙,病理多伴有肠上皮化生和(或)不典型增生,与肝胃不和证、脾胃虚弱证、脾胃湿热证、胃络瘀阻证、胃阴不足证在胃镜像形态学、病理组织学的变化存在着特异性。

慢性萎缩性胃炎浊毒蕴胃证诊断指南

1 范围

本文件规定了慢性萎缩性胃炎浊毒蕴胃证的诊断标准以及判定标准等内容。

本文件适用于慢性萎缩性胃炎浊毒蕴胃证的临床与科研工作。

2 规范性引用文件

“下列文件中的内容通过文中的规范性引用而构成本文件必不可少的条款。其中，注日期的引用文件，仅该日期对应的版本适用于本文件；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。

2021 年河北省中医药学会脾胃病专业委员会《慢性萎缩性胃炎浊毒内蕴证量化诊断标准专家共识意见》

2022 年河北省中西医结合学会浊毒证专业委员会《慢性萎缩性胃炎浊毒蕴胃证量化诊断标准专家共识意见》

2022 年《河北中医》杂志发布《慢性萎缩性胃炎浊毒蕴胃证相关症状初步研究》^{〔21〕}

3 术语和定义

下列术语和定义适用于本文件。

3.1

浊毒蕴胃证

浊毒蕴胃为慢性萎缩性胃炎的关键病机，以浊毒为病因使得机体处于浊毒状态，导致壅滞中焦，气滞血阻，终致慢性萎缩性胃炎，从而产生特有临床表现的一组或几组证候群。临床上以胃脘胀满、痞闷或疼痛，面色晦浊，大便黏腻，排便不爽或大便干，头身困重，乏力，口干口苦，小便短赤不利，舌红，舌暗红，苔黄腻或厚腻，脉弦滑或弦细滑为主要表现。

3.2

面色晦浊

面部皮肤没有光泽，血色，出现萎黄、枯黄、暗淡、污垢色等。

注：面色晦浊是浊毒蕴胃证的典型症状。

4 诊断标准

4.1 主要标准

- 4.1.1 胃脘胀满、痞闷或疼痛；
- 4.1.2 面色晦浊；
- 4.1.3 大便黏腻，排便不爽或大便干；
- 4.1.4 舌红，舌暗红，苔黄腻，苔黄厚腻。

4.2 次要标准

- 4.2.1 纳呆；
- 4.2.2 头身困重，倦怠乏力；
- 4.2.3 口干、口苦、口黏腻；
- 4.2.4 小便短赤不利；
- 4.2.5 烧心、反酸（胃脘灼热）；
- 4.2.6 脉弦滑、弦细滑、弦滑数、弦数。

符合主症加次症 2 项即可诊断浊毒蕴胃证。

附录 A
(资料性)
文件研究方法

A.1 研究方法

A.1.1 文献研究

文献整理共检索三个数据库：中国知网（CNKI）、万方数据知识服务平台（Wanfang）、维普数据库，以“慢性萎缩性胃炎”“萎缩性胃炎”“CAG”“肠上皮化生”“胃黏膜病变”“胃黏膜萎缩”“胃癌前病变”“异型增生”“浊毒蕴胃”“浊毒内蕴”“浊毒理论”为检索词，根据各数据库的特点采用主题词、关键词与自由词相结合的方式进行搜索。通过文献研究，梳理归纳浊毒蕴胃相关的症状、体征、舌象、脉象等。共检索得 334 篇文献，依据纳入和排除标准，阅读题目、摘要以及全文进行人工剔除，并运用 NoteExpress3.6.0 软件查重并剔除重复文献，确定最终纳入文献 51 篇，提取其四诊信息并进行名词术语规范化处理，共筛选条目 94 条，去除出现频率低于 5% 的 49 条条目后剩下 45 条，分别为：黄腻苔、白腻苔、滑脉、胃痛、烧心、嗳气、纳呆、舌红、舌暗红、口苦、胃痞、大便粘腻、弦滑脉、恶心、弦细脉、口干、面色晦暗、反酸、面色萎黄、弦细涩脉、口臭、胃脘隐痛、倦怠乏力、小便不利（或小便黄或黄赤）、胃脘刺痛且痛有定处、呕吐、腹泻、燥苔、寐差、胸闷、胃脘嘈杂、黑便、舌紫暗、大便干结、紫红舌、少苔、口黏、花剥苔、心烦、肢体困重、紫舌、滑数脉、头昏蒙不清、分泌物粘腻不爽、分泌物臭秽。

A.1.2 混合研究方法

围绕浊毒蕴胃辨证特点、辨证方法等，对国医大师李佃贵等浊毒证研究领域知名专家进行访谈。同时，通过广泛收集中医证型符合慢性萎缩性胃炎浊毒蕴胃证的患者进行临床调查，本研究共收集慢性萎缩性胃炎浊毒蕴胃证患者病例 383 例。

其中纳入标准：

- a) 经专家辨证为慢性萎缩性胃炎浊毒蕴胃证患者；
- b) 愿意参与调查者；
- c) 签署知情同意书。

排除标准：

- a) 经专家辨证不符合慢性萎缩性胃炎浊毒蕴胃证患者；
- b) 对调查问卷排斥，不能完成量表填写者；
- c) 精神疾患类或意识障碍不能配合者。

以病案信息完整，辨证、处方用药有代表性为搜集标准，采用离散趋势法、相关系数法、克朗巴赫系数法、因子分析法 4 种统计学方法进行诊断条目客观筛选，通过多维度分析，若有一项不符合筛选标准，则考虑删除，共删除 22 个条目，45 条条目经过统计学方法筛选后筛除嗳气、胃脘隐痛、胃脘部嘈杂不适、面色萎黄、倦怠乏力、寐差、胃脘部刺痛且痛处不移、心烦、腹泻、大便干结、恶心、胸闷、呕吐、黑便、舌红、舌紫、舌紫红、白腻苔、

少苔、花剥苔、脉弦细、脉弦细涩 22 条，共剩余胃脘部痞满不适、胃脘部疼痛、大便粘腻不爽、口干、口苦、口黏、口臭、面色晦暗、小便不利或小便黄（赤）、反酸、身体困重、食少纳呆、烧心、头昏蒙不清、分泌物粘腻不爽、分泌物臭秽、舌暗红、舌紫暗、黄腻苔、燥苔、脉滑、脉弦滑、脉滑数 23 条。

A. 1. 3 德尔菲法

基于临床研究结果，结合文献研究中各条目出现频数进行初筛，并制作专家咨询问卷，通过三轮德尔菲专家咨询对条目进行主观筛选。评价指标为：专家积极系数，即调查问卷的回收率；专家权威程度，用专家权威系数 Cr 表示，Cr 主要为专家对条目的熟悉程度（Cs）和专家对条目做的判断依据（Ca）， $Cr = (Cs + Ca) / 2$ ；专家意见集中程度，用均数，满分率和变异系数表示；专家意见协调程度，用变异系数、协调系数表示。

A. 2 临床研究

A. 2. 1 经临床调研筛选条目后，将最终保留的条目进行编制，形成“慢性萎缩性胃炎浊毒蕴胃诊断量表—质量测评表”进行量表质量（可行性、信度、效度）测评。用横断面调查的方法，选择河北省中医院脾胃病科的住院和门诊患者，根据既往临床流行病学横断面调查多因素分析的样本含量估算 Corsuch 法，样本量=课题（相关因素或变量数目）×（5-10 倍）。对调查员进行 SOP 培训，内容包括：本次调查的目的和意义、调查实施过程的方法等，使其明确职责，确保数据的可靠性及准确性。问卷以患者自评为主，调查员只负责解释字面意义并记录患者完成量表所需的时间。

量表质量测评的评价指标：

a) 可行性 主要是评测量表被接受的程度及量表被完成的质量，包括接受率、完成率、完成时间 3 方面。

b) 信度 是从可靠性方面评价量表的质量，多通过计算相关系数来反映。本研究采用分半信度（Split-half reliability）和克隆巴赫（Cronbach） α 系数来作为信度评价的指标。

c) 效度 是从有效性、准确性方面评价量表的质量，即量表是否能有效、准确地测量出所测事物的“真值”。效度越高，表示测量结果越能显示出所要测量对象的真正特征。本研究采用表面效度和内容效度、区分效度、结构效度 3 方面作为效度评测指标。

A. 2. 2 通过构建量表框架、确立条目池、条目筛选、条目赋权及确立诊断阈值这几个关键环节后，初步建立了慢性萎缩性胃炎浊毒蕴胃证诊断量表。但该量表的实际诊断能力如何，需要进一步对量表的诊断能力加以评价。本研究采用了诊断性试验的方法对慢性萎缩性胃炎浊毒蕴胃证诊断量表的性能进行了初步验证。

对多中心临床调查的既往患者，以及招募新的经诊断为慢性萎缩性胃炎浊毒蕴胃证的患者进行诊断准确性研究的横断面研究，计算其灵敏度、特异度、准确度、似然比并进行分析总结来判定该诊断标准是否具有临床价值及可行性。

采用所建立的慢性萎缩性胃炎浊毒蕴胃证诊断量表，选择河北省中医院脾胃病科科的住院和门诊患者，共 403 例，排除 20 份无效调查，最后共采用 383 份。进行辨证诊断，得到相应的辨证结果。将量表的辨证结果与临床医师辨证结果进行比较，从而绘制出相应的诊

断性试验四格表。并通过计算得出灵敏度、特异度、准确度、阳性似然比、阴性似然比等指标的结果。

WECMS

河北省中医院

《慢性萎缩性胃炎浊毒蕴胃证中医诊断量表》质量测评

姓	名	
姓	名	缩 写
性		别
年		龄
联	系	方 式
调	查	医 院
填	表	时 间

WJECMS

尊敬的朋友：

您好！我们是《慢性萎缩性胃炎浊毒蕴胃证中医诊断量表研制》课题组，感谢您参与河北省中医院《慢性萎缩性胃炎浊毒蕴胃证中医诊断量表的初步研制》的量表质量测评调研，本研究旨在建立规范化客观化的慢性萎缩性胃炎浊毒蕴胃证诊断量表，为证候辨识及评价提供有效工具，以方便您了解自身状况，同时辅助医生诊疗。在此声明，所有与临床研究有关的个人资料、隐私均会保密，不会用于除临床及科学研究以外的任何方面，敬请放心。

如您已阅读以上条文，请签名，参加者承诺：我理解并同意参加河北省中医院《慢性萎缩性胃炎浊毒蕴胃证中医诊断量表的初步研制》的质量测评调研。

知情同意书签署者姓名：_____

联 系 方 式：_____

请根据自己最近的实际情况或感觉，选择最符合您的选项打“√”。

如果某一个问题您不能肯定回答,就选择最接近您实际情况的那个答案。衷心感谢您的参与!

1、您最近出现过大便黏腻不爽吗?

①没有 ②很少 ③有时 ④经常 ⑤总是

2、您最近出现过小便不利或小便黄(赤)吗?

①没有 ②很少 ③有时 ④经常 ⑤总是

3、您最近出现过口味不和(口臭、口黏腻、口干、口苦)吗?

①没有 ②很少 ③有时 ④经常 ⑤总是

4、您最近出现过身体困重吗?

①没有 ②很少 ③有时 ④经常 ⑤总是

5、您最近感觉头昏蒙不清吗?

①没有 ②很少 ③有时 ④经常 ⑤总是

6、您最近感觉分泌物多、黏腻、臭秽吗?

①没有 ②很少 ③有时 ④经常 ⑤总是

7、您最近出现过腹部板硬感吗?

①没有 ②很少 ③有时 ④经常 ⑤总是

以下内容由医生填写(请划“√”)

1、患者面色晦暗?

①是 ②否

2、患者舌质暗红?

①是 ②否

3、患者舌质紫暗?

①是 ②否

4、患者舌苔黄腻或燥?

①是 ②否

5、患者脉象弦滑?

①是 ②否

6、患者脉象滑?

①是 ②否

7、患者脉象滑数?

①是 ②否

补充症状:

患者诊断:

西医:

中医:

调查员签名 _____

日 期 _____

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Foreword

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Introduction

The Theory of Turbid Toxin is an original concept proposed by Professor Li Diangui, a National TCM Master of Hebei Provincial Hospital of Traditional Chinese Medicine. Turbid toxin can be broadly or narrowly defined: broadly, it refers to all unclean substances harmful to the body; narrowly, it denotes viscous and filthy substances formed by long-standing dampness and food turbidity transforming into heat, which can severely damage the organs, qi, and blood ^[1]. The turbid toxin, whether externally contracted or internally generated, enters from the exterior to the interior through the collaterals, acting as a binding agent, causing turbid transformation of the body's cells, tissues, and organs – essentially poisoning them, leading to metabolic and functional abnormalities, and even organ failure ^[2,3].

Chronic atrophic gastritis (CAG) is a disease characterized by gradual atrophy and thinning of gastric mucosa due to prolonged chronic inflammation. It is considered a precancerous condition, typically caused by *Helicobacter pylori* infection, autoimmune responses, decreased gastric acid secretion, and other factors. It is closely related to gastric cancer development, with incidence and detection rates increasing with age, and the number of patients has been rising in recent years ^[4,5]. Professor Li Diangui's research team has been dedicated to studying CAG and the Theory of Turbid Toxin, proposing that turbid toxin accumulation in the stomach is a key pathological mechanism of CAG. This understanding has been applied to the clinical examination, diagnosis, and treatment of CAG, with confirmed efficacy. General clinical manifestations of CAG with the syndrome of turbid toxin accumulation in the stomach include:

1. Gastric fullness, stuffiness, or pain Turbid toxin stagnates in the stomach, preventing the ascent of clear qi and descent of turbid qi, obstructing the qi mechanism in the middle jiao; or it impairs the spleen and stomach's transportation and transformation functions, preventing the downward movement and distribution of fluids and nutrients, leading to internal accumulation. Both can cause gastric fullness and stuffiness. Turbid toxin easily enters the blood and collaterals, damaging fluids and consuming qi, leading to stomach qi and blood deficiency, resulting in "pain due to lack of nourishment."

2. Facial features When stagnated turbid toxin steams upward internally, it rises to the head and face, manifesting as coarse, yellow, and dull complexion. If turbid toxin turns into heat and overflows to the skin, it presents as oily skin. When turbid toxin invades the orifices, it can cause red and swollen throat, red,

swollen, and festering eyelids with increased eye discharge, swollen and ulcerated nose with increased nasal discharge, excessive earwax, and coughing up thick saliva.

3. Tongue coating Patients commonly present with yellow greasy coating, though variations exist depending on the severity of turbid toxin. In mild cases, the tongue is red with greasy, thin greasy, or thick greasy coating, either yellow, white, or a combination of both. In severe cases, the tongue body is purple-red or crimson, with yellow greasy coating, or yellow greasy coating in the central root area. The location of the coating varies according to the affected organs. When the turbid toxin is obstructed in the middle, the central coating is yellow and greasy; when it is obstructed in the liver and gallbladder, the coating is yellow and greasy on both sides. The color and texture of the coating change with the duration of illness: a slippery yellow coating is evident when the turbid toxin is first encountered and the fluids remain unaffected; a dry yellow coating develops when the fluids are harmed by long-term turbid toxin.

4. Excretions Internal turbid toxin accumulation can manifest as sticky and unsatisfactory stools with a foul odor, and urine that is light yellow, dark yellow, or tea-colored.

Li Diangui ^[6], based on traditional theories and years of clinical experience, established the Theory of Turbid Toxin, identifying turbid toxin as both a pathogenic factor and a pathological product. The fundamental pathological mechanisms in treating CAG from the perspective of turbid toxin theory consider spleen-stomach weakness the root cause, with qi stagnation, turbid toxin, and blood stasis as the manifestations. Both internal and external pathogenic factors can damage the spleen and stomach, leading to dysfunction in their descending and transforming, resulting in unresolved dampness and internally generated damp turbidity and phlegm. Prolonged stagnation turns into heat. Toxin is the progression of heat, and turbidity emerges from extreme dampness. The internal accumulation of turbid toxin damages yin fluids and impedes qi and blood circulation, leading to blood stasis, loss of nourishment in the stomach, and consequent gastric mucosal damage, atrophy, intestinal metaplasia, and dysplasia. Liu ^[7] believes that “turbid toxin in heart” is a crucial factor in forming CAG with the syndrome of turbid toxin accumulation in the stomach, with the two being mutually causal, thus advocating treating persistent CAG cases by addressing the “turbid toxin in heart”. Wang Shaopo ^[8] considers internal turbid toxin accumulation as a key differential factor in CAG’s progression toward malignant gastric tumors, making it the critical pathological mechanism in CAG development, with treatment primarily focusing on resolving turbidity and eliminating toxins. Han Xinpu ^[9] believes that the core pathological mechanism of

tumors is yang deficiency with toxin accumulation, where external cold easily harms the yang qi of spleen and stomach, leading to abnormal distribution of qi, blood, and fluids which in turn generates turbid pathogenic factors that further aggregates into toxins, thus forming the core pathological progression of gastric cancer involving yang deficiency, turbid transformation, turbid change, and turbid toxin. This perspective advocates exploring targeted regulation of the gastric cancer microenvironment with relevant formulas and medicines to enhance the precision of microscopic differentiation and treatment. Zhang et al.^[10] consider the intertwining of “stasis, toxin, and stagnation” as the core pathological mechanism of CAG, where “stagnation” may be the pathological element promoting the transformation of blood stasis, damp turbidity, and damp heat into stasis toxin and turbid toxin, subsequently evolving into heat toxin.

Yang^[11] discovered that CAG with the syndrome of internal turbid toxin accumulation is related to decreased serum pepsinogen (PG) and gastrin-17 (G17) levels. Lou et al.^[12] investigated the relationship between chronic gastritis (CG) with the syndrome of internal turbid toxin accumulation and Th1/Th2 balance, finding that the syndrome is closely related to Th1/Th2 dynamic balance, with “turbid toxin” possibly being the key pathological factor mediating Th1-type cytokine immune responses. Zhang et al.^[13], based on an analysis of the National TCM Master’s formula prescribed for CAG cases using the TCM inheritance support platform, revealed that the most frequent syndromes among 154 CAG patients were liver-stomach disharmony (31.43%), followed by internal turbid toxin accumulation (28.57%), and stomach yin deficiency (27.14%). The state of turbid toxin accumulation in the stomach is particularly important in the development of CAG. Xu et al.^[14], through integration and analysis of “Contemporary Renowned and Senior TCM Experts on Spleen and Stomach Disease Database (1911-2018)” and “Academic Journal Database of Spleen and Stomach Disease (1989-2018)”, discovered that the main causes of chronic atrophic gastritis include internal turbid toxin accumulation, yin deficiency with internal heat, emotional disturbance, and meridian obstruction. Yang et al.^[15], through bioinformatics analysis combined with animal experiments, found that CAG with the syndrome of turbid toxin accumulation in the stomach is closely related to the overactivation of the EGFR/MAPK/ERK signaling pathway, which regulates cell differentiation and proliferation, and the expression level of the proto-oncogene c-myc protein is also elevated. Xu et al.^[16], through observation of 86 CAG patients with the syndrome of internal turbid toxin accumulation, found a close relationship between this syndrome and tumor-specific growth factor (TSGF) and the gastric cancer monoclonal antibody MG7-related antigen (MG7-Ag). Mo et al.^[17] and Bai et al.^[18-19], through clinical experiments,

discovered that the Huazhuo Jiedu (turbidity-resolving and toxin-eliminating) formula can significantly improve clinical symptoms, gastroscopic findings, and pathological conditions in CAG patients with the syndrome of internal turbid toxin accumulation. The mechanism may be related to the regulation of cytotoxin-associated protein (CagA), vacuolating cytotoxin (VacA), and urease B (UreB) levels. Zhang^[20], by observing 311 cases of CAG patients with six different TCM syndrome types, found that the syndrome of internal turbid toxin accumulation mainly manifests endoscopically as raised nodules, erosion, and rough mucosa. Pathologically, it often accompanies intestinal metaplasia and/or dysplasia, displaying distinct morphological and histological changes compared to liver-stomach disharmony, spleen-stomach weakness, spleen-stomach damp-heat, stomach meridian obstruction, and stomach yin deficiency syndromes.

Diagnostic Guideline for Chronic Atrophic Gastritis with Syndrome of Turbid Toxin Accumulation in Stomach

1 Scope

This document establishes the diagnostic and assessment criteria for chronic atrophic gastritis with the syndrome of turbid toxin accumulation in stomach.

This document applies to the clinical practice and research related to chronic atrophic gastritis with the syndrome of turbid toxin accumulation in stomach.

2 Normative References

The content of the following documents constitutes essential provisions of this document through normative references within the text. For dated references, only the edition corresponding to that date applies to this document; for undated references, the latest edition (including all amendments) applies.

2021 Expert Consensus on Quantitative Diagnostic Criteria for Chronic Atrophic Gastritis with Syndrome of Internal Turbid Toxin Accumulation (2021), Spleen and Stomach Disease Committee of Hebei Association of Chinese Medicine

2022 Expert Consensus on Quantitative Diagnostic Criteria for Chronic Atrophic Gastritis with Syndrome of Turbid Toxin Accumulation in Stomach (2022), Turbid Toxin Syndrome Committee of Hebei Association of Integrated Medicine

2022 Preliminary Study on Symptoms Related to Chronic Atrophic Gastritis with Syndrome of Turbid Toxin Accumulation in Stomach (2022), published in Hebei Journal of Traditional Chinese Medicine^[21]

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1

Syndrome of Turbid Toxin Accumulation in Stomach

This syndrome is a key pathological mechanism of chronic atrophic gastritis, wherein turbid toxin acts as the pathogenic factor, placing the body under the influence of turbid toxin. This leads to obstruction in the middle jiao, resulting in qi stagnation and blood stasis, ultimately causing chronic atrophic gastritis, and

manifesting as one or several groups of distinctive clinical syndrome clusters. Clinically, it is primarily characterized by symptoms such as gastric fullness, stuffiness, or pain, dull complexion, sticky stools, unsatisfactory defecation or dry stools, heaviness in head and body, lack of energy, dry mouth and bitter taste, scanty and dark urine with difficult urination, red tongue, dark red tongue, yellow greasy tongue coating, thick greasy tongue coating, and wiry-slippery or wiry-thready-slippery pulse.

3.2

Dull Complexion

Facial skin appears lackluster and bloodless, presenting as withered yellow, dull yellow, lackluster, or dirty.

Note: Dull complexion is a typical symptom of the syndrome of turbid toxin accumulation in stomach.

4 Diagnostic Criteria

4.1 Primary Criteria

4.1.1 Epigastric fullness, stuffiness, or pain

4.1.2 Dull complexion

4.1.3 Sticky stools, unsatisfactory defecation or dry stools

4.1.4 Red tongue, dark red tongue, yellow greasy tongue coating, thick greasy tongue coating

4.2 Secondary Criteria

4.2.1 Poor appetite

4.2.2 Heaviness in head and body, fatigue and lack of energy

4.2.3 Dry mouth, bitter taste, sticky mouth

4.2.4 Scanty and dark urine with difficult urination

4.2.5 Heartburn, acid reflux (epigastric burning sensation)

4.2.6 Wiry-slippery, wiry-thready-slippery, wiry-slippery-rapid, or wiry-rapid pulse

Diagnosis of the syndrome of turbid toxin accumulation in stomach requires meeting the primary criteria plus any two secondary symptoms.

ANNEX A
(Informative)
Research Methods for the Document

A.1 Research Methods

A.1.1 Literature Research

The literature search was conducted across three databases: China National Knowledge Infrastructure (CNKI), Wanfang Data Knowledge Service Platform (Wanfang), and VIP Database. The search terms included “慢性萎缩性胃炎 (chronic atrophic gastritis)”, “萎缩性胃炎 (atrophic gastritis)”, “CAG”, “肠上皮化 (intestinal metaplasia)”, “胃黏膜病变 (gastric mucosal lesions)”, “胃黏膜萎缩 (gastric mucosal atrophy)”, “胃癌前病变 (precancerous gastric lesions)”, “异型增生 (dysplasia)”, “浊毒蕴胃 (turbid toxin accumulation in the stomach)”, “浊毒内蕴 (internal turbid toxin accumulation)”, and “浊毒理论 (turbid toxin theory)”. The search strategy combined subject terms, keywords, and free words according to the characteristics of each database. Through a systematic review, researchers collated and analyzed symptoms, signs, tongue manifestations, and pulse characteristics related to turbid toxin accumulation in stomach. A total of 334 papers were retrieved. Following the application of inclusion and exclusion criteria and manual screening of titles, abstracts, and full texts, duplicate articles were identified and removed using NoteExpress 3.6.0 software. Ultimately, 51 articles were selected, from which the information of four diagnostic methods was extracted and terminology was standardized. A total of 94 entries were initially screened, and after removing 49 entries that appeared with a frequency of less than 5%, 45 entries remained, including yellow greasy tongue coating, white greasy tongue coating, slippery pulse, stomach pain, heartburn, belching, poor appetite, red tongue, dark red tongue, bitter taste, gastric stuffiness, sticky stools, slippery-wiry pulse, nausea, thready-wiry pulse, dry mouth, dull complexion, acid reflux, withered yellow complexion, thready-wiry-unsmooth pulse, bad breath, dull epigastric pain, fatigue and lack of energy, difficult urination (or yellow/dark yellow urine), fixed stabbing epigastric pain, vomiting, diarrhea, dry tongue coating, poor sleep, chest tightness, epigastric noise, black stools, dark purple tongue, dry hard stools, purple-red tongue, thin tongue coating, sticky mouth, peeled tongue coating, irritability, heavy limbs, purple tongue, slippery-rapid pulse, foggy head, unsatisfactory sticky discharge, and foul discharge.

A.1.2 Mixed Research Methods

Focusing on the characteristics and methods of syndrome differentiation for turbid toxin accumulation in the stomach, interviews were conducted with renowned experts in the field, including National TCM Master Li Dianguai. Additionally, clinical data was collected from 383 patients diagnosed with chronic atrophic gastritis with the syndrome of turbid toxin accumulation in stomach.

Inclusion criteria included:

- a) Diagnosed by experts as having chronic atrophic gastritis with the syndrome of turbid toxin accumulation in the stomach;
- b) Willing to participate in the survey;
- c) Signed an informed consent form.

Exclusion criteria included:

- a) Diagnosis by experts as not fitting chronic atrophic gastritis with the syndrome of turbid toxin accumulation in the stomach;
- b) Rejection of questionnaires, inability to complete the scale;
- c) Mental illness or consciousness disorders affecting cooperation.

The criteria for data collection included completeness of medical records and representativeness in syndromes and formulas. Four statistical methods were employed for objective screening of diagnostic entries: discrete trend analysis, correlation coefficient analysis, Cronbach's alpha method, and factor analysis. Through multidimensional analysis, entries failing any screening criteria were considered for removal. Twenty-two entries were eliminated from the original 45, including belching, dull epigastric pain, epigastric discomfort with noise, withered yellow complexion, fatigue and lack of energy, poor sleep, fixed stabbing epigastric pain, irritability, diarrhea, dry hard stools, nausea, chest tightness, vomiting, black stools, red tongue, purple tongue, purple-red tongue, white greasy tongue coating, thin tongue coating, peeled tongue coating, thready-wiry pulse, and thready-wiry-unsmooth pulse. The remaining 23 entries were: epigastric stuffiness and discomfort, epigastric pain, sticky and unsatisfactory defecation, dry mouth, bitter taste, sticky mouth, bad breath, dull complexion, difficult urination or yellow (dark yellow) urine, acid reflux, heaviness in the body, poor appetite, heartburn, foggy head, unsatisfactory sticky discharge, foul discharge, dark red tongue, dark purple tongue, yellow greasy tongue coating, dry tongue coating, slippery pulse, slippery-wiry pulse, and slippery-rapid pulse.

A.1.3 Delphi Method

Based on clinical research results and the frequency of occurrence of entries in the literature, a preliminary screening was conducted, and an expert

consultation questionnaire was created for subjective screening through three rounds of Delphi expert consultation. The evaluation indicators included: expert enthusiasm coefficient, which is the questionnaire response rate; expert authority level, represented by the authority coefficient Cr , calculated as $Cr = (Cs + Ca)/2$, where Cs is the expert's familiarity with the entries and Ca is the basis of the expert's judgments; expert opinion concentration, measured by mean scores, full score rates, and the coefficient of variation; and expert opinion coordination, indicated by the coefficient of variation and coordination coefficient.

A.2 Clinical Research

A.2.1 Following the selection of entries through clinical surveys, the retained entries were compiled into a "Chinese Medicine Diagnostic Scale for Chronic Atrophic Gastritis with Syndrome of Turbid Toxin Accumulation in Stomach - Quality Assessment Form" for evaluating the scale's quality (feasibility, reliability, validity). A cross-sectional survey was conducted among inpatients and outpatients from the Department of Spleen and Stomach Diseases at Hebei Provincial Hospital of Traditional Chinese Medicine. The sample size was calculated using the Corsuch method: sample size = number of relevant factors or variables \times (5-10). Standard Operating Procedure (SOP) training was provided to the surveyors, covering the study's purpose, significance, and implementation methods, and ensuring clarity of responsibilities to guarantee data reliability and accuracy. The questionnaire was primarily self-administered by patients, with surveyors responsible only for explaining the literal meanings and recording completion time.

Quality assessment indicators for the scale included:

a) Feasibility: evaluating the scale's acceptance level and completion quality through acceptance rate, completion rate, and completion time.

b) Reliability: assessing scale quality from a reliability perspective through correlation coefficients. This study used split-half reliability and Cronbach's alpha coefficient as evaluation indicators.

c) Validity: assessing the quality of the scale from the aspects of validity and accuracy to see whether the scale can effectively and accurately measure the "true value" of what is being tested. Higher validity indicates that the measurement results more accurately reflect the true characteristics of the subject being measured. This study employed face validity, content validity, discriminant validity, and construct validity as indicators for evaluating validity.

A.2.2 After constructing the scale framework, entry pool creation, entry screening, assigning weights to items, and establishing diagnostic thresholds, a

preliminary Diagnostic Scale for Chronic Atrophic Gastritis with Syndrome of Turbid Toxin Accumulation in Stomach was developed. However, the scale's actual diagnostic capability needed further evaluation. The study used diagnostic testing to preliminarily validate the performance of the scale.

A cross-sectional study was conducted on previous patients from multi-center clinical surveys and newly recruited patients diagnosed with the condition to assess diagnostic accuracy. The study calculated sensitivity, specificity, accuracy, and likelihood ratios to determine the diagnostic criteria's clinical value and feasibility.

Using the developed diagnostic scale, 403 inpatients and outpatients from the Department of Spleen and Stomach Diseases at Hebei Provincial Hospital of Traditional Chinese Medicine were selected. After excluding 20 invalid surveys, 383 responses were finally analyzed. Syndrome differentiation was performed. The scale's diagnostic results were compared with clinical physician diagnoses based on syndrome differentiation through a 2×2 diagnostic test table. Sensitivity, specificity, accuracy, positive likelihood ratio, and negative likelihood ratios were calculated from these results.

Hebei Provincial Hospital of Traditional Chinese Medicine

**Quality Assessment of Chinese Medicine Diagnostic Scale for Chronic
Atrophic Gastritis with Syndrome of Turbid Toxin Accumulation in Stomach**

Full Name: _____

Name Abbreviation: _____

Gender: _____

Age: _____

Contact Information: _____

Hospital: _____

Date of Completion: _____

WJECMS

Dear participant,

We are the research team developing the “Chinese Medicine Diagnostic Scale for Chronic Atrophic Gastritis with Syndrome of Turbid Toxin Accumulation in Stomach.” Thank you for participating in this quality assessment survey for the preliminary scale at Hebei Provincial Hospital of Traditional Chinese Medicine. Our research aims to establish a standardized and objective diagnostic scale for this condition, providing an effective tool for syndrome identification and evaluation. This will help you better understand your health condition while assisting physicians in diagnosis and treatment. We hereby declare that all personal information and privacy related to this clinical research will be kept confidential and will not be used for any purposes other than clinical and scientific research. Please rest assured.

If you have read the above statement, please sign below. Participant’s commitment: I understand and agree to participate in the quality assessment survey for the preliminary Chinese Medicine Diagnostic Scale for Chronic Atrophic Gastritis with Syndrome of Turbid Toxin Accumulation in Stomach at Hebei Provincial Hospital of Traditional Chinese Medicine.

Name of informed consent signer: _____

Contact information: _____

Please select the option that best describes your recent condition or feelings by marking “√”.

If you are unsure about any question, select the answer that most closely matches your actual situation. We sincerely appreciate your participation.

1. Have you recently experienced sticky stools with difficult defecation?
①Never ②Rarely ③Sometimes ④Often ⑤Always
2. Have you recently experienced difficult urination or yellow/dark yellow urine?
①Never ②Rarely ③Sometimes ④Often ⑤Always
3. Have you recently experienced oral discomfort (bad breath, sticky mouth, dry mouth, bitter taste)?
①Never ②Rarely ③Sometimes ④Often ⑤Always
4. Have you recently experienced heaviness in the body?
①Never ②Rarely ③Sometimes ④Often ⑤Always
5. Have you recently experienced foggy head?
①Never ②Rarely ③Sometimes ④Often ⑤Always
6. Have you recently noticed increased, sticky, or foul discharge?
①Never ②Rarely ③Sometimes ④Often ⑤Always
7. Have you recently experienced abdominal rigidity?
①Never ②Rarely ③Sometimes ④Often ⑤Always

The following section to be completed by physician (Please mark “√”)

1. Does the patient display a dull complexion?
①Yes ②No
2. Is the patient's tongue dark red?
①Yes ②No
3. Is the patient's tongue dark purple?
①Yes ②No
4. Does the patient have yellow greasy or dry tongue coating?
①Yes ②No
5. Does the patient have a wiry-slippery pulse?
①Yes ②No
6. Does the patient have a slippery pulse?
①Yes ②No
7. Does the patient have a slippery-rapid pulse?
①Yes ②No

Additional Symptoms:

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Diagnosis:

Western Medicine Diagnosis:

Chinese Medicine Diagnosis:

Investigator's signature: _____

Date: _____

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