《慢性萎缩性胃炎浊毒蕴胃证诊断指南》

国际组织标准编制说明

一、工作简况

主要起草单位：河北省中医院

参与起草单位：河北中医药大学、瑞典中医药研究院、大醫行易健康管理、汉唐国际中医药学院、Nutti Women Therapy Centre。

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二、标准起草过程简介

1 文献检索

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检索。通过文献研究，梳理归纳浊毒证相关的症状、体征、舌象、脉象等的频次，剔除频率＜5%的条目。

2 临床调查

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。

3 德尔菲专家咨询法

3.1 河北省内初筛

经核心小组组织河北省内专家对条目初步筛选，将条目进行调整优化补充，最终确定专家咨询问卷。

3.2 第一轮专家咨询结果

根据专家意见及建议，对问卷中的条目进行调整。

3.3 第二轮专家咨询结果

根据专家意见及建议，对条目进行优化调整。

3.4 第三轮专家咨询结果

最终确立慢性萎缩性胃炎浊毒蕴胃证诊断标准。

三、主要技术内容介绍

1 文献检索结果

用频数法初筛条目，剔除频率＜5%的条目，最终得45个条目，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。

2.临床调查统计分析结果

综合离散趋势法、相关系数法、克朗巴赫系数、因子分析法，最终入选23个条目，分别为胃脘部痞满不适、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。

3.德尔菲法专家调查结果

3.1 经河北省内专家对条目筛选，基于德尔菲法，确定德尔菲法专家调查表中条目：舌质暗红或紫暗，舌苔黄腻、脘腹痞满或疼痛、大便粘腻不爽、口味不和（口黏、口臭、口苦）、烧心或反酸、脉滑或弦滑或滑数、头昏蒙不清、身体困重、纳差、小便不利（或小便黄或黄赤）、面色晦暗、寐差、分泌物黏、腻、臭秽。

3.2 第一轮专家意见

第一轮条目的均数、满分率、变异系数均达标，第一轮调查问卷中有专家提出“保留口苦，删除口干”、“增加饮水量及渴喜冷饮”、“增加纳差、嗳气频、寐差”、“增加胃脘部嘈杂不适”、“增加胃脘怕凉”，经组内谈论后结合专家回馈意见做出以下调整：1、增加“纳差、寐差”；2、去掉“口干”。

3.3 第二轮专家意见

第二轮在上述基础上做出调整，第二轮专家咨询中条目保留结果予以同意意见。

3.3 第三轮专家意见

第三轮条目的均数、满分率、变异系数均达标，最终确立慢性萎缩性胃炎浊毒蕴胃证诊断量表条目，即脘腹痞满或疼痛，舌质暗红或紫暗、舌苔黄腻或燥，大便粘腻不爽，烧心或反酸，口味不和（口黏、口臭、口苦），面色晦暗，纳差、寐差，小便不利（或小便黄或黄赤），身体困重，分泌物黏、腻、臭秽，头昏蒙不清，脉滑或弦滑或滑数。

四、重大分歧意见的处理经过和依据

1 收集意见

首先，需要收集所有参与制定诊断标准的相关方的意见和观点。包括医生、研究人员、学术界代表、行业专家等。

2 建立专家组

为了处理分歧意见，可以建立一个专家组来进行讨论和决策。专家组应该由各个相关方代表组成，以确保多方利益的平衡。

3 评估证据

专家组应该评估现有的科学证据和研究结果，以支持他们的意见和建议。这可能包括对疾病的病因、症状、流行病学数据等方面的研究。

4 辩论和讨论

专家组应该进行辩论和讨论，就不同的意见和观点进行交流，并努力达成共识。这可能需要多次会议和讨论。

5 寻求外部意见

如果专家组无法就分歧意见达成一致，可以考虑寻求外部的意见和建议。这可能包括邀请其他专家或组织进行独立评估，并提供他们的意见。

6 透明和公开

整个过程应该是透明和公开的，以确保各方的参与和监督。专家组应该记录和报告讨论和决策过程。

7 汇总意见

最终，专家组应该努力汇总各方意见，并提出一个综合的诊断标准。这个标准应该能够尽可能地反映各方的观点和建议。

8 审查和修订

制定的诊断标准应该经过审查和修订，以确保其科学性、准确性和实用性。这可能需要进一步的研究和验证。

五、其他应说明的事项

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

Draft Explanation

Ⅰ Introduction

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Ⅱ. Drafting Process of the Standard

1 Literature Search

Three databases were used: CNKI, Wanfang, and VIP database. The keywords used for the search were: chronic atrophic gastritis, atrophic gastritis, CAG, intestinal metaplasia, gastric mucosal lesions, gastric mucosal atrophy, gastric precancerous lesions, dysplasia, turbid toxicity and gastric accumulation, internal accumulation of turbid toxicity, and turbid toxicity theory. A combination of subject headings, keywords and text words were used for the search according

to the characteristics of each database. Through literature study, the frequencies of symptoms, signs, tongue manifestations and pulse conditions related to the syndrome of turbid toxicity were sorted and summarized, and entries with a frequency of less than 5% were excluded.

2 Clinical Survey

Objective screening of diagnostic entries was carried out using 4 statistical methods: dispersion tendency, correlation coefficient, Cronbach's alpha, and factor analysis. Through multi-dimensional analyses, if any item failed to meet the screening criteria, its exclusion would be considered.

3 Delphi Method

3.1 Preliminary screening within Hebei Province

The core group organized a preliminary screening of entries by experts in Hebei Province. The entries were adjusted, optimized and supplemented, and the expert consultation questionnaire was finalized.

3.2 Results of the first round of expert consultation

Adjustments to the entries in the questionnaire were made based on experts' comments and suggestions.

3.3 Results of the second round of expert consultation

The entries were optimized based on experts' comments and suggestions.

3.4 Results of the third round of expert consultation

The diagnostic criteria for chronic atrophic gastritis syndrome of turbid toxicity and gastric accumulation were established.

Ⅲ. Main Technical Contents

1 Results of Literature Search

Frequency analysis was used to preliminarily screen the entries, and those with a frequency of less than 5% were excluded. The following 45 entries were collected: yellow and slimy tongue fur, white and slimy tongue fur, slippery pulse, stomachache, heartburn, belching, anorexia, red tongue, dull red tongue, bitterness in the mouth, gastric stuffiness, sticky stool, string-like and slippery pulse, nausea, string-like and fine pulse, dry mouth, dim complexion, acid reflux, sallow complexion, string-like fine sluggish pulse, halitosis, vague epigastric pain, fatigue, dysuria(or yellow/reddish yellow urine), prickling localized epigastric

pain, emesis, diarrhea, dry tongue fur, poor sleep, chest distress, gastric noise, tarry stool, dark purple tongue, constipation, purplish red tongue, thin tongue fur, sticky in mouth, exfoliative tongue fur, vexation, heavy cumbersome limbs, purplish tongue, slippery and rapid pulse, dizziness, sticky and unpleasant secretions, odorous secretions.

2 Results of the Statistical Analysis of Clinical Survey

Comprehensively using the 4 methods, namely dispersion tendency, correlation coefficient, Cronbach's alpha, and factor analysis, 23 entries were selected: epigastric distention and fullness, epigastric pain, sticky stool, dry mouth, bitterness in the mouth, sticky in mouth, halitosis, dim complexion, dysuria or yellow (reddish) urine, acid reflux, heavy cumbersome body, low food intake and anorexia, heartburn, dizziness, sticky and unpleasant secretions, odorous secretions dull red tongue, dark purple tongue, yellow and slimy tongue fur, dry tongue fur, slippery pulse, string-like and slippery pulse, slippery and rapid pulse.

3 Results of the Delphi Survey

3.1 The entries were screened by experts in Hebei Province. Based on the Delphi method, the entries in the questionnaire were determined: dull red or dark purple tongue, yellow and slimy tongue fur, gastric distention and fullness or gastric pain, sticky stool, oral discomfort(sticky in mouth, halitosis, bitterness in the mouth), heartburn or acid reflux, (string-like or rapid) slippery pulse, dizziness, heavy cumbersome body, poor appetite, dysuria(or yellow/reddish yellow urine), dim complexion, poor sleep, sticky/slimy/odorous secretions.

3.2 First Round of Expert Advice

For the first round, the mean number, perfect rate and coefficient of variations of the entries were all qualified. Some experts suggested in the questionnaire to "keep bitterness in the mouth and delete dry mouth", "add water intake and thirst for cold drinks", "add poor appetite, frequent belching and poor sleep", "add gastric noise and discomfort", and "add intolerance of cold in the stomach". After discussion within the group and taking into account the feedback from the experts, the following adjustments were made: 1. adding "poor appetite and poor sleep"; 2. excluding "dry mouth".

3.3 Second Round of Expert Advice

For the second round, adjustments were made on the basis of the above results. The experts were agreed upon the entries to be kept.

3.4 Third Round of Expert Advice

For the third round, the mean number, perfect rate and coefficient of variations were all qualified. The entries of the diagnostic scale for chronic atrophic gastritis syndrome of turbid toxicity and gastric accumulation were finally established, namely gastric distention and fullness or gastric pain, dull red or dark purple tongue, yellow and slimy tongue fur or dry tongue fur, sticky stool, heartburn or acid reflux, oral discomfort(sticky in mouth, halitosis, bitterness in the mouth), dim complexion, poor appetite, poor sleep, dysuria(or yellow/reddish yellow urine), heavy cumbersome body, sticky/slimy/odorous secretions, dizziness, (string-like or rapid) slippery pulse.

Ⅳ. History of and Basis for Handling Major Disagreements

1 Gathering opinions

First, the views and opinions of all interested parties involved in the development of the diagnostic criteria need to be collected. The interested parties include physicians, researchers, representatives from academia, industry experts, etc.

2 Establishing Expert Groups

To deal with disagreements, an expert group could be established for discussion and decision-making. The expert group should be composed of representatives of all interested parties to ensure a balance interests for all parties.

3 Evaluating Evidences

The expert group should evaluate the available scientific evidence and research findings to support their comments and suggestions. This may include research on the causes, symptoms, epidemiologic data, etc. of the disease.

4 Debate and Discussion

The expert group should share different views and perspectives through debates and discussions, and try to reach consensus. This may require multiple meetings and discussions.

5 Seeking External Advice

If the expert group is unable to reach agreement on divergent views, seeking external advice and recommendations can be considered. This may include

inviting other experts or organizations to conduct an independent assessment and to provide their comments.

6 Transparency and Openness

The whole process should be transparent and open to ensure participation and supervision by all parties. The expert group should record and report on the discussions and decision-making process.

7 Summarizing Views

Finally, the expert group should summarize the views of all parties and come up with a comprehensive diagnostic criteria, which should be able to reflect, to the extent possible, the views and suggestions of all parties.

8 Review and Revision

The diagnostic criteria should be reviewed and revised to ensure their scientific validity, accuracy and usefulness, which may require further research and validation.

Ⅴ. Other Matters to be Clarified