国际中医技术操作规范

通关利窍针刺法治疗中风后吞咽障碍

国际组织标准编制说明

Formulation Explanations

一、工作简况

主要起草单位：天津中医药大学第一附属医院、国家中医针灸临床医学研究中心。

参与起草单位（排名不分先后）：美国亚利桑那州针灸研究所、慕尼黑中医诊所、马来西亚宝荣堂中医诊所、Herb base, Chinese medical centre, England。

主要起草人：石学敏、樊小农。

参与起草人（按姓氏拼音排序）：

中　　国：卞金玲、常颖慧、戴晓裔、杜宇征、李军、石江伟。

美　　国：刘静。

英　　国：赵俊红。

德　　国：Florian von Damnitz。

马来西亚：钟尚烨。

南　　非：马学盛。

澳大利亚：王占奎。

加 拿 大：唐慎思。

二、标准起草过程简介

该项目于 2022 年 1 月启动，成立“国际中医技术操作规范通关利窍针刺法治疗中风后吞咽障碍”开发小组，明确分工、布置任务。2023 年 9 月 13 日经世界中医药学会联合会批准后《国际中医技术操作规范 通关利窍针刺法治疗中风后吞咽障碍》公示立项。经过文献检索、证据评价、多次小组会议讨论、征求专家意见合成推荐意见，形成初稿。根据世界中医药学会联合会发布的 SCM 1.1-2021《标准化工作导则第 1 部分：标准制修订与发布》，标准起草小组多次组织审稿会，认真修改、审查，确认全部资料严谨、科学、符合要求。2023 年 4 月-5 月，该项目起草小组成员在天津召开系列标准修改会议，以内容简洁、精准、完善以及格式清晰、统一为目标对标准草案进行完善。2023 年 6、9 月，2024 年 6 月，世界中联标准部与标准起草小组召开线上会议就该标准进行讨论，会后完善标准内容和格式。2024 年 7 月 26 日，该项目起草小组成员在天津召开标准内容定稿会议，标准定稿。

三、主要技术内容介绍

通关利窍针刺法，是石学敏院士基于对中风后吞咽障碍病因病机的充分认识和深刻理解上，提出中风后吞咽障碍的根本病机是“窍闭神匿，神不导气，关窍闭阻”，确立了醒脑调神、滋补三阴、通关利窍的治则，调神通关为“使”，滋阴利窍为“用”，从窍论治中风后吞咽障碍，创立了以阴经、督脉、少阳经经穴为主的通关利窍针刺法理论和技术体系，针法在各穴的手法量学操作方面均有严格要求，且利用特殊针感量化针刺操作，如水沟穴眼球湿润为度、廉泉穴如鲠在喉为宜等，提高了临床干预的规范性、可重复性与可操作性。

天津中医药大学第一附属医院针灸学科是中国最大的针灸临床科研教学基地和国际交流中心，学科带头人为石学敏院士。学科始创于 1953 年，1962 年开设全国首个针灸病房，1988 年成为“全国针灸临床研究中心”，2002 年成为国家教育部重点学科，2008 年成为国家中医临床研究基地(中风病)，2018 年成为国家区域诊疗中心。拥有以院士为核心的教育部创新团队。目前该学科开放床位数达 1000 张，年出院患者达 1.6 万人次、年门诊量 58.8 万人次。针灸临床服务能力全国第一。“通关利窍”针刺法治疗中风后吞咽障碍技术已推广至全国多个省市地区。

石学敏院士学术团队基于“通关利窍”针刺法治疗中风后吞咽障碍进行多层次、全方位的研究，从有效吞咽、安全吞咽等方面综合验证针刺对吞咽功能的改善作用和卫生经济学价值，从 fMRI 角度探索针刺治疗的即刻和中枢效应机制。

1. 基础实验

团队基于 fMRI 技术、以健康人群为研究对象，将受试者分为针刺组和假针刺组，探索“通关利窍”针刺法的关键腧穴——廉泉穴的特异性表征（如鲠在喉）与脑区功能活动的相关性。结果显示：①针刺过程中综合针感，以及其中的酸痛感、疼痛感、深压痛感、刺痛感、麻木感以及如鲠在喉感，均与两组组间功能活动差异明显的脑区相关性较强。多种针感（酸痛感、疼痛感、深压痛感、刺痛感以及如鲠在喉感）与左侧颞下回、颞中回、海马相关性较强。②试验组针刺过程中的“酸痛感”及“如鲠在喉”感与部分区域的脑功能活动相关性较强。其中，酸痛感分别与左侧枕上回及右侧额上回相关性强；如鲠在喉感与右侧顶上回相关性较强。预试验结果显示廉泉穴的如鲠在喉感与右侧顶上回脑区的活动紧密相关，且与其他针感激活的脑区存在差异，这表明特异性表征可能是引起某些脑区活动/功能变化的关键。

研究团队还在天津市自然科学基金资助下，探索“通关利窍”针刺法治疗 PSD 的中枢效应机制。此研究以 fMRI 为技术手段，与健康人群数据相比，探究 PSD 患者特征性脑区。通过观察 PSD 患者经“通关利窍”针刺法即刻及长期治疗后脑默认网络、脑功能连接等产生的特异性改变，获取针刺即刻效应特异脑区和长期效应特异脑区。最终获得“通关利窍”

针刺法组穴的即刻及长期效应的核心效应脑区，为“通关利窍”针刺法治疗 PSD 临床效应提供可视化影像学证据、中枢效应机制证据。

另外，在国家自然青年科学基金项目资助下，探索针刺对 PSD 的皮质吞咽中枢脑区（M1）及皮质下结构（皮质-孤束核）脑功能重组及神经重塑的调节作用。此研究通过 fMRI 技术评估以 C57BL/6（缺血性脑卒中吞咽障碍模型）小鼠脑 M1 区为核心的吞咽皮质脑区功能活动强度、同步性及关联程度；采用光纤成像技术监测 C57BL/6 小鼠脑 M1 区内及皮质-孤束核通路中钙离子信号分布，评估相关区域内神经管活性。整体分析“吞咽功能–肌群电活动–皮质吞咽中枢脑功能活动–神经元活性”的相关性，验证针刺信号通过对吞咽皮质脑功能重组、调节皮质及皮质下结构神经元活性以改善吞咽功能。

2. 临床试验

2.1 随机对照研究

本团队在国家中医药管理局资助下，开展了研究，验证“通关利窍”针刺法治疗真性延髓麻痹的疗效和安全性。并在国家重点研发计划资助下，开展高质量临床试验验证“通关利窍”针刺法治疗 PSD 的临床疗效。该研究在以天津中医药大学第一附属医院、辽宁中医药大学附属医院为主导的 20 余家分中心共同展开临床试验，纳入 300 例受试者，采用分层区组随机、假针刺对照的方法，在四级质控的管理下，进一步验证了“通关利窍”针刺法治疗 PSD 的有效性和安全性，为针灸治疗 PSD 提供了高质量的循证证据。

2.2 真实世界研究

本研究团队在名老中医学术思想传承模式指导下，开展“通关利窍”针刺法作用特点和卫生经济学价值研究。结果显示在真实的医疗环境中，“通关利窍”针刺法依然有较好的安全性和外部有效性；脑梗死和糖尿病病史是影响针刺效应的危险因素；针刺治疗周期和疗效呈正相关，建议治疗周期尽可能延长至 3-4 周以上；针刺联合康复治疗与单独针刺治疗均疗效确切。其中，针刺联合康复治疗对改善吞咽功能和 NIHSS 评分方面效果更优但单独使用针刺治疗更具有经济优势。

3. 专家调查

3.1 调查表发给海内外专家

邀请海内外专家根据自己的经验，提出通关利窍针刺法对中风后吞咽障碍治疗意见，然后对专家意见反馈的调查表汇总整理，形成初步草案，与课题组通过既往课题研究获得的信息资料相结合，将这两者进行分析处理，撰写标准草案。完成后，再次发给专家，收集整理专家意见，形成“国际中医技术操作规范通关利窍针刺法治疗中风后吞咽障碍”初定稿。

3.2 召开专家会议

项目中标后，召开撰写小组会议，学习、培训研究方法，制定研究方案，明确分工，形成“国际中医技术操作规范 通关利窍针刺法治疗中风后吞咽障碍”初稿后，组织海内外专家，召开专家论证会。收集整理专家对初稿的意见，修改完善初稿。完善后再次征求专家意见，一致同意后定稿。

四、重大分歧意见的处理经过和依据

无

五、其他应说明的事项

无

International Standardized Manipulations of Chinese Medicine

Tongguan Liqiao acupuncture therapy for post-stroke dysphagia

Formulation Explanations

1. Standard development units

Main drafting units: First Teaching Hospital of Tianjin University of Traditional Chinese Medicine, National Clinical Research Center for Chinese Medicine Acupuncture and Moxibustion

Units involved in drafting (listed in random order): State of Arizona Acupuncture Institute, Munich Chinese Medicine Clinic, Malaysia Bao Rong Tang TCM Clinic, and Herb Base, Chinese Medical Centre, England

Main drafters: Shi Xuemin, and Fan Xiaonong

Drafters (listed in an alphabetic order of the surname):

China: Bian Jinling, Chang Yinghui, Dai Xiaoyu, Du Yuzheng, Li Jun, and Shi Jiangwei

USA: Liu Jing

UK: Zhao Junhong

Germany: Florian von Damnitz

Malaysia: Zhong Shangye

South Africa: Ma Xuesheng

Australia: Wang Zhankui

Canada: Tang Shensi

2. Standard developing process

The project was launched in January, 2022 when the development group of the "International Standardized Manipulations of Chinese Medicine-- Tongguan Liqiao acupuncture therapy for post-stroke dysphagia" (hereinafter referring to as the Standard) was established, and the responsibilities and tasks of each member were determined and assigned. On September 13, 2023, the project of the Standard was approved by the World Federation of Chinese Medicine Societies (WFCMS) and informed in public afterwards. The recommendation opinions were formed and the initial draft was completed after literature retrieval, evidence evaluation, multiple group meetings and discussions, and expert consultation. The Standard drafting group organized multiple review

meetings to carefully revise and review the draft, and confirmed that all data are rigorous, and scientific, and met the requirements, following the Directives for Standardization Part 1: Procedures for Standard Development, Revision and Publication (SCM 1.1-2021) issued by the WFCMS. In April to May, 2023, the drafting group members organized a series of the Standard revision meetings in Tianjin, and the draft was improved to make the standard concise, accurate and perfect with clear and unified format. In June and September 2023, and June 2024, the Standards Department of WFCMS and the Standard drafting group held online meetings to discuss the Standard, and improved its content and format after the meeting. On July 26, 2024, members of the project drafting group held a meeting in Tianjin to finalize the contents of the Standard to complete the final version.

3. Main techniques involved

"Tongguan Liqiao (unblocking main gates and orifices)" acupuncture therapy was developed by Academician Shi Xuemin based on his deep understanding on pathogens and pathogenesis of post-stroke dysphagia, who put forward that the root pathogenesis of post-stroke dysphagia was "obstructed orifices and hidden spirit which fails to guide qi, leading to gate and orifice obstructions". He then proposed the treatment principles as awakening the brain and regulating spirit, nourishing three yin meridians, and unblocking main gates and orifices. With regulating spirit and unblocking gates as the "guidance", and nourishing yin to unblock orifices as the "target", he treats post-stroke dysphagia from the view of orifices and created the Tongguan Liqiao acupuncture theory and operation system with the main focus of yin meridians, governor vessel, and acupoints along *Shaoyang* meridian. In this acupuncture method, there are strict requirements in the quantitative manipulation at each point, and the use of special needling sensation to quantify the manipulation, such as needling Shuigou (GV 26) until eyeball becomes moist, and needling Lianquan (CV 23) until the patient feels like a fishbone getting stuck in the throat, improves the standardization, repeatability and operability of clinical interventions.

The acupuncture department of the First Teaching Hospital of Tianjin University of Traditional Chinese Medicine is the largest clinical, research and teaching base and international exchange center of acupuncture in China, and the acupuncture discipline is led by Academician Shi Xuemin. The discipline was founded in 1953, and it set up the first acupuncture ward in China in 1962, which later became the National Acupuncture Clinical Research Center in 1988. The discipline was certified as a key discipline of China Ministry of Education in 2002,

and the center became the National Clinical Research Base of Traditional Chinese Medicine (Stroke) in 2008. In 2018, it became the national regional diagnosis and treatment center. The center owns Ministry of Education Innovation Team with academicians being the core. At present, the number of open beds in this discipline has reached 1,000, the annual number of discharged patients has reached 16,000, and the annual number of outpatient visits has reached 588,000. Its clinical service ability of acupuncture and moxibustion ranks first in China. The "Tongguan Liqiao" acupuncture technique for treating post-stroke dysphagia has been promoted to many provinces and cities in China.

Shi Xuemin's academic team conducted multi-level and all-round studies on the treatment of dysphagia after stroke with “Tongguan Liqiao” acupuncture method. They’ve comprehensively verified the improvement effect of the acupuncture technique on swallowing function and the value of health economics from the aspects of effective swallowing and safe swallowing; and explored the immediate and central effect mechanism of this acupuncture method from the perspective of fMRI.

3.1 Basic experiments

Based on fMRI technology and taking healthy people as the research objects, the team divided the subjects into acupuncture group and fake acupuncture group, and explored the correlation between the specific characteristics (feeling like a fishbone getting stuck in the throat) of Lianquan (CV 23), the key acupoint of "Tongguan Liqiao" acupuncture method and the functional activities of the brain area. The results showed that: (1) The comprehensive needling sensation, as well as the aching pain, pain, deep pressing pain, pricking sensation, numbness, and the feeling of being stuck in the throat were all strongly correlated with the brain regions with significant functional activity differences between the two groups. Multiple needling sensations (aching pain, pain, deep pressing pain, pricking sensatsion, and the feeling of being stuck in the throat) were strongly associated with the left inferior temporal gyrus, middle temporal gyrus, and hippocampus. (2) The feelings of "aching pain" and "being stuck in the throat" during needling in the acupuncture group had a strong correlation with brain functional activities in some regions. Among them, aching pain was strongly correlated with left gyri occipitales superiores and right gyrus frontalis superior. The feeling of being stuck in the throat showed a strong association with the right superior parietal gyrus. The preliminary test results showed that the feeling of being stuck in the throat while needling Lianquan (CV 23) was closely related to the activity of the right parietal gyrus region, which was different from the brain regions that were activated by other needling sensation,

suggesting that the specific characterization may be the key to the activity/function changes of some brain regions.

Funded by Tianjin Natural Science Foundation, the research team also explored the central effect mechanism of "Tongguan Liqiao" acupuncture method in the treatment of PSD. This study used fMRI as a technique to explore the characteristic brain regions of PSD patients by comparing with the data of healthy people. By observing the specific changes of the default brain network and brain functional connection in PSD patients after the immediate and long-term treatment of "Tongguan Liqiao" acupuncture method, the specific brain regions of the immediate effect and the long-term effect of acupuncture were obtained. Finally, the core effect brain areas of the immediate and long-term effects of "Tongguan Liqiao" acupuncture method were obtained, which provides evidence in visual imaging and central effect mechanism for the clinical effects of "Tongguan Liqiao" acupuncture method on PSD.

In addition, with the support of the National Natural Youth Science Foundation project, they explored the regulatory effects of acupuncture on the brain functional recombination and neural remodeling of the cortical swallowing center (M1) and subcortical structure (cortex-solitary nucleus) of PSD. In this study, fMRI was used to evaluate the functional activity intensity, synchronization and correlation degree of the swallowing cortex brain region centered on the M1 region of C57BL/6 (post-ischemic stroke dysphagia model) rats. Fiber optic imaging was used to monitor the distribution of calcium ion signals in the M1 region and cortex-solitary nucleus pathway of C57BL/6 rats, and to evaluate the neural tube activity in the relevant regions. The correlation of "swallowing function-muscle group electrical activity-brain functional activity in cortical swallowing center-neuronal activity" was analyzed as a whole, and it was verified that acupuncture signal could improve swallowing function by reorganizing the function of swallowing cortex and regulating the neuronal activity of cortex and subcortical structures.

3.2 Clinical trials

3.2.1 Randomized controlled trials

Funded by the China State Administration of Traditional Chinese Medicine, the team conducted a study to verify the efficacy and safety of "Tongguan Liqiao" acupuncture method in the treatment of true bulbar paralysis. Under the support of the National Key Research and Development Plan, high-quality clinical trials were carried out to verify the clinical efficacy of "Tongguan Liqiao" acupuncture method in treating PSD. More than 20 sub-centers led by the First Teaching

Hospital of Tianjin University of Traditional Chinese Medicine and the Affiliated Hospital of Liaoning University of Traditional Chinese Medicine jointly carried out this clinical trial. It included 300 subjects. The method of stratified group randomization and sham acupuncture control was adopted under the management of four-level quality control, which further verified the effectiveness and safety of "Tongguan Liqiao" acupuncture method in the treatment of PSD, providing high-quality evidence-based evidence for acupuncture treatment of PSD.

3.2.2 Real-world studies

Under the guidance of academic thought inheritance model of the famous veteran TCM doctors, the research team carried out the study on the function characteristics and health economics value of "Tongguan Liqiao" acupuncture method. Results showed that in the real medical environment, “Tongguan Liqiao” acupuncture still showed good safety and external effectiveness. Cerebral infarction and diabetes history were the risk factors affecting acupuncture effects. The therapeutic period of acupuncture was positively correlated with the therapeutic effect, and it is recommended to extend the therapeutic period to more than 3-4 weeks as far as possible. Acupuncture combined with rehabilitation therapy and acupuncture alone both showed definite effects. Among them, acupuncture combined with rehabilitation treatment has better effect on improving swallowing function and NIHSS score, but acupuncture alone has more economic advantages.

3.3 Expert consultation

3.3.1 Questionnaire sent to experts at home and abroad

Experts at home and abroad were invited to put forward their opinions on the treatment of post-stroke dysphagia by “Tongguan Liqiao” acupuncture method according to their own experience, and then their feedback were summarized to form an initial draft, which was combined with the information obtained by the project group through its previous researches. Both of them were analyzed and processed to write the Standard draft. After completion, the draft was sent to experts again for advice and feedback. The preliminary version of "International Standardized Manipulations of Chinese Medicine-- Tongguan Liqiao acupuncture therapy for post-stroke dysphagia” was then finalized.

3.3.2 Expert meetings

After winning the bid, a writing group meeting was held for research

methods learning and training, research plan formulation, and task division. After completing the first draft of the Standard, experts at home and abroad were organized for demonstration meetings. The initial draft was revised based on experts' advice collected and summarized. After the revision, experts were consulted again, and the draft was finalized after unanimous agreement.

4. Process and basis for handling major disagreements

None

5. Others should be explained

None