Special Topic Study

Observation on mind-refreshing and orifice-opening needling method plus swallowing disorder therapeutic apparatus for deglutition disorder of stroke patients in the convalescent stage

醒脑开窍针法联合吞咽障碍治疗仪治疗脑卒中恢复期吞咽障碍的观察

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Abstract

Objective: To observe the clinical effect of mind-refreshing and orifice-opening needling method plus swallowing disorder therapeutic apparatus for deglutition disorder of stroke patients in convalescence stage.

Methods: A total of 136 patients conforming to the inclusion criteria were randomized into three groups by the random number table, including group A of 46 cases, group B of 44 cases and group C of 46 cases. Patients in group A received swallowing disorder therapeutic apparatus treatment, patients in group B received mind-refreshing and orifice-opening needling method treatment, and patients in group C received mind-refreshing and orifice-opening needling method plus swallowing disorder therapeutic apparatus treatment. The treatment was given once a day for 10 d as a course, the whole treatment lasted for 4 courses. Therapeutic evaluation items including water-swallowing test (WST), standardized swallowing assessment (SSA) and modified Barthel index (MBI) were measured before treatment, after treatment and at follow-up visit (2 months after treatment).

Results: After treatment, scores of WST and MBI in all three groups increased significantly (all P<0.05), while the SSA score dropped significantly (all P<0.05). After treatment and during follow-up visit period, score of WST in group C was significantly higher than that in group A and group B (both P<0.05), while the difference between group A and group B showed no statistical significance (P>0.05); the SSA score in group C was substantially lower than that in group A and group B (all P<0.05), the difference between group A and group B showed no statistical significance (P>0.05); the SSA score in group C was substantially lower than that in group A and group B (all P<0.05), the difference between group A and group B showed no statistical significance (P>0.05); the MBI scores in group B and group C were substantially higher than that in group A (all P<0.05), the difference between group B and group C showed no statistical significance (P>0.05). After treatment and during follow-up visit period, the differences in overall therapeutic effect between group A and group B showed no statistical significance (P>0.05). After treatment and during follow-up visit period, the differences in overall therapeutic effect between group A and group B showed no statistical significance (P>0.05), while the overall therapeutic effect in group C was substantially better than that in group A and group B (all P<0.05).

Conclusion: Both mind-refreshing and orifice-opening needling method and swallowing disorder therapeutic apparatus can alleviate symptoms of deglutition disorder of stroke patients respectively, and the combination of two methods can improve the therapeutic effect.

Keywords: Acupuncture Therapy; Stroke; Poststroke Syndrome; Pseudobulbar Palsy; Deglutition Disorders; Stroke Rehabilitation; Activities of Daily Living

【摘要】目的:观察醒脑开窍针法联合吞咽治疗仪治疗脑卒中恢复期吞咽障碍的疗效。方法:将 136 例符合纳入标准的患者根据随机数字表随机分为三组,A组(46例)采用吞咽治疗仪治疗;B组(44例)采用醒脑开窍针法治疗;C组(46例)采用醒脑开窍针法联合吞咽治疗仪治疗。均每日 1 次,10 d 为 1 个疗程,共治疗 4 个疗程。于治疗前、治疗后和随访时(治疗结束后 2 个月)用洼田饮水试验(WST)、标准吞咽功能评定量表(SSA)、改良 Barthel 指数(MBI) 评价疗效。结果:治疗后,三组患者洼田饮水试验评分、MBI 评分较本组治疗前明显增加(均 P<0.05);SSA 评分较治疗前明显下降(均 P<0.05)。治疗后及随访时,C组的洼田饮水试验评分明显高于A组和B组(均 P<0.05),A、B两组差异无统计学意义(P>0.05);C组SSA评分显著低于A组和B组(均 P<0.05),A、B两组无统计学差异(P>0.05);B、C两组无统计学差异(P>0.05)。治疗后及随访时,A组与B组的总体疗效差异无统计学意义(P>0.05),C组总体疗效优于A组和B组(均 P<0.05)。结论:醒脑开窍针法和吞咽治疗仪均能改善脑卒中后吞咽障碍,两者合用可提高疗效。

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【关键词】针刺疗法; 中风; 中风后遗症; 假性延髓麻痹; 吞咽障碍; 中风康复; 日常生活活动 【中图分类号】R246.6 【文献标志码】A

Stroke is the most common cause of deglutition disorder. In China diagnostic and treatment guidelines for acute ischemic stroke, it occurs to nearly 50% of stroke patients on admission^[1]. It's also one of the risk factors for respiratory aspiration and a serious complication which happens in nearly 43%-54% of stroke patients^[2]. Aspiration can lead to aspiration pneumonia or even life-threatening apnea, and thus cause grave impact on stroke patients' quality of life (QOL) and safety. We have used mind- refreshing and orifice-opening needling method plus swallowing disorder therapeutic apparatus to treat deglutition disorder of stroke patients, and the report is now given as follows.

1 Clinical Materials

1.1 Diagnostic criteria

Conforming to the diagnostic criteria of stroke formulated in the Fourth National Academic Conference on Vascular Disease^[3], and certified by cranial CT or MRI examinations; with the symptoms of deglutition disorder including choking, prolonged catering and drinking time, difficulty chewing and muscular atrophy, retarded or disappeared pharyngeal reflex.

1.2 Inclusion criteria

Conforming to the diagnosis criteria above; clear consciousness, without mental retardation, capable of understanding and following simple instructions of researchers; stable vital signs, without fever or

<u> </u>		Gender (case)	Average age	Average duration	Types of stroke (case)		
Group	n	Male	Female	$(\overline{X} \pm s, year)$	$(\overline{x} \pm s, day)$	Hemorrhage	Infarction
A	46	26	20	48.2±9.3	21.0±6.5	13	33
В	44	23	21	47.7±9.5	22.1±6.2	12	32
С	46	26	20	48.2±8.9	20.8±6.1	11	35

Table	e 1.	Baseline	comparison	of the	three	groups
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2 Treatment Methods

Patients in all three groups received same routine medicine treatment and rehabilitation training. Symptomatic medicine treatment was chosen according to patients' condition, including neurotrophic drugs, anti- platelet agent and medicine to regulate blood pressure, lipid and glucose, and also cold stimulation therapy, breath-holding and pronouncing training, throat elevating exercise, physical and occupational therapy.

2.1 Group A

Patients in group A received the treatment of

pulmonary infection; grade 2 or higher grade evaluated by water-swallowing test (WST); aged between 20-65 years; signed an informed consent form.

1.3 Exclusion criteria

Stroke patients with severe visceral failure or in critical condition; other reasons led to deglutition disorder.

1.4 Statistical method

All data were analyzed with SPSS version 17.0 software. Enumeration data were compared using Chi-square test. Measurement data conforming to normal distribution were expressed with mean \pm standard deviation ($\overline{x} \pm s$), and compared using *t*-test; non-parametric test was used for data not conforming to normal distribution. A *P* level less than 0.05 indicated a statistical significance.

1.5 General data

A total of 136 patients who met the inclusion criteria were included in this study. They were randomized by the random number table into three groups, including group A (treated with swallowing disorder therapeutic apparatus), group B (treated with mind-refreshing and orifice-opening needling method) and group C (treated with mind-refreshing and orifice-opening needling plus method swallowing disorder therapeutic apparatus). The differences in gender, age, duration and types of stroke showed no statistical significance (all P>0.05), indicating that the three groups were comparable (Table 1).

swallowing disorder therapeutic apparatus (YS1001, Changzhou Siya Medical Apparatus Instrument Co., Ltd., China) combining conventional methods. After sterilization of skin around the neck, 2 electrode plates named channel 1 and channel 2 were pasted on patients' laryngeal prominence on one side, and the location superior to laryngeal prominence on the other side separately. Then fixed the electrode plates with bandages, and increased the electric intensity to achieve the expected sensation or muscle movement. Every treatment lasted for 30 min. During treatment, instructed patients to do the swallow movement.

2.2 Group B

Patients in group B received mind-refreshing and orifice-opening needling plus routine treatments.

Acupoints: Shuigou (GV 26), bilateral Neiguan (PC 6), Sanyinjiao (SP 6), Fengchi (GB 20), Wangu (GB 12) and Yifeng (TE 17).

Methods: After routine sterilization, filiform needles of 0.35 mm in diameter and 50 mm in length were punctured perpendicularly at bilateral Neiguan (PC 6) for 0.5-1.0 cun. Upon qi arrival, performed twirling and lifting-thrusting reducing manipulations for 1 min. Then punctured Shuigou (GV 26) towards the direction of nasal septum for 0.3-0.5 cun, performed heavy pecking sparrow method until patients felt moist in eyes or shed tears. Punctured Sanyinjiao (SP 6) along the medial border of tibia for 1.0-1.5 cun, keeping a 45° angle between shaft of the needle and skin. Upon gi arrival, performed lifting-thrusting reinforcing manipulation until patients felt 3 twitching movements on lower limbs. When punctured Fengchi (GB 20), Wangu (GB 12) and Yifeng (TE 17), kept the needle tip toward laryngeal prominence and inserted 2.0-2.5 cun. Upon gi arrival, performed twirling reinforcing method of little amplitude and high frequency. Every manipulation was done for 1 min at each acupoint. The needles were retained for 30 min every time^[4].

2.3 Group C

Patients in group C received conventional treatment combining swallowing disorder therapeutic apparatus and mind-refreshing and orifice-opening needling method which were the same as that in group A and group B.

Treatment above was done once a day, and 10 d constituted a course. The whole treatment lasted for 4 courses. There was a 1-day interval between every two courses.

3 Results

3.1 Observation items

Items below were measured before, after and follow-up visit period (2 months after treatment). 3.1.1 WST^[5]

Deglutition capability is classified into 5 degrees. I: swallowing water in one time smoothly without bucking; II: swallowing water in two servings without bucking; III: swallowing water in one time with bucking; IV: swallowing water in two servings with bucking; V: frequent bucking, cannot finish drinking water.

Normal: for cases rated as grade I, those finish drinking in 5 s; suspicious: for cases rated as grade I, those finish drinking in more than 5 s and who was rated as grade II; abnormal: grade III, IV and V.

Scoring criteria: cases rated as grade I was scored as 5 points, grade II as 4 points, grade III as 3 points, grade IV as 2 points, grade V as 1 point. The minimum score was

1 point, the maximum score was 5 points. A higher score indicated a better deglutition capability.

3.1.2 Standardized swallowing assessment (SSA)^[6]

The SSA evaluation is comprised of three sections. The first section is clinical examination, items including consciousness, head and trunk control, breathe, closure of lips, soft palate movement, larynx function, pharyngeal reflex and voluntary cough are measured, the total score ranges from 8 to 23 points. The second section is deglutition test. Patients are asked to swallow 5 mL water for three times, and the presence of larynx movement, repeated deglutition and wheezes, and larynx functions following deglutition are measured, and the total score ranges from 5 to 11 points. The third section is that the patients are asked to swallow 60 mL water in normal circumstance, then the time needed for deglutition and occurrences of cough are measured. The total score ranges from 5 to 12 points. Therefore, the minimum score of SSA is 18 points, and the maximum score is 46. A higher score indicates a worse deglutition function.

3.1.3 Activities of daily living (ADL)^[7]

ADL was evaluated using modified Barthel index (MBI), including feeding, bathing, grooming, dressing, bowels, bladder, toilet use, transfers (bed to chair and back), mobility (on level surfaces) and stairs. Each item is classified into 5 grades with corresponding scores. The total score of MBI is 100 points. A higher score indicates a better ADL circumstance.

3.2 Clinical efficacy evaluation^[8]

Cured: Flexible tongue motion, normal deglutition movement, grade I evaluated by WST.

Marked effect: Obvious improvement of deglutition disorder, grade II evaluated by WST.

Effective: Improvement of deglutition disorder, grade III evaluated by WST.

Invalid: No improvement of deglutition disorder, grade IV or V evaluated by WST.

3.3 Results

3.3.1 Clinical effect

After treatment and during follow-up visit period, the total effective rates in group A showed no statistical significance in comparing with those in group B (all P>0.05), the total effective rates in group C were superior than those in group A and group B (all P<0.05), (Table 2).

3.3.2 Comparisons of WST, SSA and MBI scores

Intra-group comparison: after treatment and during follow-up visit period, scores of the WST and MBI test increased significantly in comparing with those before treatment (all P<0.05); the SSA scores in all groups were lower than those before treatment (all P<0.05); during follow-up visit period, the changes of WST, SSA and MBI scores showed no statistical significance in comparing with those before treatment (all P<0.05). Inter-group

comparison: after treatment and during follow-up visit period, the WST scores in group C were substantially higher than those in group A and group B (all P<0.05), while the differences showed no statistical significance between group A and group B (both P>0.05); the SSA scores in group C were substantially lower than those in group A and group B (all P<0.05), while the differences

showed no statistical significance between group A and group B (both *P*>0.05); the MBI scores in group B and group C were substantially higher than those in group A (all *P*<0.05), while the differences showed no statistical significance between group B and group C (both *P*>0.05), (Table 3-Table 5).

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Group	n	Time	Cured	Marked effect	Effective	Invalid	Total effective rate (%)
A 46	46	After treatment	6	11	17	12	73.9
	40	Follow-up visit	6	15	13	12	73.9
B 4	4.4	After treatment	7	14	12	11	75.0
	44	Follow-up visit	6	16	11	11	75.0
C	16	After treatment	13	25	4	4	91.3 ¹⁾
	46	Follow-up visit	14	24	4	4	91.3 ¹⁾

Table 2. Comparison of clinical effect after treatment and during follow-up visit period (case)

Note: Compared with group A and group B, 1) P<0.05

Table 3. Comparison of WST score ($\overline{x} \pm s$, point)

Group	n	Before treatment	After treatment	Follow-up visit
A	46	1.85±0.63	$3.22{\pm}1.05^{1)}$	$3.30{\pm}1.07^{1)}$
В	44	1.77 ± 0.68	$3.52{\pm}0.95^{1)}$	$3.48{\pm}0.95^{1)}$
С	46	$1.78{\pm}0.63$	$4.02 \pm 0.86^{(1)2)}$	$4.04{\pm}0.87^{(1)2)}$

Note: Intra-group comparison, 1) P<0.05; compared with group A, 2) P<0.05

Table 4.	Comparison	of SSA score	(\overline{x})	±s, point
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Group	n	Before treatment	After treatment	Follow-up visit
А	46	30.89±2.67	$25.83{\pm}4.55^{1)}$	25.46±4.63 ¹⁾
В	44	30.84±3.14	$24.39{\pm}4.08^{1)}$	$24.55 \pm 4.04^{1)}$
С	46	30.67±2.90	22.09±3.51 ¹⁾²⁾	$22.00 \pm 3.55^{1)2)}$

Note: Intra-group comparison, 1) P<0.05; compared with group A, 2) P<0.05

Table 5. Comparison of MBI score ($\overline{x} \pm s$, point)

Group	п	Before treatment	After treatment	Follow-up visit
А	46	21.45±4.85	$44.23 \pm 5.14^{1)}$	$43.78{\pm}3.55^{1)}$
В	44	21.88±5.02	$65.51{\pm}8.06^{1)2)}$	$64.91{\pm}5.18^{1)2)}$
С	46	22.71±4.54	$66.48 \pm 7.12^{1)2)}$	$66.08 \pm 4.46^{1)2)}$

Note: Intra-group comparison, 1) *P*<0.05; compared with group A, 2) *P*<0.05

4 Discussion

In traditional Chinese medicine, stroke occurs as a result of stagnant blood, liver wind or turbid phlegm misting the brain. Mind-refreshing and orifice-opening needling method was created by academician Shi Xue-min based on the mechanism of this disease. In this technique, acupoints on yin meridians and the Governor Vessel are mainly selected, and acupuncture manipulation and stimulation intensity are standardized. It is also an innovation based on traditional acupointsselection and manipulation. Liu T, et al^[9] held that the functioning mechanism of mind-refreshing and orificeopening needling method might be explained as follows. The lower motor neuron in spinal cord layer is stimulated in the first place. Then, the active movement order is given to patients to stimulate central nerve system to send impulses. At that time, damaged upper motor neuron will send minor impulses and further induce sensitized cells in anterior horns of spinal cord to generate action potentials, realizing the recanalization of neural pathways. Many clinical researches proved that mind-refreshing and orifice-opening needling method would effectively reverse neural function damage, and improve hemodynamic items^[9-12]. Our study showed that mind-refreshing and orifice-opening needling method would effectively improve deglutition functions and ADL in stroke patients.

Swallowing disorder therapeutic apparatus is a low frequency, electrical stimulation equipment rooted on neuron facilitation technology and remodeling theory^[13]. The mechanism may be summarized as follows. On one hand, it directly stimulates pharyngeal muscles and therefore increases local muscle contraction to improve the balance of deglutition; on the other hand, it stimulates the afferent fibers of sensory nerves, by which causing further stimulation to swallow center in brain and increase its excitability, so it helps the recovery and reestablishment process of the reflex arc to improve deglutition. In this study, swallowing disorder therapeutic apparatus and mind-refreshing and orifice-opening needling method all have obvious therapeutic effect for deglutition disorder. During follow-up visit period, the changes in all evaluation items showed no statistical significance when compared with that before treatment (all *P*>0.05), indicating that the two methods have identical and steady long-term effect. The combination of two methods has a better effect than single therapy, indicating that the unity of the treatment has a synergistic effect. Therefore, the combination of the two methods has the merit of improving clinical efficacy, lowering the risk of aspiration and arising QOL.

In our study, we used WST and SSA to evaluate patients' deglutition. WST can judge the presence of deglutition disorder by observing patients' drinking condition, and further determine the degree of this disorder, while it cannot observe the presence of aspiration^[14-15]. SSA shows good sensitiveness and specificity for evaluating deglutition disorder, and has a relatively high predictability for aspiration^[16-19], which is a good remedy for WST. So the combination of the two items can give an overall view for evaluating deglutition. Due to restrictions, cases in our study were all stroke patients in convalescence stage. In the future, we can cooperate with neurology department to conduct clinical observation on stroke patients in acute stage to further explore the adaptability of such methods.

Conflict of Interest

There was no potential conflict of interest in this article.

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Statement of Informed Consent

Informed consent was obtained from all individual participants included in this study.

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