

The First Affiliated Hospital of Gannan Medical
University, Department of Rehabilitation Medicine

Efficacy Observation of Electrical Stimulation of the
Median Nerve Combined with Ear Acupressure on
Consciousness Disorders in Patients with Cranial Brain
Injury

Ethics Approval Number: LLSL-2022053105

Date: May 30, 2022

Efficacy Observation of Electrical Stimulation of the Median Nerve Combined with Ear Acupressure on Consciousness Disorders in Patients with Cranial Brain Injury

1. Subject content and significance

Consciousness disturbance after craniocerebral injury is a common neurosurgical emergency, which to the category of "unconscious", "unconscious of people" and "confused" in traditional Chinese medicine. Patients often suffer from different degrees of consciousness disturbance due toonal injury of the reticular ascending activation system of the brain stem. The high mortality rate, high disability rate and high medical expenses of coma after craniocerebral injury brought great economic burden to the country, society and families, and also brought great life pressure and mental pressure to the family members.

Median nerve electrical stimulation (MNES) is a method of stimulating the median nerve with low-frequency pulse current, which stimulates the nervous system through the median nerve-spinal nerve-cervical spinal cord-brainstem-thalamus-cortical functional area conduction pathway. Electrical stimulation can relieve theition of nerve cells, enhance the excitability of inhibited nerve cells, relieve the inhibition of the ascending reticular activating system (ARAS) in the brainstem shorten the coma time of patients, and restore function, thereby promoting the recovery of consciousness.

Auricular acupressure is a new type of needle embedding method, has a high degree of safety and is easy to operate, and has achieved good clinical efficacy. And auricular acupuncture treatment, because of its close relationship with the z-fu organs and meridians, can play a good role in the "static and left" characteristics of the pressing needle, which can produce a continuous and stable stimulation after the is inserted under the skin, continuously promote the orderly circulation of qi and blood in the meridians, and stimulate the healthy qi of the human body, so as achieve the purpose of dispelling pathogenic factors. However, there are few reports on the promotion of auricular acupressure in the recovery of consciousness after craniocerebral injury. The purpose of this study was to apply median nerve electrical stimulation and auricular pressing needle to the treatment of consciousness disorders after craniocerebral injury, order to improve the effect of coma recovery in patients with craniocerebral injury.

2.Objective

To investigate the effect of combined electroacupuncture of median nerve and auricular point on the recovery of disturbance of consciousness in patients with crancerebral injury, in order to improve the effect of coma recovery in patients.

3.Research idea (working hypothesis)

Modern rehabilitation theory shows that the functional system of

the central nervous system has the ability of plasticity and re after craniocerebral injury, and appropriate stimulation is conducive to the reinnervation of nerves. Median nerve electrical stimulation (MNES) is a cutting- treatment modality clinically for the treatment of coma, and gradually favored by experts at home and abroad, because of its significant advantages such as simplicity, effectiveness and non-invasiveness promoting awakening, and has reached rapid development and popularization in recent years. Its mechanism is to act on the reticular ascending activation system of the brainstem by low-frequency pulse stimulation (usually twice a day of median nerve electrical stimulation treatment, lasting for 60 minutes, lasting for about 8 weeks), to maintain the excited state of the cere cortex, stimulate nerve cells in various parts of the cerebral cortex, promote the release of acetylcholine, and maintain the state of awakening of the cerebral cortex.

The treatment of diseases by auricular acupoints has been documented in ancient Chinese literature. It is written in the "M Question Chapter" of "Yellow Emperor's Inner Canon: Ling Shu" that "the ear is the place where the main meridians gather" and "the meridians connect to the ear." Stimulating auricular acupoints can regulate the functions of the related meridians, playing a role in the circulation of qi and blood, and regulating the yin and yang of the zang-fu organs. The

therapy of pressing needle has been demonstrated in the book "Su Wen: Hetong Zhen Ye Lun", which advocates the "static and long-term retention" of pressing needle. Auricular pressing needle therapy is a method of inserting and fixing specific type of small needle into the auricular acupoints for a longer period. By applying a steady and stable stimulus to the auricular acupoints with needles, it can achieve the effect of smoothing the meridians and collaterals, and regulating the yin and yang of the zang-fu organs. It has advantages in improving the function of consciousness. The long-term feature of auricular pressing needle treatment makes up for the shortcomings of the short action time and long cycle of median electrical stimulation, making the stimulation continuous and stable, which can greatly reduce the treatment cycle and is more conducive to improving the disturbance of consciousness in patients.

This study aims the common disturbance of consciousness in patients with head injury, combined with the application of median nerve electrical stimulation and auricular pressing needle therapy, to observe and analyze the efficacy difference between control group and the experimental group, with the purpose of accelerating the recovery of patients' consciousness, shortening the awakening time, and improving the effect of coma recovery in patients with injury, and to alleviate the economic pressure of society and families to the maximum extent.

Ethics Batch Number (NTC): LLSL-2022053105

4. Research Methods and Design

1. Subjects

Sixty patients with head injury treated in our hospital were selected as subjects, randomly divided into control group and experimental, with 30 cases in each group.

1.1 Inclusion criteria

- ① All patients with disturbance of consciousness after brain injury;
- ② Stable vital signs no obvious bleeding, GCS score of 4-8 points;
- ③ No severe organ failure, normal heart function;
- ④ Course of disease within 10 days
- ⑤ No history of head injury, no history of pregnancy and epilepsy.

1.2 Exclusion criteria

- ① Patients with other types of critical illnesses, such as severe diseases, etc.;
- ② Allergic reactions to the electrodes and patches used in the treatment;
- ③ Relatives of patients do not cooperate and reject treatment.

1.3 Termination and handling of the trial

In the course of the trial, those who have serious adverse events, or serious complications or worsening of the condition should be immediately from the clinical trial by the doctor. When the case is

stopped, the doctor should immediately give symptomatic clinical treatment. After the case is stopped, the doctor should investigate and record cause, retain the case observation data, and take the last detection result as the final result, and conduct data analysis on the efficacy and adverse reactions.

2. Intervention measures

2.1 Control group: Conventional treatment methods were adopted, including surgery, drug therapy, nutritional support, Chinese medicine, and acupuncture, as well as prevention of complications. Meanwhile, median nerve electrostimulation (Shenzhen Dongdi Xin Technology Co., Ltd, MT1023 multifunctional electrotherapy comprehensive treatment instrument) was combined, with two treatments per day (skin electrodes were placed 2cm above the wrist transverse crease on the anterior aspect of the right forearm, using direct current asymmetric rectangular wave, stimulation intensity of 20mA, pulse width of 300ms, frequency 40Hz, working for 20 seconds per minute, resting for 40 seconds, generally lasting for 60 minutes, and lasting for about 8 weeks).

2.2 Experimental group: In addition to conventional rehabilitation treatment methods and median nerve electrostimulation, auricular acupuncture was combined, with acupuncture at heart, Shenmen, sympathetic, and subcortical points (Suzhou Medical Supplies Co., Ltd., Hua Tuo brand disposable sterile push acupuncture model 0.20×0.8mm).

The family members were instructed to massage each acupoint three times a day, each time for 10 minutes with moderate pressure, each treatment for 3 days, rest for 1 day, repeat three times, a total of 11 days in one course of treatment.

3. Observation indicators

After 4, 6, and 8 weeks of continuous intervention, the awakening conditions, including GCS, GOS outcome evaluation, CRS-R scores, and family satisfaction, were compared.

3.1 Awakening conditions: The time of patient awakening and the awakening at 4, 6, and 8 weeks after intervention were recorded.

3.2 The GCS scale (Glasgow Coma Scale) includes three dimensions: opening, language, and motor, with a full score of 15 points. The lower the score, the worse the patient's neurological function recovery.

3.3 CRS-R (Coma Recovery Scale-Revised): It adds evaluation content such as arousal response, communication ability, and auditory level compared to the GCS scale. lowest score is 0, and the highest score is 23. The higher the score, the higher the level of consciousness.

3.4 Prognosis evaluation was at 1 month after treatment based on the Glasgow Outcome Scale (GOS). A score of 5 indicates good recovery, 4 indicates moderate disability, 3 indicates disability, 2 indicates a vegetative state, and 1 indicates death.

3.5 Family satisfaction evaluation: It was divided into 5 levels

according to the Likert method, with 1 indicating very dissatisfied and 5 indicating very satisfied.

4.Statistical treatment

SPSS27.0 statistical software was used for analysis, and the count data of each group was expressed as percentage or composition ratio. The X² test was used for the percentage or composition ratio between groups. The measurement data of each group was expressed as mean \pm standard deviation ($\bar{x} \pm s$). Comparison within the group before and after treatment and comparison between the two groups were performed by t-test. $P < 0.05$ was considered statistically significant.

5.The characteristics or innovations of this topic

The research is based on evidence-based medicine and uses the median nerve electrical stimulation therapy which is widely used in clinic to increase cerebral blood flow of patients with craniocerebral injury, directly excite the cerebral cortex and the reticular structure of the brainstem, enhance the electroencephal activity, and improve the neuroelectrophysiological activity. In clinical treatment, median nerve electrical stimulation has the advantages of non-trauma, simple operation, low cost, and and effective treatment. At the same time, combined with the treatment mode of ear acupressure under the guidance of traditional Chinese medicine meridian acupoint and acupuncture, it can continuously and effectively stimulate the ear

acupoint, improve the excitement and conductivity of acupoint, and achieve the effect of benign and bidirectional regulation. Moreover, can make up for the lack of median nerve electrical stimulation time to the greatest extent, optimize clinical efficacy, further improve the prognosis of patients, and improve the quality of life. to the literature retrieval, there is no literature reporting the same research as this topic in our province, and this topic has a certain degree of innovation. At the same time, the treatment of traditional Chinese and Western medicine is the feature of this project, which can further promote the application of traditional Chinese medicine in clinic.

6.Application Prospect

Disorders of are one of the most common symptoms of craniocerebral injury, with a broad market application and good application prospects. Median nerve electrical stimulation has obvious advantages in promoting awakening the technology is relatively mature, and this treatment method is non-injurious, painless, and less expensive during treatment, and the curative effect is widely recognized by international evidencebased medicine, and it has been widely used in clinical treatment at home and abroad, and the effect of promoting awakening can be guaranteed; ear acupressure has grasped the of traditional Chinese medicine implantation acupuncture of "static and left", which can do a good job of continuous stimulation, and it is safe,

simple to operate, and be applied in community health service centers with poor conditions, and it is easy to replicate and promote.

7.The background material of domestic and foreign research progress related to this project

Although the history of the application of nerve electrical stimulation (MNS) in coma arousal is not long, because of its significant advantages in arousal, MNS has been widely used internationally to treat coma Cooper [1] et al. were the first to use the right MN to treat patients with closed head injury and coma and achieved certain results. Through several clinical studies, they that MNS could increase the level of consciousness in patients with TBI and coma, shorten the time of ICU stay (about 10 days), and to some, it could also restore the language function of patients; PeriCV [2] also studied the effect of MNS in treating patients with TBI and coma. After analyzing data, they found that the awakening rate of the stimulation group could reach 60%, while the control group only had 40%, and the stimulation group had higher on the Functional Independence Measure (FIM) scale and more significant improvement in the quality of life. Their research results show that MNS can be used for the arousal ofBI coma and is safe and effective in treatment.

At present, there are few reports on ear acupressure therapy abroad, and in China, it is mostly based different acupoints, which can

play a very good continuous stimulation effect, thus treating various intractable diseases or pain diseases that often occur. Its application range is wide, and can be used in various departments such as internal medicine, surgery, gynecology, and pediatrics. Domestic literature related to ear acupoint treatment is mainly concentrated in earupoint paste, acupressure and other therapies, mostly using round substances such as Semen Vaccariae and magnetic beads to paste on the ear acupoints Jia Jie and Li Xiu Yun [3] used acupoint acupressure combined with ear acupoint paste to assist in the treatment of cerebralorrhage disturbance of consciousness and observed that it was effective and easy to operate. He Qing Ming [4] et al. explored the role of ear acupress in the arousal after total anesthesia for craniotomy, and found that it had an exciting effect on the cerebral cortex, could accelerate the arousal, and had the of low cost, few complications, simple operation, and safety. However, at present, there are few studies on ear acupressure therapy at home and abroad, mostly focusing the treatment of insomnia and cognitive dysfunction, and there is still a large blank in the aspect of ear acupressure arousal. Lin Juan [5] et al. ear acupoint embedding therapy combined with electroencephalography to treat insomnia, and found that its curative effect had obvious advantages, and it was found that its treatment method simple and easy to operate, and suitable for popularization and application. Jiao Nini [6] et al. used ear acupressure

to treat cognitive dysfunction after laposcopic hysterectomy, and found that it could regulate autonomic nervous function disorders, relieve neurasthenia, and improve cognitive function by stimulating the heart acupoint kidney acupoint, Shenmen acupoint, sympathetic, and subcortical acupoint, further proving the feasibility of ear acupressure therapy. Li Jun7] et al. used acupuncture combined with ear acupressure to treat insomnia, taking Shenmen, sympathetic, heart, brain, and endocrine acoints, and achieved good curative effect, and found that ear acupressure was more green in treatment, without obvious side effects, and relieved and improved the insomnia of patients, which was worth clinical promotion and application.

References:

[1] Cooper JB, Jane JA, Alves WMs et al. Right median nerve electrical stimulation toen awakening from coma [J]. Brain Injury, 1999, 13(4): 261—267.

[2] Peri CV, Shaffrey ME, Farace E, et al. Pilot study of electrical stimulation on median nerve in comatose severe brain injured patients: 3- outcome [J]. BrainInj, 2001, 15(10): 903—910 mnoin.

[3] Jia Jie, Li Xiu Yun. Clinical observation of 40 cases of pressotherapy combined with auricular acupressure to treat disturbance of consciousness afterbral hemorrhage [J]. Sichuan Journal of Traditional Chinese Medicine, 2013, 31(09): 136-13.4.

[4] He Qing Ming, Yan Yun Yun, Zheng Zhi Qiang, The role of auricular acupressure in recovery of general anesthesia after craniotomy [J] Chinese Journal of Practical Neurology, 2013, 16(14): 3-41.5.

[5] Lin Juan, Chai Wei Han, Lu Hong, Wang Ting Ting. Clinical observation of insomnia treated with auricularupuncture combined with electroencephalography [J] Journal of Clinical Traditional Chinese Medicine, 2019, (115): 80-826.

[6] Ji Ni, Peng Sheng, Liu Ji 8 Rong, Zhang Chang Yu, Liu Chun Liang, Liu Sha Sha, Wang Pin The effect of auricular acupressure on postoperative cognitive dysfunction after laparoscopic hysterectomy [J]. Shanghai Journal of Acupuncture and Moxustion, 2020, 39(8); 1022-10267.

[7] Li Jun, Fan Su, Wangng Yuan, Wei Jun, Zheng Yan, Si Jiang Tao Clinical observation of treating insomnia with acupuncture combined with auricular acupressureJ] Chinese Journal of Basic Medicine of Traditional Chinese Medicine.

Date: May 30, 2022