INPLASY PROTOCOL

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Corresponding author: Cai Guofeng

hx18386239544@163.com

Author Affiliation:

Heilongjiang University of Traditional Chinese Medicine.

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Network meta-analysis of 13 nonpharmacological therapies for neurogenic bladder after spinal cord injury

Cai, GF¹; He, X²; Jia, KP³; Xu, K⁴; Sun, JH⁵; Zhang, R⁶; Gao, ZY⁷; Cui, YA⁸; Wu, ZQ⁹.

Review question / Objective: To systematically evaluate the application effect of a variety of non-drug therapies in patients with neurogenic bladder after spinal cord injury by network Meta-analysis. Methods: PubMed, EMbase, Web of Science, Cochrane Library, China National Knowledge Infrastructure (CNKI) and WangFang Database were searched by computer Date) and VIP database (from 2013 to March 20, 2023) for randomized controlled trials of non-drug therapies for patients with neurogenic bladder after spinal cord injury. Two researchers independently conducted literature search, screening, data extraction, quality evaluation, and cross-check results. RevMan 5.4 and Stata17 software were used to analyze the data of the included studies. Results: A total of 31 randomized controlled trials (RCTS) involving 2383 patients were included, covering 13 different non-drug therapies. The network meta-analysis showed that the treatment method ranked first in terms of the total effective rate, the area under the cumulative ranking curve (SUCRA) was medium-frequency pulse electrical therapy combined with conventional bladder function training (68.4%). In terms of residual urine volume, electroacupuncture combined with surface nerve stimulation combined with conventional bladder function training ranked the first (87.5%); In terms of maximum urinary flow rate, the first ranked was pelvic floor electrical stimulation and pelvic floor muscle training combined with conventional bladder function training (99.8%). In terms of average daily single urine volume, pelvic floor electrical stimulation combined with conventional bladder function training ranked first (99.9%). Conclusions: Electroacupuncture combined with surface nerve electrical stimulation combined with conventional bladder function training has the best effect in improving residual urine volume. Pelvic floor muscle electrical stimulation combined with pelvic floor muscle exercise training has the best effect in improving maximum urinary flow rate. Pelvic floor electrical stimulation combined with conventional bladder function training has the best effect in improving the average daily single urine volume. However, the number of literatures on different interventions is too small, and the quality of the included literatures is not very high, and there is publication bias. Therefore, the conclusion needs to be further verified by high-quality studies.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 April 2023 and was last updated on 22 September 2023 (registration number INPLASY202340027).

INTRODUCTION

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2013 to March 20, 2023) for randomized controlled trials of non-drug therapies for patients with neurogenic bladder after spinal cord injury. Two researchers independently conducted literature search, screening, data extraction, quality evaluation, and cross-check results. RevMan 5.4 and Stata17 software were used to analyze the data of the included studies. Results: A total of 31 randomized controlled trials (RCTS) involving 2383 patients were included, covering 13 different non-drug therapies. The network meta-analysis showed that the treatment method ranked first in terms of the total effective rate, the area under the cumulative ranking curve (SUCRA) was medium-frequency pulse electrical therapy combined with conventional bladder function training (68.4%). In terms of residual urine volume, electroacupuncture combined with surface nerve stimulation combined with conventional bladder function training ranked the first (87.5%); In terms of maximum urinary flow rate, the first ranked was pelvic floor electrical stimulation and pelvic floor muscle training combined with conventional bladder function training (99.8%). In terms of average daily single urine volume, pelvic floor electrical stimulation combined with conventional bladder function training ranked first (99.9%). Conclusions: Electroacupuncture combined with surface nerve electrical stimulation combined with conventional bladder function training has the best effect in improving residual urine volume. Pelvic floor muscle electrical stimulation combined with pelvic floor muscle exercise training has the best effect in improving maximum urinary flow rate. Pelvic floor electrical stimulation combined with conventional bladder function training has the best effect in improving the average daily single urine volume. However, the number of literatures on different interventions is too small, and the quality of the included literatures is not very high, and there is publication bias. Therefore, the conclusion needs to be further verified by high-quality studies.

Condition being studied: Acupuncture, electroacupuncture and moxibustion

combined with bladder function training, pelvic floor muscle electrical stimulation, biofeedback treatment, electrical stimulation, repeated transcranial magnetic stimulation, rehabilitation training and functional training to treat neurogenic bladder after spinal cord injury.

METHODS

Search strategy: Computer search PubMed, EMbase, Web of Science, Cochrane Library, CNKI, WangFang Date, Weipu Database (VIP), the search period is from 2013 to March 20, 2023, the search is carried out by combining subject words and free words, and adjusted according to different databases. Chinese search terms are "spinal injury", "spinal cord injury", "neurogenic bladder", "moxibustion", "acupuncture", "electroacupuncture", "low-frequency electrical stimulation", "biofeedback therapy", "repetitive transcranial magnetic stimulation", "electrical stimulation", "magnetic stimulation", "low-frequency electrical stimulation" as the subject words, taking PubMed as an example, the English database search terms include: Spinal Cord Injuries, Urinary Bladder, Neurogenic, Acupuncture Therapy, low frequency electrical stimulation, repeat transcranial magnetic stimulation, Electric Stimulation Therapy, moxibustion, etc.

Participant or population: Meet the diagnostic criteria for neurogenic bladder after spinal cord injury, regardless of age, sex, and ethnicity

Intervention: The experimental group was combined with acupuncture on the basis of the control group; Joint electroacupuncture; combined moxibustion; combined with medium frequency pulsed electrotherapy; combined with lowfrequency pulsed electrical stimulation; combined pelvic floor electromyostimulation; combined with exercise training for the pelvic floor muscles; warm needles; Combined with electrical bladder stimulation; combined warm needle; Combined electroacupuncture of the surface nerve electrical stimulation; c o m b i n e d with pelvic floor electromyography and pelvic floor muscle exercise training; The control group used routine bladder function training, including intermittent catheterization, drinking schedules, or bladder function training.

Comparator: Routine rehabilitation, nursing and other routine methods.

Study designs to be included: It meets the criteria for spinal cord injury developed by the American Spinal Injury Association and the diagnostic criteria for neurogenic bladder in the Chinese Guidelines for the Diagnosis and Treatment of Urology and Andrology Diseases (2022 Edition).

Eligibility criteria: Randomised controlled trials of different non-pharmacological therapies for neurogenic bladder after spinal cord injury. Meet the diagnostic criteria for neurogenic bladder after spinal cord injury, regardless of age, sex, and ethnicity.

Information sources: CNKI, Wan fang Database, VIP database, Cochrane library, PubMed, Embase, Web of science.

Main outcome(s): Total response rate, residual urine output, maximum urine flow rate, average daily single urine output.

Quality assessment / Risk of bias analysis: The quality evaluation of the literature is based on the Cochrane Quality Assessment Tool, which mainly includes the following aspects: (1) random sequence generation; (2) allocation hiding; (3) blinding of investigators and subjects; (4) blinded assessment of study outcomes; (5) completeness of outcome data; (6) selectively report research results; (7) Other biases. Each item was assessed as "low risk", "unclear" and "high risk", and if the above seven items were fully met, it indicated that the possibility of various biases was small, if partially met, the probability of various biases was moderate, and if it was not met at all, it indicated that the risk of bias was high. Two review authors independently assessed quality and cross-checked and, if there was

disagreement with the results, a third investigator was consulted.

Strategy of data synthesis: RevMan 5.4 and Stata 17 were used for data analysis, the total effective rate in the outcome measures was dichotomous variable, odds ratio (OR) and 95% confidence interval were used for effect size analysis, residual urine output, maximum urine flow rate, and daily mean urine output were continuous variables, normalized mean difference (SMD) was used for effect size analysis, and RevMan 5.4 software was used for literature quality evaluation and direct meta-analysis. The size of heterogeneity was judged by I^2 , and when $I^2 > 50\%$ and P<0.05, the source of heterogeneity was looked for and sensitivity analysis was performed, and when there was no obvious source of heterogeneity, a random-effects model was selected, and when $l^2 \leq 50\%$ and P≥0.05, a fixed-effect model was selected. Frequency-based network metaanalysis using Stata 17 software, grid plotting, preprocessing data using network commands, plotting network evidence, inconsistency testing if a closed loop occurs, because this study formed a closed loop, caused by a three-arm study, so no consistency test was performed, efficacy ranking using the area under the cumulative ranking curve (SUCRA), funnel plotting to assess whether the included studies had publication bias and small sample effects.

Subgroup analysis: If the network evidence map shows the formation of a closed loop between different studies, the ifplot command is used to detect the inconsistency, and the inconsistency factor value and 95% credible interval of each closed loop are calculated to evaluate the degree of consistency between the direct and indirect comparisons.

Sensitivity analysis: Given that different levels of methodological quality of the trial may affect the findings, sensitivity analyses will be performed to assess the robustness of the results by excluding high-risk studies. Country(ies) involved: China.

Keywords: Spinal cord injury; Neurogenic bladder; Network meta-analysis; Acupuncture and moxibustion; Electroacupuncture.

Contributions of each author:

Author 1 - He xue. Email: hx18386239544@163.com Author 3 - ZHANG Rui. Author 4 - XU Ke. Author 5 - SUN Jiahong. Author 6 - TANG Rui. Author 7 - MA Shuang. Author 8 - YIN Cheng. Author 9 - WANG Yusong. Author 9 - Cai Guofeng. Email: hx18386239544@163.com