

Effects of electroacupuncture on patients with chronic urinary retention caused by a lower motor neuron lesion

An exploratory pilot study

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Abstract

Chronic urinary retention (CUR) is defined as a non-painful bladder that remains palpable or percussible after the patient has passed urine. Acupuncture may decrease PVR and improve bladder function in patients with neurogenic CUR. The aim of this study was to preliminarily observe the effectiveness of electroacupuncture (EA) for patients with CUR caused by a lower motor neuron lesion and to provide some therapeutic data for further study.

This study was a pilot study of 30 patients with CUR caused by a lower motor neuron lesion. Patients were treated with EA for 12 weeks with 36 sessions of EA.

Responders were defined as participants with a decline in postvoid residual urine (PVR) volume after spontaneous urination of $\geq 50\%$ from baseline. The proportion of responders, change in PVR volume from baseline after spontaneous urination, and the proportion of patients with severe difficulty with urination, who required assistance with bladder emptying and with stool retention, were measured at weeks 4, 8, and 12.

Thirty patients were included in this study, and 23 completed 12 weeks of treatment. The proportion of responders at weeks 4, 8, and 12 was 6.67%, 28%, and 43.48%, respectively. Decrease in PVR volume, compared with baseline, was significant at all assessment timepoints. The proportion of patients with severe difficulty with urination, who required assistance with bladder emptying and with stool retention, decreased after treatment.

EA is a potential treatment for improving bladder function in patients with CUR caused by a lower motor neuron lesion.

Abbreviations: AEs = adverse events, CIC = clean intermittent catheterization, CUR = chronic urinary retention, DSM = detrusor smooth muscle, EA = electroacupuncture, PVR = postvoid residual urine volume, SNS = sacral nerve stimulation.

Keywords: chronic urinary retention, electroacupuncture, lower motor neuron lesion, pilot study

1. Introduction

Chronic urinary retention (CUR) is defined as a non-painful bladder that remains palpable or percussible after the patient has passed urine.^[1] Criteria for diagnosis typically include postvoid residual urine volume (PVR) ≥ 300 mL.^[2] Neurogenic CUR may

be caused by a variety of diseases and events. Injuries to the sacral plexus, cauda equina, or sacral spinal cord, as well as pelvic floor nerve lesions after pelvic surgery and peripheral neuropathy due to diabetes^[3] generally affect lower motor neurons, resulting in detrusor underactivity, acontractile detrusor, or detrusor areflexia.^[4]

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The authors declare no competing interests.

Trial Registration: Acupuncture Clinical Trial Registry (AMCTR), www.acmctr.org, Identifier: AMCTR-IPN-18000238.

Registration date: 3th December, 2018.

The study protocol was approved by the Ethics Committee of Guang'anmen Hospital, China Academy of Chinese Medical Sciences.

Informed consent was obtained from each patient before the performance of any study-specific procedure.

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There are no exact figures on the overall prevalence of neuro-urological disorders in the general population. The prevalence of neurogenic CUR due to lower motor neuron dysfunction varies depending on lesion type.^[3] Patients with neurogenic CUR usually manifest with voiding difficulty, bladder distention, bladder without sensation, bladder dilation, and/or overflow incontinence.^[5] A large amount of residual urine may lead to complications such as hydronephrosis, renal impairment, repeated urinary tract infections, and bladder stones.^[6]

Management of CUR typically includes clean intermittent catheterization (CIC) or transurethral bladder indwelling catheterization, suprapubic cystostomy, sacral anterior root stimulation,^[7] intravesical electrostimulation.^[8] However, few well-designed studies have investigated bladder rehabilitation, and the number of drugs with demonstrated efficacy for treating detrusor underactivity is limited.^[3] The incidence of asymptomatic bacteriuria in patients with intermittent catheterization is 50%; this value rises to 100% in patients with long-term indwelling catheters.^[9] The medical device required for sacral nerve stimulation (SNS) is expensive.^[10] More studies are therefore required to explore effective and safe treatment options for neurogenic CUR.

The results of previous studies performed at our institution showed that acupuncture may decrease PVR and improve bladder function in patients with neurogenic CUR.^[11–13] The purpose of this prospective pilot study was to preliminarily observe the effectiveness of electroacupuncture (EA) for patients with CUR caused by a lower motor neuron lesion and to provide some therapeutic data for further study.

2. Methods

This study was conducted in accordance with the principles of the Declaration of Helsinki and was approved by the Ethics Committee of Guang'anmen Hospital, China, Academy of Chinese Medical Sciences. Trial registration identifier: AMCTR-IPN-18000238. Data of the results from this study will be planned to disseminate in conferences or peer-reviewed publications.

2.1. Participants

2.1.1. Inclusion criteria.

1. CUR caused by lower motor neuron damage; lower motor neuron damage caused by injury to the sacral plexus, cauda equina, and/or sacral spinal cord; pelvic floor nerve lesion after pelvic surgery; peripheral neuropathy due to diabetes.
2. Duration of disease >3 months.
3. PVR \geq 300 mL with micturition desire.
4. \geq 18 years old.
5. CIC or transurethral bladder indwelling catheterization.
6. \geq 4 weeks of treatment and \geq 1 record of assessment after treatment.
7. Signed informed consent and voluntary participation in the study.

2.1.2. Exclusion criteria.

1. Urinary retention due to bladder outlet obstruction (eg, bladder neck contracture, urethral stricture, prostate cancer, prostatic hyperplasia)
2. Urinary system tumors or stones, urinary disorder caused by lesion or injury affecting the thoracic spinal cord, cervical spinal cord, and brain.

3. Suprapubic cystostomy.
4. Severe heart, liver, kidney, mental, or coagulation disorder.
5. Previous implantation with a cardiac pacemaker, SNS electrode, pudendal nerve stimulation electrode, or bladder stimulation electrode.
6. Pregnancy or lactation.

2.1.3. Intervention. Bilateral Ciliao (BL32), Zhongliao (BL33), and Huiyang (BL35) were inserted with needles. The type of needle used depended on patient somatotype (diameter 0.30 mm, length 75 mm or diameter 0.40 mm, length 100 mm; Hwato Brand, Suzhou Medical Appliance Factory, China). Bilateral BL32 and BL33 were needled to a depth of 70–95 mm with an angle of 45° to 60° inward and downward into the second and third sacral foramen. Bilateral BL35 were needled to a depth of 60 to 70 mm, with a slightly superolateral direction, using needles (diameter 0.30 mm, length 75 mm). The electric stimulators (SDZ-V electroacupuncture apparatus, Suzhou Medical Appliance Factory, China) were transversely connected to bilateral BL32, BL33, and BL35 with a continuous 10-Hz wave (5–10 mA intensity).

For each treatment session, needles were retained for 30 minutes. The participants were treated three times a week, on alternate days, for 12 successive weeks (36 sessions in total for each patient). Basic treatment including CIC or transurethral bladder indwelling catheterization was administered, depending on the patient's condition.

2.1.4. Outcomes. The proportions of responders at weeks 4, 8, 12. Responders were defined as participants with a decrease in PVR volume after spontaneous urination of \geq 50% from baseline. Spontaneous urination was defined as urination without assisted bladder emptying (including increasing abdominal pressure or other auxiliary manual methods). The PVR volume of patients with CIC was the average value of 2 measurements, obtained in the same manner, with an interval ranging from 6 hours to 3 days. The PVR volume of patients with indwelling catheterization was measured once a month, which is usually the time interval for replacing a clean urinary catheter. Before replacing a clean urinary catheter, 500 ml normal saline would be infused into the bladder, if the patients had spontaneous urination, PVR volume was measured by abdominal ultrasound; otherwise, PVR volume was calculated as transurethral urine output after insertion of a clean catheter.

Satisfactory spontaneous urination responders were defined as participants with PVR volume \leq 100 mL, without hydroureter, hydronephrosis, and recurrent symptomatic urinary tract infection. Recurrent symptomatic urinary tract infection was defined as \geq 2 episodes of symptomatic urinary tract infection during the treatment and/or follow-up periods. Change in PVR volume after spontaneous urination was measured at weeks 4, 8, and 12, for comparison with measurements obtained at baseline.

Difficulty with urination was divided in 4 categories: none, mild, moderate, and severe. If the degree of difficulty with urination varied across assessments, the most serious degree of difficulty was recorded at weeks 4, 8, and 12.

The proportion of patients with catheterization, assisted bladder emptying, or stool retention was calculated at weeks 4, 8, and 12. The incidence of recurrent symptomatic urinary tract infection, vesical calculus, hydroureter, and/or hydronephrosis was recorded at weeks 4, 8, and 12.

2.1.5. Safety assessment. EA-related adverse events (AEs) were recorded within 24 hours of occurrence. Treatment-related AEs included pain, subcutaneous hematoma, localized infection

and pigmentation, broken needle, fainting, nausea, headache, dizziness, insomnia, vomiting, and palpitations during or after treatment.

2.2. Statistical analysis

SPSS software version 20.0 (SPSS Inc., Chicago, IL) was used for statistical analysis. All tests were 2 sided, with significance level of 0.05. Baseline characteristics of patients were evaluated with descriptive analyses. A paired-samples *t* test was used to analyze PVR volume. The Wilcoxon rank-sum test was used to analyze category data such as the degree of difficulty with urination. Fisher exact test was used to analyze the proportion of patients who needed catheterization or assistance with bladder emptying, as well as the proportion of patients with stool retention. Missing data were not imputed for outcomes analyses.

3. Results

All patients with CUR were invited to participate and screened for eligibility. A total of 55 patients with CUR visited Guang'an Men Hospital during the period from March 1, 2017 to September 30, 2018. During this period, a total of 30 patients were included in the study (after a 1-week baseline evaluation). Baseline characteristics are shown in Table 1. After baseline screening, 25 patients were excluded for the following reasons: tethered cord syndrome (2), surgery for spinal cord hemangioma (1), myelitis (2), spinal cord injury (6), suprapubic cystostomy (2), no record after treatment (4), course of disease <3 months (3), PVR volume < 300 mL (5). All patients received

≥4 weeks of treatment. Figure 1 presents a flow chart of the study.

The outcomes of this study are shown in Tables 2 and 3 and Figure 2. The proportion of responders (patients with a decline in PVR volume after spontaneous urination of ≥50% from baseline) were 6.67%, 28%, and 43.48% at week 4, week 8, and week 12, respectively. The proportion of patients with satisfactory spontaneous urination was 3.33%, 16%, and 26.09% at week 4, week 8, and week 12, respectively. The change in PVR volume from baseline at week 4, week 8, and week 12 was -189.38 ± 152.69 (CI, -270.74 to -108.02) mL, -305.63 ± 181.15 (-402.15 to -209.10) mL, and -393.75 ± 124.33 (-460.0 to -327.50) mL, respectively. The difference in PVR volume was statistically significant between baseline and week 4, week 8, and week 12, respectively ($P < .001$). Additionally, after treatment, 2/23 (8.7%) patients had no difficulty during urination, and the proportion of patients with severe difficulty with urination decreased to 5/23 (21.7%). Moreover, the proportions of patients with stool retention or requirement for assistance with bladder emptying decreased after treatment.

Three of the patients included in the study had hydronephrosis at baseline. Two of these three, as well as another patient without hydronephrosis at baseline, had hydronephrosis at weeks 4, 8, and 12. Two patients with recurrent symptomatic urinary tract infection and 1 without at baseline were found to have recurrent symptomatic urinary tract infection at weeks 4, 8, and 12. No incidence of hydroureter or vesical calculus was reported during the study period. There was no incidence of severe AEs related to EA (Table 4).

4. Discussion

CUR severely impacts individual health and quality of life.^[14] Improvement ≥50% in at least one urinary tract symptom is considered to be predictive of prognosis.^[15,16] The proportion of patients with a decline in PVR volume after spontaneous urination of ≥50% from baseline increased until the end of week 12. Incomplete bladder emptying is a serious risk factor for urinary tract infection.^[3] Moreover, catheterization negatively impacts quality of life and is associated with a high rate of urinary tract infection. Treatment for CUR seeks to improve voiding ability, to prevent recurrent urinary tract infection, and to protect renal function. The proportion of participants with PVR volume ≤100 mL, without hydroureter, hydronephrosis, and recurrent symptomatic urinary tract infection, increased after treatment. The number of patients with stool retention decreased, suggesting that EA treatment improved bowel function.

The results of this study are consistent with those reported in our previous case-series. One study included 15 patients with neurogenic urinary retention secondary to cauda equina injury.^[14] Ten of these patients recovered the capacity for self-voiding without catheterization. However, response rate (decrease in PVR volume from baseline ≥50%) was not assessed in this previous study. In a prospective randomized clinical study on the effect of SNS,^[17] 71% of patients either eliminated the need for catheterization or significantly reduced residual volumes by ≥50%, and 58% no longer needed catheterization. The response rate, 70%, was similar to that reported previously in another study.^[18] The SNS was approved by US Food and Drug Administration and is reported to be effective for relieving voiding symptoms.^[19] The rate of success, defined as improvement ≥50% in key voiding

Characteristics	Participants (n=30)
Age, mean (SD), y	46.17 (18.24)
Sex	
Male	22 (73.33)
Female	8 (26.67)
Diagnosis	
Cauda equina injury	26 (86.67)
Peripheral neuropathy due to diabetes	1 (3.33)
Sacral plexus injury	2 (6.67)
Coni medullaris injury	1 (3.33)
Course of disease (SD), mo.	5.83 (4.13)
Difficulty with urination [†] (%)	
None	0 (0)
Mild	0 (0)
Moderate	2 (6.7)
Severe	28 (93.3)
Patients with catheterization (%)	30 (100.0)
Patients with assisted bladder emptying (%)	12 (40.0)
Patients with stool retention (%)	21 (70.0)
Patients with recurrent symptomatic urinary tract infection	2 (6.67)
Patients with vesical calculus	0 (0)
Patients with hydroureter	1 (3.33)
Patients with hydronephrosis	3 (10.0)
Patients with recurrent symptomatic urinary tract infection [‡]	2 (6.67)

PVR=postvoid residual.

* Values are reported as numeral (%) unless otherwise indicated.

[†] If the degree of difficulty with urination varied across assessments, the most serious degree of difficulty was recorded.

[‡] Recurrent symptomatic urinary tract infection is defined as ≥2 episodes of symptomatic urinary tract infection during the treatment and/or follow-up.

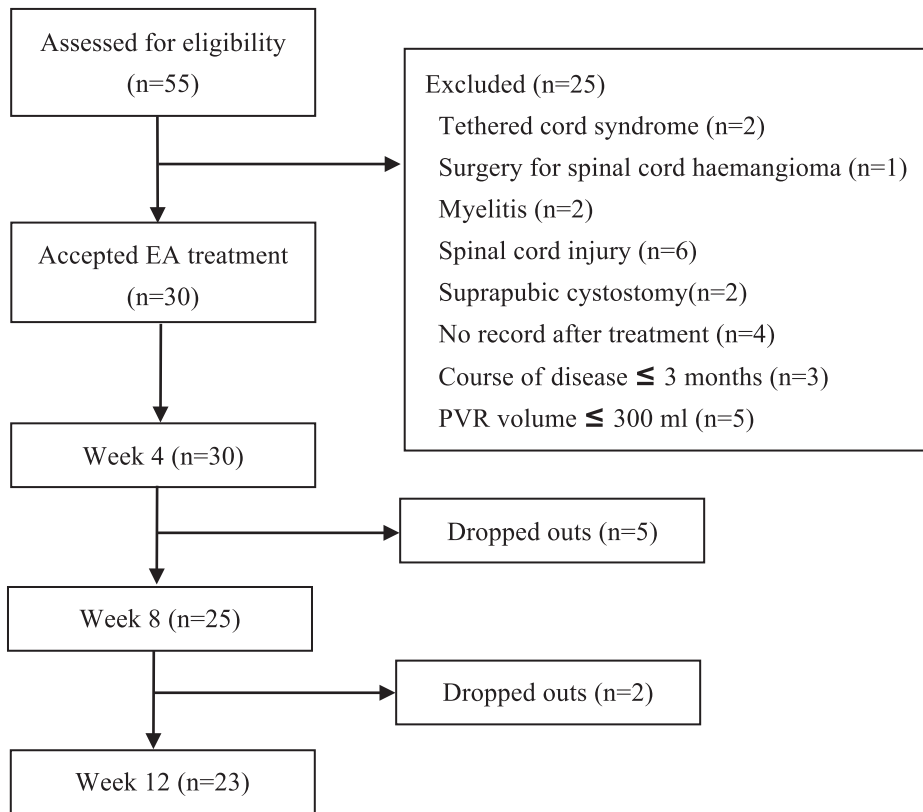


Figure 1. Flow-chart of study design.

Table 2

Outcome measures among responders.

Outcomes	Week 4 (n=30)	Week 8 (n=25)	Week 12 (n=23)
Responders (%)*	2 (6.67)	7 (28.00)	10 (43.48)
Satisfactory spontaneous urination responders† (%)	1 (3.33)	4 (16.00)	6 (26.09)

* Responders were defined as patients with a decline in postvoid residual urine (PVR) volume after spontaneous urination of $\geq 50\%$ from baseline. Spontaneous urination was defined as urination without assisted bladder emptying (including increasing abdominal pressure or other auxiliary manual methods).

† Satisfactory spontaneous urination responders were defined as participants with PVR volume ≤ 100 mL, without hydroureter, hydronephrosis, or recurrent symptomatic urinary tract infection. Recurrent symptomatic urinary tract infection is defined as ≥ 2 episodes of symptomatic urinary tract infection during the treatment and/or follow-up periods.

parameters (eg, catheterized volume per catheterization).^[20] The effect of SNS in these studies were greater than that observed in our study. However, patients with complications of technical failure, pain, or discomfort may require reoperation.^[17] In our study, PVR volume after spontaneous urination

decreased $\geq 50\%$, compared with baseline, in 43.48% of patients. After 12 weeks of EA treatment, 26.09% of patients no longer required catheterization, with PVR volume ≤ 100 mL. Although EA was not as effective as SNS, acupuncture is easy to perform, safe, and relatively inexpensive. Neuromodulation

Table 3

Degree of urination difficulty among patients.

Degree of difficulty with urination* (%)	Week 4 (n=30)	P value	Week 8 (n=25)	P value	Week 12 (n=23)	P value
None	1 (3.33)	<.001	2 (8.0)	<.001	2 (8.7)	<.001
Mild	2 (6.7)		9 (36.0)		11 (47.8)	
Moderate	9 (30.0)		6 (24.0)		5 (21.7)	
Severe	18 (60.0)		8 (32.0)		5 (21.7)	
Patients with catheterization (%)	24 (80.0)	<.001	19 (76.0)	<.001	13 (56.5)	<.001
Patients with assisted bladder emptying (%)	11 (36.7)	<.001	7 (28.0)	<.001	6 (26.1)	<.001
Patients with stool retention (%)	12 (40.0)	<.001	10 (40.0)	<.001	9 (39.1)	<.001

* If the degree of difficulty with urination varied across assessments, the most serious degree of difficulty was recorded.

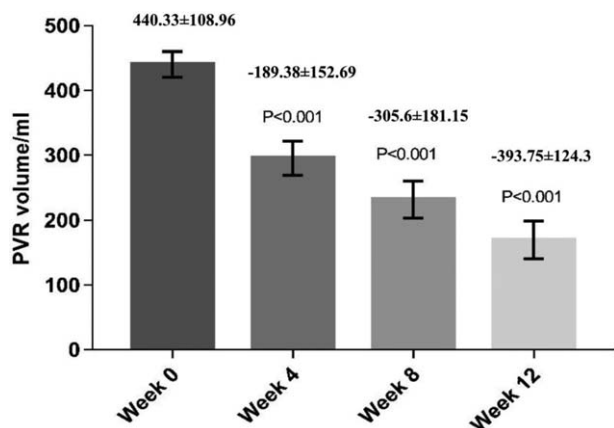


Figure 2. The change from baseline of the postvoid residual volume.

by foraminal stimulation of the sacral nerve depends on electrical stimulation of afferent axons that modulate sensory processing of the voiding reflex pathways of the central nervous system.^[17] In our previous study in a rat model,^[21] stimulation with 2-Hz EA at BL33 enhanced activity of the detrusor smooth muscle (DSM). Acupuncture at BL32 and BL33 may activate S2–3 afferent nerve fibers to promote DSM contractions. However, the underlying mechanism by which EA improves CUR requires further investigation.

5. Limitations

There are some limitations to this study. Firstly, urodynamic studies were not conducted. In further studies, adding objective outcomes such as index of urodynamic studies including value of cystometry will make assessment of the effectiveness of EA on urination function more comprehensively. Secondly, there was no follow-up assessment of EA for patients in this study. Thirdly, because the purpose of this study was to preliminarily observe the effectiveness of EA, control group was not set, however, sham control will be included in further study to evaluate the efficacy of EA. Therefore, a system for long-term assessment should be designed before conducting further studies. Thirdly, because this study was an observational study with a small sample size, spontaneous remission of the disease and anticipated/placebo effects of EA cannot be ignored. A rigorously designed randomized controlled trial will be needed to evaluate the effect of EA.

Table 4
Adverse events related to electroacupuncture *

Adverse Event	Participant, No. (%) n=30
Overall	4 (13.33)
Severe adverse events	0 (0)
Subcutaneous hematoma	1 (3.33)
Sharp pain	1 (3.33)
Localized pigmentation	2 (6.67)

* Adverse events were analyzed in all participants who received treatment. Adverse events were counted by type rather than frequency in the same participant. Multiple types of adverse events occurring in a single participant were defined as independent adverse events. An adverse event with multiple occurrences in a single participant was defined as 1 adverse event.

6. Conclusions

EA is a potential treatment for improving bladder function in patients with CUR caused by a lower motor neuron lesion. Further randomized sham-controlled studies with large sample sizes and long-term follow-up will be needed to assess the efficacy and safety of EA on CUR.

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