2019

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Is electroacupuncture effective in improving quality of life for women with urinary incontinence?

Shelby Kaminsky, PA-S

A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies
Philadelphia College of Osteopathic Medicine
Philadelphia, Pennsylvania

December 14, 2018
ABSTRACT

OBJECTIVE: The objective of this selective evidence based medicine (EBM) review is to determine whether or not “Is electroacupuncture effective in improving quality of life for women with urinary incontinence?”

STUDY DESIGN: A systematic review of 3 peer-reviewed studies published between the years of 2014 and 2017.

DATA SOURCES: Two randomized placebo-controlled studies and one comparative study evaluating if electroacupuncture (EA) and/or the use of tolterodine improves the quality of life and therapeutic effects of those with urinary incontinence (UI). Sources were selected from PubMed and Cochrane Library based off of their relevance to the clinical question and the outcomes being patient oriented.

OUTCOME(S) MEASURED: The outcomes measured depended on the study, although all were patient oriented. Quality of life was measured through The International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF), whereas evaluation of therapeutic effects and UI severity were self-reported.

RESULTS: The study conducted by Lui Z, Liu Y, Xu H, et al.,\(^1\) showed statistically significant improvement of quality of life (95% CI, p<0.001), as well as reduction of UI symptoms depicted by self-reported SUI severity (p=0.03), and evaluation of therapeutic effects (p<0.001). The study conducted by Xu H, Liu B, Wu J, et al.,\(^2\) revealed statistically significant results as well with the self-evaluation of therapeutic effect having a p-value of <0.001, and quality of life having a p-value=0.001. Lastly, the study conducted by Jin C, Zhou X, Pang R\(^3\) had a statistically significant result for quality of life (p<0.001), indicating that both groups responded to their respective treatment. At the end of week 8, there was no difference of patient-reported improvement between groups, indicating that tolterodine didn’t provide additional benefit.

CONCLUSIONS: The evidence presented in this review reveals that there is satisfactory data to conclude that EA improves the quality of life of women who have UI. This review also indicates that tolterodine doesn’t provide additional benefit of UI symptoms. Further research is warranted to evaluate symptom improvement from EA compared to traditional pelvic floor training exercises.

KEY WORDS: Electroacupuncture and urinary incontinence
INTRODUCTION

Stress Urinary Incontinence (SUI) can be defined as an involuntary loss of urine on physical exertion, sneezing or coughing.\textsuperscript{1,2} Mixed Urinary Incontinence (MUI) can be defined as involuntary loss of urine associated with urgency and also with exertion, effort, sneezing, or coughing.\textsuperscript{3}

Urinary incontinence (UI) is a common disorder and is encountered in almost every medical specialty. Around 34.4\% of American women experience MUI but in certain populations, SUI has a prevalence of around 49\%.\textsuperscript{1,3} UI causes “psychological burden, affects relationships, lowers physical productivity, and decreases quality of life in women,” making it a worthwhile topic to research and evaluate.\textsuperscript{1} This disorder is also financially taxing and requires multiple office visits. In 2007, an estimated cost of $65.9 billion was used in the treatment of overactive bladder with urge urinary incontinence (UUI).\textsuperscript{4} In 2009, an estimated 8.1 million visits were made by US women in regards to overactive bladder treatment with anticholinergic medications.\textsuperscript{5}

It is known that “continence depends on having intact micturition physiology as well as the functional ability to toilet oneself.”\textsuperscript{6} UI can be classified as stress, urge, mixed, or overflow. SUI is due to urethral hypermobility, and intrinsic sphincteric deficiency, whereas UUI is due to detrusor overactivity.\textsuperscript{6} MUI has a combination of stress and urge pathophysiology. As of now, quick and effective treatments of UI are unknown. Conservative therapies that have been used as treatment include pelvic floor muscle training, bladder training, incontinence pads, weight loss, dietary changes, and smoking cessation.\textsuperscript{7} If patients are refractory to conservative therapies, other alternatives include pessaries, topical vaginal estrogen, anticholinergic medications, or surgery.\textsuperscript{7}
Pelvic floor muscle training, also known as Kegel exercises, is a free and simple option as a first line conservative therapy for UI. Due to pelvic floor muscle training taking up to 3 months before benefit is observed, there is a need for a quicker, easier, and more effective treatment for UI.² Electroacupuncture (EA), a specialized therapeutic method in which a small electrical charge is applied to needles that are inserted into specific points,³⁸ may be used as the alternative to relieve the symptoms of UI in a timelier manner.

**OBJECTIVE**

The objective of this selective evidence based medicine (EBM) review is to determine whether or not “Is electroacupuncture effective in improving quality of life for women with urinary incontinence?”

**METHODS**

This paper evaluates two randomized, placebo-controlled studies and one comparative study assessing EA, and its benefit on UI. One of articles also evaluates the use of tolterodine, “an antimuscarinic agent that has been shown to inhibit detrusor overactivity via binding to muscarinic receptors in the detrusor smooth muscle,”³ in combination with EA. The inclusion criteria and exclusion criteria used for selection are found in Table 1.

The keywords “electroacupuncture” and “urinary incontinence” were used and sources were selected based on their relevance to the clinical question and if they included patient-oriented outcomes. The articles were written in English and published in peer-reviewed journals. The articles were found from PubMed and Cochrane Library with inclusion criteria of being published after 2008. The statistics reported included p-values, Confidence Interval (CI), Relative Benefit Increase (RBI), Absolute Benefit Increase (ABI), and Number Needed to Treat (NNT).
Table 1 - Demographics of included studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Type</th>
<th># Pts</th>
<th>Age (yrs)</th>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
<th>W/D</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liu¹</td>
<td>Randomized, Participant-blinded, sham EA-controlled Study</td>
<td>504</td>
<td>EA group: 54.5 ± 8.3 Control group: 56.2 ± 8.4</td>
<td>40-75 y/o, had SUI, and had incontinence pad weight gain &gt;1g in the 1-hr pad test</td>
<td>Urinary frequency or urgency, pad wt gain ≤1g in 1-hr pad test, UTI, hx of pelvic or UI surgery, residual urine volume of &gt;30 mL or maximal flow rates &lt;20mL/s, not 40-75 y/o, POP &gt;stage 2</td>
<td>18</td>
<td>18 sessions (over 6 weeks) of EA involving the lumbosacral region or sham EA with no skin penetration on sham acupoints</td>
</tr>
<tr>
<td>Xu²</td>
<td>Randomized, Placebo-controlled Study</td>
<td>80</td>
<td>EA group: 59.05 ± 7.91 Sham EA group: 57.97 ± 8.42</td>
<td>40-75 y/o, had SUI, visible involuntary leakage from urethra synchronous w/ increased abdominal pressure, and had an incontinence pad weight gain &gt;1g in 1-hr pad test</td>
<td>Other types of UI, UTI, hx of pelvic or UI surgery, residual urine volume of &gt;30 mL or maximal flow rates &lt;20mL/s, POP &gt;Stage 2, specialized tx for SUI, meds affecting bladder fx, pregnant, breastfeeding</td>
<td>0</td>
<td>EA in acupoints of bilateral BL33 and BL35 or sham EA 20mm lateral to acupoints BL33 and BL35 with blunt needle tips piercing adhesive pads, not piercing skin surface</td>
</tr>
<tr>
<td>Jin³</td>
<td>Comparative Study</td>
<td>71</td>
<td>EA group: 57 ± 8 Combo Therapy group: 56 ± 9</td>
<td>Female, had MUI for &gt;1 yr, recorded &gt;1 UI episode per 24 hrs in bladder diary, and &gt;2g of urine loss based on a 24-hr pad test</td>
<td>UTI, bladder obstruction, closed-angle glaucoma, IC, POP &gt;Stage 2, previous UI surgery or post-void residual volume more than 100mL.</td>
<td>0</td>
<td>EA at acupoints BL32, BL35, SP6, and ST36, 3x/wk for 8 weeks or same as first group plus tolterodine 2mg PO BID</td>
</tr>
</tbody>
</table>
OUTCOMES MEASURED


RESULTS

The study conducted by Lui Z, Liu Y, Xu H, et al., was a randomized, participant-blinded, sham EA-controlled clinical study that was conducted at 12 hospitals in China.\(^1\) In this study, 987 women were screened and 504 women were randomized into two groups via a central randomization system.\(^1\) Participants were placed into the experimental group which received EA (n=252) or the control group which received sham EA (n=252).\(^1\) Of the 504 participants to start the trial, 486 women completed the 6-week treatment, although all 504 women’s data were used in the primary analysis.\(^1\) Inclusion criteria for this trial included women who were 40-75 years old, had SUI, and an incontinence pad weight gain >1g in the 1-hr pad test; exclusion criteria can be found in Table 1. The experimental group received EA at acupoints BL 33, and BL 35, 3 times per week for 6 consecutive weeks, for a total of 18 sessions.\(^1\) The control group received sham EA using a blunt-tipped placebo needle that did not penetrate the skin.\(^1\)

The outcomes in this study included quality of life, SUI severity, and evaluation of therapeutic effects. The p-values were calculated using the Wilcoxon rank-sum test. The International Consultation on Incontinence Questionnaire-Short Form, assessed the influence of UI on quality of life during the previous 4 weeks.\(^1\) The results of this questionnaire proved that the EA group had a greater decrease from baseline over the sham EA group with between-group differences of 1.5 points (95% CI, p<0.001).\(^1\) The SUI severity was rated by participants in a 72-
hour bladder diary at baseline and at week 6 as either none, mild, medium, or severe (Table 2).

Table 2 displays that almost the equivalent amount of Sham EA Group participants rated their SUI severity the same at the end of week 6 as it was at baseline. This is in contrast to the EA Group, where there is a curtail in SUI severity based on the number of participants that classified severity at week 6 less than what it was originally at baseline. By week 6, 85.4% of participants reported at least medium help from EA.\textsuperscript{1} The p-value at the end of week 6 was 0.03, indicating that the results are statistically significant and those who received EA had higher improvement than the sham EA group.\textsuperscript{1}

**Table 2: Subjectively-based SUI severity\textsuperscript{1}**

<table>
<thead>
<tr>
<th>Severity of SUI</th>
<th>Baseline</th>
<th>Week 6</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EA Group</td>
<td>Sham EA Group</td>
</tr>
<tr>
<td>None</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>Mild</td>
<td>116</td>
<td>127</td>
</tr>
<tr>
<td>Medium</td>
<td>103</td>
<td>104</td>
</tr>
<tr>
<td>Severe</td>
<td>26</td>
<td>17</td>
</tr>
</tbody>
</table>

The participant self-evaluation of therapeutic effect data was converted to dichotomous data and can be found in Table 3. These results are statistically significant, with a p-value of <0.001, indicating that EA did improve patient’s symptoms of UI more than the Sham EA.\textsuperscript{1}

**Table 3: Treatment Effects**

<table>
<thead>
<tr>
<th>Study</th>
<th>CER</th>
<th>EER</th>
<th>RBI</th>
<th>ABI</th>
<th>NNT</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lui\textsuperscript{1} (2017)</td>
<td>70%</td>
<td>99%</td>
<td>41%</td>
<td>0.290</td>
<td>4</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

The study conducted by Xu H, Liu B, Wu J, et al. was a randomized, placebo-controlled study conducted in Guang’anmen hospital in Beijing, China.\textsuperscript{2} In this study, 181 women were assessed for eligibility and 80 were randomized into the study using a central randomization system.\textsuperscript{2} The experimental group (n=40) received EA at BL 33 and BL 35, whereas the control
group (n=40) received sham EA with blunt-tipped needles 20mm lateral to acupoints BL 33 and BL 35. Both groups were treated with 3 sessions per week on alternate days for a total of 6 weeks. Inclusion criteria for this study included women who were 40-75 years old, had SUI, visible involuntary leakage from urethra synchronous with increased abdominal pressure, and had an incontinence pad weight gain >1g in the 1-hr pad test; exclusion criteria can be found in Table 1.

The outcomes in this study included patient-reported evaluation of therapeutic effects and quality of life. The patient self-evaluation of therapeutic effect at week 6 was statistically significant, with a p-value of <0.001 when compared between groups. This data was converted to dichotomous data and can be found in Table 4. Quality of life was measured with the International Consultation on Incontinence Questionnaire-Short Form. At week 6, the median change from baseline in the EA group was 1.75 points in the questionnaire, whereas the median change from baseline for the sham EA group was 0 points in the questionnaire. These results are considered significant with the p-value between groups of 0.001.

**Table 4: Treatment Effects**

<table>
<thead>
<tr>
<th>Study</th>
<th>CER</th>
<th>EER</th>
<th>RBI</th>
<th>ABI</th>
<th>NNT</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xu (2016)</td>
<td>62.50%</td>
<td>100%</td>
<td>60%</td>
<td>0.375</td>
<td>3</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

The study conducted by Jin C, Zhou X, Pang R was a comparative study that included 71 women, recruited from Guang An Men hospital and hospital of Acupuncture and Moxibustion in China. The first group (n=34) received only EA 3 times a week for 8 weeks, whereas the second group (n=37) received EA 3 times a week for 8 weeks in addition to tolterodine 2 mg twice a day orally. The EA acupoints used were BL 32, BL 35, SP 6, and ST 36. Inclusion criteria include women who have had MUI for >1 yr, recorded >1 UI episode per 24 hrs in
bladder diary, and >2g of urine loss based on a 24-hr pad test; exclusion criteria can be found in Table 1.

The outcome in this study included patient quality of life which was measured by the International Consultation on Incontinence Questionnaire (ICIQ), as seen in Table 5. The results are statistically significant, p-value <0.001, indicating that both groups responded well to their respective treatments. Although both groups showed improvement in UI symptoms, there is no difference of patient-reported improvement between groups from baseline to week 8. This indicates that the use of tolterodine didn’t provide additional benefit in improving symptoms.

Table 5: ICIQ Score at Baseline and Post-Treatment

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Post-Treatment</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EA</td>
<td>CT</td>
<td>EA</td>
</tr>
<tr>
<td>How much does leaking urine interfere with your everyday life? (Score 0-10)</td>
<td>8</td>
<td>8</td>
<td>4</td>
</tr>
</tbody>
</table>

Abbreviations: EA, Electroacupuncture; CT, Combination Therapy

SAFETY AND TOLERABILITY

Acupuncture is a relatively well tolerated and a safe treatment method for many conditions when performed by skilled providers. The articles used had few adverse events observed during their trials. The study conducted by Lui Z, Liu Y, Xu H, et al. reported that there were four cases of subcutaneous hematomas, three cases of fatigue, one case of sharp pain, and one case of palpitations. The study conducted by Xu H, Liu B, Wu J, et al. reported there were two cases of hematomas at the needling site, three cases of persistent pain after EA, and one case of fatigue. The study conducted by Jin C, Zhou X, Pang R did not report any adverse events.


DISCUSSION

UI is a burden that many women have to face on a daily basis and although there are many non-invasive and conservative treatments available, quicker treatment options are desired. Based on the previously discussed successful results, as well as the few adverse outcomes from treatment, EA seems to be a strong and expeditious option for treating UI.

It is suggested that EA improves SUI because the pelvic floor electric stimulation may increase the maximum urethral closure pressure, as well as stimulate the pudendal nerve therefore strengthening the pelvic floor muslces.\(^1\) Xu H, Liu B, Wu J, et al. concurs that neuromodulation of the bladder is the possible mechanism as to why EA works for UI. The authors further discuss that in order to achieve the desired effect from EA, the proper acupoints must be chosen based on what anatomical parts of the body need to be stimulated. In this particular case for UI, it is imperative to target the bladder, hence why all three trials used acupoint BL 33 and BL 35. BL33 is located on the posterior branch of the S3 sacral nerve, and BL 35 is located on the pudendal nerve.\(^2\)

In order to further improve MUI symptoms, treatment must also target the cause of detrusor overactivity. The antimuscarinic medication tolterodine, has been shown to inhibit detrusor muscle activity, and has been proven to increase bladder capacity in rats.\(^3\) Although there was not a significant difference of UI symptom improvement when comparing EA vs combined therapy in this trial, the use of tolterodine has been proven to be a viable option for treatment in particular patient populations. This medication, listed on the Beers Criteria, may potentially be inappropriate to prescribe to the geriatric population due to the fact that it has anticholinergic properties.\(^9\)
LIMITATIONS

The study conducted by Lui Z, Liu Y, Xu H, et al. had multiple limitations reported in their study including the following: “the participant blinding assessment was only performed in 2 of the 12 centers; the use of fixed block randomization could not prevent bias from the prediction of treatment allocation in participants; there was no adjustment made for multiple comparisons for secondary outcomes; the 18 sessions of EA treatment over 6 weeks may be burdensome; and the EA procedures in the study can be technically challenging.”¹

The limitations of the study conducted by Xu H, Liu B, Wu J, et al. includes lack of validation on the blinding effect of the Sham EA group, which may overstate the treatment effect of the EA group, as well as the trial’s small sample size.²

The limitations of the study conducted by Jin C, Zhou X, Pang R includes lack of a parallel placebo-control group, and nonblind design.³ This study also only did a “post hoc power analysis, but not a prestudy power analysis.”³

CONCLUSION

Based on the two RCTs and the one comparative study, there is satisfactory data to conclude that EA improves the quality of life of women who have UI. Future studies should compare EA to traditional pelvic floor training exercises to determine if there is comparable benefit, and if so, what length of therapy is needed to see the similar benefit.

One flaw noted was within the first article. There were eight participants that never received EA therapy, yet their data was used in the primary analysis.¹ A second flaw noted was that the same ethnicity was used in all three trials. It would be beneficial to diversify the subjects studied, as this condition occurs across multiple ethnicities.
REFERENCES


