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Electroacupuncture for stress-related urinary incontinence in elderly women: data analysis from two randomised controlled studies

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ABSTRACT

Objective To compare the efficacy of electroacupuncture (EA) in elderly and non-elderly women with stress urinary incontinence (SUI) or stress-predominant mixed urinary incontinence (MUI).

Methods This study was a secondary analysis of two randomised controlled trials involving 252 women with SUI and 132 women with stress-predominant MUI who were treated with the same EA regimen. Elderly women were defined as those aged >60 years. The main outcome measure was the proportion of patients with ≥50% decrease in the mean 72-hour urinary incontinence episode frequency (IEF) from baseline to week 6. Overall, 1004 women were recruited in the SUI and MUI trials. In the EA group, those with urge-predominant or balanced MUI at baseline were excluded from the current study, resulting in a sample size of 384.

Results Out of 384 patients with SUI or stress-predominant MUI who were treated with EA, 371 completed the study. After 6-week treatment, the proportion of women who achieved ≥50% decrease in mean 72-hour IEF from baseline was 57.3% (51/89) in the elderly group and 60.70% (173/285) in the non-elderly group; the between-group difference was not significant (3.11%, 95% CI −9.83% to 16.05%; p=0.637). Similar outcomes were observed at weeks 4, 16 and 28. Both groups showed reduction in the 72-hour IEF, amount of urine leakage (assessed by 1-hour pad test) and International Consultation on Incontinence Questionnaire-Short Form score from baseline with no significant between-group difference. No obvious EA-related adverse events were observed during the study.

Conclusion EA may be an effective and safe alternative treatment for SUI or stress-predominant MUI in both elderly and non-elderly women. Age may not affect the treatment outcomes of acupuncture.

Trial registration numer NCT01784172, NCT02047032.

INTRODUCTION

Urinary incontinence, the involuntary loss of urine, is a common complaint in women. Stress urinary incontinence (SUI) or stress-predominant mixed urinary incontinence (MUI) is characterised by involuntary leakage of urine from the urethra on physical exertion, sneezing or coughing.[1] The reported prevalence of SUI or stress-predominant MUI ranges is from 4% to 36%.[2 3] The main pathophysiological mechanisms and treatment modalities for stress-predominant MUI are similar to those of SUI, which provides the rationale for considering these two diseases collectively.[4 5] The physical and psychological damages of patient with these clinical characteristics adversely affect the daily life of the afflicted individual; in addition, women with SUI or stress-predominant MUI are more likely than men to have a poor quality of life.[6]

Most evidence-based guidelines recommend behavioural interventions as the first-line approach for treatment of patients with SUI or stress-predominant MUI; however, these require long-term patient compliance and are difficult to perform.[7 8] Midurethral sling implantation is considered as the gold standard for treatment of patients with SUI characteristics, but postoperative pain and the risk of organ injury are some of the disadvantages of this approach.[9] There is a need to develop effective and safe non-surgical therapies for these conditions. The incidence rate of significant incontinence has been shown to increase with age.[10] Guidelines suggest older people with urinary

incontinence deserve special consideration,[11] because all types of urinary incontinence become common with age and coexist with other diseases. Studies showed that age might be related to the efficacy of these interventions. The efficacy of the elderly with SUI may be similar or poorer than the non-elderly, however, the evidence was of low quality.[12 13]

Available data suggest that acupuncture may have good effects for SUI or stress-predominant MUI. In 2017, we reported a randomised clinical trial of electroacupuncture (EA) for treatment of SUI; in 2019, we reported a randomised non-inferiority trial of EA in women with MUI, including 132 stress-predominant MUI patients.[14 15] The two trials have already demonstrated the efficacy of EA in women with SUI or stress-predominant MUI, but the influence of patients' age on the efficacy of EA remains unknown.

In consideration of the identical EA regimen in the two trials, we combined the participants in the SUI trial and stress-predominant participants in the MUI trial. The objective of this secondary analysis was to assess the effect of EA in elderly versus non-elderly women with SUI or stress-predominant MUI.

METHODS

This was a secondary post hoc analysis of two randomised clinical trials. A total of 1004 women were recruited in the SUI and MUI trials. In both the trials, participants were randomly assigned to receive EA or other treatment in a 1:1 ratio via a central randomisation system for clinical research. The participants, outcome assessors and statisticians were blinded to group allocation. The research protocols were developed and executed in accordance with the principles of the Declaration of Helsinki and were approved by institutional review board at each participating centre (see online supplementary appendix 1). The rationale and design of the two trials have been published in the respective protocols; all participants provided written informed consent prior to randomisation. Briefly, we summarise the two trials below.

The SUI trial was a multicentre, randomised, sham EA controlled trial that tested the effect of EA on urinary leakage among women with SUI. The study enrolled 504 participants at 12 Chinese hospitals between 8 October 2013 and 15 May 2015. All recruited participants were Chinese women (age: 40–75 years) with SUI who had incontinence pad weight gain >1 g in the 1-hour pad test. In the EA group, 252 participants received 18 sessions of EA (30 min per session, 3 sessions per week) over six consecutive weeks involving the lumbosacral region at bilateral Zhongliao (BL33) and Huiyang (BL35) with a continuous wave of 50 Hz and a current intensity of 1–5 mA for 30 min. Follow-up was conducted for 24 weeks after the treatment; 482 participants completed the study.

The MUI trial was conducted from 1 March 2014 to 10 October 2016. It was a randomised non-inferiority trial that assessed the effect of EA versus PFMT plus solifenacin therapy in women with MUI. Five hundred women (age range: 35–75 years) with MUI since at least 3 months were recruited; 132 stress-predominant MUI participants in the EA group received the same EA regimen as that in the SUI trial over 12 weeks with a follow-up period of 24 weeks. The observation time points and measurements in the two original trials are presented in online supplementary appendix 2.1.

We combined the EA group of the two trials in this secondary analysis. Those with urge-predominant or balanced MUI at baseline were excluded from the current study. This resulted in a sample size of 384 women. These included 92 elderly women and 292 non-elderly women as defined by WHO criteria for elderly in the Asia-Pacific region, that is, age >60 years.[16]

OUTCOME MEASURES

The main outcome was defined as the proportion of participants with ≥50% decrease in the mean 72-hour incontinence episode frequency(IEF) from baseline at week 6. Other measurements were: proportion of participants with ≥50% reduction in 72-hour IEF at weeks 4, 16 and 28; the mean change in 72-hour IEF from baseline at weeks 2, 4, 6, 8, 10, 12, 15, 16, 17, 18, 20, 24, 27, 28, 29, 30, 32 and 36; the mean change in the amount of urine leakage (AUL), as measured by the 1-hour pad test, at weeks 2, 4, 6 and 12; and the mean change in score on the validated Chinese version of the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) at weeks 4, 6, 8, 12, 16, 18, 20, 24, 28, 30, 32 and 36. The observation measurements and different observation time points including treatment and follow-up periods are detailed in online supplementary appendix 2.1. All adverse events were documented throughout the trials.

The 1-hour pad test was performed as recommended by the International Continence Society.[1] Briefly, participants were instructed to wear a preweighed pad and drink 500 mL water in 15 min. Subsequently, they were asked to perform several strenuous activities including going up and down 24 steps, standing and sitting 10 times, coughing and running. After completing the activities, the pad was reweighed to measure the amount of urinary leakage.

A 72-hour IEF was measured using the 72-hour bladder diary. Participants were instructed to record the time and frequency of urinary incontinence, the type and volume of liquid intake, and the activities that triggered the leakage.[17]

ICIQ-SF scores range from 0 (best outcomes) to 21 (worst outcomes) with 2.52 as the minimal clinically important difference. A Chinese version of ICIQ-SF was used in the study to measure the influence of urinary incontinence on the quality of life.[18]

It contained three items pertaining to the frequency, amount of leakage and overall impact on the quality of life; a fourth non-scored item was used to assess the type of incontinence.

STATISTICAL ANALYSIS

Descriptive statistics were used for demographics, baseline characteristics and safety variables. The primary efficacy variable in the intention-to-treat (ITT) population was analysed using a generalised linear model with a binomial distribution, adjusted for imbalances in baseline variables (ie, educational level, menopause, coexisting diseases, duration and 72-hour IEF). The same analyses were used to analyse the ≥50% reduction in 72-hour IEF from baseline at weeks 4, 6, 16 and 28. The general linear model, with treatment and unequally distributed baseline variables as covariates, was used for continuous outcomes (ie, 72-hour IEF, ICIQ-SF score and 1-hour AUL). Safety data were provided for descriptive purposes only. Any missing data were not imputed. All statistical tests were two sided, and p values less than 0.05 were considered indicative of statistically significant difference.

RESULTS

A total of 384 participants were enrolled in the secondary analysis and 371 participants completed the study (3 dropped out in the elderly group and 10 in the non-elderly group). There were 92 (24.0%) women in the elderly group and 292 (76.0%) in the non-elderly group. The mean age was 66.3 years old in the elderly (SD 3.8) and 50.6 years old in the non-elderly (SD 6.2). Out of 384 participants, 252 were menopausal. The mean BMI in the study population was 24.9 kg/m^2. The mean duration of SUI was 6.9 years. Baseline characteristics were similar between groups except for SUI duration, 72-hour IEF, menopausal status and educational level. These factors were adjusted for in the statistical analysis. The baseline characteristics of participants in the two groups are summarised in table 1.

The proportion of patients with ≥50% reduction in mean 72-hour IEF from baseline at week 6 was 57.3% (51/89) in the elderly group and 60.7% (173/285) in the non-elderly group; the between-group difference of 3.11% (95% CI −9.83% to 16.05%; p=0.637) was not statistically significant. Similar results were obtained with respect to the proportion of patient with ≥50% reduction in mean 72-hour IEF from baseline at weeks 4, 16 and 28 (p>0.05 for all). According to the subgroup analysis of the SUI and MUI trials, no significant between-group differences were observed at weeks 4, 6, 16 and 28 (p>0.05 for all, except p=0.043 of MUI trial at week 28). Table 2 shows the detailed results of the proportion of patients with ≥50% reduction in mean 72-hour IEF and the subgroup analysis.

The trends of change from baseline in the results of 72-hour IEF, AUL and ICIQ-SF score are shown in figure 1A–C. As can be seen from the dotted-line chart, all parameters exhibited a consistent downward

Table 1 Baseline patient characteristics

	Elderly (n=92)	Non-elderly (n=292)	Total	P value*
Age, mean (SD)	66.3 (3.79)	50.6 (6.24)	54.4 (8.84)	<0.001
BMI, mean (SD)†	25.3 (4.11)	24.7 (5.11)	24.9 (4.85)	0.577
Race, no (%)				0.708
Han	89 (96.7)	285 (97.6)	374 (97.4)	
Minority	3 (3.3)	7 (2.4)	10 (2.6)	
Educational level, no (%)				0.004
Primary education or below	33 (35.9)	119 (40.8)	152 (39.6)	
Secondary education	48 (52.2)	164 (56.2)	212 (55.2)	
Tertiary education	11 (12.0)	9 (3.1)	20 (5.2)	
Childbearing, no (%)	92 (100.0)	290 (99.3)	382 (99.5)	>0.999
Menopause, no (%)	89 (96.7)	163 (55.8)	252 (65.6)	<0.001
Coexisting diseases, no (%)‡	21 (22.8)	33 (11.3)	54 (14.1)	0.006
Duration, mean (SD) years	9.4 (8.44)	6.1 (6.11)	6.9 (6.87)	<0.001
72-hour IEF (mean)	11.6 (11.41)	8.0 (8.10)	8.8 (9.11)	<0.001
1 hour AUL (mean)	20.6 (26.98)	17.6 (22.76)	18.3 (23.84)	0.286
ICIQ-SF score (mean)§	11.4 (3.63)	10.6 (3.21)	10.8 (3.33)	0.052

*All tests were two sided. P<0.05 was considered significant.

†Calculated as weight in kilograms divided by height in metres squared.

‡Coexisting diseases include disease have no affect outcome measurements and confirm to inclusion criteria.

§ICIQ-SF scoring was additive (0–21), with higher scores indicating worse outcomes.

AUL, the amount of urine;BMI, body mass index; ICIQ-SF, International Consultation on Incontinence Questionnaire-Short Form; IEF, incontinence episode frequency.

Table 2 Proportion of patients having a 50% or greater reduction in 72-hour IEF compared with baseline at each interview point by study*

	Week 6 (main outcome)	Week 4	Week 16	Week 28
Combined trial				
Elderly (n=92)	51/89 (57.30)	32/90 (35.56)	61/89 (68.54)	65/89 (73.03)
Non-elderly (n=292)	173/285 (60.70)	123/286 (43.01)	191/282 (67.73)	198/282 (70.21)
Difference	3.11 (−9.83 to 16.05)	4.04 (−8.52 to 16.61)	−1.65 (−13.92 to 10.63)	−3.06 (−14.64 to 8.52)
P value	0.637	0.528	0.793	0.604
SUI trial				
Elderly (n=56)	38/54 (70.37)	23/54 (42.59)	39/54 (72.22)	42/54 (77.78)
Non-elderly (n=196)	124/192 (64.58)	86/192 (44.79)	118/189 (62.43)	123/189 (65.08)
Difference	−5.90 (−21.52 to 9.72)	−0.90 (−17.04 to 15.24)	−7.58 (−23.80 to 8.35)	−13.09 (−27.22 to 1.04)
P value	0.459	0.913	0.351	0.07
MUI trial				
Elderly (n=36)	13/35 (37.14)	9/36 (25.00)	22/35 (62.86)	23/35 (65.71)
Non-elderly (n=96)	49/93 (52.69)	37/94 (39.36)	73/93 (78.49)	75/93 (80.65)
Difference	15.70 (−5.71 to 37.11)	10.30 (−10.08 to 30.68)	18.14 (−1.20 to 37.49)	18.94 (0.57 to 37.30)
P value	0.151	0.322	0.066	0.043

*Data are described as number/total number of patients (%), unless otherwise indicated.
IEF, incontinence episode frequency; MUI, mixed urinary incontinence; SUI, stress urinary incontinence.

trend over time. At week 6, the mean change in the 72-hour IEF from baseline in the elderly group was −4.1 (95% CI −5.2 to −3.1), while the corresponding change in the non-elderly group was −3.9 (95% CI −4.4 to −3.3); the between-group difference in this respect (0.3, 95% CI −1.0 to 1.5; p=0.688) was not statistically significant. Similar results were observed at weeks 2, 4, 6, 8, 10, 16, 18, 20, 24, 28, 30, 32 and 36 (p>0.05 for all). With respect to the mean change in AUL from baseline at weeks 2, 4, 6, and 12, both groups showed a progressive decrease over time; the between-group differences in this respect were not statistically significant at all time points (p>0.05 for all). The mean change in ICIQ-SF score from baseline at weeks 4, 6, 8, 12, 16, 18, 20, 24, 28, 30, 32 and 36 also showed a decreasing trend in both groups; however, there was no significant between-group difference in this respect (p>0.05 at all time points). The outcome measures are detailed in online supplementary appendix 2.2.

The incidence of adverse events related to EA treatment during the treatment period was 2.17% in the elderly group and 1.37% in the non-elderly group. No serious adverse events occurred in any of the groups. Details of adverse events during the two trials are displayed in table 3.

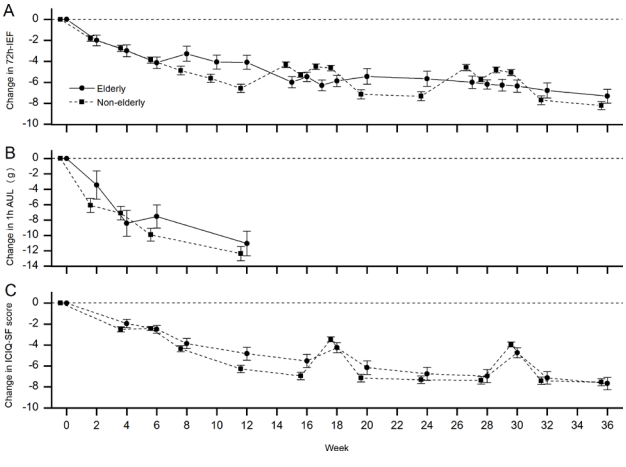

Figure 1 Changes in 72-hour IEF, 1-hour AUL and ICIQ-SF score from baseline at various time points.

AUL, amount of urine leakage; IEF, incontinence episode frequency; ICIQ-SF, International Consultation on Incontinence Questionnaire-Short Form.

DISCUSSION

In this secondary analysis, we examined the data from two randomised controlled trials of SUI or stress-predominant MUI to compare the efficacy of EA in elderly and non-elderly women. The results showed no significant difference between the proportion of patients with ≥50% reduction in mean 72-hour IEF from baseline at week 6, with elderly group of 57.3% and the non-elderly group of 60.7%. Besides, the changes from baseline to the observed weeks in 72-hour IEF, AUL and the ICIQ-SF score in the elderly and non-elderly groups all had considerable reductions, with no between-group differences. The outcomes suggest that women with SUI or stress-predominant MUI show good response to EA and that the response is not correlated with age.

The effect comparisons of surgical treatment between older and younger cohorts have been reported in previous studies. Similar conclusions were shown in a review[19]: when compared with younger

Table 3 Adverse events*†

	Elderly (n=92)	Non-elderly (n=292)
EA-related adverse events		
Overall	2 (2.17)	4 (1.37)
Fatigue	0 (0.00)	2 (0.68)
Unbearable pain	1 (1.09)	0 (0.00)
Haematoma	1 (1.09)	2 (0.68)
EA-unrelated adverse events		
Overall	27 (29.35)	45 (15.41)
Upperrespiratory infection	2 (2.17)	12 (4.11)
Pneumonia	1 (1.09)	0 (0.00)
Cold	18 (19.57)	24 (8.22)
Pharyngitis	0 (0.00)	1 (0.34)
Chronic bronchitis	2 (2.17)	0 (0.00)
Cough	0 (0.00)	1 (0.34)
Dizziness	1 (1.09)	1 (0.34)
Headache	0 (0.00)	1 (0.34)
Herpes zoster	0 (0.00)	1 (0.34)
Diarrhoea	1 (1.09)	1 (0.34)
Facial oedema	0 (0.00)	1 (0.34)
Urinary tract infection	1 (1.09)	0 (0.00)
Uterine fibroids	0 (0.00)	1 (0.34)
Knee osteoarthritis	1 (1.09)	0 (0.00)
Others	0 (0.00)	1 (0.34)

*Adverse events were analysed for all patients who received treatment and were counted by type rather than frequency in the same patient. Adverse events of different types occurring in a single patient were defined as independent adverse events. A single adverse events type with multiple occurrences in a single patient was defined as one adverse event.

†Data are reported as no (%) unless otherwise indicated.

EA, electroacupuncture.

women, elderly women have almost similar outcomes after surgery, though they may have greater associated morbidity and a longer recovery period. Some subgroup analyses of randomised controlled trials showed that the elderly had poor response to surgical treatment. A study involving 970 women with SUI who underwent tension-free vaginal tape treatment showed that the subjective cure rate in elderly women was lower than that in non-elderly women.[13] Another research of 537 women comparing retropubic to transobturator tape found that increasing age was an independent risk factor for surgery failure.[20] Results of studies in non-operative treatment on elderly women with SUI are consistent with ours. Some studies of PFMT in elderly women found that in older patients with SUI, the outcome measures were comparable to those in the younger. The effect of PFMT in patients with SUI did not seem to decrease with age.[21–23] Two randomised controlled trials of tolterodine treatment in the elderly found a similar efficacy and side effect profile to the younger.[24 25] In our study, no significant between-group differences were observed with respect to most parameters. This implies that EA may improve SUI or stress-predominant MUI in women irrespective of the age.

We defined the proportion of patients with ≥50% decrease in the mean 72-hour IEF as the main outcome measured using the bladder diary; 50% reduction in IEF can be considered as the threshold for clinical significance in the treatment of SUI.[26] After 6-week EA treatment, a high percentage of women in both groups achieved ≥50% reduction in 72-hour IEF from baseline. In addition, in both the SUI and MUI trials, we had performed subgroup analysis of patients who achieved ≥50% decrease in mean 72-hour IEF disaggregated by age. At the corresponding time points (weeks 4, 6, 16 and 28), no significant between-group differences were observed in both the trials, which is consistent with the results of the present study. After EA treatment, the proportions of patients who had achieved ≥50% reduction in 72-hour IEF from baseline at week 28 were 73.03% in the elderly group and 70.21% in the non-elderly group; the outcomes are comparable to 69.98% at the endpoint after duloxetine treatment.[27]

The consistent changes were found in 72-hour IEF from baseline to the observed weeks in both the elderly and non-elderly groups. At week 12, the change was −4.1 (−5.4 to −2.8) and −6.6 (−7.3 to −5.8), respectively. A previous study investigated the effects of a pelvic floor muscle rehabilitation programme among elderly women with SUI (age >60 years); after 12-week intervention, the 3-day leakage episodes decreased from 4.6±4.2 to 1.1±1.6 (p=0.003), which were similar to our results.[28] Changes from the baseline of the AUL were measured by 1-hour pad test, which is used to quantify urine leakage due to SUI. Both groups showed good reduction in AUL at weeks 2, 4, 6 and 12; no significant between-group differences were observed in this respect at any of the time points. In a clinical trial of pelvic floor muscle treatment, the mean decrease in AUL at week 12 was 7.9 g (SD 12.1).[29] In comparison, EA treatment showed better efficacy as the mean decrease in AUL at week 12 in our secondary analysis was −11.1 g (−14.2 to −7.9) in the elderly group and −12.4 g (−14.2 to −10.5) in the non-elderly group. We also found good reductions in the ICIQ-SF score from baseline to the observed weeks in both groups; however, there were no significant between-group differences in this respect, either. In the two age groups, the reduction was greater than −2.52 (the minimal clinically important difference) (range, −2.4 to −7.7) at most time points with the exception of week 4 in the elderly group (−2.0). These results are comparable to that reported from a previous study of clinical symptoms improvement after pelvic floor muscle exercise.[30] In our study, we observed a low incidence of adverse events, and most events were mild and transient.

Continence is maintained by bladder wall stability, an intact pelvic floor and nerve supply to the bladder,

which also requires mobility, manual dexterity and the cognitive ability to react to bladder filling.[31] Weakness of pelvic floor muscles and bladder neck is the cause of SUI.[32] Age might be an important factor that affects the treatment outcomes in women with SUI. With age, physiological changes in the lower urinary tract can have a predisposition to SUI. The changes in ageing bladder include increased collagen content, changes to gap junctions, increased space between myocytes and the sensitivity of sensory afferents changes.[33] Bladder capacity and urethral closure pressure decrease, while the postvoid residual volume and overactivity of the detrusor muscle increase, which may lead to SUI.[34] The mechanism of action of EA may involve stimulation of S3 via BL33 and that of pudendal nerve via BL35, which promotes pelvic floor muscle contraction and augments muscle strength; this may partially explain our results.[35] Our results suggest that outcomes of EA therapy in women with SUI may not be affected by age. It may be inferred that compared with other therapeutic modalities, the efficacy of EA in women with SUI may not be affected by geriatric factors.

There were several limitations in our secondary analysis. First, the two trials actually had some differences that may have affected the outcomes of this study. These included the two diseases (SUI and stress-predominant MUI) are not exactly the same; the age range of participants (SUI trial: 40–75 years; MUI trial: 35–75 years) and the duration of treatment and follow-up. Second, potential bias cannot be ruled out because the secondary analysis was not predefined during the design of the primary studies. Lastly, our study population exclusively composed of Chinese women; therefore, our findings may not be applicable to other ethnic groups.

CONCLUSION

EA may have good effects in both elderly and non-elderly women with SUI or stress-predominant MUI. The age factor may not affect the treatment outcomes. Further large-scale studies are required to provide more definitive evidence and to explore the underlying mechanisms.

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