Effectiveness and safety of acupuncture for overactive bladder: a randomised controlled trial (abridged secondary publication)

ZX Lin *, NHT Chan, YK Kwan, H Zhang, YT Chan, KYS Tam

KEY MESSAGE

Both active and sham acupuncture had a beneficial effect on improving overactive bladder symptoms. Both significantly reduced the incontinence frequency, the daytime and night urinary frequency, as well as scores of Urinary Distress Inventory, Incontinence Impact questionnaire, and Overactive Bladder Symptom Score. The treatment effects could last for at least 3 months. The night urinary frequency decreased more significantly in the active acupuncture group than in the sham control group after controlling for baseline nocturnal micturitions. Adverse effects were mild. Further research is needed to investigate the placebo effect of acupuncture for overactive bladder.

Hong Kong Med J 2022;28(Suppl 3):S45-7
HMRF project number: 13141941

[1] ZX Lin, [2] NHT Chan, [2] YK Kwan, [1] H Zhang, [1] YT Chan, [3] KYS Tam

[1] *School of Chinese Medicine, Faculty of Medicine, The Chinese University of Hong Kong*
[2] *Department of Medicine and Geriatrics, Tuen Mun Hospital*
[3] *Yan Oi Tong – The Chinese University of Hong Kong Chinese Medicine Centre for Training and Research*

* Principal applicant and corresponding author: linzx@cuhk.edu.hk

Introduction

Overactive bladder (OAB) is characterised by urgency, frequency, and nocturia and has negative impact on the quality of life of patients.[1] In Hong Kong, it is estimated that 15% of the population have OAB.[2] Treatment methods for OAB include pharmacological therapy, behavioural therapy, and physical therapy; all are largely unsatisfactory owing to the adverse effects of medication and limited efficacy of behavioural or physical therapies.[3] Acupuncture may have clinical meaningful effect on urge incontinence[4] and may improve OAB symptoms.[5] The present study aimed to determine the effectiveness and safety of acupuncture for OAB.

Methods

Patients aged 60 to 90 years who were diagnosed with OAB and were able to complete the 3-day voiding diary, Urinary Distress Inventory (UDI-6), Incontinence Impact questionnaire (IIQ-7), and Overactive Bladder Symptom Score (OABSS) were invited to participate. Those were excluded who had OAB symptoms caused by stroke or spinal injury, life-threatening infection, unconsciousness or severe cognition deficits, dementia caused by Alzheimer disease or other neurodegenerative diseases, previous incontinence surgery, short-term active diuretic treatment or diuretic medication, previous acupuncture for OAB within 2 months, pregnancy, or diseases such as untreated urinary tract infection, urogenital tumours, prostate tumour, benign prostatic hyperplasia, or chronic urinary retention.

Participants were randomly assigned to active or sham acupuncture for OAB. Treatments were administered twice per week for 8 consecutive weeks by registered Chinese medicine practitioners with ≥3 years of clinical experience. The active acupuncture group received a standardised 30-minute acupuncture session, in addition to standard care. Based on traditional Chinese medicine theory, the pathogenesis of OAB symptoms is mainly attributed to insecurity of kidney qi (腎氣不固).[6] The following acupuncture points were used: BL32 (Ciliao 次髎) [bilateral], BL33 (Zhongliao 中髎) [bilateral], BL40 (Weizhong 委中) [bilateral], BL23 (Shenshu 腎俞) [bilateral], SP6 (Sanyinjiao 三陰交) [bilateral], KI3 (Taixi 太溪) [bilateral], BL28 (Pangguangshu 膀胱俞) [bilateral], CV4 (Guanyuan 關元), and CV 3 (Zhongji 中極). The sham acupuncture group received sham acupuncture treatment in the same acupuncture points using blunt needles, with no penetration through the skin.

The primary outcome measure was the reduction in the frequency of incontinence episodes[3] as derived from the 3-day voiding diary. Secondary outcome measures included the scores of IIQ-7, UDI-6, and OABSS, as well as the level of nerve growth factor (NGF), which is a biologic marker related to OAB symptoms, at the baseline, week 8, and week 20. Adverse events were also recorded.

Between-group differences were tested by the independent *t* test for continuous data, the Chi-square test for frequency data, or the Mann-Whitney *U* test for incontinence episodes. The generalised linear model was used to compare primary and

secondary outcomes between two groups after controlling baseline night urine frequency. All tests were two-sided. A P value of <0.05 was considered statistically significant.

Results

A total of 55 female and 45 male patients (mean age, 68.5 years) with OAB were recruited between June 2016 and September 2019 through post advertisement. They were randomly assigned to received active acupuncture (n=51) or sham acupuncture (n=49). Two participants in each group withdrew from the study. The two groups were comparable in terms of baseline characteristics, except that the mean number of nocturnal micturitions was higher in the active acupuncture group than in the sham acupuncture group (8.08±4.66 vs 5.73±3.54).

In both groups, incontinence frequency and daytime and night urinary frequency decreased significantly after treatment and at follow-ups. The decrease in the night urinary frequency was greater in the active acupuncture group than in the sham acupuncture group after controlling for baseline nocturnal micturitions (P=0.0288). However, between-group differences in the decrease in incontinence frequency and daytime urinary frequency were not significant after controlling for baseline nocturnal micturitions.

Scores of IIQ-7, UDI-6, and OABSS decreased significantly after treatment and at follow-up in both groups, but there was no significant difference between groups. The level of NGF in urine samples was too low to be measured. Two patients reported mild adverse reactions such as mild uncomfortable feeling towards acupuncture treatment and skin allergic to the adhesive tape.

Discussion

Our study suggests a beneficial effect of acupuncture on improving OAB symptoms (in terms of reduction of the incontinence frequency and the daytime and night urinary frequency). The effect could last for at least 3 months. Active acupuncture achieved more pronounced improvement in the night urinary frequency than sham acupuncture did. The reduction in OAB symptoms was largely attributable to the acupuncture treatment. Nonetheless, sham acupuncture also produced treatment effect. Sham acupuncture can produce about 33% to 56% placebo effect for patients with OAB.[3,7] We applied sham acupuncture needles to the true acupuncture points. It is plausible that the sham acupuncture could elicit treatment effects. In addition, the possible specific acupuncture treatment effect may be too small to be differentiated from the placebo effect. OAB is a chronic disease with fluctuating symptoms affected by lifestyle, diet (alcohol and caffeine intake), mood, and sex (especially those with natural delivery of baby). It is difficult to measure all variables in the clinical trial. All these confounding factors render it difficult to test the effectiveness of acupuncture for the treatment of OAB.

This study has limitations. Like all acupuncture trials, it is difficult to keep the patients blinded to their treatment group, especially when the needles were on the acupuncture points for 30 minutes. Some patients had received previous acupuncture treatment for other disorders. The concentration of the NGF in the urine samples was too low to measure. In future trial, different sham acupuncture design that presses blunt needles outside true acupuncture points can be used. Those with no prior experience in acupuncture can be recruited. Objective outcome measures should be used to minimise the expectation of the acupuncture treatment.

Conclusions

Acupuncture treatment (both active and sham needling) could decrease the OAB symptoms in terms of the incontinence frequency and the daytime and night urinary frequency. Active acupuncture resulted in more significant improvement in night urinary frequency than sham acupuncture. Acupuncture may be a safe treatment option for patients with OAB.

Acknowledgements

We thank Mr Chun-Kam Lee, Mr Kit Ngan, Miss Lai Mei Kwan for conducting the acupuncture treatments and outcome assessments, Prof Lisa Xian for assisting in performing NGF experiments, and Prof Yuanqi Guo for advice on acupuncture techniques.

Funding

This study was supported by the Health and Medical Research Fund, Food and Health Bureau, Hong Kong SAR Government (#13141941). The full report is available from the Health and Medical Research Fund website (https://rfs1.fhb.gov.hk/index.html).

Disclosure

The results of this research have been previously published in:

1. Chan YT, Zhang HW, Guo YQ, et al. Effectiveness and safety of acupuncture for elderly overactive bladder population in Hong Kong: study protocol for a randomized controlled trial. Trials 2018;19:376.
2. Lin ZX, Chan NHT, Kwan YK, et al. A randomized controlled trial to assess the effectiveness and safety of acupuncture for overactive bladder: a study in Hong Kong population. Chin Med 2020;15:108.

References

1. Wang L, Wang L, Shi G, et al. Efficacy and safety of ginger-salt-indirect moxibustion for urge urinary incontinence after stroke: protocol for a pilot multicenter randomised controlled trial. BMJ Open 2014;4:e006326.
2. Siu JY. The illness experiences of women with overactive bladder in Hong Kong. Qual Health Res 2014;24:801-10.
3. Emmons SL, Otto L. Acupuncture for overactive bladder: a randomized controlled trial. Obstet Gynecol 2005;106:138-43.
4. Engberg S, Cohen S, Sereika SM. The efficacy of acupuncture in treating urge and mixed incontinence in women: a pilot study. J Wound Ostomy Continence Nurs 2009;36:661-70.
5. Kitakoji H, Terasaki T, Honjo H, et al. Effect of acupuncture on the overactive bladder [in Japanese]. Nihon Hinyokika Gakkai Zasshi 1995;86:1514-9.
6. World Health Organization Western Pacific Region. WHO international standard terminologies on traditional medicine in the western pacific region. Available from: http://myweb.polyu.edu.hk/~hswhocc/resource/PCH/WHOIST_traditional_medicine.pdf. Accessed 6 February 2015.
7. Dincer F, Linde K. Sham interventions in randomized clinical trials of acupuncture: a review. Complement Ther Med 2003;11:235-42.