

## Effect of external treatment of traditional Chinese medicine in elderly patients with nocturia: a Meta-analysis

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**ADMINISTRATIVE INFORMATION****Support** - This meta-analysis did not receive any financial support.**Review Stage at time of this submission** - Completed but not published.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY2024110026**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 6 November 2024 and was last updated on 6 November 2024.**INTRODUCTION**

**Review question / Objective** To evaluate the effect and value of traditional Chinese medicine external treatment (TCMET) in elderly patients with nocturia.

**Condition being studied** Nocturia is a condition that causes people to "wake up to pee at night." It is often clinically classified as nocturia when the amount of nocturnal urine produced surpasses one-third of the daily average or when there are more than two episodes each night. According to studies, nocturia affects roughly two-thirds of middle-aged and older people. Nocturia incidence and prevalence might change depending on the diagnostic criteria and the patient's location. The incidence is often observed to increase with age, and in the two age categories over 60 and over 80 years old, respectively, the incidence is 70% and 80%. In Shanghai, China, there was a 36.4% frequency of nocturia, with 47.4% men and 52.6% women. According to a study by Tikkinen et al., the

prevalence of nocturia in Finnish people aged 18 to 79 years was 12% in men and 13% in women when voiding at least twice a night was the diagnostic criterion for nocturia rather than 37% in men and 43% in women when voiding at least once a night was the diagnostic criterion for nocturia. According to Wang et al. research findings, 57.5% of patients over 18 had a nocturnal voiding frequency of once and 24.7% had a nocturnal voiding frequency of twice. According to research by Wen et al., males who used at least two voids each night as the diagnostic standard for nocturia had a prevalence of nocturia of 30.8% in mainland Chinese women. Hence, nocturia has a vast patient population and has affected many people.

Although there are many patients with nocturia, the aetiology of nocturia has not yet been clarified, and the current aetiology of nocturia is roughly classified as physiological and pathological[8]. Physiological conditions are mainly psychological factors, environmental factors, and bad living habits; pathological conditions are mainly kidney

and bladder diseases, hypertension, diabetes, and other factors. Nocturia harms patients' health and can seriously interfere with the patient's nocturnal sleep, causing fatigue, weakness, memory loss, and other accompanying symptoms, affecting the quality of daily life. In more severe cases, there may be anxiety and depression in patients. Western medicine or surgery is primarily used in clinical treatment. Although the types of western medicine that can be selected are diverse, most have the characteristics of a long course of treatment and side effects, thus affecting patients' compliance with treatment. A unique Chinese medicine method can effectively avoid Western medicine's limitations in China. Traditional Chinese medicine (TCM) has an exceptional understanding of the aetiology and pathogenesis of senile nocturia, and the treatment methods are diverse. TCM believes that the kidney dominates the water, and voiding function requires normal transpiration and gasification of the kidney yang. At the same time, the elderly mostly show kidney yang deficiency failure syndrome, resulting in the loss of kidney opening and closing function and increased nocturia. Traditional Chinese medicine external treatment(TCMET) is a characteristic therapy with multiple treatment modalities, such as acupuncture, acupuncture, and acupoint application of traditional Chinese medicine. While some research has reported on the clinical effectiveness of TCMET in the treatment of nocturia, a high-level evidence-based medical evidence demonstration has yet to be made. Using a meta-analysis, this research further proved the effectiveness and safety of TCMET in patients with nocturia.

## METHODS

**Participant or population** The subjects in the literature have been diagnosed with nocturia, diagnostic criteria: nocturnal urine volume of more than 1/3 of the total daily urine volume or nocturia frequency  $\geq 2$  times the disease.

**Intervention** The intervention measures are traditional Chinese medicine external treatment(TCMET), mainly including acupuncture, acupuncture, external application of traditional Chinese medicine, auricular point pressing bean therapy, and massage.

**Comparator** Control group: the presence or absence of the control group is not limited. If there is a control group, the control group must be conventional western medicine treatment or conventional care and can not be traditional Chinese medicine treatment or other ETTTCM.

**Study designs to be included** Randomized controlled trials (RCTs) and Non-RCTs.

**Eligibility criteria** Inclusion criteria (1) The subjects in the literature have been diagnosed with nocturia, diagnostic criteria: nocturnal urine volume of more than 1/3 of the total daily urine volume or nocturia frequency  $\geq 2$  times the disease. No restrictions were imposed on the sex, age, race, and disease duration of the study subjects. (2) The intervention measures are traditional Chinese medicine external treatment(TCMET), mainly including acupuncture, acupuncture, external application of traditional Chinese medicine, auricular point pressing bean therapy, and massage. (3) Control group: the presence or absence of the control group is not limited. If there is a control group, the control group must be conventional western medicine treatment or conventional care and can not be traditional Chinese medicine treatment or other ETTTCM. (4) Outcome measures were: Times of nocturia, Pittsburgh sleep quality index (PSQI) scale score and overall response rate. PSQI scores were assessed by the Pittsburgh Sleep Quality Index of Buysse Dj et al., a site sleep expert, to evaluate the subjects' sleep quality [9]. Criteria for efficacy: (a) clinical cure: frequency of nocturnal urination  $\leq 1$ ; (b) markedly effective: frequency of nocturnal urination reduced by more than 50%; (c) effective: frequency of nocturnal urination reduced by 25% to 50%; (d) ineffective: no significant improvement or even aggravation of symptoms. Exclusion Criteria: (1) Unable to extract relevant study data. (2) Small sample study with a sample size of less than 10 in the test or control group. (3) Low-quality literature. (4) Exclude non-English literature and non-Chinese literature. (5) The same clinical study is published in multiple publications to be the most complete and up-to-date. (6) Case reports, literature reviews, systematic reviews, letters, and duplicate publications. (7) Basic medical research (cell and animal experiments).

**Information sources** A total of 7 databases were searched, including PubMed, Embase, Cochrane Library, Chinese National Knowledge Infrastructure (CNKI), Chinese Biomedical Literature Database (CBM), VIP Chinese Science and Technology Journal Full-text Database (VP-CSJFD), and Wanfang database.

**Main outcome(s)** Outcome measures were: Times of nocturia, Pittsburgh sleep quality index (PSQI) scale score and overall response rate. PSQI scores were assessed by the Pittsburgh Sleep Quality Index of Buysse Dj et al., a site sleep expert, to evaluate the subjects' sleep quality. Criteria for efficacy: (a) clinical cure: frequency of nocturnal

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urination  $\leq 1$ ; (b) markedly effective: frequency of nocturnal urination reduced by more than 50%; (c) effective: frequency of nocturnal urination reduced by 25% to 50%; (d) ineffective: no significant improvement or even aggravation of symptoms.

**Quality assessment / Risk of bias analysis** The quality of the non-randomized trial literature was assessed using the Methodological Index for Non-randomized Studies (Minors) score scale. A rating of greater than 12 points served as the benchmark for the research. The quality of the literature for randomized controlled trials was assessed using a modified Jadad scale. A study was deemed poor if it received fewer than or equal to 3 points and of excellent quality if it received more than 3 points.

**Strategy of data synthesis** Stata 17.0 software was used in this meta-analysis to analyze the literature data statistically. For studies without a control group, single-arm meta-analysis combined the response rate after TCMET treatment, with effect size (ES) as the effect index (reflecting the incidence of specific events). For studies with a control group, relative risk (RR) was used as the effect index (the ratio of the response treatment group's risk to that of the control group), and weight mean difference (WMD) and standard mean difference (SMD) were used to express continuous variable data. A 95% confidence interval (CI) was also provided. For the included studies, a test for heterogeneity was conducted. A fixed effect model was employed for the combined analysis if there was no heterogeneity across the included studies ( $P > 0.1$  and  $I^2 < 50\%$ ); otherwise, a random effect model was used.

**Subgroup analysis** Subgroup was employed to cope with clinical heterogeneity when it was substantial, and  $P < 0.05$  was considered significant.

**Sensitivity analysis** Sensitivity analysis was employed to cope with clinical heterogeneity when it was substantial, and  $P < 0.05$  was considered significant.

**Country(ies) involved** China.

**Keywords** External treatment of traditional Chinese medicine; Nocturia; Pittsburgh sleep quality index; Response rate.

#### **Contributions of each author**

Author 1 - Jinhua Geng.

Author 2 - Chunyan Ruan.

Author 3 - Qiaoli Lin.