

INPLASY PROTOCOL

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Conflicts of interest:

None declared.

Vaginal electrical stimulation for overactive bladder syndrome in women: a systematic review and meta-analysis

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Review question / Objective: To evaluate the efficacy and safety of vaginal electrical stimulation (VES) for the treatment of overactive bladder (OAB) syndrome in women.

Condition being studied: Meta-analyses of electrical stimulation for OAB include percutaneous tibial nerve stimulation (PTNS) and sacral neuromodulation (SNM), both of which can improve voiding diary. To date, there is no meta-analysis of VES for OAB. Women suffer from OAB more than men, and this trend is more pronounced with ageso this study aimed to evaluate the efficacy and safety of vaginal electrical stimulation (VES) for the treatment of overactive bladder (OAB) syndrome in women.

Eligibility criteria: (1) type of study: RCT (2) type of participants: people (age ≥ 18 years) who were clearly diagnosed with non-idiopathic or idiopathic OAB according to the diagnostic criteria (3) (3) type of study: outlined in American Urological Association or according to the patient's symptoms of frequency, urgency and urge incontinence (3) type of intervention: studies should utilize either VES alone or VES in combination with other therapies (medications, pelvic floor muscle training (PMFT), bladder training (BT), Biofeedback, sham vaginal electrical stimulation).

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 April 2022 and was last updated on 31 May 2022 (registration number INPLASY202240074).

INTRODUCTION

Review question / Objective: To evaluate the efficacy and safety of vaginal electrical stimulation (VES) for the treatment of overactive bladder (OAB) syndrome in women.

Rationale: Electrical stimulation for overactive bladder becomes a new treatment.

Condition being studied: Electrical stimulation is mainly divided into

transcutaneous tibial electrical stimulation, Pudendal Neuromodulation, and transvaginal electrical stimulation. A meta-analysis of transcutaneous electrical tibial stimulation for the treatment of OAB has been demonstrated, and this study aimed to explore the safety and efficacy of transvaginal electrical stimulation for the treatment of OAB.

METHODS

Search strategy: #1 (Overactive bladder [MeSH Terms]) OR (Overactive Bladder OR Overactive Urinary Bladder OR Overactive Detrusor OR Overactive Detrusor Function OR Bladder Overactivity OR Detrusor Overactivity OR Urinary Incontinence OR Urgency OR Urgency Urinary Incontinence OR Urgent Incontinence OR Urinary Urge Incontinence) #2Vaginal electrical stimulation OR VES OR Intravaginal Electrical Stimulation OR IVES OR Vaginal Electrotherapy OR Transvaginal Electrical Stimulation
#3 #1 AND #2.

Participant or population: Patients with oab.

Intervention: studies should utilize either VES alone or VES in combination with other therapies (medications, pelvic floor muscle training (PMFT), bladder training (BT), Biofeedback, sham vaginal electrical stimulation).

Comparator: other therapies such as medications, pelvic floor muscle training (PMFT), bladder training (BT), Biofeedback, sham vaginal electrical stimulation.

Study designs to be included: RCT only.

Eligibility criteria: (1) type of study: RCT (2) type of participants: people (age ≥ 18 years) who were clearly diagnosed with non-idiopathic or idiopathic OAB according to the diagnostic criteria (3) (3) type of study: outlined in American Urological Association or according to the patient's symptoms of frequency, urgency and urge incontinence (3) type of intervention: studies should utilize either VES alone or

VES in combination with other therapies (medications, pelvic floor muscle training (PMFT), bladder training (BT), Biofeedback, sham vaginal electrical stimulation).

Information sources: PubMed, Embase, Scopus, Web of science, Cochrane, CNKI, VIP database, Wan Fang database, CBM.

Main outcome(s): Voiding diary.

Additional outcome(s): QOL; Side effect.

Data management: Data were extracted and checked by two reviewers (Dexing Wang, Xu Zou) independently according to a predesigned dataset. When difference arose, they were resolved through discussion, and if opinions differed, an arbitrator (Jin Yu) was consulted for a decision. When conducting a multi-arm study, data from groups that met the inclusion criteria were analyzed and the sample size for other groups were not calculated when calculating the total sample size.

Quality assessment / Risk of bias analysis: Risk of bias within studies were assessed independently by two reviewers (Jia Peng Huang, De Xin Wang) using Cochrane Risk of Bias Tool. 3 risk assessments, namely high risk (red), low risk (green), and unclear (yellow) will be selected according to the criteria for assessing risk of bias. The following study characteristics were extracted: Random sequence generation (selection bias), Allocation concealment (selection bias), Blinding of participants and personnel (performance bias), Blinding of outcome assessment (detection bias), Incomplete data (attrition bias), selective reporting (reporting bias) and Other bias. When difference arose, they were resolved through discussion, and if opinions differed, an arbitrator (Jin Yu) was consulted for a decision.

Strategy of data synthesis: Meta-analysis was performed using REVMAN 5.4 software. Continuous variables were calculated using a mean difference (MD)

and the corresponding 95% confidence interval (CIs). Dichotomous variables were computed using a relative risk (OR) and the corresponding 95% CIs. Statistical heterogeneity among studies for each outcome was estimated using a standard χ^2 test and the I² test ($p > 0.1$, I² 50% indicated significant heterogeneity, and a random effects model would be used).

Subgroup analysis: No.

Sensitivity analysis: To test the robustness of the review conclusions, a sensitivity analysis will be performed for the primary outcome according to the following criteria: sample size, heterogeneity quality and statistical model (random-effects or fixed-effects model).

Language: English and Chinese or other language which can be translated to English.

Country(ies) involved: China.

Other relevant information: TSA, Publication bias and GRADED evidence will be included.

Keywords: vaginal electrical stimulation, overactive bladder, meta-analysis.

Dissemination plans: Through peer-review and academic journal.

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