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Comparison of nonimplantable electrical stimulation in women with urinary incontinence: a systematic review and network meta-analysis of randomized controlled trials

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This study examined the effectiveness of various electrical stimulation methods in alleviating symptoms and enhancing the quality of life for women with urinary incontinence. We conducted a systematic search of PubMed, Cochrane Library, PEDro, EMBASE, and ClinicalTrials.gov from inception to August 2024. Randomized controlled trials (RCTs) that meet following criteria were included, urinary continence in women, using various electric stimulation treatments and evaluated outcomes related to symptoms, quality of life. Thirty RCTs were subjected to risk of bias assessment, certainty of evidence, and network meta-analysis. Statistical analysis was performed using a random-effects model, with continuous variables expressed as standardized mean difference (SMD) and 95% confidence interval (CI). Percutaneous tibial stimulation (SMD −1.86, 95% CI −2.77 to −0.96) and intravaginal stimulation (SMD −0.97, 95% CI −1.55 to −0.38) significantly reduced symptom severity. Additionally, percutaneous tibial, intravaginal, transcutaneous tibial, and trans-sacral stimulations improved quality of life. Percutaneous tibial stimulation was the most effective, followed by intravaginal stimulation. Despite moderate to low confidence in the evidence, large-scale RCTs are needed to evaluate long-term benefits of these treatment.

Keywords Electric stimulation, Network meta-analysis, Systematic review, Urinary incontinence.

Urinary incontinence is a chronic condition that imposes burden on the quality of life of women. According to updated prevalence estimates for the period from 2015 to 2018 in the United States, over 60% of community-dwelling adult women experienced some form of urinary incontinence; this proportion is higher than that reported previously[1]. Population aging, obesity, parity, smoking, diabetes, and hysterectomy are potential risk factors for urinary incontinence[2]. Untreated urinary incontinence can lead to various problems, such as difficulties in maintaining employment, participating in social interactions, and preserving personal independence, and thus, has negative effects on both physical and psychological well-being[3].

Several nonsurgical interventions have been reported for managing urinary incontinence, including behavioral therapy, pelvic floor exercises, anticholinergic and antimuscarinic drug use, and electrical stimulation. These conservative approaches are typically used as first- and second-line therapies[4]. Various methods of electrical stimulation have been employed in treatment, including the transcutaneous tibial approach, intravaginal devices, and electrical needle placement at the sacral or tibial nerve. These approaches are simple, minimally

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invasive, safe, and contribute to improved patient compliance and decreased symptom-related discomfort. If the conservative treatments are ineffective, several surgical procedures can address the problems that cause urinary incontinence, including sling procedures, bladder neck suspension, or artificial urinary sphincter. Regarding interventions, several systematic reviews have already compared different options regarding their efficacy, safety and even long-term outcomes[5–7].

To date, no comprehensive evidence has indicated the method that yields the most effective outcomes in terms of alleviating urinary incontinence symptoms and improving women's quality of life. Therefore, the research question for this review was as follows: Among existing electrical stimulation methods, which provides the clinical favorable outcomes for improving symptoms of urinary incontinence in women?

Methods

This network meta-analysis was prospectively registered in the International Prospective Register of Systematic Reviews (PROSPERO; registration number: CRD42023438144). Our protocol adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) extension statement for network meta-analysis[8].

Eligibility criteria

We selected randomized controlled trials (RCTs) that evaluated women with urinary incontinence that are stress, urge, mixed, or overflow. The intervention group received various electrical stimulation treatments, such as existing technique, electroacupuncture, intravaginal stimulation, pelvic floor stimulation, percutaneous tibial stimulation, trans-sacral stimulation, transcutaneous tibial stimulation and so on, while a control group employed a sham device or a conventional approach, such as lifestyle modification or Kegel exercise. Included studies were required to evaluate outcomes related to symptoms, quality of life, or other relevant parameters.

We excluded studies that patients were under bladder dysfunction caused by nervous system conditions, such as spinal cord injury or central nervous system tumor, cerebral palsy, Parkinson's disease, cauda equina syndrome. Studies that were not peer-reviewed, such as reference papers and letters to the editor, presented only study protocols, or that did not evaluate symptoms or quality of life as study outcomes were excluded.

Search strategy

We searched for relevant studies published in PubMed, Cochrane Library, PEDro, EMBASE and ClinicalTrials.gov databases from their inception to August 31, 2024. The following keywords and their combinations were employed for the search: ((electric* AND stimula*) OR neuromodula* OR electroacupun*) AND (woman OR women OR female))) AND (urin* OR incontinen* OR bladder) NOT (fecal). The search filters of the databases were used to identify RCTs if applicable. We used "randomized controlled trial" in PubMed and EMBASE, and "trial" in Cochrane Library and PEDro. No language restrictions were applied. We used a translation tool to evaluate if the study was suitable for our review. All of the data included in our studies were from the full text. If the data is unavailable, we contacted the authors for requesting detailed data. If we did not receive a response from them, the studies then were excluded from quantitative analysis.

Study selection

The retrieved RCTs were imported into EndNote X9 software. After duplicate entries were identified and removed through manual screening, 2 authors independently screened the studies on the basis of their titles and abstracts in accordance with the inclusion criteria. Subsequently, we reviewed the full text and determined the eligibility of the remaining studies. Any discrepancies were resolved through discussion with a third reviewer.

Data extraction

The following parameters were obtained from each RCT: mean age, number of participants in each arm, electrical protocols used in different groups, treatment duration, outcome measurements, and inclusion/exclusion criteria. We contacted authors through email to obtain missing outcome data if needed.

Outcome measures

Our primary outcome measure was the severity of urinary incontinence symptoms. We considered urination frequency recorded in the bladder diary as indicative of symptom severity. When data from a bladder diary were not available, another outcome related to incontinence severity was used. If daily frequency is not available in the included studies, we used daytime frequency, nocturia times, or incontinence episodes in order instead. If there were no above-mentioned parameters available in the studies, we substituted them with scores in the questionnaire that evaluated symptom severity into our quantitative test.

The secondary outcome was patient-reported improvements in quality of life. In the network meta-analysis, we included only trials employing questionnaires that encompassed composite measures to examine the effect of incontinence on daily life or overall well-being. We calculated the difference in scores between post-intervention and baseline to assess the degree of quality of life improvement. Commonly-used questionnaires in assessing quality of were the Incontinence Impact Questionnaire, Short Form (IIQ-7), the Overactive Bladder Quality of Life Short-form Questionnaire (OAB-q SF), the Incontinence Quality of Life Questionnaire and the King's Health Questionnaire (KHQ) throughout the included studies. If multiple questionnaires were used in a trial, we considered the one most frequently employed across the trials in our meta-analysis.

For our network meta-analysis, we extracted data only for the measures of highest priority in each study. If trials reported data at multiple time points for the same outcome, we used only data corresponding to the longest follow-up duration.

We examined the risk of bias by using the Cochrane risk-of-bias tool (version 2.0), which is used to assess the quality of RCTs[9]. Besides, certainty of evidence was examined using the Grading of Recommendations, Assessment, Development, and Evaluation approach[10]. This approach involves assessing the certainty of evidence derived from the included RCTs on the basis of their study design, risk of bias, inconsistency, imprecision, indirectness, publication bias, and effect sizes. Assessment was compared by 2 independent reviewers. Disagreements were resolved through discussion and consultation with a third author.

Statistical analysis

Network meta-analysis is performed to simultaneously compare 3 or more interventions. This approach combines both direct and indirect estimates, creating a network of studies. Network meta-analysis enables the estimation of the relative effects of any pair of interventions, and the yielded estimates are more precise than any single direct or indirect estimate. Moreover, network meta-analysis allows for ranking and estimating the hierarchy of interventions. We performed network meta-analysis by using the ShinyNMA Version 1.01 website (https://jerryljw.shinyapps.io/ShinyNMA_/). ShinyNMA synthesizes results and provides a rationale for choosing R software (version 4.1.0) and specific packages, namely metafor (version 2.4-0), netmeta (version 1.3-0), or BUGSnet (version 1.0–4).

We used continuous data by changing baseline measurements. The transitivity assumption underlying network meta-analysis was evaluated by examining the distribution of clinical and methodological variables that can serve as effect modifiers across treatment comparisons[11]. A random-effects model was used. We conducted a head-to-head comparison by calculating the standard mean difference (SMD) and 95% confidence interval (CI). For assessing treatment efficacy ranking, we used the *P* score averaged over all competing treatments[12]. Inconsistency in the network meta-analysis was evaluated using loop-specific heterogeneity and local incoherence estimates and by comparing differences in the effect sizes between standard meta-analyses (direct comparisons) and indirect comparisons[11]. If inconsistencies were present, we performed sensitivity analysis by removing one study at a time to determine whether the absence of any particular study substantially altered the results.

Results

Study selection

A search of the electronic databases yielded 1881 articles. Among these, 778 were removed due to duplication, and 708 were excluded after screening their titles and abstracts. The full texts of the remaining 395 trials were examined, several were excluded for various reasons: unavailability of the full text; nonrandomized study design; noncompliance with the eligibility criteria; or being a review article, conference paper, study protocol, secondary analysis, reply article, or thesis.

Among the 39 articles that met the eligibility criteria, 9 were excluded because of the unavailability of data related to primary or secondary outcomes. Although we attempted to contact authors for data[13,14], we did not receive responses from them[15–21]. Finally, 30 RCTs were included in the quantitative analysis. Figure 1 presents a PRISMA flow diagram of the study selection strategy[8].

Study characteristics

In the 30 selected RCTs, interventions were categorized as transcutaneous tibial stimulation, percutaneous tibial stimulation, trans-sacral stimulation, intravaginal stimulation, pelvic floor stimulation, and electroacupuncture. Conventional training or sham devices were prespecified as a control or placebo group. Most of the studies employed a 2-arm comparison design, except that Ahmed et al.[22], Correia et al.[23], Falcão Padilha et al.[24], and Sonmez et al.[25] incorporated a 3-arm comparison design and Firinci et al.[26] allocated the population into 4 groups. The main characteristics and inclusion/exclusion criteria of the 30 RCTs are described in Supplementary Table S1 online[22–51].

Risk of bias of included studies

Findings regarding the risk of bias of the included studies are presented in Supplementary Table S2 online. Most of the studies had a low risk of bias in terms of the randomization process, but 6 studies had some concerns[27,28,32,46,47,51]. In terms of deviation from the intended intervention, 3 studies exhibited some concerns[28,38,48], and 3 other studies in that from the intervention adherence[39,41,51]. For missing outcome data, 4 studies had some concerns[32,38,39,44], and 2 studies exhibited a high risk of bias[28,31]; the remaining studies displayed low risk. Nearly all the studies exhibited some concerns in outcome measurement, with patient-reported data making this an intrinsic and unavoidable limitation. With the exception of one study[43], all the other studies exhibited a low risk of bias in the selection of reported results.

Certainty of evidence

Supplementary Table S3 online presents the evidence profile obtained using the GRADE method. When each intervention was compared with the placebo group, the majority of the studies exhibited a moderate level of certainty in terms of outcomes related to symptom severity and quality of life. However, some interventions yielded evidence with a low level of certainty. This was particularly the case for quality of life when comparing between transcutaneous tibial stimulation and placebo and for symptom severity when comparing between trans-sacral stimulation and placebo, between intravaginal stimulation and placebo, and between pelvic floor stimulation and placebo. The certainty of evidence in these instances was mainly reduced due to the presence of a high risk of bias. The importance of the findings was ranked high across all the comparisons.

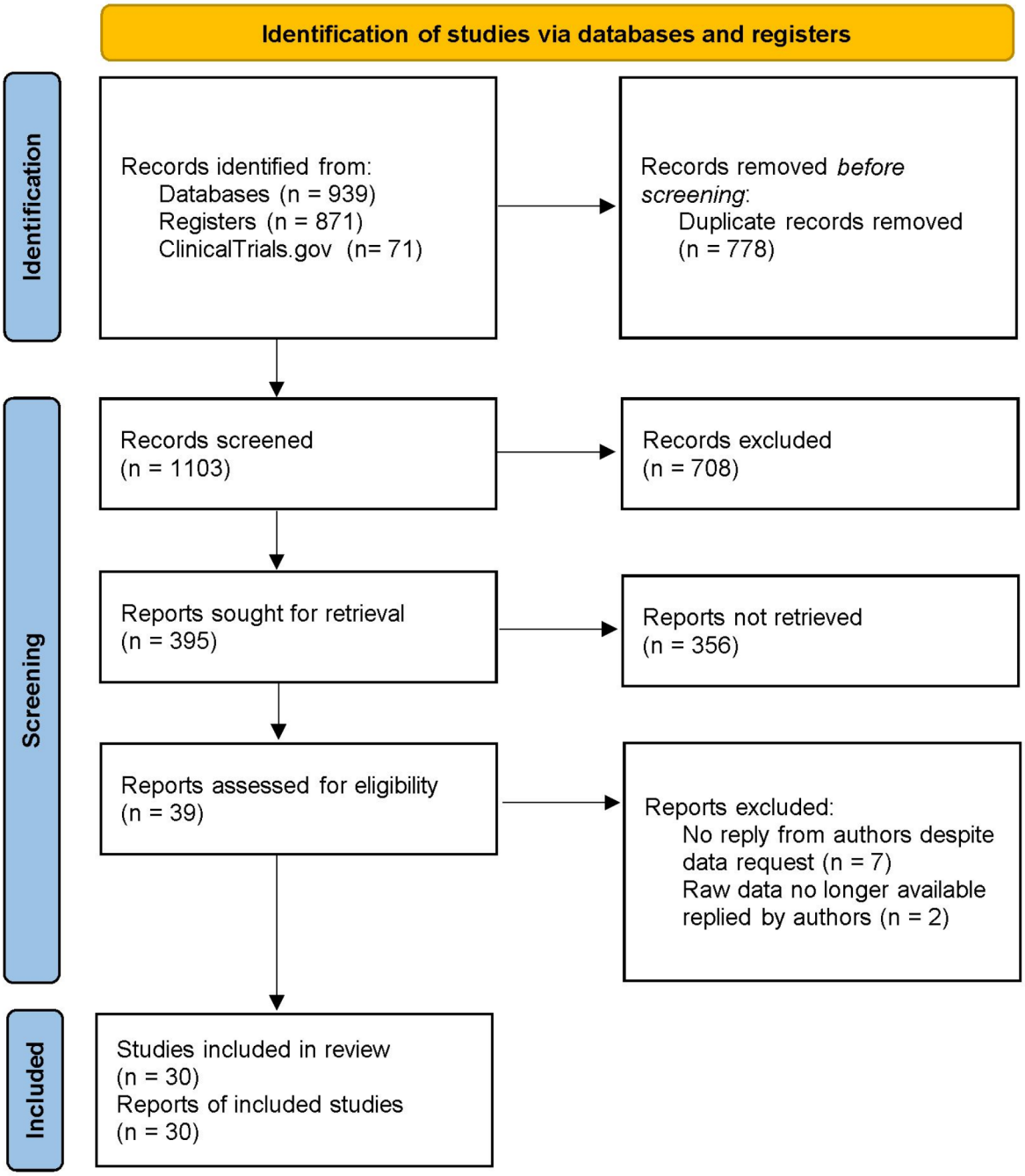

Fig. 1. PRISMA flow diagram for study selection strategy.

Synthesis of results: network meta-analysis of symptom severity

Our network meta-analysis included 2447 participants across 30 RCTs. Figure 2a presents a network diagram of the included trials for each intervention with respect to symptom severity. At least one placebo-controlled trial was included for each intervention. Figure 3a presents the forest plots of multiple interventions compared with the placebo group in relation to symptom severity. The pooled SMDs and 95% CIs in the network meta-analysis revealed that percutaneous tibial stimulation and intravaginal stimulation led to significant improvement in symptom severity compared with the control intervention. However, electroacupuncture, pelvic floor stimulation, transcutaneous tibial stimulation, and trans-sacral stimulation did not exhibit significant differences.

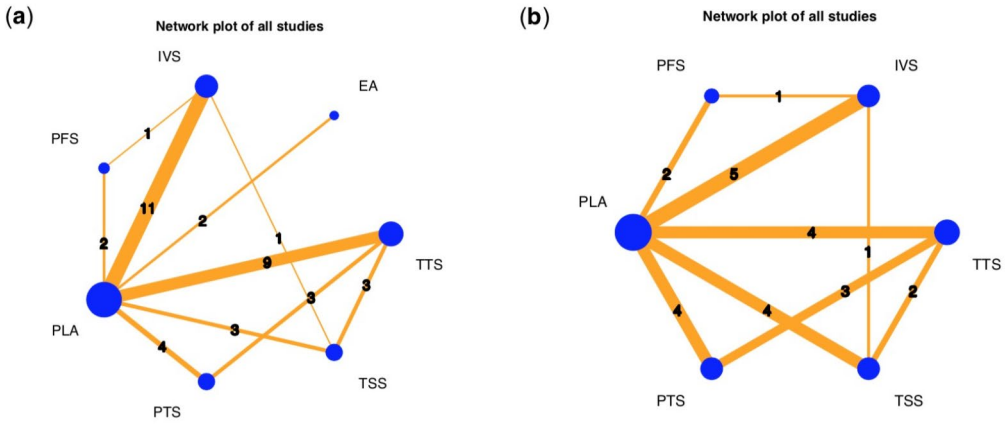

Fig. 2. Network plot of studies examining (**a**) symptom severity and (**b**) quality of life. Node size (blue circle) is proportional to the number of trials evaluating that intervention, and yellow lines indicate the number of comparisons between each treatment. EA, electroacupuncture; IVS, intravaginal stimulation; PFS, pelvic floor stimulation; PLA, control/placebo group; PTS, percutaneous tibial stimulation; TSS, trans-sacral stimulation; TTS, transcutaneous tibial stimulation.

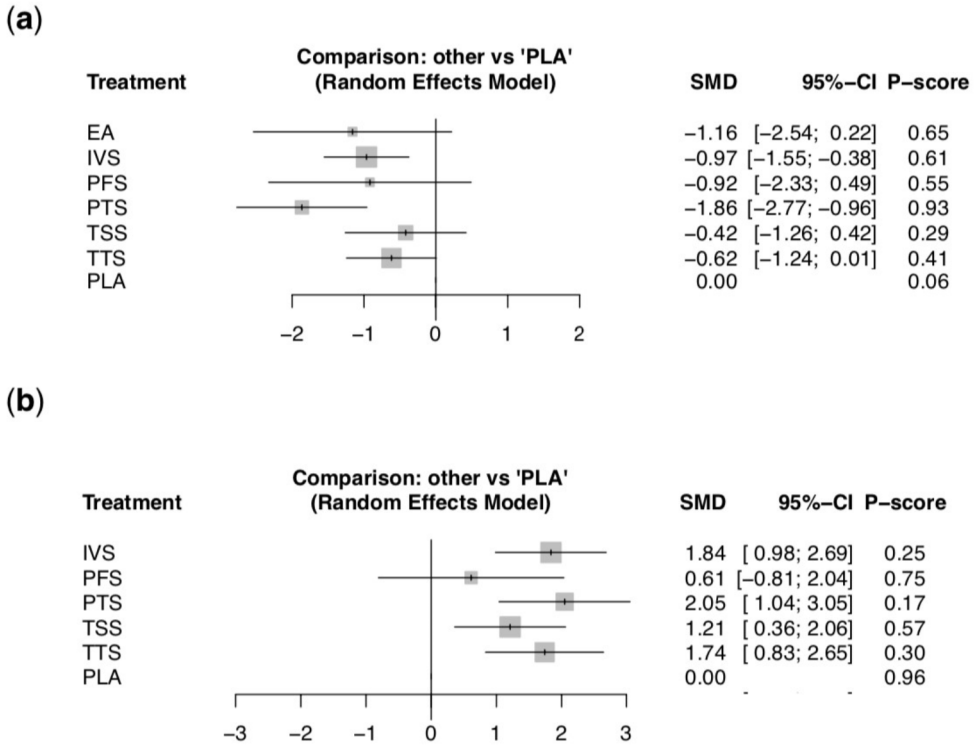

Fig. 3. Forest plot of (**a**) symptom severity and (**b**) quality of life. EA, electroacupuncture; IVS, intravaginal stimulation; PFS, pelvic floor stimulation; PLA, control/placebo group; PTS, percutaneous tibial stimulation; TSS, trans-sacral stimulation; TTS, transcutaneous tibial stimulation.

We synthesized head-to-head studies to determine differences among stimulation interventions. Table 1 presents the results of the pairwise meta-analysis of interventions for improvement in symptom severity. Figure 4a illustrates the distribution of probability rankings for each intervention. The results revealed that percutaneous tibial stimulation was the most effective intervention, followed by electroacupuncture, intravaginal stimulation, pelvic floor stimulation, transcutaneous tibial stimulation, trans-sacral stimulation, and control interventions.

(a) Symptom severity						
PTS	NA	NA	NA	−0.84 [−2.02–0.34]	NA	−2.06 [−3.10- −1.02]
−0.70 [−2.35–0.95]	**EA**	NA	NA	NA	NA	−1.16 [−2.54 − 0.22]
−0.90 [−1.97 − 0.18]	−0.20 [−1.70–1.31]	**IVS**	0.26 [−1.81–2.32]	NA	−0.06 [−2.02–1.90]	−1.02 [−1.63-−0.40]
−0.95 [−2.62–0.73]	−0.24 [−2.21–1.73]	−0.05 [−1.50–1.41]	**PFS**	NA	NA	−0.77 [−2.29–0.75]
−1.25[−2.18-−0.31]	−0.54 [−2.06–0.97]	−0.35 [−1.19–0.50]	−0.30 [−1.84–1.24]	**TTS**	−0.19 [−1.35–0.97]	−0.69 [−1.38- 0.00]
−1.44 [−2.62- −0.27]	−0.74 [−2.36–0.88]	−0.54 [−1.51 − 0.42]	−0.50 [−2.13–1.13]	−0.20 [−1.07–0.68]	**TSS**	−0.22 [−1.37–0.94]
−1.86 [−2.77- −0.96]	−1.16 [−2.54 − 0.22]	−0.97 [−1.55- −0.38]	−0.92 [−2.33–0.49]	−0.62 [−1.24 − 0.01]	−0.42 [−1.26–0.42]	**PLA**

(b) Quality of life.					
PLA	−0.54 [−2.30–1.21]	−0.91 [−2.10–0.27]	−2.24 [−3.45- −1.03]	−2.07 [−3.15- −0.98]	−2.35 [−3.57- −1.12]
−0.59 [−2.23–1.05]	**PFS**	NA	NA	−0.62 [−3.03–1.79]	NA
−1.10 [−2.09- −0.12]	−0.51 [−2.40–1.37]	**TSS**	−0.07 [−1.73–1.60]	−0.11 [−2.43–2.20]	NA
−1.35 [−2.37- −0.33]	−0.76 [−2.68–1.16]	−0.25 [−1.45–0.96]	**TTS**	NA	−1.58 [−2.98- −0.19]
−1.82 [−2.81- −0.83]	−1.23 [−2.98 − 0.52]	−0.72 [−1.99 − 0.55]	−0.47 [−1.85–0.91]	**IVS**	NA
−2.62 [−3.72- −1.51]	−2.02 [−4.00- −0.05]	−1.51 [−2.91- −0.11]	−1.26 [−2.44- −0.09]	−0.79 [−2.26–0.68]	**PTS**

Table 1. Network meta-analysis results of each intervention. Data are expressed as the standardized mean difference [95% confidence interval]. Significant results are in underscored. The upper part is pair-wised meta-analysis for symptom severity for 6 kinds of electric stimulation methods and placebo. The lower part is pair-wised meta-analysis for assessing quality of life for 5 kinds of electric stimulation methods. 'NA' means data not applicable. EA, electroacupuncture; IVS, intravaginal stimulation; PFS, pelvic floor stimulation; PLA, control/placebo group; PTS, percutaneous tibial stimulation; TSS, trans-sacral stimulation; TTS, transcutaneous tibial stimulation.

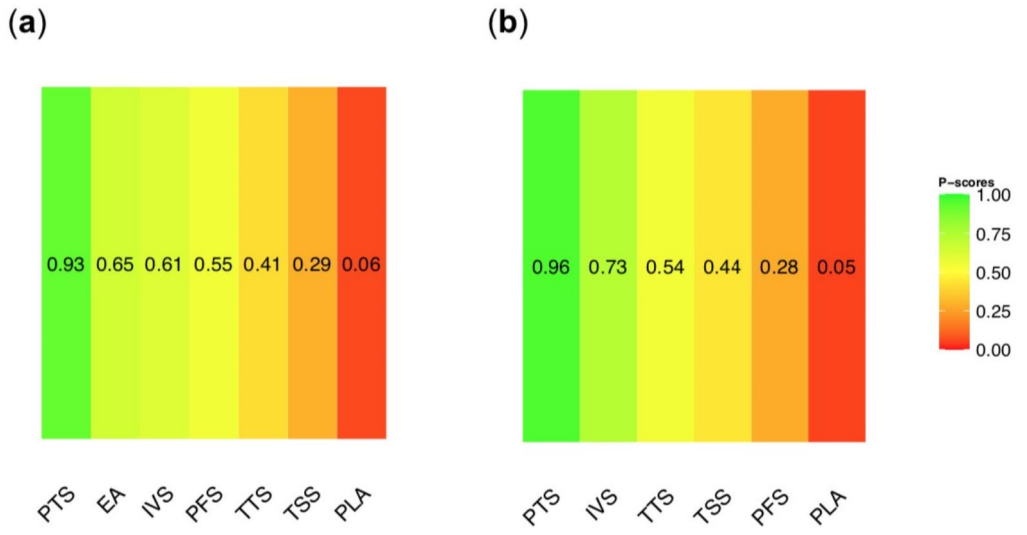

Fig. 4. Distribution of probability rankings for each electrical approach in terms of (**a**) symptom severity and (**b**) quality of life. EA, electroacupuncture; IVS, intravaginal stimulation; PFS, pelvic floor stimulation; PLA, control/placebo group; PTS, percutaneous tibial stimulation; TSS, trans-sacral stimulation; TTS, transcutaneous tibial stimulation.

The network plot exhibited the formation of several loops (Fig. 2a), and the loop-specific heterogeneity revealed no significant inconsistencies between direct and indirect comparisons (Supplementary Table S4 online).

Synthesis of results: network meta-analysis of quality of life

Figure 2b presents another network plot for each intervention concerning quality of life, except for electroacupuncture, which did not have outcomes related to quality of life. The pooled SMDs and 95% CIs in the network meta-analysis revealed that nearly all the interventions, with the exception of pelvic floor stimulation, significantly improved the quality of life compared with the control intervention. Figure 3b presents the forest

plots of multiple interventions compared with the placebo group in terms of quality of life. The distribution of probability rankings revealed that percutaneous tibial stimulation was the most effective, followed by intravaginal stimulation, transcutaneous tibial stimulation, trans-sacral stimulation, and pelvic floor stimulation (Fig. 4b). The network plot depicted the formation of several loops (Fig. 2b). The loop-specific heterogeneity indicated significant local inconsistencies in the comparison between transcutaneous tibial stimulation and placebo ($P = .008$, Supplementary Table S5 online). Thus, we conducted sensitivity analysis and determined that after removing the study conducted by Zonić-Imamović et al.[51], who included transcutaneous and percutaneous tibial stimulation as interventions, the inconsistency in the comparison between transcutaneous tibial stimulation and placebo was corrected (Supplementary Table S6 online). Sensitivity analysis indicated that the results of the network meta-analysis were reliable. The significance of the comparisons between all interventions and placebo and the order of probability rankings remained consistent even after the sensitivity test.

Adverse events

None of the 39 included RCTs explicitly reported severe adverse events in the intervention groups. Few adverse effects were observed, and most of them were related to device-related discomfort or local tenderness[32], vaginal irritation[26,45,49], and bleeding/discomfort at the needle site[16,33,37]. The interventions were generally relatively safe and well tolerated by participants.

Discussion

Main finding

This is the first network meta-analysis of RCTs to investigate the effectiveness of different nonimplantable electrical stimulation approaches in women with urinary incontinence. Our findings revealed that percutaneous tibial stimulation and intravaginal stimulation led to improvement in symptom severity and that nearly all types of stimulation, except pelvic floor stimulation, exerted a positive effect on the quality of life. No severe adverse effects were reported. However, the certainty of the evidence for each intervention compared with placebo ranged from moderate to low.

Strengths and limitations

This study has several strengths. First, this is the first network meta-analysis to compare the efficacy of various electrical stimulation approaches. Therefore, we can provide evidence-based recommendations that can guide clinicians in daily practice. Second, we included 30 RCTs enrolling 2447 participants, which provided adequate data for quantitative analysis. Third, we included 6 types of electrical stimulation approaches and placebo treatments in our comparisons. Thus, our findings provide valuable insights into the advantages and disadvantages of different approaches.

This study also has several limitations. First, the number of included articles was uneven for every intervention. Particularly, those focusing on electroacupuncture and pelvic floor stimulation were relatively small. Second, different intervention protocols, follow-up durations, and participant characteristics may have introduced variability into the transitivity of the network meta-analysis, warranting caution when extrapolating results to other patient groups. Third, the use of self-reported outcomes introduces an unavoidable risk of bias in quantitative studies. To overcome this limitation, we used another grading system to evaluate the certainty and importance of the included studies.

Interpretation

Percutaneous tibial stimulation was determined to be the most effective method in our findings. Nonetheless, some disadvantages have been described. Percutaneous tibial stimulation is a slightly invasive method that requires individuals to visit a medical facility for therapy. In addition, for managing overactive bladder and preventing symptom recurrence, repeat treatments of percutaneous tibial stimulation have been proposed[52]. This may raise concerns regarding the inconvenience of frequent visits to a medical facility instead of being able to undergo the treatment at home.

A discrepancy between direct and indirect estimates concerning the quality of life was observed in the comparison of transcutaneous tibial stimulation versus placebo (Supplementary Table S5 online). After excluding one trial, we noted correction of this inconsistency. Overactive Bladder Questionnaire short form is a specific questionnaire with 2 subscales used to assess the symptoms and quality of life of patients with urinary disorders. The percutaneous tibial stimulation group demonstrated more improvement on the quality of life subscale than did the transcutaneous tibial stimulation group when comparing scores before and after the intervention, as reported by Zonić-Imamović et al.[51] Other studies[22,48,50] that also used the OAB-q-SF quality of life subscale observed improvement either within groups or between groups from baseline to endpoint. However, the magnitude of improvement was not as pronounced as that observed in Zonić-Imamović et al. The differences can be attributed to study design. Although the protocols for electrical stimulation used in these 4 studies did not differ substantially, the participants in Zonić-Imamović et al. received transcutaneous tibial stimulation at home, but percutaneous tibial stimulation was applied by an operator. Whether the variance in this study was influenced by examiners or access to medical instruction remains unclear.

A review including both RCTs and non-RCTs indicated the effectiveness of electroacupuncture for women with stress urinary incontinence[53]. Additionally, a Chinese observational study observed a decline in urine leakage following electroacupuncture treatment[54]. The only RCT with a large number of participants included in our study also demonstrated a significant decrease in urine leakage after a 6-month electroacupuncture intervention. However, the difference in the SMD between this intervention and placebo was not significant. Besides, the absence of closed loops in the network and being the only one focused on electroacupuncture may have contributed to this result. Further research is needed to understand the long-term effects.

Intravaginal stimulation was primarily employed in the context of stress urinary incontinence[55]. Despite its effectiveness in both symptom severity and quality of life improvement in our study, some disadvantages, such as discomfort, the need for probe sterilization, and the risk of vaginal and urinary infection were reported[45,56]. Thus, an alternative, less invasive approach that is more comfortable for users is necessary.

For clinical concerns, percutaneous tibial stimulation might be the preferred option to relieve symptom as well as maintain quality of life. Intravaginal stimulation could be an alternative that can be performed at home, however, invasiveness would still be a problem. For less invasive, both trans-sacral stimulation and transcutaneous tibial stimulation can be considered to improve quality of life although they are less effective in symptoms relief compared to others. As for pelvic floor stimulation and electroacupuncture, their effect on urinary incontinence showed less beneficial than those of the other treatments.

Conclusion

The current evidence suggests that percutaneous tibial stimulation is the most effective approach for improving symptom severity and quality of life. This finding highlights the possibility of considering percutaneous tibial stimulation as a preferred option in the future. However, large-scale RCTs are warranted to determine the benefits, long-term effects, cost-effectiveness and application on different patient groups of all electrical stimulation interventions.

Data availability

Te datasets generated during and analyzed during the current study are available from the corresponding authoron reasonable request.

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Author contributions

T-YY and C-YY conceptualized and designed the study and drafted the manuscript. H-CC critically revised the manuscript for intellectual content. T-YY conducted a comprehensive search for articles that met the eligibility criteria. T-YY and C-YY extracted the relevant data and assessed the quality of the selected trials. RE and T-HL provided statistical expertise, analyzed and interpreted the data. C-WW and H-CC contributed equally to this

study.

Declarations

Competing interests
The authors declare no competing interests.

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