INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Meta-analysis of the efficacy of transcutaneous electrical stimulation in the treatment of obstructive sleep apnea

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Review question / Objective: **To evaluate the effect of transcutaneous electrical stimulation (TES) on patients with obstructive sleep apnea (OSA).**
Eligibility criteria: **Studies met the following inclusion criteria were included: (i) patients should be diagnosed with OSA; (ii) patients who receive TES due to OSA will be included in the experimental group; (iii) human randomized controlled trials (ACT); therefore, excluded Case reports, in vitro experiments and animal studies. If multiple studies report overlapping data, the most comprehensive one is included in the meta-analysis. If only the abstract is available, the corresponding author of the abstract will be contacted via email to obtain the original data. If we cannot reach the author after sending the email at least 3 times, the record will be discarded.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 November 2021 and was last updated on 24 November 2021 (registration number INPLASY2021110092).

INTRODUCTION

Review question / Objective: **To evaluate the effect of transcutaneous electrical stimulation (TES) on patients with obstructive sleep apnea (OSA).**

Condition being studied: **Obstructive sleep apnea is characterized by repeated upper airway collapse during sleep, resulting in airflow restriction or complete cessation. Untreated OSA can lead to long-term cardiovascular complications, such as hypertension, coronary artery disease, and heart failure. It can also reduce the quality**

of life of patients due to excessive daytime sleepiness and neurocognitive impairment. With the increase in obesity, the prevalence of OSA has steadily increased. Therefore, how to effectively treat OSA has always been the direction of clinical efforts. Continuous positive airway pressure is currently the first-line method for the treatment of moderate to severe OSA, which can effectively reduce the risk of death and improve the quality of life of patients, but the long-term compliance is not high. Other treatments include ear, nose, and throat surgery, behavioral changes, oral appliances, and neuromuscular electrical stimulation. Electrical stimulation can contract the genioglossus muscle, which is the upper airway dilator, and move the tongue forward, thereby expanding the glossopharyngeal airway and keeping the upper airway unobstructed. Among them, transcutaneous electrical stimulation (TES) is a non-invasive method in which stimulation electrodes are attached to the submental skin. Compared with other electrical stimulations, patients tolerate TES better, but there are differences in efficacy between different studies.

METHODS

Participant or population: Diagnosed as obstructive sleep apnea.

Intervention: The patients who accept TES for OSA would be included by experimental group; the types of TES equipment and the applicated location will not be restricted.

Comparator: Self-control before stimulus.

Study designs to be included: (1) Double-blind or single-blind randomized trial; (2) Double-blind or single-blind controlled trial; (3) Prospective observational study; (4) With more than 5 eligible patients.

Eligibility criteria: Studies met the following inclusion criteria were included: (i) patients should be diagnosed with OSA; (ii) patients who receive TES due to OSA will be included in the experimental group; (iii) human randomized controlled trials (ACT); therefore, excluded Case reports, in vitro experiments and animal studies. If multiple studies report overlapping data, the most comprehensive one is included in the meta-analysis. If only the abstract is available, the corresponding author of the abstract will be contacted via email to obtain the original data. If we cannot reach the author after sending the email at least 3 times, the record will be discarded.

Information sources: We searched 5 databases including PubMed, Cochrane Library, Web of Science, CNKI, Wanfang Data, etc., and the deadline for retrieval was October 2021.We screened the eligible research literature and extracted data according to the inclusion and exclusion criteria that we have formulated.

Main outcome(s): The apnea hypopnea index (AHI), average oxygen saturation (SaO2), the lowest oxygen saturation (LSAT) and oxygen desaturation index (ODI) before and after treatment are included.

Quality assessment / Risk of bias analysis: The risk of bias for each selected trial was performed by two independent reviewers using the Cochrane Collaboration 's tool. Disagreements were resolved by discussion or consulting the third reviewer. We used the following six separate criteria: (1) random sequence generation; (2) Allocation concealment; (3)Blinding (performance bias and detection bias); (4) Incomplete outcome data; (5) Selective reporting; (6) Other bias. Particularly, we used the Grades Profiler as the Grading of Recommendation, Assessment, Development, and Evaluation (GRADE) system to grading the quality of the evidence.

Strategy of data synthesis: We used the Review Manager software V.5.3 to carry out statistical analysis. If there was no statistical heterogeneity among the results, a fixed effects model would be used for meta analysis. Otherwise, the heterogeneity source would be further analyzed and a random-effects model would be used for meta-analysis after excluding the effects of significant clinical

heterogeneity. But when there was significant clinical heterogeneity, we used subgroup analysis or sensitivity analysis, or only descriptive analysis.

Subgroup analysis: If one of the outcome parameters demonstrates statistically significant differenced between intervention groups, we would plan to use subgroup analyses.

Sensitivity analysis: In order to evaluate the robustness and validity of the results, the leave-one-out sensitivity analysis was conducted by removing each study in turn and reevaluating the resulting effect on the overall estimate.

Country(ies) involved: China.

Keywords: obstructive sleep apnea, transcutaneous electrical stimulation, apnea hypopnea index.

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