INPLASY PROTOCOL

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Conflicts of interest:
The authors report no conflicts of interest in this work.

Selective dorsal neurotomy in the treatment of premature ejaculation: a protocol for systematic review and meta-analysis

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Review question / Objective: **The purpose of this study is to further evaluate the effectiveness and safety of selective dorsal penile neurotomy in the treatment of PE. The results will provide urologists and andrologists with clinical surgery decisions.**
Condition being studied: **Premature ejaculation (PE) affects 8% - 30% of adult men worldwide. Recently, the incidence of PE is on the rise. A series of prior studies suggested that the incidence of PE is related to various biological factors as low testosterone, low serum vitamin D, diabetes, lower urinary tract symptoms (LUTS), and other psychological factors. At present, the major treatments include selective serotonin reuptake inhibitors (SSRIs) antidepressants (dapoxetine, paroxetine), topical anesthetics (TAs), phosphodiesterase-5 inhibitor (PDE5i), circumcision, and SDN. The previous study found that SDN is effective for PE.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 July 2020 and was last updated on 19 July 2020 (registration number INPLASY202070084).

INTRODUCTION

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METHODS

Participant or population: Inclusion criteria: ·Patients who have regular sexual life for more than three months with the fixed sexual partner before the operation, clinically diagnosed as premature ejaculation (≥ 18 years old). Exclusion criteria: ·Patients who have used antidepressants, topical anesthetics, and other drugs to treat premature ejaculation within 3 months. ·Patients with a history of congenital genitourinary abnormalities. ·Patients with any other disease that the decline of testosterone level. ·Patients with other serious diseases which make them could not complete the trial.

Intervention: The patients in the treatment group received selective dorsal penile neurotomy (no restriction on the methods of operation and course of treatment).

Comparator: The control group could gain a placebo, no treatment, SSRIs antidepressants, TAs, PDE5is, exercise, or guideline-recommended conventional treatment.

Study designs to be included: All the RCTs of selective dorsal penile neurotomy for patients with PE will be included without publication status restriction or writing language let.

Eligibility criteria: The inclusion and exclusion criteria are as follows.

Information sources: The electronic databases of MEDLINE, PubMed, Web of Science, EMBASE, Cochrane Library, Clinicaltrials. org, China National Knowledge Infrastructure Database (CNKI), Wan fang Database, China Biology Medicine Database (CBM), VIP Science Technology Periodical Database, Chinese Clinical Trial Registry will be retrieved. They will be searched until MAY 2021 to recognize related studies. The search strategy that will be run in the PubMed and adjusted to fit the other database when necessary is presented. Grey literature will be retrieved through Open Grey. Besides, the reference lists of manual review articles will be searched for any possible titles matching the inclusion criteria.

Main outcome(s): 1) IELT (intravaginal ejaculation latency time) which could assess the time from when the penis is inserted into the vagina until the beginning of ejaculation.

Quality assessment / Risk of bias analysis: Selection bias, detection bias, attrition bias, performance bias and other bias will be an assessment based on the Cochrane Collaboration Network Risk Assessment Tool. The tool assesses the risk of bias mainly in the following 7 aspects: random sequence generation, allocation concealment, the blinding method for patients, researchers and outcomes assessors, incomplete result data, and selective reports. The risk of bias will be evaluated and checked by two review authors. Discrepancies between review authors on the risk of bias will be resolved through discussion with a third review author.

Strategy of data synthesis: The RevMan5.3 software will be used to conduct the meta-analysis (If feasible). Descriptive analysis or systematic narrative synthesis will be performed to summarize and explain the characteristics and findings of the included studies and provide the information in the texts and tables. For dichotomous data (e.g., effective and ineffective), we will calculate risk ratio (RR) and 95% confidence intervals (CIs). For continuous data, which will be pooled as mean difference (MD).

Subgroup analysis: If necessary, we will identify the source of heterogeneity through subgroup analysis and manage the heterogeneity: 1) The site of selective dorsal penile neurotomy. 2) The duration and severity of PE. 3) whether with other sexual dysfunctions. 4) demographic characteristics of the patients: age, marital and family status, region, race. 6) follow-up time.

Sensibility analysis: Sensitivity analysis will be used to test the reliability and stability of the meta-analysis results, and to assess the source of heterogeneity. We will compare the results before and after by excluding trials with a high risk of bias or eliminating each study individually one study each time and then pooling the remaining studies.

Country(ies) involved: China.

Keywords: dorsal penile neurotomy; surgery; premature ejaculation; protocol.

Contributions of each author:
Author 1 - Guangsen Li - Author 1 drafted the manuscript.
Author 2 - Degui Chang - The author conducted the data extraction.
Author 3 - Di'ang Chen - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.
Author 4 - Peihai Zhang - The author preformed the data management.
Author 5 - Yaodong You - The author uesd the software according to the above rule.
Author 6 - Xiaopeng Huang - The author validated the final manuscript.
Author 7 - Jian Cai - The author read, provided feedback and approved the final manuscript.