INPLASY PROTOCOL

Corresponding author:
YIguang Wang

wangyiguang666@163.com

Author Affiliation:
Beijing University of Chinese Medicine Third Affiliated Hospital

Conflicts of interest:
The authors have no conflicts of interest to declare.

Effectiveness and safety of vaginal laser therapy for stress urinary incontinence: a meta-analysis

Wang, Y[1]; Wang, C[2]; Song, F[3]; Zhou, Y[4]; Wang, Y[5].

Review question / Objective: The purpose of this study is to evaluate the effectiveness and safety of laser treatment of SUI by a meta-analysis.

Condition being studied: Stress urinary incontinence (SUI) is defined as a complaint of involuntary loss of urine on effort or physical exertion, or on sneezing or coughing, with an estimated prevalence Of 4—35% among middle-aged women. Based on the Stamey's incontinence scoring system, SUI is regularly categorized as mild (incontinence with coughing or straining), moderate (incontinence with change in position or walking), or severe (total incontinence at all times). This disease can co-occur with other types of urinary incontinence, or appears as symptoms in other diseases. For instance, mixed urinary incontinence(MUI) is a combination of urge and stress urinary incontinence. Genitourinary syndrome of menopause (GSM), scilicet vulvovaginal atrophy, can result in a series of vaginal discomfort like vagina vestibule and vagina dryness, burning sensation, discomfort, vulvovaginal irritation, and irritative symptoms of the lower urinary tract including urinary frequency, urgency, incontinence and recurrent urinary tract infections. SUI is related to pelvic floor dysfunction, altered metabolism of the connective tissue that causes decreased collagen production leading to insufficient support of the urogenital tract. Childbirth trauma or aging can result in decreasing collagen content because of destruction and reduced synthesis of collagen fibers in the pelvic floor.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 August 2020 and was last updated on 01 August 2020 (registration number INPLASY202080001).

INTRODUCTION

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Rationale: Stress urinary incontinence (SUI) is defined as a complaint of involuntary loss of urine on effort or physical exertion, or on sneezing or coughing, with an estimated prevalence Of 4—35% among

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METHODS

Search strategy: In this single-arm meta-analysis, the studies included were published on PubMed, EMBASE and Cochrane Library from inception to July 2020 without language restrictions. The literature search was performed using a combination of MeSH terms and keywords: [Urinary Incontinence, Stress] AND [(lasers) OR laser]. Reference lists of eligible articles were also scrutinized for additional studies that could have been omitted from the database searches. Fig.1 shows the flow chart of the study selection, opening in a separate window of the study selection.

Participant or population: Patients of stress urinary incontinence.

Intervention: Vaginal laser treatment including Erbium YAG laser and CO2 laser.

Comparator: Pelvic floor muscle training, behavioral therapies, and surgery.

Study designs to be included: Prospective randomized and nonrandomized clinical studies, retrospective clinical studies, and pilot studies.

Eligibility criteria: Studies of reviews, comments, letters, animal experiments, cell experiments, duplicated publications or studies without sufficient data were also excluded.

Information sources: In this single-arm meta-analysis, the studies included were published on PubMed, EMBASE and Cochrane Library from inception to July 2020 without language restrictions.

Main outcome(s): We extracted the outcome measures regarding the subjective and objective index which included ICIQ-SF,1-h pat test and PISQ-12. Changes of scores before and after treatment were evaluated through meta-analysis.

Additional outcome(s): Subgroup analysis was performed according to geographic region, type of UI, severity of UI, age, BMI.

Quality assessment / Risk of bias analysis: All the included studies will be evaluated based on the guidelines of Cochrane Handbook for Systematic Reviews of Interventions . The quality of each trial will be categorized into 'low', 'unclear', or 'high' risk of bias according to the

following items: adequacy of generation of the allocation sequence, allocation concealment, blinding of participants and personal, blinding of outcome assessors, incomplete outcome data, selected reporting the results and other sources of bias (such as comparable baseline characteristic, inclusion and exclusion criteria).

Strategy of data synthesis: The evaluations chosen for this test were the following: ICIQ-SF and 1-h pad test. Standard mean differences (SMDs) and 95% confidence intervals (CIs) were expressed as the response index of the efficacy of laser. A value of $P \leq 0.05$ was considered statistically significant. The heterogeneity of included studies was assessed by I2. I2 statistic and P. value was calculated to assess heterogeneity among Studies. Studies with an I2 75% was considered high heterogeneity.

Subgroup analysis: In the case of high heterogeneity, we will conduct a subgroup analysis to identify the sources of heterogeneity. Subgroup analysis was performed according to geographic region, type of UI, severity of UI, age, BMI. The meta-analysis was graphically represented by the forest plot; the publication bias was represented by the inverted funnel plot. Owing to incomplete data, we cannot analyze the menopausal status and the number of previous deliveries (parity) as the source of heterogeneity.

Sensibility analysis: We will conduct sensitivity analyses by omitting studies one by one to probe the impact of an individual study.

Language: Only English articles will be involved.

Country(ies) involved: China, Germany, Turkey, USA, Italy, Croatia, Slovenia, Chile.

Keywords: Meta-analysis; stress urinary incontinence; laser; effectiveness.

Contributions of each author:
Author 1 - Yunong Wang - Conception and design, provision of study materials or patients, collection and assembly of data, data analysis and interpretation, manuscript writing, final approval of manuscript.
Author 2 - Chengli Wang - Conception and design, administrative support, data analysis and interpretation, manuscript writing, final approval of manuscript.
Author 3 - Feipeng Song - Provision of study materials or patients, collection and assembly of data, manuscript writing, final approval of manuscript.
Author 4 - Yaguang Zhou - Provision of study materials or patients, manuscript writing, final approval of manuscript.
Author 5 - Yiguang Wang - Conception and design , administrative support, manuscript writing, final approval of manuscript.