

INPLASY PROTOCOL

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Effect of estrogen on vaginal complications of pessary use: A systematic review and meta-analysis

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None declared.

Review question / Objective: We aimed to systematically review the impact of local estrogen use in combination with pessary on vaginal complications in postmenopausal women with pelvic organ prolapse (POP).

Condition being studied: Nowadays, even though vaginal estrogen is suggested to be used as a concurrent therapy in pessary users by most practitioners, there are still limited studies and controversial results to confirm the positive effect of local vaginal estrogen use on preventing pessary related vaginal complications.

Information sources: We searched the databases including Medline, Embase, Pubmed, Clinical Trials and the Cochrane Central Register of Controlled Trials for relevant literature published in English, as well as contacted with authors, trial registers, or grey literature.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 05 April 2022 and was last updated on 05 April 2022 (registration number INPLASY202240024).

INTRODUCTION

Review question / Objective: We aimed to systematically review the impact of local estrogen use in combination with pessary on vaginal complications in postmenopausal women with pelvic organ prolapse (POP).

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METHODS

Search strategy: The following combination of the medical subject headings (MeSH) or keywords were included depending on different databases: “estrogen”, “pessary”, and “pelvic organ prolapse”.

Participant or population: Postmenopausal women with POP who used vaginal pessary will be eligible for this review, with no exclusions based on ethnicity.

Intervention: Vaginal estrogen.

Comparator: placebo drug or no intervention.

Study designs to be included: RCT and cohort study.

Eligibility criteria: a) studies evaluating the effect of vaginal local estrogen use on vaginal complications in postmenopausal women with POP who use pessary, (b) randomized clinical trials (RCTs), prospective cohort studies or retrospective studies, and (c) studies published in English language.

Information sources: We searched the databases including Medline, Embase, Pubmed, Clinical Trials and the Cochrane Central Register of Controlled Trials for relevant literature published in English, as well as contacted with authors, trial registers, or grey literature.

Main outcome(s): Pessary related complication of vaginal ulceration, vaginal discharge, vaginal bleeding, bacterial vaginosis.

Quality assessment / Risk of bias analysis: The quality of the studies was assessed with the Cochrane risk of bias tool for the clinical trials, which including the following domains: sequence generation, blinding assessment of outcome, selective reporting bias, attrition, sequence generation, allocation concealment, blinding of patients and investigators, other sources of bias. The quality of the cohort

study was assessed with the Newcastle Ottawa Scale (NOS).

Strategy of data synthesis: All analyses were carried out with the Cochrane Review software (Review Manager v.5.3 for Windows) and Microsoft Excel, 2016. Heterogeneity between studies was based on the results of the chi-square and I² statistics. A fixed-effect model was used in low heterogeneity studies which I² value < 50 %, whereas a random-effect model was used in high heterogeneity studies which I² value ≥50 %.

Subgroup analysis: The meta-analysis was performed with subgroups according to the study design and the follow-up duration.

Sensitivity analysis: Sensitivity analysis was performed by eliminating references one by one. Unpublished randomized trails and conference abstracts without peer-review were excluded for strength the outcome reliability.

Language: English.

Country(ies) involved: China.

Keywords: Estrogen; pessary; postmenopausal; pelvic organ prolapse.

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