

Effects of perioperative vaginal estrogen as adjuvant therapy on long-term outcomes of pelvic floor prolapse repair with autologous tissue

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - The review has not yet started.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2025100039

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 October 2025 and was last updated on 13 October 2025.

INTRODUCTION

Review question / Objective Population / Participants Postmenopausal women undergoing repair of vaginal apical prolapse with autologous tissue Intervention / Exposure perioperative vaginal estrogen as adjuvant therapy Comparator / Context Placebo cream was used vaginally during the perioperative period Outcome long-term outcomes of pelvic floor prolapse repair with autologous tissue Study Characteristics / Design Randomized Controlled Trial.

Condition being studied Pelvic organ prolapse (POP) is a prevalent condition among postmenopausal women, characterized by the descent of pelvic organs due to weakened pelvic support structures, often necessitating surgical intervention. This systematic review and meta-analysis aimed to evaluate the efficacy of perioperative vaginal estrogen therapy, administered as a cream, compared to placebo in enhancing surgical outcomes of pelvic floor prolapse repair.

METHODS

Participant or population Postmenopausal women undergoing repair of vaginal apical prolapse with autologous tissue.

Intervention perioperative vaginal estrogen as adjuvant therapy.

Comparator Placebo cream was used vaginally during the perioperative period.

Study designs to be included Randomized Controlled Trial.

Eligibility criteria All the RCTs meet the standard of “PICO” mentioned above will be included. Studies were excluded based on the following criteria: (1)Non randomized controlled trials, metaanalyses, systematic reviews, reviews, comments, case reports, and animal experiments (2)duplicate publications (3)literature with

incomplete information or inability to obtain the full text.

Information sources The following electronic databases will be searched: The Cochrane Library, Embase, PubMed, and Web of Science.

Main outcome(s) The primary outcome is the long-term success rate of pelvic floor prolapse repair, defined as the absence of prolapse symptoms and the need for reoperation at 12 months post-surgery.

Quality assessment / Risk of bias analysis In this meta-analysis, the quality of the included studies will be assessed using the Risk of Bias 2 (ROB2) tool, which is specifically designed for randomized controlled trials. The ROB2 tool evaluates several key domains to determine the risk of bias in the included studies. These domains encompass random sequence generation, allocation concealment, the use of blinding, data completeness, selective reporting, and other potential sources of bias. Each domain will be rated as having a low, high, or some concerns regarding the risk of bias.

Strategy of data synthesis RevMan 5.4 software was used to assess the quality of the six included studies and to generate risk-of-bias plots and forest plots. A risk-of-bias assessment was conducted on the included studies using Stata18.0, and a funnel plot was generated. Effect measures for outcome indicators were selected based on variable types: relative risk (RR) was used for binary variables, mean difference (MD) for continuous variables, and 95% confidence intervals (CI) were calculated for both. Study heterogeneity was assessed using the I^2 statistic. When $I^2 > 50\%$ and $P < 0.1$, a high degree of heterogeneity among the included studies is indicated, and a random-effects model is applied. Conversely, low heterogeneity is assumed, and a fixed-effects model is used for analysis.

Subgroup analysis Subgroup analysis will be considered for outcomes showing substantial heterogeneity.

Sensitivity analysis We plan to conduct a sensitivity analysis using the leave-one-out method to evaluate the stability of the overall effect size regarding the impact of perioperative vaginal estrogen as adjuvant therapy on the long-term outcomes of pelvic floor prolapse repair with autologous tissue, by iteratively excluding each individual study.

Country(ies) involved China.

Keywords “postmenopausal women,” “vaginal apical prolapse,” “autologous tissue repair,” “perioperative vaginaestrogen,” “placebo cream,” “pelvic floor prolapse repair,” “randomized controlled trial.”

Contributions of each author

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