INPLASY PROTOCOL

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Corresponding author:
Yanhui Li

18663090353@163.com

Author Affiliation:
Qilu Hospital of Shandong University

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None declared.

Efficacy of non-invasive photodynamic therapy for female lower reproductive tract diseases associated with HPV infection: a comprehensive meta-analysis

Li, Y[1].

Review question / Objective: **The critical point of this study was to comprehensively evaluate the curative effect of Photodynamic therapy (PDT) in diseases of female lower reproductive tract associated with the human papillomavirus (HPV) infection.**
Condition being studied: **Traditional clinical recommendations for treating diseases of the female lower reproductive tract include topical therapy with drugs, surgery, intravaginal radiation, carbon dioxide (CO2) laser, etc. Although medication is easy to administer, it has a high recurrence rate and adverse effects such as burning sensation, pain, and dyspareunia. The other traditional treatment method is usually invasive, repeated operation of vaginal perforation, scar, easy recurrence, fertility decline, and other shortcomings. At present, the treatment strategy for cervical squamous intraepithelial lesion, vaginal squamous intraepithelial lesion, condyloma acuminatum, and vulvar lichen sclerosis are to protect the normal organ structure and function as much as possible, reduce recurrence, prevent disease progression and carcinogenesis, and preserve female reproductive function.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 November 2022 and was last updated on 19 November 2022 (registration number INPLASY2022110092).

INTRODUCTION

Review question / Objective: **The critical point of this study was to comprehensively evaluate the curative effect of Photodynamic therapy (PDT) in diseases of female lower reproductive tract associated with the human papillomavirus (HPV) infection.**

Rationale: **Up to now, there are some randomized controlled trials of female lower genital tract disease treatment. While there are no early screening methods or comprehensive management guidelines.**

Condition being studied: **Traditional clinical recommendations for treating diseases of**

the female lower reproductive tract include topical therapy with drugs, surgery, intravaginal radiation, carbon dioxide (CO2) laser, etc. Although medication is easy to administer, it has a high recurrence rate and adverse effects such as burning sensation, pain, and dyspareunia. The other traditional treatment method is usually invasive, repeated operation of vaginal perforation, scar, easy recurrence, fertility decline, and other shortcomings. At present, the treatment strategy for cervical squamous intraepithelial lesion, vaginal squamous intraepithelial lesion, condyloma acuminatum, and vulvar lichen sclerosis are to protect the normal organ structure and function as much as possible, reduce recurrence, prevent disease progression and carcinogenesis, and preserve female reproductive function.

METHODS

Search strategy: For PubMed library searches, whenever possible use a combination of (MeSH) and keywords: ("cervical intraepithelial neoplasia" [MeSH] or "cervical intraepithelial lesions " [MeSH]) and ("Photodynamic" [all fields] or "Photodynamic therapy" [all fields]), ("vaginal intraepithelial neoplasia "[MeSH] or "vaginal intraepithelial lesions" [MeSH]), ("Vulvar lichen sclerosis" [MeSH], (" Condyloma acuminatum" [MeSH], and "cervical intraepithelial neoplasia "Entry Terms (Synonyms) or" cervical intraepithelial lesions" and ("Photodynamic" [all fields] or "Photodynamic therapy"), Entry Terms (Synonyms)" vaginal intraepithelial lesions", Entry Terms (Synonyms)"Condyloma acuminatum".

Participant or population: Diseases of the female lower reproductive tract.

Intervention: Patients are treated with PDT and other treatments; Clarify the efficacy of certified treatments; Results include HPV-DNA, cytology and histology, and colposcopy biopsy (complete response, recurrence, and HPVclearance).

Comparator: rugs, surgery, intravaginal radiation, carbon dioxide (CO2) laser, etc.

Study designs to be included: Randomized controlled clinical trial (RCT); Prospective clinical trial; Retrospective clinical study.

Eligibility criteria: Diseases of the female lower reproductive tract are treated with PDT and other treatments; Clarify the efficacy of certified treatments; Results include HPV-DNA, cytology and histology, and colposcopy biopsy (complete response, recurrence, and HPV clearance).

Information sources: PubMed, EMBASE, Scopus, Cochrane Library, and China National Knowledge Infrastructure databases were searched.

Main outcome(s): This meta-analysis indicated that PDT had a significant advantage in complete response. Meanwhile, the recurrence of female lower genital tract disease was compared between PDT and other treatments.

Additional outcome(s): Furthermore, the meta-analysis reported HPV clearance after PDT versus other therapies.

Data management: Odds ratio (OR) was as a practical measure, and a meta-analysis was performed with the Mantel-Haenszel method.

Quality assessment / Risk of bias analysis: Sensitivity analysis was implemented to detect heterogeneity in the included studies. Begg' and Egger' tests evaluated publication bias.

Strategy of data synthesis: Meta-analyses were performed using pooled OR (odds ratios) and 95% CI (confidence intervals) for binary variables calculated by fixed or random-effects models.

Subgroup analysis: No.

Sensitivity analysis: The I^2 was used to assess the heterogeneity of the studies. I^2 test: $0\% < I^2 < 40\%$, mild heterogeneity;

40%≤I²≤60%, moderate heterogeneity; 75%≤I²≤100%, severe heterogeneity. Sensitivity analysis detects sources of heterogeneity in studies. Begg' and Egger' tests publication bias exists in quantitative assessment.

Language restriction: **No language restrictions were imposed.**

Country(ies) involved: **China.**

Keywords: **Photodynamic therapy; Non-invasive; Diseases of the female lower reproductive tract; HPV.**

Contributions of each author:
Author 1 - Yanhui Li.
Email: 18663090353@163.com