

INPLASY PROTOCOL

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Effect of diverting stoma for rectovaginal fistula : a protocol of systematic review and meta-analysis

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

Review question / Objective: To evaluate the effect of diverting stoma versus non-diverting stoma treatment for rectovaginal fistula patients.

Condition being studied: Rectovaginal fistula is a pathologic channel between the anterior wall of the rectum and the posterior wall of the vagina but once the disease will seriously affect the patient's quality of life and generally not self-healing, most require surgical intervention. At present, diverting stoma is mainly used in patients with severe, complex and Crohn's disease. Due to the lack of large sample clinical studies, its clinical effectiveness is still controversial.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 September 2020 and was last updated on 17 September 2020 (registration number INPLASY202090070).

INTRODUCTION

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quality of life and generally not self-healing, most require surgical intervention. At present, diverting stoma is mainly used in patients with severe, complex and Crohn's disease. Due to the lack of large sample clinical studies, its clinical effectiveness is still controversial.

METHODS

Participant or population: Patients with rectovaginal fistula.

Intervention: Diverting stoma.

Comparator: Non-diverting stoma (eg: vaginal, coloanal or colorectal anastomosis, plug, seton drainage and rectal advancement flap).

Study designs to be included: Randomized controlled trials (RCTs), A semi-randomized controlled trial and Clinical research which assessed the efficacy and safety of diverting stoma for rectovaginal fistula will be included.

Eligibility criteria: Subjects: patients with rectovaginal fistula, age, countries and The economic situation were not restricted. Intervention measures: diverting stoma were used as the intervention measures in the treatment group, while non-diverting stoma (eg: vaginal, coloanal or colorectal anastomosis, plug, seton drainage and rectal advancement flap) was used as the intervention measures in the control group. Outcome measures: cure rate, effective rate, inefficiency, recurrence rate, adverse reactions, Infection rates, The operation time, The length of time.

Information sources: Pubmed, Embase, Cochrane Library, Chinese Biomedical Literatures Database (CBM), China National Knowledge Infrastructure (CNKI), WangFang Database (WF), Chinese Scientific Journal Database (VIP).

Main outcome(s): The cure rate, recurrence rate, Infection rates.

Quality assessment / Risk of bias analysis: According to the improved Jadad scoring scale, the quality of the included literature was evaluated. 1-3 were classified as low quality and 4-7 as high quality. Risk of bias (quality) assessment. Included randomised studies will be assessed for risk of bias by two independent raters (FWQ/YSB) using the Cochrane Collaboration's tool for assessing risk of bias in randomised trials. Any disagreements will be resolved through discussion or consultation with a third reviewer (AMW).

Strategy of data synthesis: RevMan 5.4 software (Cochrane Collaboration) was used for the meta-analysis. Dichotomous data were reported as risk ratio (RR) with 95% confidence intervals (CI), while continuous data were reported as standardized mean difference (SMD) with 95% CIs. The Higgins I² test was used to test heterogeneity with a significance level set at 50%. If heterogeneity was not significant (I² ≤ 50%), the fixed effects model was used for meta-analysis. Otherwise, the random effects model was used (I² ≥ 50%). If possible, we investigated the potential explanations for heterogeneity and conducted subgroup analysis.

Subgroup analysis: If the necessary data are available, subgroup analysis will be carried out according to different factors as follows: 1. Control interventions (eg, vaginal, coloanal or colorectal anastomosis, plug, seton drainage and rectal advancement flap). 2. Outcome indicators (eg, non-diverting stoma eg: vaginal, coloanal or colorectal anastomosis, plug, seton drainage and rectal advancement flap).

Sensitivity analysis: Sensitivity analysis: To assess the influence of each individual study, leave-one-out sensitivity analysis was performed iteratively by removing one study at a time to confirm that the findings were not influenced by any single study.

Country(ies) involved: China.

Keywords: rectovaginal fistula; diverting stoma; diversion; stoma; ostomy.

Contributions of each author:

Author 1 - Wenqiang Fu - drafted the manuscript.

Author 2 - Mingwei An - provided statistical expertise.

Author 3 - Sibin Yi - contributed to the development of the selection criteria, and the risk of bias assessment strategy.