INPLASY PROTOCOL

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Corresponding author:
Yu Shen

hi_moke@163.com

Author Affiliation:
West China Hospital, Sichuan University.

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None declared.

Pelvic floor reconstruction after abdominoperineal resection: a network meta-analysis comparing primary closure, biological mesh reconstruction, omentoplasty, and myocutaneous flap closure

Shen, Y[1]; Yang, T[2]; Li, Y[3]; Meng, W[4]; Wang, Z[5].

Review question / Objective: **The present study aims to perform a network meta-analysis (NMA) comparing the outcomes of the major available surgical techniques for pelvic floor reconstruction, providing evidence for surgeons in making the appropriate decision when dealing with the dead pelvic space after APR.**
Eligibility criteria: **1) report on patients who underwent APR or ELAPE surgery; 2) comparing at least two pelvic reconstruction methods among primary closure, biological mesh reconstruction, omentoplasty, and myocutaneous flap closure; 3) published after the year of 2000. When two or more studies were reported based on the same samples, the study with the longest follow-up was included.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 03 July 2021 and was last updated on 03 July 2021 (registration number INPLASY202170009).

INTRODUCTION

Review question / Objective: **The present study aims to perform a network meta-analysis (NMA) comparing the outcomes of the major available surgical techniques for pelvic floor reconstruction, providing evidence for surgeons in making the appropriate decision when dealing with the dead pelvic space after APR.**

Condition being studied: **For rectal cancer, approximately 1 in 5 patients require an abdominoperineal resection (APR). APR has become the standard treatment for patients with low rectal cancer (LRC), particularly those with ultra-low rectal**

tumors at the stage of T3/T4 or those with predicted poor anal function, with less positive circumferential margin (CRM) and low local recurrence rate. However, the dead pelvic space, left after the removal of the rectum and mesorectum, may lead to the liquid accumulating and the intraabdominal contents descending into the pelvic cavity, finally resulting in an increased risk of postoperative complications, such as perineal wound infection, intestinal obstruction, and perineal hernia (PH). To deal with this dead space and prevent the occurrence of perineal complications, reconstruction of the perineal floor is a key step and consequently, several surgical techniques have been introduced. Based on primary closure, the classic approach of pelvic floor reconstruction, the widely used pelvic floor reconstruction programs can be roughly divided into two categories, the partition technique and filling technique, depending on their mechanism. The partition technique, take the biological mesh reconstruction as an example, is characterized by separating the abdominal and pelvic cavity with an absorbed prosthesis. A systematic review showed that biological mesh reconstruction had low incidences of perineal complications and was feasible in practice. The filling techniques, such as omentoplasty and myocutaneous flap closure, are feathered by filling the pelvic dead space with a pedicled omentoplasty or myocutaneous flaps. The filling technique could obliterate the large defect and guarantee the perineal wound healing by improving the blood supply, but companied with prolonged operation time and increased trauma. Although there have been previous meta-analyses comparing the outcomes of part of these strategies, there is still no consensus on which technique is the optimal method for pelvic floor reconstruction.

METHODS

Participant or population: All patients receive APR.

Intervention: Reconstruction of pelvic floor.

Comparator: Complications after reconstruction of pelvic floor.

Study designs to be included: RCT and observational studies.

Eligibility criteria: 1) report on patients who underwent APR or ELAPE surgery; 2) comparing at least two pelvic reconstruction methods among primary closure, biological mesh reconstruction, omentoplasty, and myocutaneous flap closure; 3) published after the year of 2000. When two or more studies were reported based on the same samples, the study with the longest follow-up was included.

Information sources: Electronic databases, contact with authors, trial registers.

Main outcome(s): The major outcomes were the incidence of perineal complications, including perineal wound complications (perineal wound infection, perineal wound dehiscence, and delayed perineal healing), PH, and small bowel obstruction (SBO). Delayed perineal healing was defined as perineal healing beyond 4 weeks.

Quality assessment / Risk of bias analysis: Bias risk assessment The risk of bias of the selected studies was assessed according to the Cochran Handbook criteria. The following bias risk domains were evaluated by two reviews (Y. S and TH. Y) independently and categorized as high risk, uncertain risk, and low risk of bias: selection bias (including random sequence generation and allocation concealment), performance bias (blinding of participants and personnel), detection bias (blinding of outcome assessment), attrition bias (incomplete outcome data), reporting bias (selective reporting), and other bias. Comparison-adjusted funnel plots for the endpoints were used to investigate publication bias for the different comparisons included in the current NMA. Quality of evidence assessment Quality of evidence was assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach. Risk of bias, indirectness,

imprecision, inconsistency, and publication bias were evaluated separately and finally got a rating that leveled the direct, indirect or mixed evidence into high, moderate, low and very low quality.

Strategy of data synthesis: **NMA was conducted to determine the efficacy of each pelvic reconstruction approach. For binary data, odds ratios (ORs) and 95 percent confidence intervals (95% CI) were pooled using the frequency statistical method. The OR value was considered to be statistically significant if the 95% CI did not include the value 1. The probability of ranking of treatment for each outcome of interest was calculated. A probability of ranking over 90% was considered to be high enough to be confidently reported as the correct ranking position of a certain intervention for that outcome of interest.**

Subgroup analysis: **None.**

Sensitivity analysis: **None.**

Country(ies) involved: **China, America, Egypt, Ireland.**

Keywords: **Abdominoperineal resection; Omentoplasty; Pelvic floor reconstruction; Network meta-analysis.**

Contributions of each author:
Author 1 - Yu Shen.
Author 2 - Tinghan Yang.
Author 3 - Yaru Li.
Author 4 - Wenjian Meng.
Author 5 - Ziqiang Wang.