

# INPLASY PROTOCOL

To cite: Liu et al. Effect of prophylactic closure on adverse events after colorectal endoscopic submucosal dissection: A meta-analysis. Inplasy protocol 202050037. doi: 10.37766/inplasy2020.5.0037

Received: 10 May 2020

Published: 10 May 2020

**Corresponding author:**  
Yangyu Zhang

jluyyz@163.com

**Author Affiliation:**  
First Hospital  
of Jilin University

**Support:** Finance department  
of Jilin

**Review Stage at time of this submission:** Formal screening of search results against eligibility criteria.

**Conflicts of interest:**  
None.

## Effect of prophylactic closure on adverse events after colorectal endoscopic submucosal dissection: A meta-analysis

Liu, MQ<sup>1</sup>; Zhang, YY<sup>2</sup>; Wang, YQ<sup>3</sup>; H Zhu, H<sup>4</sup>; Xu, H<sup>5</sup>.

**Review question / Objective:** How does endoscopic closure impact on the incidence of adverse events compared to non-closure after colorectal endoscopic submucosal dissection (ESD)?

**Condition being studied:** Endoscopic submucosal dissection (ESD) has a high en bloc resection rate and is widely performed for large colorectal lesions. However, colorectal ESD is associated with a high frequency of adverse events (AEs), and the efficacy of prophylactic endoscopic closure after ESD for preventing AEs is still controversial. This meta-analysis was conducted to assess the efficacy of closure on AEs following colorectal ESD.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 10 May 2020 and was last updated on 10 May 2020 (registration number INPLASY202050037).

### INTRODUCTION

**Review question / Objective:** How does endoscopic closure impact on the incidence of adverse events compared to non-closure after colorectal endoscopic submucosal dissection (ESD)?

**Condition being studied:** Endoscopic submucosal dissection (ESD) has a high en bloc resection rate and is widely performed for large colorectal lesions. However, colorectal ESD is associated with a high frequency of adverse events (AEs), and the efficacy of prophylactic endoscopic closure after ESD for preventing AEs is still

controversial. This meta-analysis was conducted to assess the efficacy of closure on AEs following colorectal ESD.

## METHODS

**Search strategy:** We identified studies through a literature search of three databases (PubMed, Embase and the Cochrane Library) with the last search performed in December 31, 2019. Key words were “endoscopic submucosal dissection” OR “ESD” AND “closure” OR “clip” AND “colon”, “colorectal”, “colorectum”, “rectum”, “large intestine” OR “large bowel”. The reference list of included studies was scrutinized to identify any additional studies missed through the original search strategy. We restricted the studies to those written in English.

**Participant or population:** Inclusion criteria: patients undergoing endoscopic submucosal dissection(ESD) for colorectal lesions. Exclusion criteria: patients occurred adverse events during colorectal ESD.

**Intervention:** Patients were treated with prophylactic endoscopic closure of the mucosal defect after colorectal ESD, which was defined as endoscopic closure performed to reduce the risk of delayed (postoperative) adverse events.

**Comparator:** Patients were treated with non-closure of the mucosal defect after colorectal ESD.

**Study designs to be included:** Randomized controlled trials (RCTs) or observational studies (prospective or retrospective, case-control, or cohort studies).

**Eligibility criteria:** (1) population: patients undergoing endoscopic submucosal dissection for colorectal lesions; (2) intervention: prophylactic endoscopic closure after ESD, which was defined as endoscopic closure performed to reduce the risk of delayed (postoperative) adverse events; (3) comparator: non-closure; (4) outcome: incidence of delayed bleeding,

delayed perforation, or PECS following ESD; (5) study type: randomized controlled trials (RCTs) or observational studies (prospective or retrospective, case-control, or cohort studies).

**Information sources:** We identified studies through a literature search of three electronic databases (PubMed, Embase, and the Cochrane Library), and the reference list of included studies was scrutinized to identify any additional studies missed through the original search strategy.

**Main outcome(s):** 1. Delayed bleeding was defined as clinical evidence of bleeding manifested by melena or hematochezia after the procedure. 2. Delayed perforation was defined as occurring after the completion of the ESD procedure. 3. Post-ESD coagulation syndrome(PECS) was characterized as a local peritoneal inflammation in the absence of frank perforation, such as abdominal pain, increases in WBC count, C-reactive protein levels and body temperature.

**Additional outcome(s):** None.

**Quality assessment / Risk of bias analysis:** For RCTs, the quality of each study was assessed using the Cochrane risk of bias tool(version 5.1.0). The methodologic quality of observational studies were assessed using the Newcastle-Ottawa scale (NOS). The quality of all studies was assessed by two investigators.

**Strategy of data synthesis:** The statistical analyses of the meta-analysis were conducted using RevMan version 5.3 software (The Cochrane Collaboration, Copenhagen). The pooled odds ratios (ORs) and corresponding 95% confidence intervals (95% CIs) were calculated utilizing a fixed or random effects model. Heterogeneity analysis was calculated using both  $\chi^2$ -based Q statistics and the  $I^2$  test. A P value < 0.10 for the Q statistics or  $I^2$  value  $\geq 50\%$  indicated significant heterogeneity, necessitating a random-effect model for meta-analysis. Otherwise,

---

a fixed-effect model was conducted. Publication bias was measured by Egger's test; an Egger's test P value  $\leq 0.05$  would be interpreted as statistically significant. A sensitivity analysis was also performed in order to evaluate the stability of the results. The publication bias assessment and sensitivity analysis were performed using STATA version 12.0 software.

**Subgroup analysis:** If the necessary data are available, subgroup analysis will be done by RCT/observational studies and the number of patients.

**Sensibility analysis:** Sensitivity analysis was performed by the successive omission of single studies to assess the integrity of summary results.

**Language:** English.

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

**Keywords:** Endoscopic submucosal dissection; Prophylactic endoscopic closure; Meta-analysis; Bleeding.

**Contributions of each author:**

Author 1 - Mingqing Liu - Performed study design and drafted the manuscript.

Author 2 - Yangyu Zhang - Performed study design and drafted the manuscript.

Author 3 - Yueqi Wang - Literature search, performed data collection, quality assessment.

Author 4 - He Zhu - Literature search, performed data collection, quality assessment.

Author 5 - Hong Xu - Evaluated included studies and critical review of the manuscript.