

Identifying Risk Factors for Delayed Bleeding Post-Endoscopic Submucosal Dissection in Early Gastric Cancer: A Systematic Review and Meta-Analysis

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Xu, SY; Lou, QF; Yu, AY; Tong, YF; Ding, Q.

Corresponding author:
Qi Ding

18258283459@163.com

Author Affiliation:
Endoscopy Center, Affiliated
Hangzhou First People's Hospital.

ADMINISTRATIVE INFORMATION

Support - N/A.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 30 April 2025 and was last updated on 30 April 2025.

INTRODUCTION

Review question / Objective Patients undergoing endoscopic submucosal dissection (ESD) for early gastric cancer. Presence of specific risk factors (e.g., long operation time, lesions in the upper stomach, advanced age, antithrombotic drug use, resection size >40 mm, hemodialysis, presence of ulcers). Patients without the specified risk factors. Incidence of delayed bleeding post-ESD. Systematic review and meta-analysis of observational studies (retrospective or prospective).

Condition being studied The condition under investigation is delayed bleeding following endoscopic submucosal dissection (ESD) for early gastric cancer.
Description of the Health Condition/Disease
Early Gastric Cancer (EGC):

Early gastric cancer refers to malignant tumors confined to the superficial layers of the stomach (mucosa or submucosa) without deep invasion or

distant metastasis. It is often asymptomatic and detected through screening in high-prevalence regions, such as East Asia.

Prognosis is excellent if treated early, with 5-year survival rates exceeding 90% after curative resection.

Endoscopic Submucosal Dissection (ESD):

ESD is a minimally invasive endoscopic procedure used to remove early-stage gastric tumors en bloc. It preserves the stomach and avoids surgical resection, reducing morbidity and recovery time.

While effective, ESD carries risks, including delayed bleeding, defined as clinically significant bleeding occurring days to weeks post-procedure (typically 3–14 days after ESD).

Delayed Bleeding:

A serious complication characterized by hematemesis (vomiting blood), melena (black

stools), or hemodynamic instability (e.g., drop in hemoglobin, hypotension).

May necessitate emergency interventions, such as repeat endoscopy, blood transfusion, or surgery, increasing hospitalization duration and healthcare costs.

Reported incidence ranges from 3% to 13% in the included studies, highlighting its clinical relevance.

METHODS

Participant or population The population of interest comprises patients undergoing endoscopic submucosal dissection (ESD) for early gastric cancer (EGC). This systematic review and meta-analysis synthesized data from 11 observational studies (retrospective or prospective), encompassing 1,945 patients and 21,153 lesions.

Intervention Antithrombotic Management: Temporary discontinuation or bridging therapy for patients on antithrombotics (e.g., aspirin, clopidogrel) under hematologist/cardiologist guidance.

Comorbidity Optimization: Addressing uremia in hemodialysis patients to improve coagulation status.

Comparator The meta-analysis compares natural cohorts (exposed vs. unexposed to risk factors) rather than actively applied interventions. However, the results provide a foundation for designing targeted interventions to mitigate modifiable risks (e.g., optimizing antithrombotic management, reducing operation time) in future clinical trials.

Study designs to be included To address the objective of identifying and quantifying risk factors for delayed bleeding after endoscopic submucosal dissection (ESD) for early gastric cancer, the following study designs were included: Observational Studies: Retrospective Cohort Studies: Analyzed pre-existing data from medical records or databases to assess associations between risk factors and delayed bleeding. Prospective Cohort Studies: Followed patients undergoing ESD prospectively to track delayed bleeding outcomes and associated risk factors. Multicenter Cohort Studies: Large-scale studies pooling data across.

Eligibility criteria N/A.

Information sources PubMed, Embase, Cochrane Library.

Main outcome(s) The primary outcome of this systematic review and meta-analysis is the identification and quantification of risk factors associated with delayed bleeding after endoscopic submucosal dissection (ESD) for early gastric cancer.

Quality assessment / Risk of bias analysis The methodological quality of the included studies was assessed using the Newcastle-Ottawa Scale (NOS), which evaluates the quality of non-randomized studies in three domains: selection, comparability, and outcome. Studies were scored on a scale of 0 to 9, with higher scores indicating better methodological quality. Studies with NOS score of ≥ 7 were considered to be of high quality and were included in the meta-analysis.

Strategy of data synthesis Data were extracted from the included studies using a standardized extraction form. The extracted data included study characteristics (e.g., study design, sample size, patient demographics), procedure details (e.g., operation time, lesion location, resection size), and outcomes (e.g., incidence of delayed bleeding, risk factors identified). The extraction process was performed independently by two reviewers, and any discrepancies were resolved through discussion.

Subgroup analysis Subgroup analyses were conducted to assess the consistency of these findings across different study populations and methodologies. The results remained consistent across subgroups, indicating the robustness of the identified risk factors.

Sensitivity analysis N/A.

Country(ies) involved China.

Keywords Endoscopic submucosal dissection, early gastric cancer, delayed bleeding, risk factors, meta-analysis.

Contributions of each author

Author 1 - Shouyuan Xu - drafted the manuscript.

Email: 15924190270@126.com

Author 2 - QiFeng Lou - provided statistical expertise.

Author 3 - Aiyu Yu - contributed to the development of the selection criteria.

Author 4 - Yufeng Tong - provided feedback and approved the final manuscript.

Author 5 - Qi Ding - drafted the manuscript.

Email: 18258283459@163.com