INPLASY PROTOCOL

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None declared.

The safety and efficacy of cold polypectomy for duodenal neoplaisa: A systemic review and meta-analysis

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Review question / Objective: **The aim of this systemic review and meta-analysis is to clarify the safety and efficacy of using cold polypectomy in removing duodenal neoplasia. To this end, the proposed systematic review and meta-analysis will address the following question: the complete ressection and lesion residual rate, the procedure time and hospitalization duration, the delayed bleeding and peforation rate, possible risk factors that cause complications of using cold polypectomy in removing duodenal neoplasia.**
Eligibility criteria: **Inclusion criteria: i)studies involving cold polypectomy or cold EMR for the treatment of duodenal neoplaisa;ii) studies including safety and efficacy data on the removal of duodenal neoplasia under endoscopic procedure; and iii) complete articles in English. Exclusion criteria: i)studies revealing non-duodenal neoplasia; ii)animal studies; iii)abstract and case reports; iiii) studies with<5 patients.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 05 April 2022 and was last updated on 05 April 2022 (registration number INPLASY202240021).

INTRODUCTION

Review question / Objective: **The aim of this systemic review and meta-analysis is to clarify the safety and efficacy of using cold polypectomy in removing duodenal neoplasia. To this end, the proposed systematic review and meta-analysis will address the following question: the complete ressection and lesion residual rate, the procedure time and hospitalization duration, the delayed bleeding and**

peforation rate, possible risk factors that cause complications of using cold polypectomy in removing duodenal neoplasia.

Rationale: The standardized treatment for duodenal neoplasia still remains unknown owing to its low prevalence and incidence. According to the anatomical structure of duodenum, conventional elelctrocautery and electrotomy might cause damage to the duodenal wall that leading to complications such as peforation subsequently. Recently, the cold polypectomy raised due to the less damage and mucous defect. However, the exact efficacy and safety of the cold polypectomy is controversial. This systemic review and meta-analysis is aim to clarify the aforementioned problems and no relavent previous study has yet been reported. Additionaly, this review enables us to choose the exact tpye of cold polypectomy to deal with certain type of duodenal neoplasia under certain circumstance.

Condition being studied: We aim to clarify the procedure time and hospitalization duration, lesion size and location, complete ressection and recurrence rate, delayed bleeding, peforation and surgical intervention rate, potential risk factors of compilcations including patient related factors, lesion related factors, intraoperative assessment, post-operative management, follow-up after the procedure of cold polypectomy in removing duodenal neoplasia.

METHODS

Search strategy: PubMed, Web of Science, Embase, and Cochrane Library were searched for relevant articles. The daterange was from the inception of the database to April 5, 2022. The studies were limited to those published in English. Synonyms for “cold polypectomy” such as cold snare polypectomy, CSP, endoscopic treatment, endoscopic ressection, endoscopic management were combined using the Boolean operator “OR.” A similar search strategy was used for “duodenal neoplasia,” which was combined with duodenal adenomas, duodenal tumor, early duodenal cancer, non-ampullary duodenal epithelial tumor, superficial duodenal tumor by using the Boolean operator “OR.” Both search results were combined using the Boolean operator “AND.” The MeSH terms, such as “cold EMR,” “cold snare polypectomy,” “SNADT,” "Familial Adenomatous Polyposis,” “Endoscopy, Gastrointestinal,” and “Endoscopic Management” were also used when possible.

Participant or population: Patients with duodenal neoplasia treated by cold polypectomy under endoscope will be eligible for this review, with no exclusions based on ethnicity, age or gender.

Intervention: This systemic review and meta-analysis is aim to clarify the efficacy and safety of cold polypectomy in treating duodenal noeplasia Additionaly, this review enables us to choose the exact tpye of cold polypectomy to deal with certain type of duodenal neoplasia under certain circumstance.

Comparator: This review aims to evlauate the efficacy and safety of cold polypectomy in removing duodenal neoplasia compared to other procedures including hot polypectomy.

Study designs to be included: The systematic review addressing safety and efficacy of cold polypectomy in removing duodenal neoplasia will frequently include prospective randomized clinical trails, retrospective studies and prospective pilot studies.

Eligibility criteria: Inclusion criteria: i)studies involving cold polypectomy or cold EMR for the treatment of duodenal neoplaisa;ii) studies including safety and efficacy data on the removal of duodenal neoplasia under endoscopic procedure; and iii) complete articles in English. Exclusion criteria: i)studies revealing non-duodenal neoplasia; ii)animal studies; iii)abstract and case reports; iiii) studies with<5 patients.

Information sources: PubMed, Web of Science, Embase, and Cochrane Library as bibliographic databases. Other non-bibliographic database sources including manual and wed searching.

Main outcome(s): The main outcomes include the adverse events rate of cold polypectomy in the removal of duodenal neoplasia. Moreover, outcomes of the comparison of cold snare vs. cold EMR or hot polypectomy was included. Outcomes based on different portion of duodenum of lesions and the size of lesions were also performed.

Additional outcome(s): Additional outcome include the selection of the exact type of cold polypectomy in the removal of certain size of duodenal lesions under specific circumstance.

Data management: The Forest plots, funnel plot and Egger test were conducted for data management. Using SPSS 25 software for stastical analysis. Graphpad for relavant plots if applicable.

Quality assessment / Risk of bias analysis: Two reviewers independently assessed the methodologic quality using the Newcastle-Ottawa Scale (NOS) for studies, and scores of 7–9 corresponded to high quality. The authors were blinded to each other, respectively. Disagreements were resolved by face-to-face discussion and a third author for adjudication.

Strategy of data synthesis: Data analysis was conducted using SPSS 25 software. Odds ratio (OR) was selected for the assessment of the risk of adverse events. Pooled estimates with 95% confidence interval (CI) were calculated using the weighted variance technique. The Higgins I2 statistic was employed to determine the total variation across studies due to heterogeneity. The I2 < 20%, 20-50% and ≥ 50% corresponded to low, moderate and high heterogeneity. Considering that the studies vary greatly in results, methodology, definition of PPB, and population, the random-effects model was used regardless of heterogeneity. We conducted a meta-regression to test the potential confounders (publication year, lesion size and location, and single center/ multicenter,). A funnel plot, forest plot and Egger linear regression test were used to evaluate publication bias.

Subgroup analysis: Subgroups involved i)outcomes of the comparison of cold snare vs. cold EMR or hot polypectomy; ii) Outcomes based on different portion of duodenum of lesions and the size of lesions were also performed.

Sensitivity analysis: The forest plot, funnel plot and Egger test were conducted to display sensitivity change for complete ressection rate, technical success rate, adverse events rate and residual rate.

Language: English.

Country(ies) involved: China.

Keywords: cold polypectomy; duodenal neoplasia; endoscopic ressection; delayed bleeding.

Contributions of each author:

Author 1 - Yinmeng Zhang - Author 1 drafted the manuscript.
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