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**Effect of Helicobacter pylori eradication on gastric cancer risk in patients with intestinal metaplasia or dysplasia: a meta-analysis of randomized controlled trials**

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**ADMINISTRATIVE INFORMATION**

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**Review Stage at time of this submission** - Completed but not published.  
**Conflicts of interest** - None declared.  
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**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 2 March 2025 and was last updated on 2 March 2025.

**INTRODUCTION**

**Review question / Objective** Can the H. pylori eradication decrease the risk of gastric cancer in patients with IM or dysplasia?  
The purpose of this study was to summarize the evidence from randomized controlled trials (RCTs) investigating H. pylori eradication on gastric cancer risk in patients with IM or dysplasia to determine the evidence base.  
**Condition being studied** Observational studies suggest that Helicobacter pylori (H. pylori) is associated with an increased risk of gastric cancer, yet the effect of H. pylori eradication on gastric cancer risk in patients with intestinal metaplasia (IM) or dysplasia remains controversial. The purpose of this study was to summarize the evidence from randomized controlled trials (RCTs) investigating H. pylori eradication on gastric cancer risk in patients with IM or dysplasia to determine the evidence base.

**METHODS**

**Participant or population** The Inclusion criteria included: (1) Precursor status: all of the included patients had IM or dysplasia; (2) Intervention: patients either did or did not receive H. pylori eradication; and (3) Outcomes: the incidence of gastric cancer was reported. The exclusion criteria included: (1) patients with other Precursor status; (2) both intervention and control group received H. pylori eradication; and (3) the incidence of gastric cancer was not available or calculated.  
**Intervention** patients received H. pylori eradication.  
**Comparator** patients did not receive H. pylori eradication.  
**Study designs to be included** Design: the study should design as RCT.

**Eligibility criteria** We do not have any additional inclusion or exclusion criteria.

**Information sources** The electronic databases of PubMed, Embase, Cochrane Library, Web of science and China National Knowledge Internet database were systematically searched for articles published through May 2024 using (“*helicobacter pylori*” OR (“*helicobacter*” AND “*pylori*”) OR “*helicobacterpylori*”) AND (“stomach neoplasms” OR (“stomach” AND “neoplasms”) OR “stomach neoplasms” OR (“gastric” AND “cancer”) OR “gastric cancer”) as core search terms. Additional potential included trials were searched for using the aforementioned terms on <http://www.ClinicalTrials.gov>, which registers trials that are completed but not yet published. Finally, manual searches of the reference lists of all relevant original and review articles were conducted to identify additional eligible studies.

**Main outcome(s)** Outcomes: the incidence of gastric cancer was reported.

**Quality assessment / Risk of bias analysis** The study quality was assessed using the Jadad scale (1), which is based on randomization (1 or 0), concealment of the treatment allocation (1 or 0), blinding (1 or 0), completeness of follow-up (1 or 0), and the use of intention-to-treat analysis (1 or 0). In this meta-analysis, a study with a score of 4 or greater was regarded as high quality.

**Strategy of data synthesis** The incidence of gastric cancer was presented as frequencies and percentages. The pooled relative risk (RR) and 95% confidence interval (CI), as well as the heterogeneity of the included studies, were computed using random-effect (DerSimonian and Laird) models. Heterogeneity between studies was investigated using the Q statistic, and P values < 0.10 were indicative of significant heterogeneity. Each trial was sequentially excluded to carry out a sensitivity analysis to assess the influence of each single study on the meta-analysis. In addition, to investigate the potential heterogeneity between RCTs, a meta-regression was performed based on publication year, sample size, mean age, percentage male, and follow-up duration. Subsequently, subgroup analyses were conducted for gastric cancer studies according to country, publication year, sample size, mean age, percentage male, Precursor status, *H. pylori* diagnosis, follow-up duration, and study quality. Ratios and P values between subgroups were calculated using the Chi-square test and meta-regression. Publication bias was evaluated using funnel plots and Egger's and Begg's tests, with P-

values less than 0.05 considered to indicate significant publication bias. Two-tailed P-values less than 0.05 were considered statistically significant. All statistical analyses were performed with STATA 10.0 software (Stata Corporation, College Station, TX, USA).

**Subgroup analysis** Subgroup analyses were conducted to evaluate the effect of *H. pylori* eradication on gastric cancer incidence in specific subgroup. Overall, we noted no significant differences in gastric cancer risk between *H. pylori* eradication and no therapy if the study not conducted in other country, the sample size less than 500, percentage male < 50.0%, follow-up duration < 5.0 years, or if the study was of lower quality. *H. pylori* eradication was found to be associated with a reduced risk of gastric cancer in all other subsets.

**Sensitivity analysis** A sensitivity analysis was conducted to evaluate the influence of each single trial on the overall analysis. We noted that the conclusion was not affected following sequential exclusion of any study from the pooled analysis.

**Country(ies) involved** China.

**Keywords** Gastric cancer, *Helicobacter pylori*, Precursor, cancer risk, meta-analysis.

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