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HELICOBACTER PYLORI INFECTION RECURRENCE IN DEVELOPED VERSUS DEVELOPING COUNTRIES – A SYSTEMATIC REVIEW AND META-ANALYSIS

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Abstract – *Objective:* Half of the world's population is infected with *Helicobacter pylori* (*H. pylori*), which can cause gastric diseases and must be eradicated. The reinfection rate, the colonization rate with a new strain usually after more than 12 months of successful eradication, is considered higher in developing countries than developed countries due to lower investment in sanitation and hygiene or a higher population density. The study aimed to analyze and understand *H. pylori* recurrence rates in developed and developing countries and compare the results from 2013 to 2023 to those between 1992 and 2006.

Patients and Methods: PubMed, Google Scholar, Embase, and Scopus databases were searched up to December 31, 2023, using the keywords "*Helicobacter pylori*" or "*H. pylori*" and "recurrence" or "recrudescence" or "reinfection". Clinical studies examining the recurrence rate of *H. pylori* following successful eradication therapy were included, specifically those that provide clear, quantifiable results for comparison. Meta-analysis was performed with comprehensive meta-analysis software, version 4 (Biostat Inc., Englewood, NJ, USA).

Results: 5,808 articles were screened and 20 articles (35 data sets with 16,785 participants) from 11 countries were finally enrolled for analysis. The annual recurrence rate ranged from 0% to 18.80%. The annual reinfection rates in developing and developed countries were 0.040, 95% CI 0.030 to 0.052, and 0.030, 95% CI 0.018 to 0.051, respectively.

Conclusions: No significant change in the recurrence rate between developed and developing countries was demonstrated, possibly due to better hygiene status in developing countries as achieved in the last decade.

Keywords: *H. pylori*, Recurrence, Recrudescence, Reinfection, Meta-analysis.

Abbreviations: *H. pylori* = *Helicobacter pylori*, OR = odds ratio, ER = estimated rate, CI = confidence interval.

INTRODUCTION

Helicobacter pylori (H. pylori) infection is common in the upper gastrointestinal tract. *H. pylori* usually colonizes the antrum of the stomach and progresses to the corpus and fundus in cases of chronic gastritis. This bacterium can cause several diseases, such as gastritis, duodenal and gastric peptic ulcer, gastric cancer, and gastric lymphoma. According to a meta-analysis published in 2017[1], over half of the world's population is currently infected with *H.*

pylori. In addition, it was also reported in the same review that the prevalence of *H. pylori* infection varied from as low as 18.9% in Switzerland to 87.7% in Nigeria. Thus, *H. pylori* should be eliminated when diagnosed, and gastritis should be cured.

Accurate diagnosis is of high importance. The gold standard test is the urea breath test, a diagnostic method quick to perform, sensitive, reliable, and noninvasive. Other methods include endoscopy and biopsy (for histology or PCR), serology, and stool antigen tests. Nowadays, there is no available vaccine against *H. pylori*. There are different treatments for eradicating the bacterium, which may change between countries, especially because of changing resistance to several antibiotics, such as clarithromycin and metronidazole. The main treatment accepted today is bismuth quadruple therapy with a high-dose proton pump inhibitor for 14 days.

The recurrence of *H. pylori* is defined as the negative value of diagnostic tests in infected patients who have finished eradication therapy at least 4 weeks before and turn positive during the follow-up period. Low income and poor hygiene are two of the risk factors of *H. pylori* recurrence[2]. *H. pylori* recurrence is generally divided into recrudescence and reinfection. Recrudescence refers to the recolonization of the same strain within 12 months. This likely occurs when a small number of bacteria, possibly in a coccoid form that wasn't eliminated, begin to proliferate and recolonize the gastric mucosa, ultimately becoming detectable again. Reinfection is defined as infection with a new strain, usually after more than 12 months of successful eradication. Family members infected with *H. pylori* may be the source of reinfection in developing countries[3].

Developing countries often face challenges such as inadequate sanitation practices, a low socioeconomic status among their populations, and high population density. All of these factors seem to be related to a higher prevalence of *H. pylori* infection[2]. In a previous meta-analysis, it was concluded that reinfection tends to occur significantly more in developing countries than in developed countries[4].

The goal of this meta-analysis and systematic review is to provide more accurate, recent knowledge on *H. pylori* recurrence (recrudescence and reinfection) in developed and developing countries. We hypothesized that the difference between developing and developed countries will be smaller than previously published.

MATERIALS AND METHODS

Identification of Studies and Data Extraction

We searched the PubMed, EMBASE, Scopus, and CENTRAL databases until December 31, 2023, to identify human studies written in English. The following search text and/or Medical Topic Heading (MeSH) terms were used: *Helicobacter pylori* OR *H. pylori [All Fields]* AND *recurrence* OR *recrudescence* OR *reinfection.* To retrieve the original studies, a manual search was also conducted through the bibliographies of editorials and review articles. This meta-analysis was performed according to PRISMA guidelines[5].

Selection Criteria – Primary Endpoints

Inclusion and exclusion criteria were decided upon before starting the study investigation. Appropriate studies were included provided that the following criteria were met: a. complete articles with data that can be extracted; b. written in English, and c. studies that examined *H. pylori* status at least 12 months after a successful eradication.

Recurrence of H. pylori infection within 12 months following successful eradication is classified as recrudescence, while any recurrence occurring after 12 months is deemed reinfection. The term "recurrence" includes recrudescence and reinfection together. Studies that did not meet these criteria were excluded. We selected studies that used ^{13}CUBT, stool antigen, or gastric biopsy for histology, culture, or PCR for *H. pylori* diagnosis.

Heterogeneity, Sensitivity, and Publication Bias

The heterogeneity of the studies was calculated using the Cochran Q test and I^2 inconsistency index, and it was considered to be present if the *Q*-test *p*-value was less than 0.10. The higher the I^2, the greater the heterogeneity[6]. The sensitivity testing was conducted by removing individual studies from the overall result. The publication bias was analyzed using a funnel plot complemented by Begg-Mazumdar and Egger statistics[7]. We also used the MINORS method by Slim et al[8] to evaluate the quality of non-randomized studies for meta-analysis.

Statistical Analysis

We used Comprehensive meta-analysis software (Version 4, Biostat Inc., Englewood, NJ, USA). Pooled estimated ratios (ERs) and 95% confidence intervals (CIs) were calculated using the random effects model to compare *H. pylori* recurrence in individual studies. The studies in the analysis are assumed to be a random sample from a universe of potential studies, and this analysis will be used to make an inference to that universe.

RESULTS

A Systematic Review of the Selected Studies[9-28]

In the study by Carraher et al[9] (Canada, 2013), the Aboriginal community in the Northwest Territories was examined for *H. pylori* infection and offered treatment. Forty-three participants with a negative post-treatment UBT test underwent UBT again after one year, and two were positive (4.7%).

In Morgan et al[10] (Latin America, 2013), 1,463 participants with *H. pylori* infection were divided into three groups of treatment. One thousand ninety-one participants with UBT-negative results posttreatment had a 1-year follow-up. One hundred twenty-five turned positive after one year, with a recurrence rate of 11.5%.

Benajah et al[11] (Morocco, 2013) analyzed 256 participants who had a successful *H. pylori* eradication assessed by UBT, histology, and culture. Two hundred thirty-nine participants had a follow-up after six months, and 222 participants continued to a follow-up after 12 months. After six months, one person was positive (0.42%) and another one was positive after 12 months (0.45%). Both of them were from a rural environment, did not have running water or a private well, and were poor.

In the study by Yakoob et al[12] (Pakistan, 2013), 102 participants with successful eradication of *H. pylori* had follow-up after one year with UBT. If positive, the participants went through endoscopy and biopsies. Six participants were reinfected after 12 months with a recurrence rate of 6%.

In the study by Vanderpas et al[13] (Belgium, 2013), 68 participants were cured of *H. pylori* infection and were followed up for 5 years. All participants went through clinical indication for biopsy and *H. pylori* culture for assessing reinfection. In 5 years, almost half of the participants became positive. The annual reinfection rate was 9.72%.

In the study by Bruce et al[14] (Alaska, 2014), 229 participants with negative UBT after eradication were divided into people living in rural or urban places. The groups were tested by UBT at 4, 6, 12, and 24 months after eradication. Participants living in urban communities had a recurrence rate of 4.4%, 3.3%, 2.03%, and 4.1% for 4, 6, 12, and 24 months, respectively. Participants living in rural communities had a recurrence rate of 10.1%, 3.2%, 3.3%, and 6.9% for 4, 6, 12, and 24 months, respectively.

In another study by Sivapalasingam et al[15] (Bolivia, 2014), two rural villages in Bolivia were tested for the prevalence of *H. pylori* infection (80%). Four hundred sixty-two participants who were cured had a follow-up after one year of eradication with UBT. Fifty-seven participants were reinfected with a reinfection rate of 12%.

In Kim et al (Korea, 2014[16]), 2,691 patients with *H. pylori* infection received first-line therapy and second-line therapy if the first failed. *H. pylori* infection and the success of eradication were assessed by histology, rapid urease test, or UBT. Eight hundred fifty-six participants had a follow-up within a year and after two years. Thirty-one participants were positive within one year, with a recrudescence rate of 3.6%. Sixteen participants were positive within two years, with a reinfection rate of 0.97%.

Otero Regino et al[17] (Colombia, 2015) analyzed 86 participants who were selected from a previous study to assess the recurrence rate as follow-up research. The follow-up time ranged from 31 to 56 months and was assessed by stool antigen. 5 participants became positive 32, 37, 42, 44, and 56 months after successful eradication, with an annual reinfection rate of 1.59%. This rate in Bogotá is low and less than that previously reported for other regions of Colombia.

Zhou et al[18] (China, 2016) studied 743 participants after successful eradication of *H. pylori*. After one year of follow-up, 13 patients were positive in UBT with a recurrence rate of 1.75%. Risk factors for the recurrence of *H. pylori* infection were peptic ulcer, contact history with individuals having *H. pylori* infection, and hospitalization.

In the study by Vilaichone et al[19] (Thailand, 2017), 105 participants with successful eradication of *H. pylori* went through one and two years of follow-up, assessed by UBT. Forty participants were from a rural area, and 65 were from an urban area. In urban areas, after 1 year, 2 participants were positive, and after two years, only one, with recurrence rates of 5.1% and 3.8%, respectively. In rural areas, after 1 year, none of the participants were positive, and after two years, three participants had recurrence rates of 0% and 7.5%, respectively.

Sánchez Cuén et al[20] (Mexico, 2017) analyzed 128 successful *H. pylori* eradication in patients and also examined them for reinfection and recrudescence. Cultures and polymerase chain reaction (PCR) was performed on gastric biopsies for strain identification before the eradication and those with a positive UBT one year after eradication treatment. Reinfection occurred in 9 participants (7%) and recrudescence in 3 participants (2.3%).

In the study conducted by Yu et al[21] (2019) in China, a healthcare center carried out a health check-up within a hospital to investigate the prevalence and recurrence of *H. pylori* infection. One thousand one hundred sixty-five participants with successful eradication of *H. pylori* were assessed with UBT for 3 years of follow-up. The annual recurrence rate was 2.66%.

Choi et al[22] (Korea, 2019) analyzed 7,770 patients who were infected with *H. pylori* and cured successfully. Among them, 3,567 participants had a follow-up after more than a year. *H. pylori* reinfection occurred in 420 patients during a median follow-up of 39.1 months. The reinfection rate after 12 months was assessed as 3.06%.

Nam et al[23] (Korea, 2019) examined 647 participants who were confirmed to be successfully eradicated and were annually followed by screening endoscopy and UBT. The median follow-up interval was 42 months. Twenty-one participants were reinfected with *H. pylori* with a reinfection rate of 3.25% and an annual recurrence rate of 0.91%.

Zhou[24] (Jiangjin District, China, 2020) assessed 400 participants who went through *H. pylori* eradication and were retested after one year to assess the recurrence rate. Nineteen of them were found positive by UBT, with a reinfection rate of 4.75%. Reducing the frequency of meals and ensuring that family members receive treatment may be factors that help lower the recurrence of *H. pylori* infection.

Zhang et al[25] (Baoding, China, 2020) studied 218 children (4-16 years old) with successful eradication of *H. pylori* and were examined for recurrence. After one year of follow-up, 41 children were positive (18.8%) in a UBT. The reinfection rate was higher in children under 10 years old than above 10. Residence in urban areas, higher household income, and having lunch at home were significant protective factors against recurrence.

Xie et al[26] (China, 2020) analyzed 2,059 participants with successful eradication of *H. pylori* and had a follow-up for seven years. The status of *H. pylori* infection during the follow-up period was directly determined by UBT, histology, culture, or fecal antigen testing. One hundred twenty-nine participants had a positive UBT within one year with a recrudescence rate of 6.27%. Eighty-seven participants retested positive between one year to six years, with an annual reinfection rate of 1.5%.

Lucero et al[27] (Chile, 2021) studied 61 children (8-11 years old) infected with *H. pylori*, evaluated by blood markers (pepsinogen I and II), and divided into two groups: eradication treatment *vs.* no treatment. Thirty out of 31 children from the first group were cured, and none from the

second group. *H. pylori* is assessed by stool antigen detection or UBT. During follow-up (every month or a few months for three years), four children had recurrence (13%); two after 8 months, one after 15 months, and one after 28 months.

Lim et al[28] (Korea, 2023) analyzed a total of 996 patients. Among them, 228 patients underwent successful eradication treatment and were retested within 1 year to determine the recrudescence rate. Nine participants turned positive on UBT with a recrudescence rate of 3.9%. Three hundred fifty-eight participants were retested for *H. pylori* infection after two years, and 21 turned positive with a reinfection rate of 5.9%.

Meta-Analysis Results[9-28]

Our literature search revealed 5,808 studies that looked at *H. pylori* recurrence after a successful eradication (Figure 1). We excluded studies not on human beings and not in full text and studies not written in English, duplications, editorials, or review articles. We were left with 20 studies (35 data sets) that fulfilled the inclusion criteria, 19 in developing countries and 16 in developed countries, published up to December 31, 2023 from Canada, Belgium, Alaska (USA), South Korea, Morocco, Pakistan, Bolivia, Colombia, China, Thailand, and Mexico.

In total, 16,785 individuals underwent successful H. pylori eradication therapy and were monitored for a minimum of 12 months thereafter. Together, follow-up was 928,785 patient-years, with an average and standard deviation of 1.58±1.40 years. The annual recurrence rate ranged from 0% to 18.80%. The proportion of *H. pylori* recurrence was 0% to 18.80% within a year and 0.91% to 9.72% in more than a year after eradication. The mean effect size of event rate (ER) (annual recurrence rate of *H. pylori* infection) was 0.040, 95% CI 0.029 to 0.053 (**Supplementary Figure 1**). The corresponding figures for recrudescence and reinfection in developing and developed countries were 0.049, 95% CI 0.032 to 0.075, 0.036, 95% CI 0.013 to 0.095, 0.040, 95% CI 0.030 to 0.052, and 0.030, 95% CI 0.018 to 0.051, respectively (**Supplementary Figure 2**, **Supplementary Figure 3**, **Supplementary Figure 4**, **Supplementary Figure 5**).

The Q-statistic provides a test of the null hypothesis that all studies in the analysis share a common effect size. If all studies shared the same true effect size, the expected value of Q would be equal to the degrees of freedom (the number of studies minus 1). The Q-value is 388.164 with 34 degrees of freedom and $p < 0.001$. Using a criterion alpha of 0.100, we can reject the null hy-

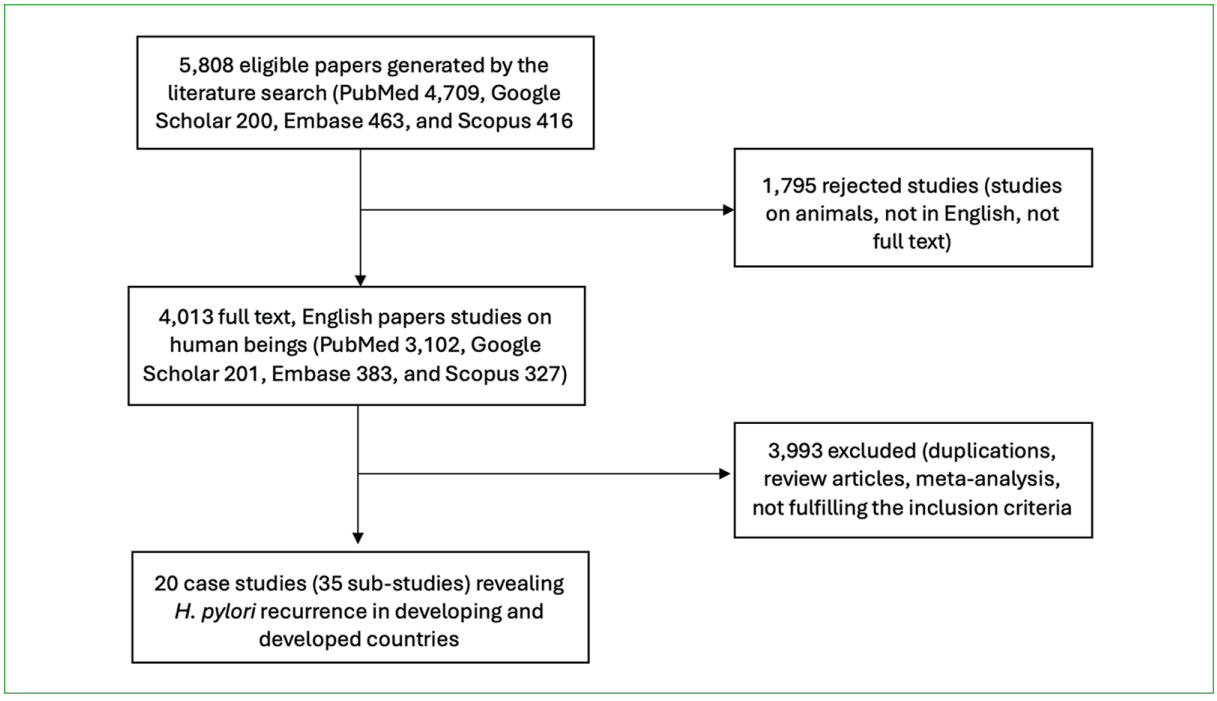

Figure 1. Flow chart of studies included in the meta-analysis.

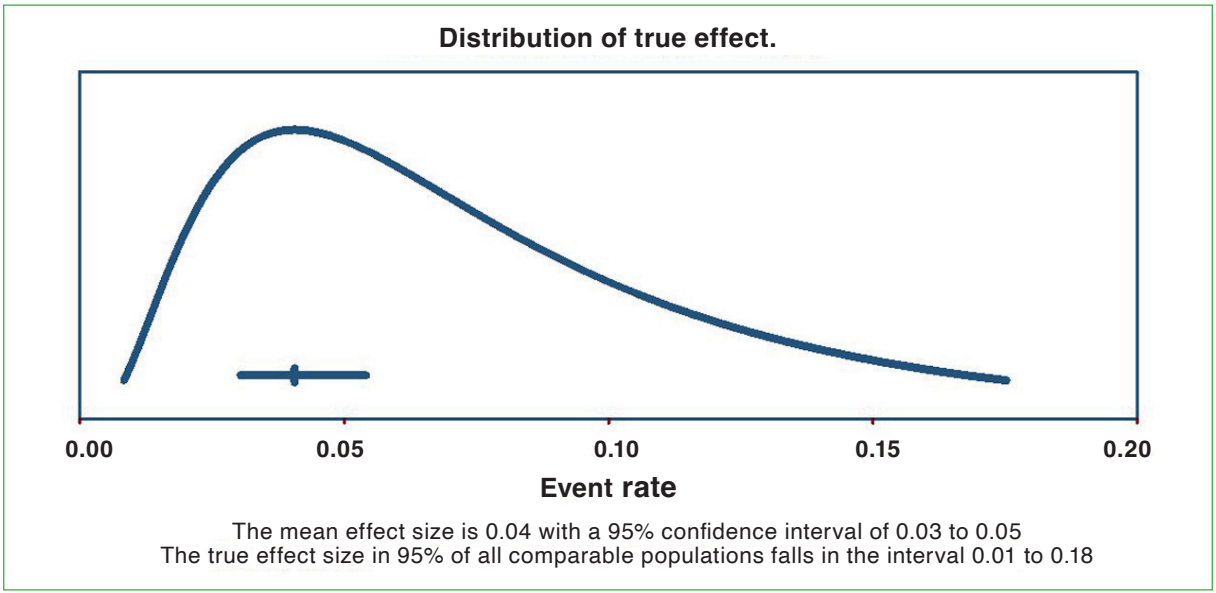

Figure 2. *H. pylori* recurrence rate – distribution of true effect.

pothesis that the true effect size is the same in all these studies. The I-squared statistic is 91%, which tells us that 91% of the variance in observed effects reflects variance in true effects rather than sampling error. Tau-squared, the variance of true effect sizes, is 0.604 in logit units. Tau, the standard deviation of true effect sizes, is 0.777 in logit units. If we assume that the true effects are normally distributed (in logit units), we can estimate that the prediction interval is 0.008 to 0.175. The true effect size in 95% of all comparable populations falls in this interval (Figure 2). The funnel plot is symmetrical and denies a significant publication bias (Figure 3).

We measured sensitivity by excluding individual studies and recalculating the overall meta-analysis outcome. Deviations from the primary were in the range of 0.012 (95% CI 0.001 to 0.167), and 0.115 (95% CI 0.097 to 0.135), with a median of 0.036. Compared ERs lower and

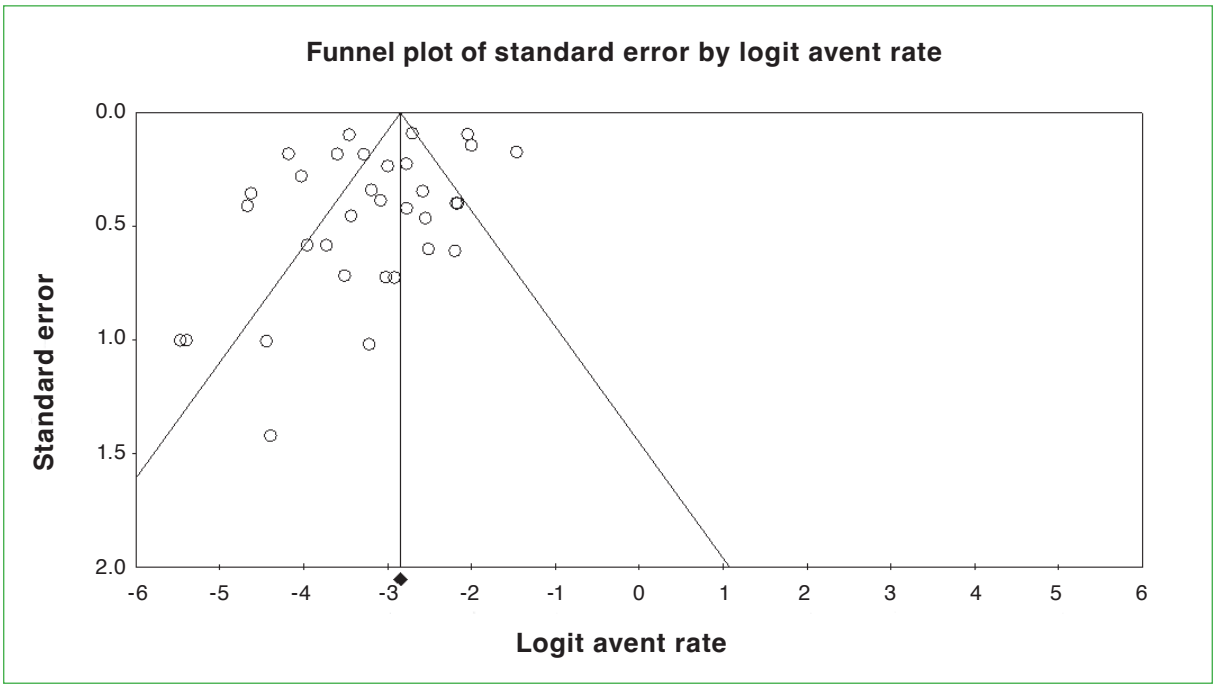

Figure 3. Funnel plot for publication bias.

higher than the median, ER 0.019 (95% CI 0.015 to 0.025) and ER 0.071 (95% CI 0.054 to 0.93) achieved very similar results and did not significantly deviate from the primary score of ER at 0.040 (95% CI 0.029 to 0.053), within the prediction interval of 0.024 to 0.093.

When rural and urban areas were compared in developed and developing countries together, ERs of 0.073 and 0.036 were found, respectively. This means that the ER in rural areas is twice that of the urban areas in developed and developing countries alike.

The quality of the studies was measured using the MINORS method (**Supplementary Table 1**). Scores of 0.92 to 1.67 were found, with a median of 1.17. We separately performed a meta-analysis of 18 studies with scores of 0.92 to 1.17 and 18 studies with scores of 1.17 to 1.67. ERs were 0.029, 95% CI 0.017 to 0.047, and 0.045, 95% CI 0.029 to 0.070, respectively, with a large area of overlap and with no statistically significant difference.

DISCUSSION

This work investigated the *H. pylori* recurrence differences in developing and developed countries in the last decade. The annual recurrence rate ranged from 0% to 18.80%. The recrudescence proportion was as low as 0% in Thailand[19] and as high as 18.8% in Baoding, China[25]. The reinfection proportion was the lowest, 0.91%, in Korea[23] and the highest, 9.72%, in Belgium[13]. There was no significant change in the recurrence rate between developing and developed countries. A previous meta-analysis[4] showed an annual recurrence rate of 1.45% in developed countries and 12.00% in developing countries. It seems like these differences have become smaller over the years. As we know, the recurrence of *H. pylori* is affected by sanitation facilities, crowdedness, and hygiene[2]. In 2023, the United Nations Children's Fund and World Health Organization published a report[29] on global progress and challenges in water, sanitation, and hygiene, highlighting disparities between rural and urban areas from 2000 until 2022. According to this report, 2.1 billion people gained access to safely managed drinking water, and the number of people lacking at least basic drinking water services decreased from 1.2 billion to 703 million. Moreover, since 2015, safely managed drinking water coverage has increased by 6 percent in rural areas and one percent in urban areas. Coverage of safely managed sanitation has increased by 10% in rural areas and 5% in urban areas. Coverage of basic hygiene services has increased by 12 percent in rural areas but remains unchanged in urban areas. All the above show a decrease in differences between rural and urban areas, which may probably affect our results. Our meta-analysis includes four papers (14 sub-studies) that specifically compared rural and urban areas, demonstrating that the recurrence rate of *H. pylori* infection is higher in rural than in urban areas, in developed and developing countries alike, so there is still progress to be made.

Limitations

There are some limitations in our study. First, in every country, we can find rural and urban places. Therefore, it is important to verify every subject's exact location and sanitation status. Second, the decrease in differences between developed and developing countries could be caused by improving eradication therapy in developing countries. Finally, the definition of developing and developed countries is not established and is changing very fast in many countries[30]. According to a systematic review of drinking water sanitation from 2007 to 2018 in China, sanitation has improved but still does not meet the threshold for drinkable water, and therefore, China still counts as a developing country. More research is urgently needed to map developing and developed countries and correlate a more accurate definition with the *H. pylori* recurrence rate.

CONCLUSIONS

The present data provide insight into the global *H. pylori* annual recurrence, recrudescence, and reinfection rates in developed and developing countries, which ranged from 0% to 18.8%

after a successful eradication. This study did not find a significant change in the recurrence rate of *H. pylori* between developed and developing countries, which may indicate a decrease in the difference in sanitation and hygiene status between the two.

Conflict of Interest

The authors have declared no conflicts of interest.

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None to declare.

Authors' Contributions

Both authors performed the research and wrote the article.

Data Availability

The data are accessible from the corresponding author upon reasonable request.

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