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Tegoprazan-Containing Versus Proton Pump Inhibitor-Containing Therapy for First-Line Eradication of *Helicobacter pylori*: A Meta-Analysis of Randomized Controlled Trials

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ABSTRACT

Introduction: Concerns have been raised regarding the decreasing success rates of the standard treatment of *Helicobacter pylori* (proton pump inhibitor (PPI) and two/three antibiotics) and the long-term effects carried by PPI. Despite conflicting data, Tegoprazan, a potassium-competitive acid blocker, is hypothesized to be superior to PPI for eradicating *H pylori*. This systematic review and meta-analysis aim to determine the superiority of Tegoprazan-containing therapy to PPI-containing therapy for *H pylori* eradication.

Methods: A systematic literature search identified studies published until December 12, 2024, from MEDLINE, EMBASE, SCOPUS, and CENTRAL. The search strategy included the following keywords: "Tegoprazan," "Proton Pump Inhibitors," *and "Helicobacter pylori*." Only randomized controlled trials (RCTs) that compared the efficacy of Tegoprazan to any PPI were included. Risk of bias assessment was performed using the Cochrane Risk of Bias 2 (RoB2) tool for RCTs. The random-effect model was used to calculate the pooled risk ratio (RR) and its 95% Confidence Interval (95% CI) from the intention-to-treat population.

Results: Six RCTs with low risks of bias were included in this meta-analysis. All studies included treatment-naïve patients and compared first-line *H pylori* treatment. The overall eradication rates of Tegoprazan-containing ($N = 1052$) versus PPI-containing therapy ($N = 1058$) were 83.37% and 80.06%, respectively (RR 1.045; 95% CI 1.008–1.084; $I^2 = 0\%$). Tegoprazan-containing therapy demonstrated comparable treatment-emergent adverse event (TEAE) rates compared to PPI-containing therapy (46.48% vs. 46.31%; RR 1.026; 95% CI 0.952–1.106; $I^2 = 48\%$).

Conclusion: This meta-analysis demonstrated that Tegoprazan-containing therapy is superior to PPI-containing therapy for first-line *H pylori* eradication, with comparable safety profiles.

1 | Introduction

The first-line standard treatment of *Helicobacter pylori*, for more than 20 years, consists of a proton pump inhibitor (PPI) in addition to two or three antibiotics. The eradication rates of these treatment regimens have decreased due to the increasing number of drug-resistant *H pylori* worldwide, especially with clarithromycin [1, 2]. Vonoprazan, a novel acid-suppressive drug first used in Japan in the drug class of potassium-competitive acid blockers (P-CABs), has recently been approved by the United States Food and Drug Administration (FDA) for use in eradicating *H pylori* infection. A previously available meta-analysis of randomized controlled trials (RCTs) concluded that Vonoprazan-containing triple therapy achieved significantly higher eradication rates compared to PPI-containing triple therapy (91.4% vs. 74.8%; $p < 0.05$) with remarkably lower adverse events [3].

Tegoprazan, another type of P-CAB developed in South Korea, has been approved to eradicate *H pylori* infection and heal gastroesophageal reflux disease (GERD) and gastric ulcers in South Korea since July 2018 [4]. As with other P-CABs, Tegoprazan suppresses gastric acid by competitively antagonizing the potassium binding site of the proton pump, resulting in a more potent and long-lasting acid suppression than PPIs [5, 6]. Additionally, compared to Vonoprazan, Tegoprazan has more rapid, potent, and sustained acid suppression; thus, it is speculated to have similar or even better efficacy in treating acid-related disorders [7]. However, evidence comparing Tegoprazan to PPIs for *H pylori* eradication is lacking, and available RCTs are limited by low sample size. Therefore, this systematic review and meta-analysis aims to summarize available data comparing the efficacy and safety of Tegoprazan-containing therapy to PPI-containing therapy for *H pylori* eradication.

2 | Methods

This systematic review and meta-analysis is written in compliance with the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) 2020 guidelines (Table S1). Before writing this systematic review, a protocol was created and registered with the International Prospective Register of Systematic Reviews (CRD42023413653).

2.1 | Search Strategy

We searched the following electronic databases: MEDLINE, EMBASE, SCOPUS, and CENTRAL (the Cochrane Library) for studies indexed in the database until December 12, 2024. Since early phase studies of Tegoprazan were conducted in South Korea, we performed manual handsearching of studies in two Korean Medical Databases (KMbase and KoreaMed). Additionally, we performed a manual search for conference proceedings published in Gut, Gastroenterology, the American Journal of Gastroenterology, and the United European Gastroenterology Journal, as well as clinical trial registries (ClinicalTrials.Gov, EU Clinical Trials Register [EUCTR], WHO International Clinical Trials Registry Platform [ICTRP]). Additional relevant studies were searched by examining reference and citation lists of included studies. To avoid potential language bias, there were no language restrictions used. The complete search strategy was formulated with the help of an experienced librarian and with the following keywords: "Tegoprazan," "Proton Pump Inhibitor," and "*Helicobacter pylori*" (Table S2).

2.2 | Eligibility Criteria

Only randomized controlled trials (RCTs) that randomize adult patients with treatment-naïve (no prior treatments) *H pylori* infection to Tegoprazan and any PPI were included in this systematic review. Abstract-only studies and unpublished clinical trials with available results were also eligible for inclusion.

2.3 | Study Selection, Data Extraction, and Quality Assessment

All studies retrieved from the databases using the search strategy and additional studies, including conference proceedings or unpublished trials, were compiled in Endnote 20. Removal of duplicate studies was performed by the Endnote 20 program. Then, two reviewers (DMS and EL) completed the study selection through title and abstract screening and full-text review according to the eligibility criteria. For the included studies, data extraction and risk of bias assessment were performed by two other independent reviewers (MI and ID). Data were extracted using a standardized Excel form, consisting of the first author and publication year, study design, study location, treatment information (regiment, duration, follow-up after treatment completion), baseline characteristics of participants (*N*, age, proportion of female, smokers, alcohol drinkers, underlying gastric severity, CYP2C19 genotype, and amoxicillin and clarithromycin susceptibility) and outcome (*H pylori* eradication rate presented in the Intention-to-Treat [ITT] Principle, and Treatment-emergent adverse event [TEAE] presented in the ITT principle).

The risk of bias in the included RCTs was assessed with the Cochrane Risk of Bias 2 (RoB2) tool. The RoB2 tool assessed for "low risk," "some concern," and "high risk" of bias (i) arising from the randomization process, (ii) due to deviations from the intended intervention, (iii) due to missing outcome data, (iv) in the measurement of the outcome, (v) in the selection of the reported result, and (vi) overall impression [8]. Any discrepancies in the data extraction and risk of bias results between the two reviewers were arbitrated by a third reviewer.

2.4 | Data Analysis

Meta-analysis was done using the "meta" package of the R program (Vienna, Austria). The random-effect model was used to derive the risk ratio for the pooled eradication and TEAE rates and its 95% Confidence Interval (95% CI). The between-study heterogeneity was calculated using the I^2 statistic, where substantial heterogeneity was considered if

$I^2 > 50\%$ [9]. Exploratory subgroup analysis was done to test for subgroup differences between antibiotic-susceptible and antibiotic-resistant *H pylori* strains. Tests for small-study effect were not performed since the included studies were fewer than 10 [10]. A two-tailed p value of < 0.05 was considered statistically significant.

3 | Results

Of 168 reports retrieved from databases, 28 reports were assessed for eligibility based on their full texts. Six RCTs [6, 11–14] comprising 14 different reports (Table S3) were finally included in this systematic review (Figure 1); reasons for exclusion are documented in Table S4. A total of 2110 patients with *H pylori* were randomized to Tegoprazan-containing therapy ($n = 1052$) and PPI-containing therapy ($n = 1058$). One study compared a 7-day treatment duration of Tegoprazan-containing therapy to Lansoprazole-containing therapy [6], one compared 10 days of Tegoprazan-containing sequential therapy to Esomeprazole-containing sequential therapy [14], one compared 14 days of Tegoprazan-containing therapy to 14 days of Lansoprazole-containing therapy [11] while the other three compared 14 days of Tegoprazan-containing therapy to 14days ofEsomeprazole-containing therapy [12, 13, 15] (Tables 1 and S5). Aside from a study using sequential therapy [14], two studies compared quadruple therapy [11, 12] and the remaining compared triple therapy [6], dual therapy [13], and PPI-bismuth quadruple therapy with Tegoprazan dual therapy [15]. All studies included treatment-naïve *H pylori* patients and compared first-line *H pylori* treatment. Eradication rates were assessed at least 28 days after treatment completion. Overall, the mean age groups were between 38 and 61 years old, with approximately similar proportions of males and females. Most patients in this systematic review had at least some degree of atrophic gastritis. Additionally, only one study conducted complete CYP2C19 genotyping [6], and only three studies had antibiotic susceptibility testing data. Overall, the risks of bias in the included RCTs were low (Table S6).

The overall eradication rate of Tegoprazan-containing therapy compared to PPI-containing therapy was 83.36% and 80.06%, respectively (RR 1.045 [95% CI 1.008 to 1.084]; $I^2 = 0\%$) (Figure 2A). Additionally, the eradication rates in antibiotic-susceptible versus antibiotic-resistant *H pylori* strains were compared (study $n = 1$). There were no significant subgroup differences between the resistance statuses of clarithromycin, amoxicillin, and metronidazole (p interaction > 0.1) (Figure S1–S3). Furthermore, there was no significant difference based on study location (p interaction $= 0.80$) and PPI types (p interaction $= 0.86$) (Figure S4).

As for the overall TEAE, Tegoprazan-containing therapy demonstrated a non-significant increase in events (46.48% vs. 46.31%) compared to PPI-containing therapy (RR 1.026 [95% CI 0.952 to 1.106]; $I^2 = 48\%$) (Figure 2B).

4 | Discussion

To the best of our knowledge, this is the first meta-analysis of only RCTs that compared the efficacy of Tegoprazan to PPI in eradicating *H pylori* infection. For the eradication of *H pylori* infection, Tegoprazan-containing therapy was found to be significantly superior to PPI-containing therapy, although with only a slight increase in efficacy. Despite the lack of power, there were

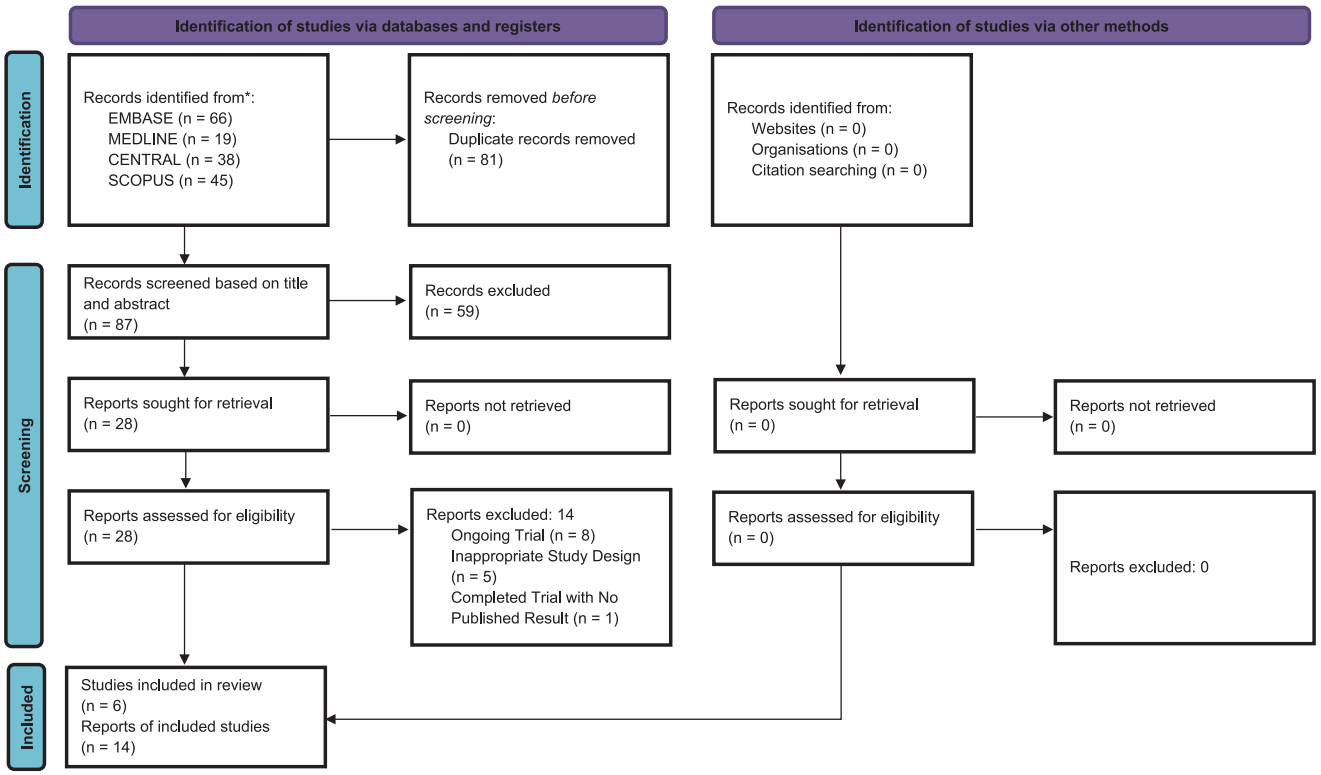

FIGURE 1 | 2020 PRISMA flow diagram.

TABLE 1 | Characteristics of included studies.

Study ID	Location	Treatment regiment	Tx duration	Follow-up	*N*	Age (year)	Female	Smoking	Alcohol	Gastric severity	CYP2C19 genotype	Susceptibility		Eradication rate
												AMX	CAM	
Choi YJ (2022) NCT03317223	South Korea	TPZ 50 mg Bid AMX 1 g Bid CAM 500 mg Bid	7 days	28–56 days	175	54.7 ± 11.2	90 (51)	26 (15)	57 (33)	PUD: 50 (29) Atrophic gastritis: 125 (71)	E/I: 127 (89) P: 16 (11)	S/I: 29 (78) R: 8 (22)	S/I: 27 (73) R: 10 (27)	110/175 (62.9)
		LPZ 30 mg Bid AMX 1 g Bid CAM 500 mg Bid	7 days	28–56 days	175	53.2 ± 10.9	92 (53)	24 (14)	76 (43)	PUD: 50 (29) Atrophic gastritis: 125 (71)	E/I: 129 (85) P: 22 (15)	S/I: 28 (72) R: 11 (28)	S/I: 26 (67) R: 13 (33)	106/175 (60.6)
Kim JS (2023) NCT04674774	South Korea	TPZ 50 mg Bid TET 500 g Qid MET 500 mg Tid Bi 300 mg Qid	14 days	28 days	105	58.0 ± 11.3	44 (42)	41 (40)	54 (55)	PUD: 43 (41) Atrophic gastritis: 53 (50)	NR	5[a]	4[a]	84/105 (80.0)
		LPZ 30 mg Bid TET 500 g Qid MET 500 mg Tid Bi 300 mg Qid	14 days	28 days	106	57.9 ± 10.0	47 (44)	28 (28)	52 (53)	PUD: 45 (42) Atrophic gastritis: 51 (48)	NR	3[a]	10[a]	82/106 (77.4)
Kong Q (2024) NCT05870683	China	TPZ 50 mg Bid AMX 750 mg Tid	14 days	56 days	184	45 (36–54)	100 (54)	41 (22)	53 (29)	NR	NR	NR	NR	158/184 (85.9)
		ESO 20 mg Tid AMX 750 mg Tid	14 days	56 days	184	42 (33–55)	94 (51)	31 (17)	55 (30)	NR	NR	NR	NR	155/184 (84.2)
Lee JW (2024) NCT06382493	South Korea	TPZ 50 mg Bid AMX 1 g Bid TPX 50 mg Bid CAM 500 mg Bid MET 500 mg Bid	10 days (5 + 5)[b]	28–56 days	202	61.3 ± 11.6	123 (61)	12 (6)	34 (17)	PUD: 10 (5) Gastritis: 157 (78)	NR	NR	NR	176/202 (87.1)
		ESO 40 mg Bid AMX 1 g Bid ESO 40 mg Bid CAM 500 mg Bid MET 500 mg Bid	10 days (5 + 5)[b]	28–56 days	204	61.7 ± 11.6	110 (54)	11 (5)	42 (21)	PUD: 5 (2) Gastritis: 144 (71)	NR	NR	NR	171/204 (83.8)

(Continues)

TABLE 1 | (Continued)

Study ID	Location	Treatment regiment	Tx duration	Follow-up	*N*	Age (year)	Female	Smoking	Alcohol	Gastric severity	CYP2C19 genotype	Susceptibility		Eradication rate
												AMX	CAM	
Lin X (2024) ChiCTR2300071997	China	TPZ 50 mg Bid AMX 1 g Tid	14 days	56 days	107	41.5 ± 12.7	66 (62)	10 (9)	21 (20)	PUD: 4 (4)	NR	NR	NR	92/107 (86.0)
		ESO 20 mg Bid Bi 240 mg Bid AMX 1 g Bid CAM 500 mg Bid	14 days	56 days	107	41.2 ± 13.5	60 (56)	14 (13)	21 (20)	PUD: 6 (6)	NR	NR	NR	91/107 (85.0)
Zhou L (2024) NCT05577468[c]	China	TPZ 50 mg Bid AMX 1 g Bid CAM 500 mg Bid Bi 600 mg Bid	14 days	28–35 days	279	38.6 ± 12.7	166 (60)	20 (7)	NR	PUD: 16 (6) Chronic gastritis: 259 (94)	NR	S/I: 81 (93) R: 6 (7)	S/I: 52 (60) R: 35 (40)	257/279 (92.1)
		ESO 20 mg Bid AMX 1 g Bid CAM 500 mg Bid Bi 600 mg Bid	14 days	28–35 days	282	38.6 ± 13.2	194 (69)	14 (5)	NR	PUD: 25 (9) Chronic gastritis: 255 (91)	NR	S/I: 96 (94) R: 6 (6)	S/I: 59 (58) R: 43 (42)	242/282 (85.8)

Abbreviations: AMX: amoxicillin; Bi: bismuth; Bid: twice daily; CAM: clarithromycin; E/I: extensive/intermediate metabolizer; LPZ: lansoprazole; MET: metronidazole; P: poor metabolizer; PUD: peptic ulcer disease; R: resistance; RPZ: rabeprazole; S/I: susceptible/intermediate; TPZ: Tegoprazan.

[a]TPZ-containing therapy: $N = 28$; LPZ-containing therapy: $N = 25$.

[b]Sequential Therapy: first regiment includes TPZ 50 mg/ESO 40 mg + AMX 1 g Bid for 5 days | Second regiment includes TPZ 50 mg/ESO 40 mg + CAM 500 mg + MET 500 mg Bid for 5 days.

[c]Baseline data percentage calculated from $N = 275$ in Tegoprazan-containing therapy and $N = 280$ in Esomeprazole-containing therapy.

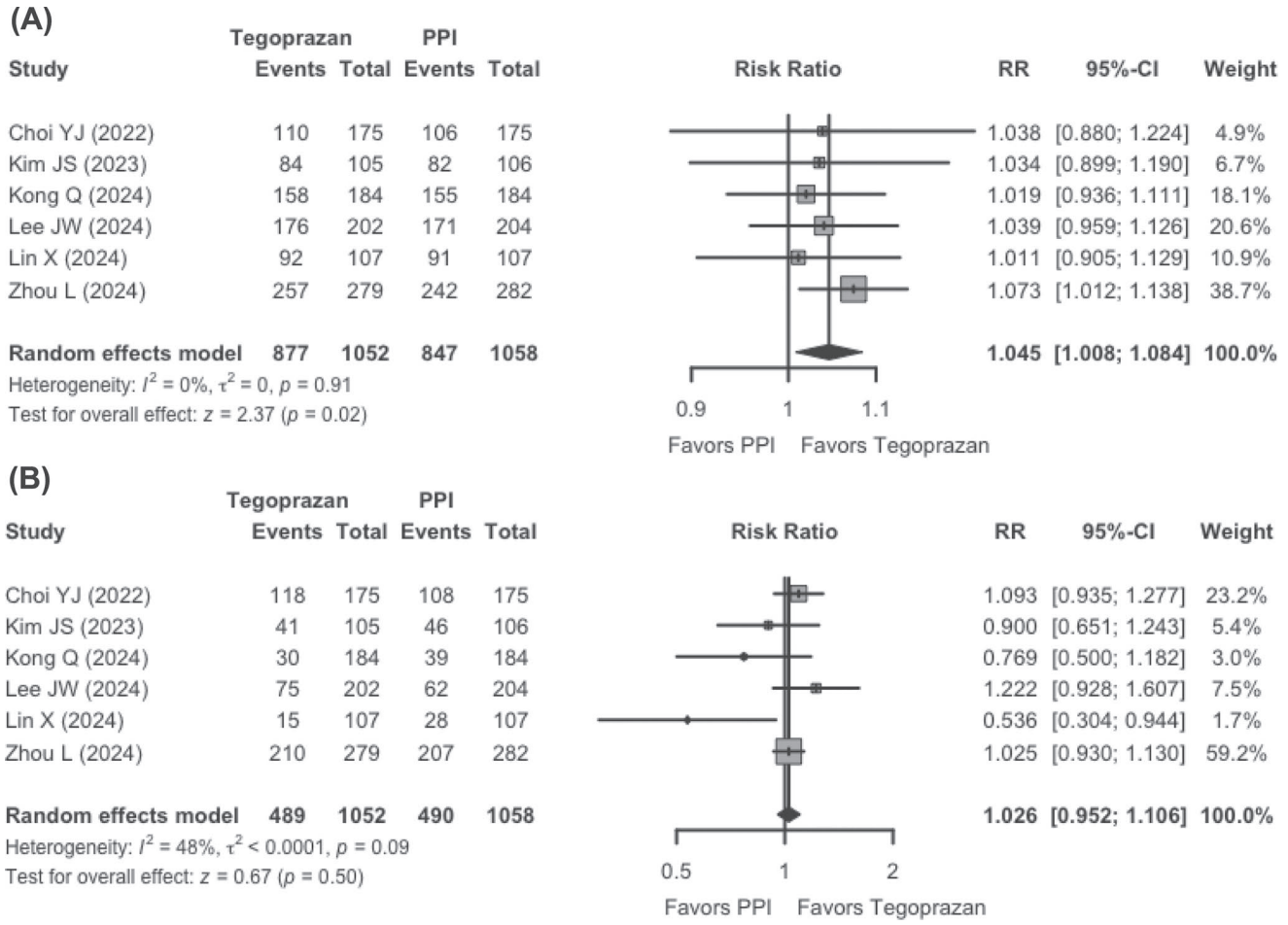

FIGURE 2 | Forest plot demonstrating the (A) eradication rate and (B) any treatment-emergent adverse event (TEAE) in Tegoprazan-containing therapy compared to PPI-containing therapy.

no significant differences in eradication rates in clarithromycin-, amoxicillin-, and metronidazole-susceptible and resistant strains. Our study also showed a similar TEAE risk in patients receiving Tegoprazan compared to PPI.

Previous meta-analyses demonstrated that Vonoprazan, the most commonly studied P-CAB, is superior in eradicating *H pylori* compared to PPI [3, 16, 17]. This efficacy was mainly shown in Clarithromycin-resistant *H pylori* strains but not in Clarithromycin-susceptible strains. The longer duration of acid suppression has been proposed to be responsible for the higher efficacy of Vonoprazan-containing therapy in Clarithromycin-resistant individuals [18]. Compared to PPI, P-CAB has also been shown to achieve a more prolonged duration of acid suppression, particularly at nighttime. This has been proposed as a mechanism by which P-CAB can achieve higher efficacy in treating nonerosive gastritis, GERD, and gastric ulcers. More significant acid suppression will lead to less degradation of antibiotics, resulting in higher serum levels of antibiotics in the stomach [19]. Tegoprazan was supposed to show similar, or even slightly better, efficacy to Vonoprazan, as supported by an open-label randomized trial, which showed Tegoprazan achieving more prolonged acid suppression in the stomach than Vonoprazan [7]. However, despite our study showing that Tegoprazan is superior to PPI for eradicating *H pylori*, the magnitude of the superiority of Vonoprazan compared to PPI was not replicated.

All studies used 13C-UBT to determine treatment success 28–56 days after completing treatment, with the exception of one study [15], which used either 13C- or 14C-UBT. This approach aligns with the latest ACG guideline for the treatment of *H pylori*, which acknowledges that nonendoscopic UBT and fecal antigen tests, as well as biopsy-based methods are highly accurate for confirming treatment success if performed at least 4 weeks after completing therapy [20]. Notably, the primary limitation of UBT is its reduced sensitivity due to an increased likelihood of false-negative results following the recent use (within 2–4 weeks) of PPIs, bismuth, or antibiotics. Interestingly, there is currently no sufficient data to determine whether PCAB use affects UBT results [21]. However, considering that all studies performed testing after 28 days of follow-up post-treatment completion, the likelihood of false-negative findings is minimal.

Tegoprazan appears to be well tolerated in participants with *H pylori*, with a similar rate of TEAE to PPI therapy. This data was similar to a meta-analysis, which showed no significant increase in adverse events of Vonoprazan to PPI among 18 RCTs [22]. Additionally, another randomized trial showed similar

rates of TEAE, which were mild in patients who were administered Tegoprazan and Vonoprazan [7]. Since both drugs are from the same PCAB family, they are likely to show similar safety profiles. However, one should note that these safety profiles are considered short term, and longer-term safety profiles for Tegoprazan still need to be investigated.

There are some limitations inherent to this systematic review. Only six RCTs were included in our meta-analysis, all with a low risk of bias but only with a small to moderate sample size. Furthermore, one RCT [12] is currently available as conference abstracts, with no full-text publication. However, to date, this meta-analysis has more than tripled the statistical power of individual RCTs, incorporating a total of 2110 patients randomized into the two arms. Furthermore, all included studies were conducted in Asia (South Korea [$n = 3$] and China [$n = 3$]), limiting the generalizability of our findings to the broader populations. Another limitation is the lack of antibiotic susceptibility data, which may act as a confounding factor in *H pylori* treatment. Treatment failure may be due to *H pylori* resistance itself rather than the choice of Tegoprazan or PPI [23], particularly given the high clarithromycin resistance reported in South Korea [24]. This limitation affects not only the individual studies but also the overall findings of this meta-analysis. Although antibiotic susceptibility testing is not yet routinely performed, its increasing availability has led the ACG guideline [20] to recommend its use when the choice of therapy remains unclear (particularly after considering prior treatments, past antibiotic exposure, and history of penicillin allergy). Furthermore, our subgroup analysis on antibiotic-susceptible *H pylori* strains is severely underpowered and no longer adheres to the initial ITT principle. Therefore, further studies are warranted to explore the role of Tegoprazan in treating *H pylori* strains resistant to antibiotics.

Overall, more RCTs in different populations and with larger sample sizes are needed to confirm the superiority of Tegoprazan to PPI, especially in different antibiotic-susceptible *H pylori*, before this novel P-CAB is adopted in clinical guidelines for treating *H pylori* infection.

Acknowledgments

The authors have nothing to report.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

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

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Supporting Information

Additional supporting information can be found online in the Supporting Information section.