

H. pylori 치료

: 이제 바꾸어야 하는가?

삼성서울병원 소화기내과 김태세

헬리코박터 검사 적응증

- The determination of when to test for—and treat—H. pylori should be viewed as a single, rather than 2 separate and distinct decisions.

ACG Clinical Guideline: Treatment of H. pylori infection. Am J Gastroenterol 2024;119:1730–1753.

- 치료할 계획이 있을 때 검사 하면 되지만, 현실은 복잡합니다.

검사 급여 기준 (고시 제2022-204호)

- 1. 헬리코박터필로리(Helicobacter Pylori) 검사는 다음과 같은 경우에 요양급여를 인정하며, 동 검사를 위해 시행 하는 생검료(내시경하 생검료), 생검 시 사용되는 치료재료는 별도 산정함.
 - 가. 내시경 등으로 위 및 십이지장의 소화성궤양(반흔기포함), 저등급 MALT 림프종(low grade gastric mucosa associated lymphoid tissue lymphoma)이 확인된 환자
 - 나. 조기위암절제술 시행 환자
 - 다. 특발성 혈소판감소성 자반(증) (Idiopathic Thrombocytopenic Purpura, ITP) 환자
- 2. 위암 가족력[부모, 형제,자매 (First degree)]에서 시행한 경우「선별급여 지정 및 실시 등에 관한 기준」에 따라 본인부담률 50%로 적용함(동 검사를 단독으로 시행하는 경우 생검료, 생검 시 사용되는 치료재료는 본인부담률 50%로 적용)
- 3. 상기 1, 2. 이외에 시행하는 경우에는 「선별급여 지정 및 실시 등에 관한 기준」에 따라 **본인부담률을 90%로 적용함** (동 검사를 단독으로 시행하는 경우 생검료, 생검 시 사용 되는 치료재료는 본인부담률 90%로 적용)
- 4. 상기 1 ~ 3.에도 불구하고 「요양급여 적용 기준 및 방법에 관한 세부사항」에서 세부인정사항을 별도로 정한 항목은 해당 고시에서 정한 기준을 적용함.

치료 급여 기준 (고시 제2022-111호)

• 보험 급여

- 소화성 궤양
- 저등급 MALT(Mucosa Associated Lymphoid Tissue) 림프종
- 조기 위암 절제술 후
- 특발성 혈소판 감소성 자반증 (idiopathic thrombocytopenic purpura)
- 위선종의 내시경절제술 후

• 전액 본인 부담 (100/100)

- 위암 가족력[부모, 형제, 자매(first degree)의 위암까지]
- 위축성 위염
- 헬리코박터 파일로리(H.pylori) 감염이 음성인 저등급 MALT(Mucosa Associated Lymphoid Tissue) 림프종 환자에게 제균요법으로 투여하는 경우
- 기타 진료상 제균요법이 필요하여 환자가 투여 동의

Table 1. Characteristics of each *Helicobacter* diagnosis method

Method	Sensitivity, %	specificity, %	Advantage	Disadvantage	
Non-invasive method					
UBT	96	95	Fast and simple High sensitivity and specificity	No antibiotic resistance data Limited to post-gastrectomy patients	→ Sampling error가 없다는 장점
Serology test	85	79	Fast and simple Cheap Low false-negative	Low sensitivity and specificity Inability to distinguish active and past infection	→ PPI 복용과 무관한 장점 감염 3주후 양성, 제균 후 역가 감소 (1년 이상 필요할 수도)
SATs					
Immunochromatographic assay	83	94	Rapid and simple	Requiring highly sensitivity	
Enzyme immunoassay	96	96	Cheap Alternatives to UBT	Influence on specimen condition Affected by constipation and colorectal polyps	
Rapid urine test					
Immunochromatographic assay	82.4-100.0	66.7-100.0	Convenience of specimen collection	Low sensitivity and specificity	→ 국내 민감도 77.4% 권고 X
ELISA	86.3-99.0	91.5-100.0	Cheap	Inability to distinguish active and past infection False-positive to proteinuria	
Invasive method					
Biopsy	95	99	High sensitivity and specificity Additional pathologic information	Sampling error Requiring special staining	→ Giemsa 염색 민감도 높음
RUT	85-95	95-100	High specificity Availability in post-gastrectomy patient	Sampling error Depending on reaction time, substrate types Need to extra visit	→ 24시간 이후 양성은 각종 균 배양으로 인해 위양성 높아 결과 반영 X
PCR	100	98	High sensitivity and specificity Antibiotic resistance data	Expensive Expertise of equipment	→ Clarithromycin R (DPO-PCR 유용)
Culture	85-95	100	High specificity Antibiotic resistance data	Sampling error Easy to contamination Prolonged bacterial culture time	→ 배양 속도 느려 1차 진단 검사 X 제균 실패 경우 고려

UBT, urea breath test; SATs, stool antigen tests; RUT, rapid urease test; ELISA, enzyme-linked immunosorbent assay; PCR, polymerase chain reaction.

H. pylori 의 치료

진료지침 2013 → 2020 (1차 치료)

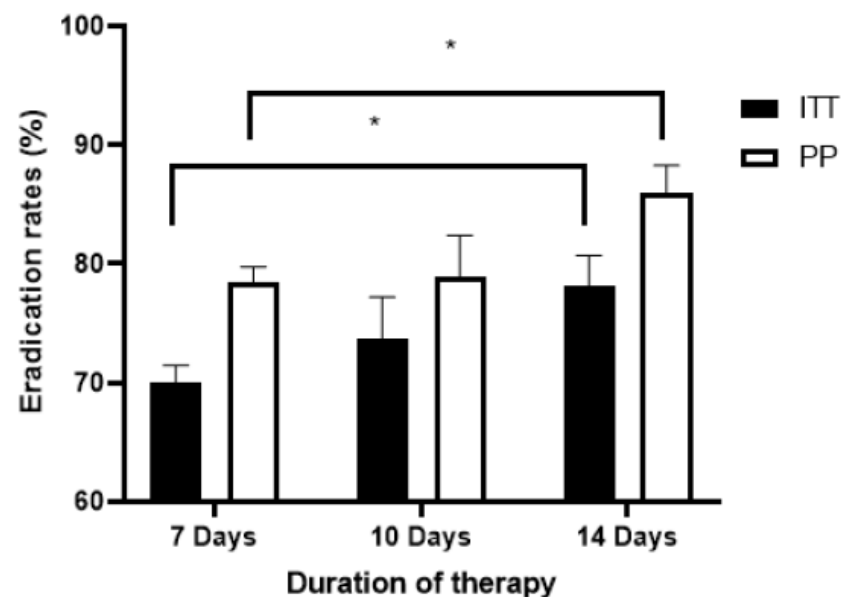
전통적 방법: PPI + amoxicillin + clarithromycin 7-14일

Clarithromycin 내성률 증가로 인한 제균율 감소 (< 80%)

2020년 지침 개정

(1) PPI 3제 14일, (2) Bismuth 포함하지 않은 4제 10일 순차 또는 동시 치료, (3) Clarithromycin 내성 검사에 따른 선택, (4) 일부 환자에서 BQT 10-14일

STT 1주 70.0% → 2주 78.1%
- pooled analysis



Supplementary Fig. 3. Pooled eradication rates of standard triple therapy by treatment duration from randomized controlled trials performed in Korea. Eradication rates of standard triple therapy (STT) for 7 days were 70.0% (95% CI, 68.5~71.4%) in intention-to-treat (ITT) analysis and 78.4% (95% CI, 77.0~79.7%) in per protocol (PP) analysis. Eradication rates of STT for 10 days were 73.7% (95% CI, 69.8~77.2%) in ITT analysis and 78.9% (95% CI, 74.9~82.4%) in PP analysis. Eradication rates of STT for 14 days were 78.1% (95% CI, 75.2~80.7%) in ITT analysis and 86.0% (95% CI, 83.4~88.3%) in PP analysis. * $P < 0.05$.

10일 동시 치료

- 순차치료에 비해 근소하게 높은 제균율
- 14일 표준 3제요법에 비해서는 17% 높은 제균율
- Bismuth 4제와 차이 없음

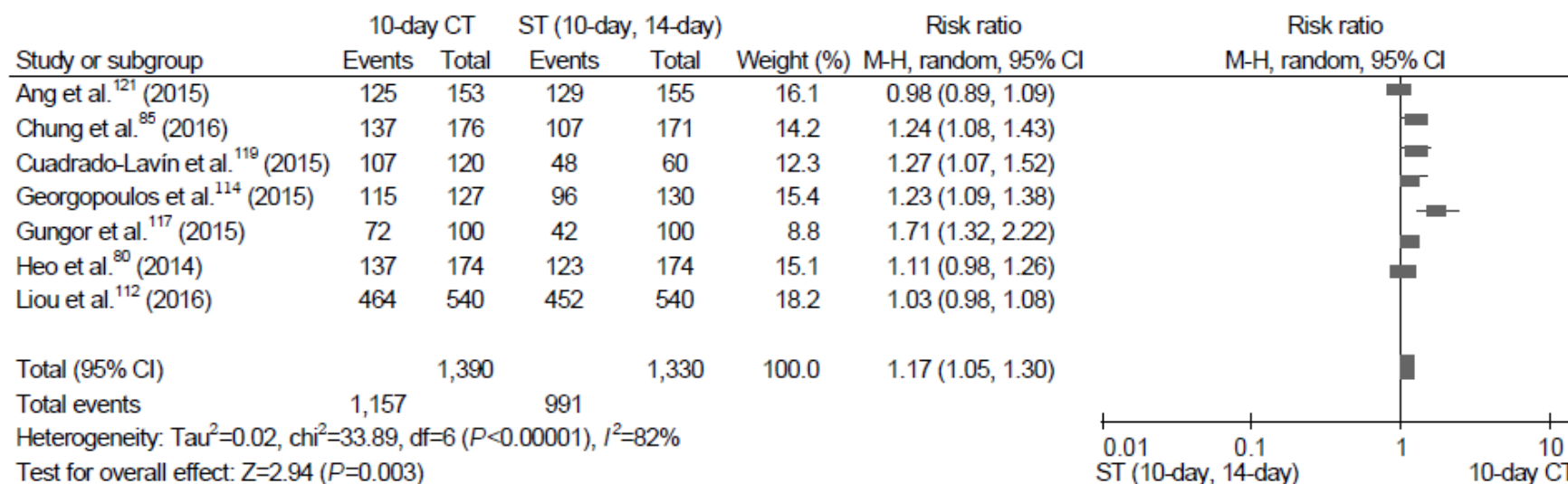


Fig. 6. Comparison of 10-day concomitant therapy (CT) and 10-/14-day standard triple (ST) therapy in intention-to-treat analysis. M-H, Mantel-Haenszel test.

2020 가이드라인 요약

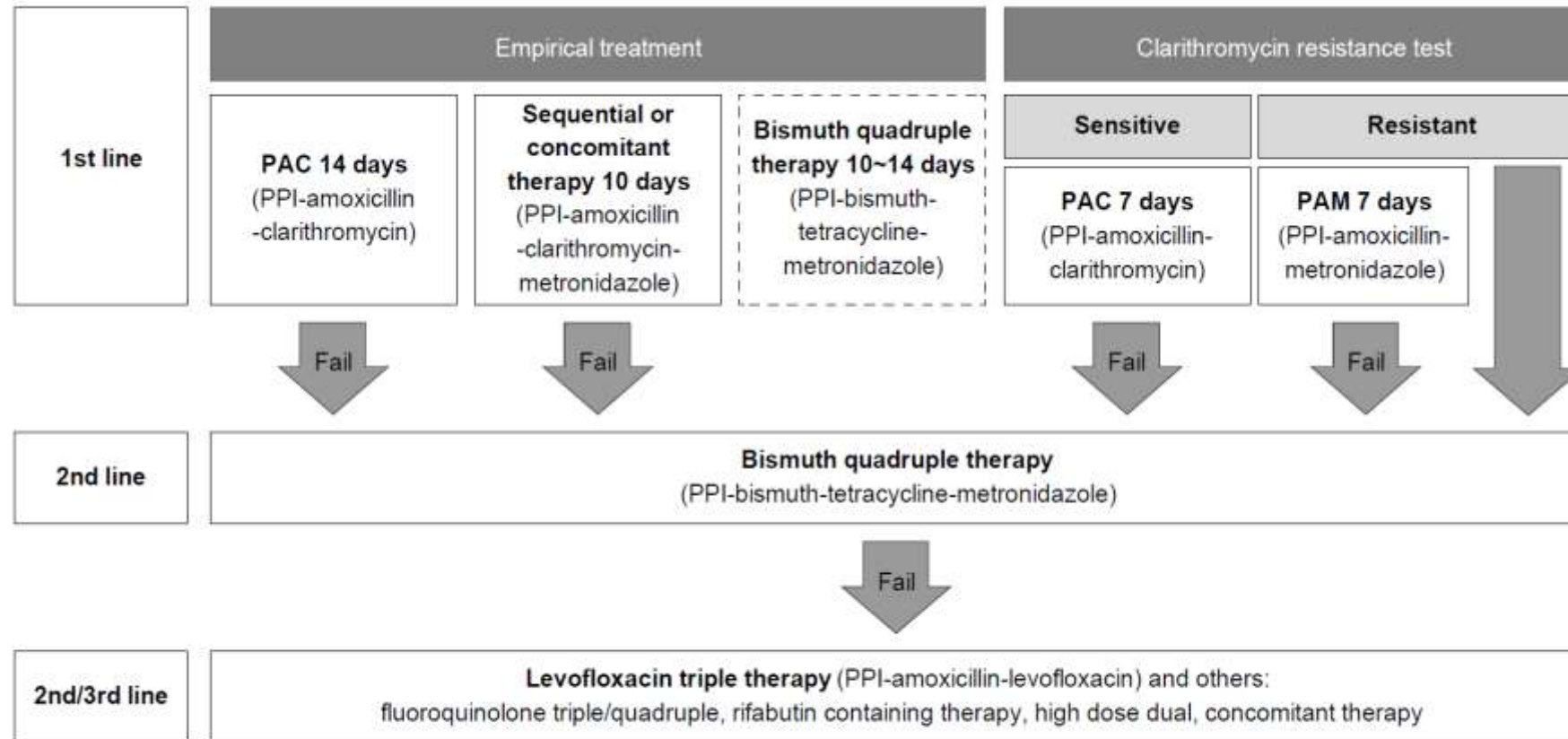


Fig. 10. Proposed algorithm for the treatment of *Helicobacter pylori* infection. Bismuth quadruple therapy as a first-line therapy is dotted because it is less preferred than other regimens. PPI, proton pump inhibitor.

2025 가이드라인

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Availability of Data and Material
All data generated or analyzed during
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Treatment of *Helicobacter pylori* Infection in Korea: An Evidence-Based Analysis of the Upcoming 2025 Guideline

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The efficacy of clarithromycin-containing triple therapy (TT) against *Helicobacter pylori* has declined in Korea, with recent first-line eradication rates falling below 70%. Clarithromycin resistance exceeded 30%, undermining the standard regimen for *H. pylori*. These trends necessitate

→
공청회

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Availability of Data and Material
The datasets generated or analyzed
during the study are available from the
corresponding author on reasonable
request.

Conflicts of Interest
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participation. Members with identified
conflicts were excluded from voting
on the relevant recommendations.
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Evidence-Based Guidelines for the Diagnosis and Treatment of *Helicobacter pylori* Infection in Korea: 2025 Revised Edition

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Table 4. Summary of recommendations

Statement	Recommendation	Strength of recommendation	Level of evidence	Expert agreement
1	<i>H. pylori</i> eradication therapy is suggested for the prevention of gastric cancer in patients with <i>H. pylori</i> gastritis.	Weak	Moderate	95.3% (61/64)
2	<i>H. pylori</i> eradication therapy is suggested for patients with confirmed <i>H. pylori</i> infection and gastric hyperplastic polyps ≤ 10 mm, to achieve polyp regression or size reduction.	Weak	Low	81.3% (52/64)
3	PCR or sequencing-based testing is suggested for <i>H. pylori</i> infection diagnosis and antibiotic resistance detection to guide first-line treatment selection.	Weak	Very low	95.3% (61/64)
4-1	Tailored therapy based on clarithromycin resistance testing (antibiotic susceptibility testing) is recommended as first-line eradication therapy for <i>H. pylori</i> infection.	Strong	Moderate	96.9% (62/64)
4-2	Based on clarithromycin resistance testing, 10-day BQT is recommended for resistant strains, and 7-day clarithromycin-based triple therapy for susceptible strains.	Strong	Moderate	84.4% (54/64)
5	Ten-day concomitant therapy is recommended as first-line empirical eradication therapy for <i>H. pylori</i> infection.	Strong	High	68.8% (44/64)
6-1	Ten to 14-day BQT may be used as first-line empirical eradication therapy for <i>H. pylori</i> infection.	Weak	Moderate	71.9% (46/64)
6-2	BQT is associated with higher adverse event rates and potential utility as salvage therapy; its use as first-line therapy is suggested when other eradication regimens cannot be used.	Weak	Expert consensus	84.4% (54/64)
7	Clarithromycin-based triple therapy may be used in a limited fashion when antibiotic susceptibility testing is unavailable and regional clarithromycin resistance is expected to be below 15%.	Weak	Moderate	Revised consensus 73.9% (34/46)
8	P-CAB-based antibiotic combination therapy may substitute for PPI-based antibiotic combination therapy as first-line eradication treatment for <i>H. pylori</i> infection.	Strong	Moderate	98.4% (63/64)
9-1	Ten to 14-day BQT is recommended as second-line eradication therapy when clarithromycin-based triple therapy or concomitant therapy has failed.	Strong	Moderate	100% (64/64)
9-2	When BQT has failed as first-line or second-line therapy, rifabutin-based triple therapy or modified BQT incorporating previously unused antibiotics may be considered. Levofloxacin-based therapy may be attempted in a limited fashion, considering regional resistance patterns.	Weak	Very low	89.1% (57/64)
9-3	Referral to a specialized <i>H. pylori</i> center capable of antibiotic susceptibility testing-guided tailored therapy is suggested when two or more lines of eradication therapy have failed.	Weak	Expert consensus	81.3% (52/64)

P-CAB, potassium-competitive acid blocker; PCR, polymerase chain reaction; BQT, bismuth-based quadruple therapy; PPI, proton pump inhibitor.

Key changes

1. New philosophy: **dual pillar strategy**

- PCR-based **tailored** therapy
- **Empirical quadruple** therapy (CT or bismuth-based regimens)

2. Changes in first-line therapy

- Empirical **clarithromycin triple therapy is no longer recommended** as routine first-line treatment
- Sequential therapy & PAM removed
- mBQT introduced
- **P-CAB** formally incorporated into treatment regimens

3. Systematic salvage therapy algorithm

- After 2 or more failures → **referral to specialized centers** for susceptibility guided therapy

4. New indications for *H. pylori* eradication

- **Gastric cancer prevention**
- Regression/prevention of recurrence of **hyperplastic polyps**

H. pylori

어떻게 진단하고 치료할 것인가?

헬리코박터 진단과 치료



보수 현실주의파의 주장

Empirical therapy도 실제로 충분히 잘 된다. 안 되면 두 번 하면 그만이다.

- 특히 concomitant therapy, P-CAB triple 14일
- 첫 치료 성공률 70%이고 BQT로 salvage 성공률 95%이니, $0.7 + (0.3 * 0.95) = 0.985 = 98.5\%$ 면 충분하다.

Strong acid suppression으로 resistance 일부 극복 가능하다

- P-CAB의 등장

처음부터 제일 독한 regimen 쓰면 남는 카드가 없다.

- Tetracycline tolerance, BQT 관련 adverse event rate

Tailored therapy는 현실적 제약이 크다

- 추가 내시경 필요, 비용, 검사 접근성 (일부 병원 PCR 불가)

진보 stewardship파의 주장

Clarithromycin 내성 > 30% 면 empirical triple therapy는 부적절하다

- P-CAB 쓰더라도 backbone 자체가 Clarithromycin exposure 인 것은 부적절하다

첫 치료 성공률이 최소 >90% 는 되어야 한다

- Secondary resistance 증가
- Cumulative antibiotics exposure 증가

BQT도 심각한 부작용은 많지 않다.

Tailored therapy로 precision medicine 해야 한다

- 그렇게 비싸지도, 불편하지도 않다.

H. pylori 진단: 가능하면 PCR로

Statement 3. PCR or sequencing-based testing is suggested for H. pylori infection diagnosis and antibiotic resistance detection to guide first-line treatment selection.

Strength of recommendation: weak; level of evidence: very low

Expert agreement: 95.3% (61/64)

H. pylori 진단: 가능하면 PCR로

- 기존 검사의 한계: Clarithromycin 내성 확인 불가
 - Histology, rapid urease test, urea breath test, and stool antigen test
 - 확인하지 않기에는 Clarithromycin 내성률이 너무 높음.
 - 배양 검사: 가장 확실하지만 오래 걸리고 배양 성공률 낮음.
- DPO-PCR 검사의 장점
 - 감염 + Clarithromycin 내성 동시 확인
 - 23S 리보솜 RNA 점돌연변이 PCR (A2142G, A2143G)
 - Concordance rate of over 95% with phenotypic tests such as the E-test



Korean Registry on the Current Management of *Helicobacter pylori* (K-Hp-Reg): Interim Analysis of Adherence to the Revised Evidence-Based Guidelines for First-Line Treatment

Hyo-Joon Yang¹, Joon Sung Kim², Ji Yong Ahn³, Ok-Jae Lee⁴, Gwang Ha Kim⁵, Chang Seok Bang⁶, Moo In Park⁷, Jae Yong Park⁸, Sun Moon Kim⁹, Su Jin Hong¹⁰, Joon Hyun Cho¹¹, Shin Hee Kim¹⁰, Hyun Joo Song¹², Jin Woong Cho¹³, Sam Ryong Jee¹⁴, Hyun Lim¹⁵, Yong Hwan Kwon¹⁶, Ju Yup Lee¹⁷, Seong Woo Jeon¹⁶, Seon-Young Park¹⁸, Younghee Choe², Moon Kyung Joo¹⁹, Dae-Hyun Kim²⁰, Jae Myung Park²¹, Beom Jin Kim⁸, Jong Yeul Lee²², Tae Hoon Oh²³, Jae Gyu Kim⁸, and Korean College of Helicobacter and Upper Gastrointestinal Research

**Prospective, nationwide, multicenter, registry study
at 66 primary, secondary, and tertiary hospitals in Korea**

2021년 3월 → 2023 8월 midpoint

제균 성공률 (K-Hp-Reg)

Variables	mITT set, No. (%)	Success, No.	Failure, No.	Eradication rate, %		
				ITT	mITT	PP
Overall	6,319 (100.0)	5,121	1,198	70.5	81.0	81.5
First-line treatment regimens						
CTT, 14 day	2,655 (42.0)	2,068	587	66.9	77.9	78.4
ST, 10 day	164 (2.6)	141	23	77.5	86.0	85.9
CT, 10 day	640 (10.1)	537	103	69.9	83.9	84.7
BQT, 10–14 day	280 (4.4)	258	22	84.6	92.1	92.0
TT	1,342 (21.2)	1,186	156	76.8	88.4	88.9
CTT, 7 day	888 (14.1)	631	257	64.3	71.1	71.3
Others	350 (5.6)	300	50	77.3	85.7	86.4

The intention-to-treat (ITT) set included all patients who were registered and received first-line *H. pylori* treatment.

The modified ITT (mITT) set included all patients who completed follow-up after first-line treatment.

The per-protocol (PP) set included all patients who completed follow-up with ≥80% drug compliance for first-line treatment.

EGC, early gastric cancer; MALT, mucosa-associated lymphoid tissue; CAG, chronic atrophic gastritis; IM, intestinal metaplasia; CTT, clarithromycin-based triple therapy; ST, sequential therapy; CT, concomitant therapy; BQT, bismuth quadruple therapy; TT, tailored therapy; NA, not available.

항생제 내성률 (K-Hp-Reg)

H. pylori antibiotics resistance

PCR

Cla-r 358/1,143 (**31.3**)

Culture

Cla-r 167/501 (33.3)

Met-r 154/484 (31.8)

Cla-r + Met-r 73/484 (**15.1**)

→ NEW 진료지침 위원회의 인식

- 1) Unacceptably low eradication rate of Clarithromycin based triple therapy (**66.9% by ITT**)
- 2) Unacceptably high Clarithromycin resistance rate (**31.3% by PCR**)

CTT 연도별 제균율 (9 RCTs)

Table 2. Evidence table about the eradication rate of 14-day clarithromycin-containing TT in *H. pylori* infection

Study	Indication	Number of enrolled subjects	Eradication rate (ITT)	Eradication rate (PP)
Kim et al. ¹⁹ (2007)	PUD	261	75.5% (197/261)	86.6% (194/224)
Kim et al. ²⁰ (2008)	PUD	112	80.4% (90/112)	85.9% (79/92)
Kim et al. ²¹ (2008)	PUD	93	91.4% (85/93)	92.1% (82/89)
Kim et al. ²² (2011)	HP infected patients	204	75.0% (153/204)	85.0% (153/180)
Choi et al. ²³ (2012)	PUD	115	80.0% (92/115)	84.4% (92/109)
Kim et al. ²⁴ (2012)	PUD	104	74.0% (77/104)	82.8% (77/93)
Kim et al. ²⁵ (2020)	HP infected patients	191	66.0% (126/191)	79.7% (114/143)
Lim et al. ²⁶ (2023)	HP infected patients	270	66.7% (180/270)	74.6% (179/240)
Kim et al. ²⁷ (2024)	HP infected patients	153	68.6% (105/153)	75.5% (105/139)

TT, triple therapy; HP, *Helicobacter pylori*; PUD, peptic ulcer disease; ITT, intention-to-treat; PP, per protocol.

80% 미만의 제균 성공율 → 1st line option으로 고려하기 어렵다는 결론

Tailored therapy is the new pillar

Statement 4-1. Tailored therapy is recommended based on clarithromycin resistance testing (antibiotic susceptibility testing) as first-line eradication therapy for H. pylori infection.

Strength of recommendation: strong; level of evidence: moderate

Expert agreement: 96.9% (62/64)

Statement 4-2. Based on clarithromycin resistance testing, 10-day BQT is recommended (standard-dose PPI twice daily, metronidazole 500 mg three times daily, bismuth 120 mg and tetracycline 500 mg four times daily) for resistant strains, and 7-day clarithromycin-based triple therapy (standard-dose PPI, amoxicillin 1 g, and clarithromycin 500 mg, all twice daily) for susceptible strains.

Strength of recommendation: strong; level of evidence: moderate

Expert agreement: 84.4% (54/64)

Meta-analysis of 4 Korean RCTs

(published up to August 2024)

Analysis	Tailored	Empirical	RR
ITT	84.3%	77.3%	1.11 (1.05–1.17)
PP	91.6%	84.8%	1.08 (1.03–1.13)

- In most studies, clarithromycin-resistant patients received BQT and clarithromycin-susceptible patients received TT.
- The control group included regimens that were previously recommended as first-line therapies (clarithromycin-based TT, BQT, CT, or metronidazole-based TT).

Empirical Therapy Versus Tailored Therapy of *Helicobacter pylori* in Korea: Results of the K-CREATE Study

Joon Sung Kim¹ | Byung-Wook Kim¹  | Jin Il Kim² | Woo Chul Chung³  | Sung Woo Jung⁴  | Chang Seok Bang⁵  |
Gwang Ha Kim⁶  | Seon Woo Jeon⁷  | Moon Kyoung Joo⁸ | Si Hyung Lee⁹ | Yun Jeong Lim¹⁰  | Jae Kyu Sung¹¹ |
Seung Young Seo¹² | Sun Young Park¹³ | Wan Sik Lee¹⁴ | Hang Lak Lee¹⁵ | Ki Bae Kim¹⁶ | Heung Up Kim¹⁷

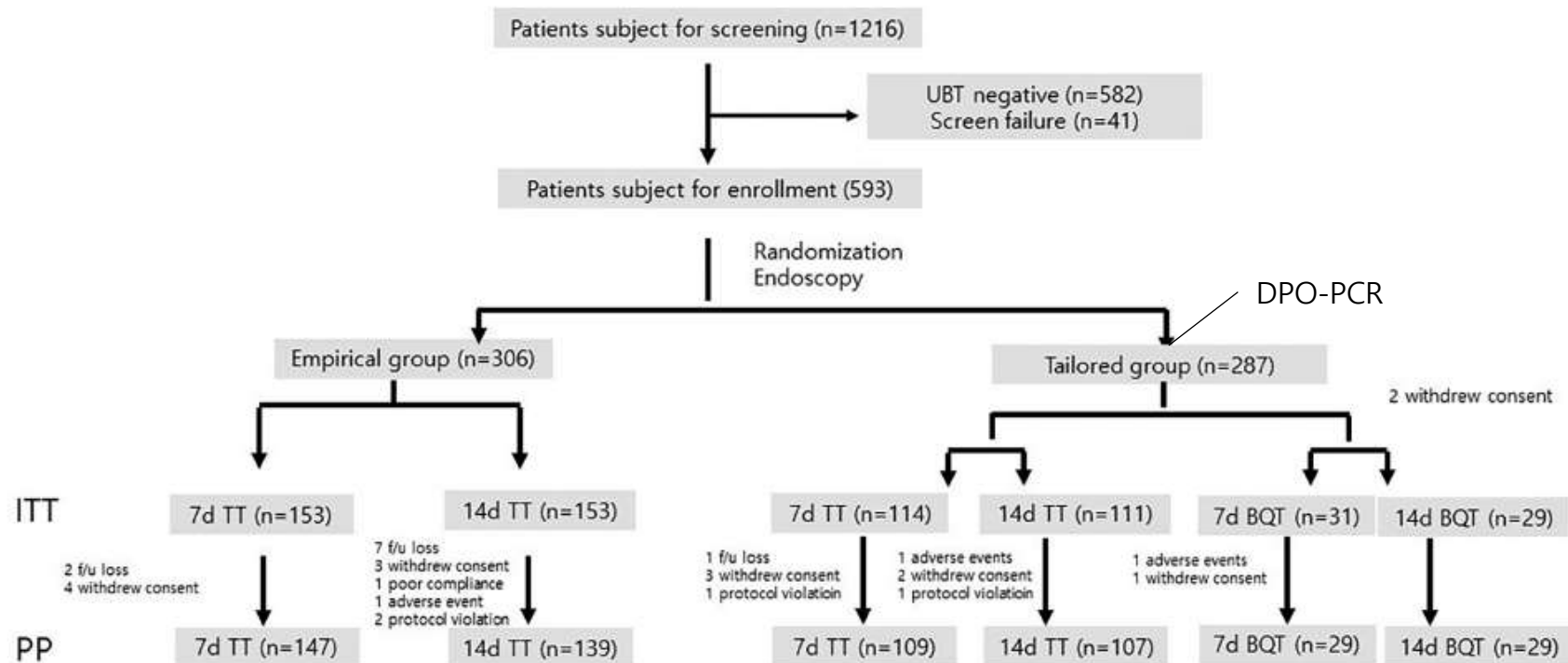


FIGURE 1 | Flow diagram of patients enrolled in the study. BQT, bismuth quadruple therapy; f/u, follow-up; ITT, intention-to-treat; PP, per-protocol; TT, triple therapy.

Tailored > Empirical TT

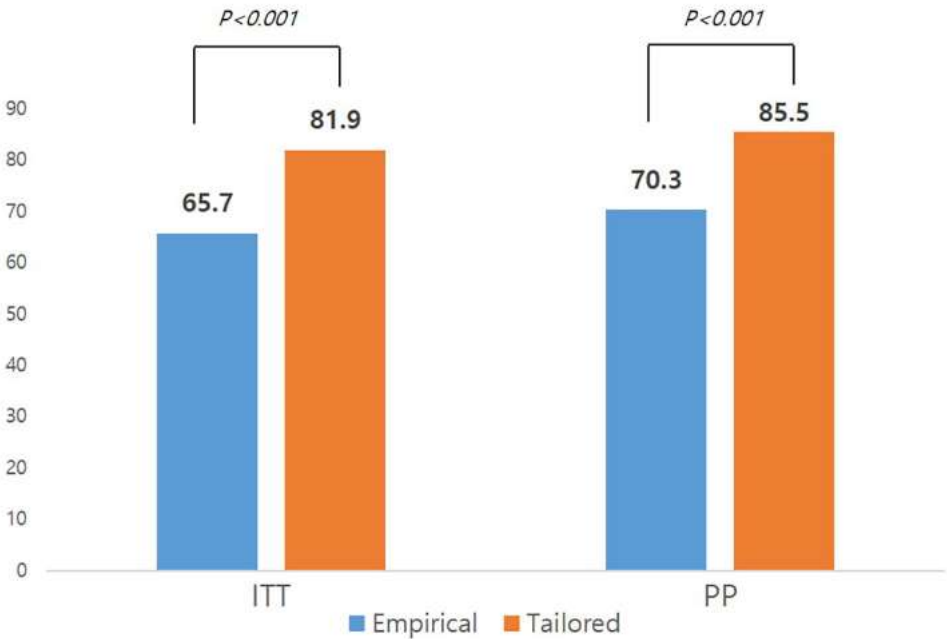


FIGURE 2 | Eradication rates of empirical and tailored therapy. ITT, intention-to-treat; PP, per-protocol.

Empirical therapy			
	7-day TT	14-day TT	<i>p</i>
ITT	62.7 (96/153)	68.6 (105/153)	0.278
PP	65.3 (96/147)	75.5 (105/139)	0.058
TT as tailored therapy (patients without point mutations)			
	7-day	14-day	<i>p</i>
ITT	81.6 (93/114)	81.1 (90/111)	0.924
PP	85.3 (93/109)	84.1 (90/107)	0.805
BQT as tailored therapy (patients with point mutations)			
	7-day	14-day	<i>p</i>
ITT	87.1 (27/31)	86.2 (25/29)	1.000*
PP	93.1 (27/29)	86.2 (25/29)	0.670*

Abbreviations: BQT, bismuth quadruple therapy; ITT, intention-to-treat; PP, per-protocol; TT, triple therapy.

*Fisher exact test.

→ Tailored 7일과 14일 차이 없음

Tailored therapy

- Clarithromycin resistance가 높은 지역 (우리나라)에서는 empirical therapy를 clarithromycin-based triple therapy로 하는 것보다 tailored therapy가 우월하다.
- Treatment duration of tailored therapy
 - Clarithromycin R → **BQT**
 - Highest eradication rates with **10-day** regimens (ITT 86.4%, PP 92.9%)
 - Clarithromycin S → **Clarithromycin-based TT**
 - Comparable rates between **7-day** (ITT 80.2%, PP 89.7%) and 14-day regimens.
 - **PAM → removed** (MTZ resistance 29.5%)
- 모든 종류의 empirical therapy보다 우월한 것은 아니다.
 - Head-to-head comparisons of tailored therapy versus empirical CT: lack of evidence

Pitfalls of tailored therapy

- **Tailored therapies do not always guarantee complete eradication**
 - Coexistence of *H. pylori* strains with different resistance profiles can lead to treatment failure.
 - Rare atypical mutations (e.g., A2142C) may be missed.
 - Variations in bacterial density across different gastric regions.
 - Lack of adherence
 - Resistance to other antibiotics
 - Tailored regimens often focus solely on clarithromycin resistance, potentially overlooking resistance to the other antibiotics included in the regimen.

Tailored therapy의 미래

- 파라핀 포매 블록으로 할 수 있다면?

제품명	NamuPlex™ HP-CLA Real-time PCR kit	Allpex® <i>H.pylori</i> & ClariR Assay	U-TOP™ HPy-ClariR Detection Kit
검체	위생검 조직, FFPE	위생검 조직	위생검 조직
시간	1시간 30분	2시간	2시간 40분
검출 바이러스	<i>H.Pylori</i> A2142G A2143G	<i>H.Pylori</i> A2142G A2143G	<i>H.Pylori</i> A2142G A2143G
장비	CFX96dx	CFX96dx	CFX96dx

Tailored therapy의 미래

- 파라핀 포매 블록으로 할 수 있다면?

	Conventional PCR		real-time PCR		
			SML Genetree	B	C
위생검조직 (28)	H.Pylori (+)	14	14/14	14/14	13/14
	A2143G	6	6/6	6/6	5/6
	A2142G	2	2/2	2/2	2/2
	H.Pylori (-)	6	5/6	5/6	6/6
	real-time PCR 일치율		96.4%(27/28)	96.4%(27/28)	92.9%(26/28)
FFPE (16)	H.Pylori (+)	9	9/9	8/9	8/9
	A2143G	5	5/5	4/5	4/5
	A2142G	1	1/1	1/1	1/1
	H.Pylori (-)	1	1/1	1/1	1/1
	real-time PCR 일치율		100%(16/16)	87.5%(14/16)	87.5%(14/16)

→ External validation with larger samples is required

→ 임상에서 재현 된다면 병리와 보관 조직으로 PCR 시행할 수 있을 것으로 기대

Another pillar: **empirical therapy**

Table 6. Summary of recommended first-line, second-line, and third-line *H. pylori* treatments in the 2025 guidelines

Treatment line	Approach	Regimen components	Duration (day)	Key restrictions/considerations
First-line	Tailored (PCR-guided)	C-susceptible: PPI/P-CAB+A+C	14	Requires PCR/AST confirmation of susceptibility
First-line	Empirical	C-resistant: BQT (PPI/P-CAB+B+M+T)	10–14	Recommended precision approach; ITT ≥90%
		CT: PPI/P-CAB+A+M+C	10	Stewardship concern (3 antibiotics); reserve for high resistance risk
		BQT: PPI/P-CAB+B+M+T	10–14	Tetracycline availability/tolerability issues possible
		mBQT-PACB: PPI/P-CAB+A+C+B	14	Efficacy reduced in high-level clarithromycin resistance
		mBQT-PAMB: PPI/P-CAB+A+M+B	14	Preferred mBQT; bypasses clarithromycin resistance
Second-line	Empirical	BQT: PPI/P-CAB+B+M+T	10–14	Standard salvage; metronidazole resistance overcome by higher dose/duration
Third-line	Empirical/AST-guided	Alternative: PAMB (PPI/P-CAB+A+M+B)	14	If tetracycline unavailable or not tolerated
		Rifabutin TT: PPI/P-CAB+A+rifabutin	10–14	Low resistance (0.8%); monitor for myelotoxicity; Tbc resistance concern
		mBQT with unused antibiotics: PPI/P-CAB+B+(A or L)+(unused antibiotics)	14	Avoid previously used antibiotics except A/M
		Levofloxacin TT: PPI/P-CAB+A+L	10–14	Limited use; resistance 36%–43%; only if susceptible or no prior fluoroquinolone exposure
	AST-guided	Susceptibility-guided regimen	Per AST	Strongly recommended; referral to specialised centre; ITT ≥80%–90%

PCR, polymerase chain reaction; PPI, proton pump inhibitor; P-CAB, potassium-competitive acid blocker; PACB, PPI+amoxicillin+clarithromycin+bismuth; PAMB, PPI+amoxicillin+metronidazole+bismuth; TT, triple therapy; BQT, bismuth-quadruple therapy; mBQT, modified BQT; CT, concomitant therapy; AST, antibiotic susceptibility test; ITT, intention-to-treat; A, amoxicillin; C, clarithromycin; B, bismuth; M, metronidazole; T, tetracycline; L, levofloxacin.

Another pillar: **empirical therapy**

- **Quadruple therapies**

- Concomitant therapy: PACM
- Bismuth based quadruple therapies
 - BQT: PBMT
 - mBQT: PACB, PAMB

- **Sequential therapy (ST) → removed**

- Inferior eradication rates compared to CT
- Low compliance

Empirical therapy: CT

Statement 5. Ten-day concomitant therapy is recommended (standard-dose PPI, clarithromycin 500 mg, amoxicillin 1 g, and metronidazole 500 mg, all twice daily) as first-line empirical eradication therapy for H. pylori infection.

Strength of recommendation: strong; level of evidence: high

Expert agreement: 68.8% (44/64)

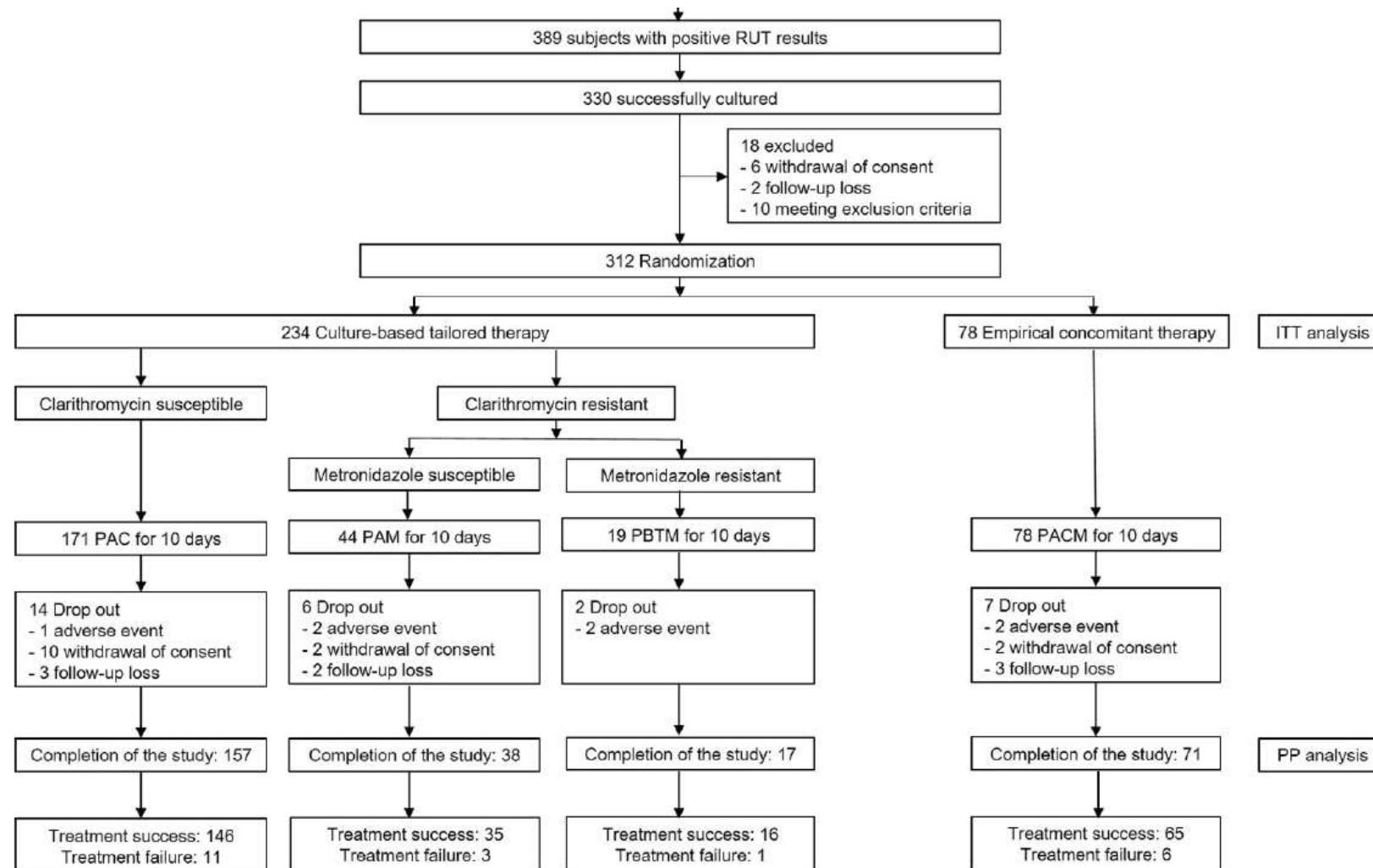
Concomitant therapy (PACM 10 days)

- Superior & simpler to sequential therapy
- Comparable efficacy to 14-day regimen
 - No significant benefit of extending to 14 days in Korean studies
- High eradication rates: **ITT 85.1%, PP 90.6%**
- Similar adverse event rate compared with other regimens

Tegoprazan 50mg	1	T	50	mg	2 회	2P	Q ⁺	10 일	[처음] 처방되는 약입니다.
Amoxicillin 500mg	2	C	1000	mg	2 회	2P	Q ⁺	10 일	[처음] 처방되는 약입니다. 유사코드 주의 약물입니다.
Clarithromycin 500mg	1	T	500	mg	2 회	2P	Q ⁺	10 일	[처음] 처방되는 약입니다.
Metronidazole 250mg	2	T	500	mg	2 회	2P	Q ⁺	10 일	[처음] 처방되는 약입니다.

Culture-based susceptibility-guided tailored versus empirical concomitant therapy as first-line *Helicobacter pylori* treatment: A randomized clinical trial

Jeong Hoon Lee¹ | Byung-Hoon Min² | Eun Jeong Gong³ | Jun Young Kim⁴ |
 Hee Kyong Na¹ | Ji Yong Ahn¹ | Do Hoon Kim¹ | Kee Don Choi¹ |
 Yang Won Min² | Hyuk Lee² | Jun Haeng Lee² | Hwoon-Yong Jung¹ | Jae J. Kim²



Concomitant = Tailored

- Culture 기준, 동시 치료 10일
- Dual resistance = 8%

TABLE 2 *H. pylori* eradication rates of each therapy group and eradication rates according to each treatment regimen and antimicrobial susceptibility.

		Culture-based tailored therapy	Empirical concomitant therapy	<i>p</i> value
Intention-to-treat		84.2% (197/234)	83.3% (65/78)	0.859
95% CI		79.1%–88.4%	73.9%–90.3%	
Per-protocol		92.9% (197/212)	91.5% (65/71)	0.702
95% CI		88.9%–95.8%	83.4%–96.4%	
Resistance pattern (Per-protocol)				
Clarithromycin	metronidazole			
Susceptible	susceptible	94.5% (120/127; PAC)	97.5% (39/40; PACM)	0.681
Susceptible	resistant	86.7% (26/30; PAC)	100% (14/14; PACM)	0.290
Resistant	susceptible	92.1% (35/38; PAM)	90.9% (10/11; PACM)	1.000
Resistant	resistant	94.1% (16/17; PBTM)	33.3% (2/6; PACM)	0.008

Abbreviations: CI, confidence interval; PAC, lansoprazole, amoxicillin, and clarithromycin; PACM, lansoprazole, amoxicillin, clarithromycin, and metronidazole; PAM, lansoprazole, amoxicillin, and metronidazole; PBTM, lansoprazole, bismuth potassium citrate, tetracycline and metronidazole.

Table 3. Evidence table about the eradication rate of CT in *H. pylori* infection (meta-analysis)

Study	Eradication rate (ITT) (before 2018)	Eradication rate (PP) (before 2018)	Eradication rate (ITT) (after 2018)	Eradication rate (PP) (after 2018)
10-day CT, overall (n=23 before 2018) (n=10 after 2018)	85% (82%–88%)	91% (88%–93%)	85% (85%–85%)	93% (91%–95%)
10-day CT, Korean studies (n=7 before 2018) (n=4 after 2018)	84% (77%–89%)	92% (88%–94%)	82% (79%–85%)	93% (91%–95%)
14-day CT, overall (n=6 before 2018) (n=19 after 2018)	86% (76%–92%)	94% (88%–97%)	86% (84%–87%)	91% (89%–92%)
14-day CT, Korean studies (n=2 before 2018) (n=3 after 2018)	79% (72%–85%)	94% (50%–99%)	84% (80%–87%)	90% (87%–93%)

Data are presented as effect size (95% CI).

CT, concomitant therapy; ITT, intention-to-treat; PP, per protocol; CI, confidence interval.

SMC data

- 2021.06.30. ~ 2026.06.30 Concomitant 10-14일 처방 받은 환자 중 UBT 결과가 보고된 685명
- Success rate = **640/685 = 93.4%**

Concerns for CT

- Uses three antibiotics simultaneously
- Antibiotics stewardship concerns

Bismuth quadruple regimens

- BQT (PBMT), mBQT (PAMB, PACB)
- Bismuth-based regimens typically include **a bismuth salt plus two antibiotics and an acid suppressor**, meaning that they use only two antibiotics rather than three.
- Bismuth compounds have multimodal antibacterial actions against H.pylori and help **overcome resistance by synergizing with antibiotics** and perhaps **mildly suppressing H. pylori** on their own.
 - Direct disruption of bacterial cell walls and membranes, biofilm dissolution, etc.
 - 40% improved eradication rates for Clarithromycin R strains
 - 26% improved eradication rates for Metronidazole R strains

Bismuth quadruple regimens

Statement 6-1. Ten to 14-day BQT may be used as first-line empirical eradication therapy for H. pylori infection.

Strength of recommendation: weak; level of evidence: moderate

Expert agreement: 71.9% (46/64)

Statement 6-2. BQT is associated with higher adverse event rates and potential utility as salvage therapy; therefore, its use as first-line therapy is suggested when other eradication regimens cannot be used.

Strength of recommendation: weak; level of evidence: expert consensus

Expert agreement: 84.4% (54/64)

mBQT

Regimen	ITT eradication rate	PP eradication rate	Comparison
PAMB	87–93%	Up to 95%	Non-inferior to CT/BQT
PACB	77.8–93%	Up to 95%	Generally effective; efficacy varies by study

Gut Microbes 2020;11:1314-1323.
Helicobacter 2018;23:e12466.
Gut 2015;64:1715-1720.
PLoS One 2018;13:e0197096.
Microorganisms 2025;13:519.

mBQT

- Comparable efficacy to conventional BQT
- Less treatment burden compared to BQT

Tegoprazan 50mg	1	T	50	mg	2 회	2P	Q ⁺	14 일
Amoxicillin 500mg	2	C	1000	mg	2 회	2P	Q ⁺	14 일
[처음] 처방되는 약입니다. 유사코드 주의 약물입니다.								
Metronidazole 250mg	2	T	500	mg	2 회	2P	Q ⁺	14 일
[처음] 처방되는 약입니다.								
Denol(R)	1	T	300	mg	4 회	4A	Q ⁺	14 일
[처음] 처방되는 약입니다. [KIMS][신장애] 데놀정은(는) 신손상 환자에게 금기인 제품입니다. Ccr : 56.2, eGFR : 71.4, 검사일자 : 2026-05-28								

3. 상호작용

- 1) 테트라사이클린계 항생물질의 흡수를 저해할 수 있으므로 병용투여하지 않는다.
- 2) 제산제에 의해 효과가 감소될 수 있으므로 이 약 투여 전후 30분 동안에는 제산제를 투여하지 않는다.

14-day Clarithromycin TT

Statement 7. Clarithromycin-based triple therapy may be used in a limited fashion when antibiotic susceptibility testing is unavailable and regional clarithromycin resistance is expected to be below 15%.

Strength of recommendation: weak; level of evidence: moderate

Expert agreement: 73.9% (34/46) [second-round vote after first-round non-consensus at 53.1%]

14-day Clarithromycin TT

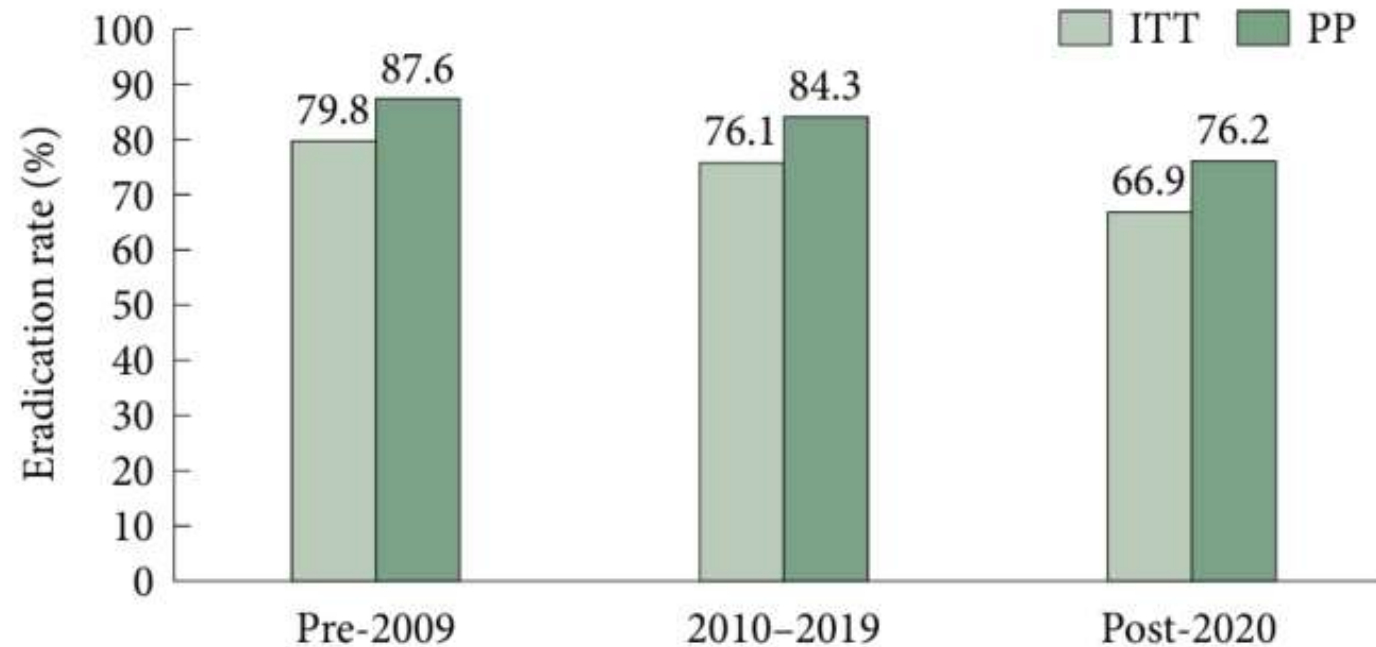


Fig. 7. *H. pylori* eradication rates with 14-day standard triple therapy by study period (Korean randomized controlled trials). ITT, intention-to-treat analysis; PP, per-protocol analysis.

14-day Clarithromycin TT

- Following public hearing deliberation, a revised conditional recommendation permitting limited use when susceptibility testing is unavailable and regional resistance is expected to be below 15% achieved 73.9% agreement.

Salvage after treatment failure

- With more effective first-line treatment, the overall proportion of patients requiring salvage therapy should decrease.
- The overarching principle is to **avoid repeating any antibiotic to which the strain has already been exposed and to use the most effective available** regimen for salvage, taking into account cumulative resistance.

Salvage after treatment failure

Statement 9-1. Ten to 14-day BQT is recommended as second-line eradication therapy when clarithromycin-based triple therapy or concomitant therapy has failed.

Strength of recommendation: strong; level of evidence: moderate

Expert agreement: 100% (64/64)

2nd line therapy

- **BQT (PBMT)**

- Reaffirmed as the standard second-line regimen in Korea for patients in whom first-line therapies (e.g., 10-day CT or tailored therapy) have failed.
- Successful second-line BQT improves the cumulative eradication rate to approximately 95%
- **10–14 days is recommended over 7 days.**

9 RCTs: 7 days vs 10-14 days

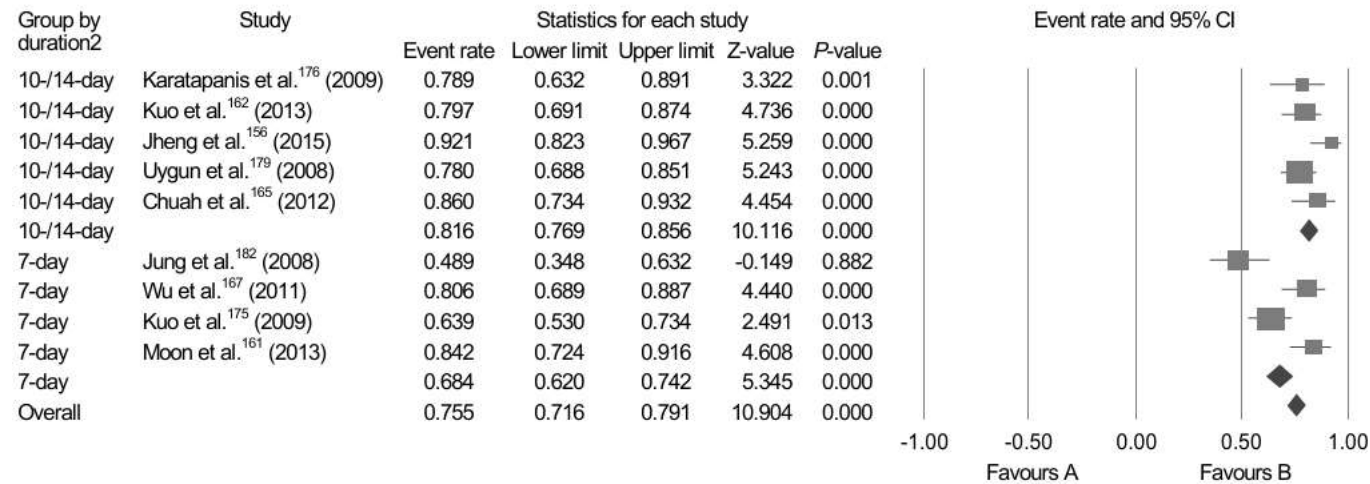
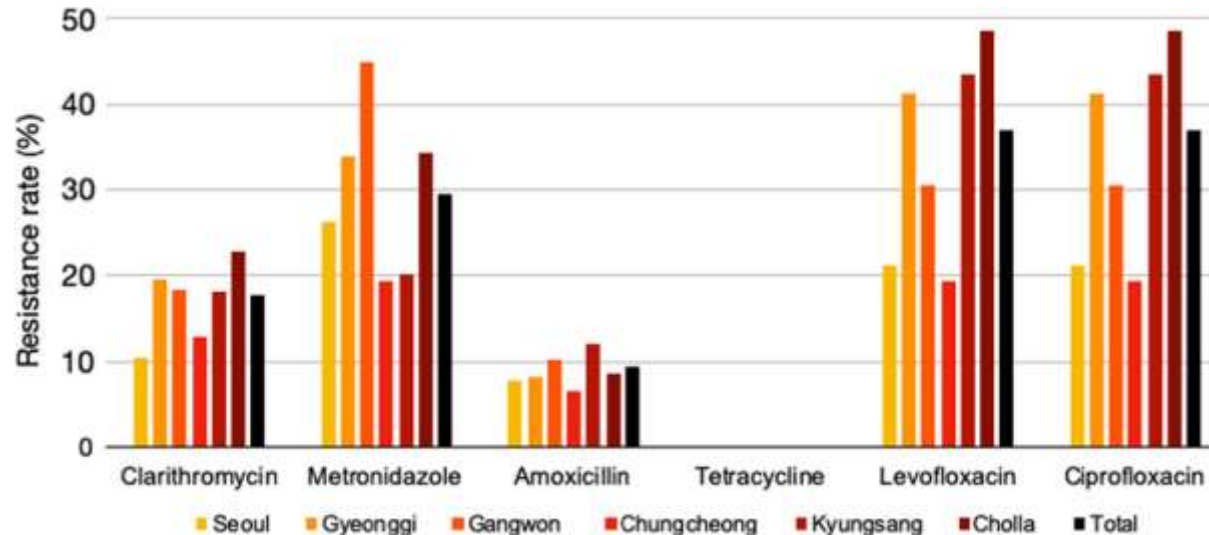


Fig. 8. Meta-analysis of nine studies that compare bismuth quadruple therapy with other regimens after the failure of first-line clarithromycin triple therapy. The pooled eradication rate of bismuth quadruple therapy as a second-line therapy is 75.5% (95% CI, 71.6~79.1%).

- Significantly higher OR for eradication (OR 2.02; 95% CI, 1.32-3.07)
- No difference in drop-out rates (OR 1.11, 95% CI, 0.78-1.59)

Metronidazole resistance

- 2019 국내 MTZ resistance rate = 29.5%



- Resistance can often be overcome by increasing the dosage and duration of treatment.

Third-line rescue therapy

Statement 9-2. When BQT has failed as first-line or second-line therapy, rifabutin-based triple therapy or modified BQT incorporating previously unused antibiotics may be considered.

Levofloxacin-based triple or quadruple therapy may be attempted in a limited fashion, considering regional antibiotic resistance patterns.

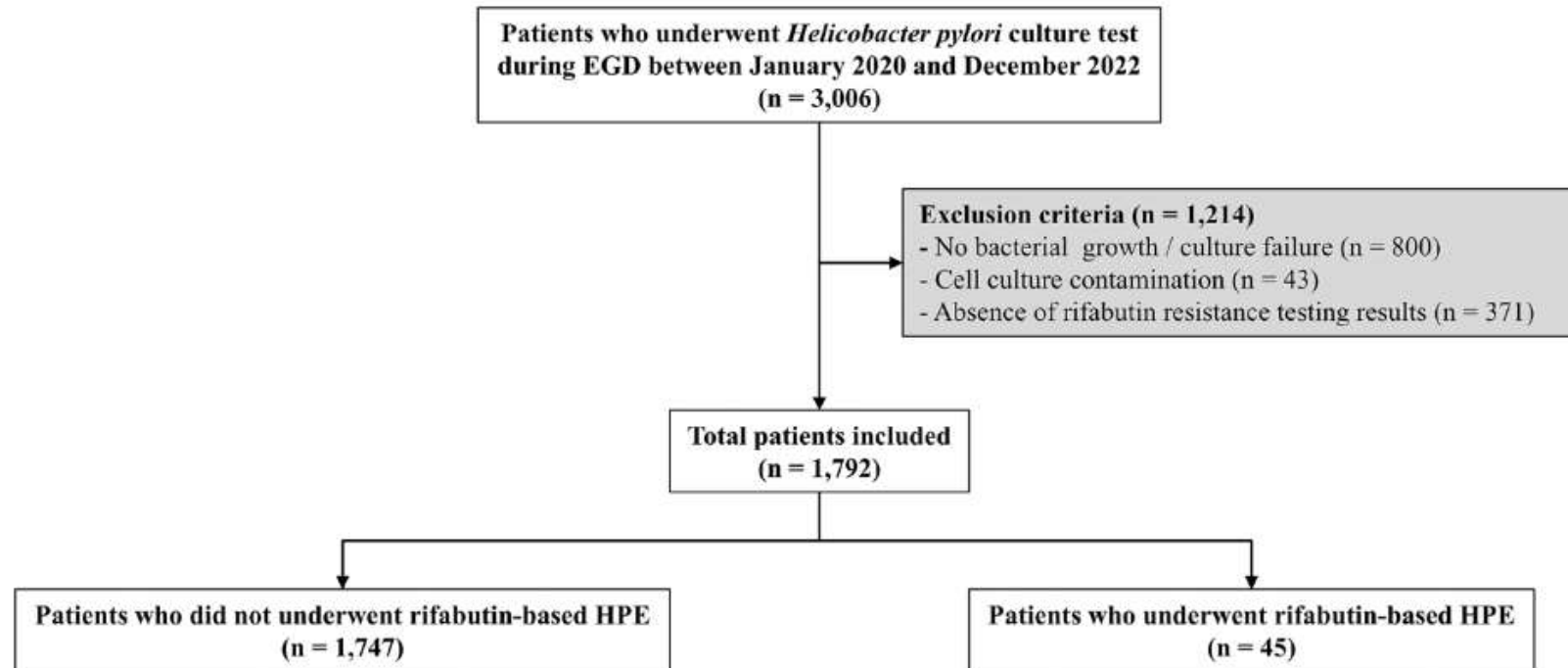
Strength of recommendation: weak; level of evidence: very low

Expert agreement: 89.1% (57/64)

Third-line rescue therapy

- Preferred rescue regimens
 - **Rifabutin TT**
 - **modified BQT** (incorporating previously unused antibiotics)
 - **Levofloxacin-based therapy** (in restricted cases)

AMC data



Rifabutin resistance rate = 0.8%

Successful eradication rate = 68.9% (ITT), 73.8% (PP)

Adverse event = 42.2%

AMC data

TABLE 3 | Clinical characteristics and adverse events of patients who underwent rifabutin-based *Helicobacter pylori* eradication regimen.

	Total (n = 45)
History of tuberculosis treatment, n (%)	4 (8.9%)
Multidrug resistance, n (%)	44 (97.8%)
Lines of rifabutin-based treatment, n (%)	
First line	2 (4.4%)
Second line	8 (17.8%)
≥ Third line	35 (77.8%)
Adverse event, n (%)	19 (42.2%)
GI symptom ^a	15 (33.3%)
Systemic symptom ^b	6 (13.3%)
Myelosuppression	0 (0.0%)
Allergic reaction ^c	1 (2.2%)

Abbreviation: GI, gastrointestinal.
^aGI symptom includes nausea, vomiting, diarrhea, dyspepsia, abdominal pain, and stool color change.
^bSystemic symptoms include headache, dizziness, fatigue, and myalgia.
^cThe symptom of the patient who showed antibiotic allergy was rash.

Adverse event = 42.2%
 Serious adverse event = 0%
 Discontinuation = 0%

Caution for Rifabutin TT

- **Cost** (Rifabutin 급여 기준 1알 = 2,300원)
- Rare but serious **myelotoxicity**
- Potential for **inducing resistance** in *Mycobacterium tuberculosis*.

mQT (3rd line)

- **Two antibiotics** to which the patient has not been previously exposed.
 - **Plus bismuth and a strong acid suppressant**
 - For example, if a patient fails to respond to regimens containing clarithromycin, metronidazole, and tetracycline, the third-line mQT might utilize levofloxacin or amoxicillin.

Tegoprazan 50mg	1	T	50	mg	2 회	2P	Q ⁺	14 일	Third line
Amoxicillin 500mg	2	C	1000	mg	2 회	2P	Q ⁺	14 일	Third line
[처음] 처방되는 약입니다. 유사코드 주의 약물입니다.									
Levofloxacin 500mg	1	T	500	mg	1 회	M	Q ⁺	14 일	Third line
Denol(R)	1	T	300	mg	4 회	4A	Q ⁺	14 일	Third line
[처음] 처방되는 약입니다.									

[KIMS][신장애] 데놀정은(는) 신손상 환자에게 금기인 제품입니다. Ccr : 56.2, eGFR : 71.4, 검사일자 : 2026-05-28

mQT (3rd line)

- Generally, reusing clarithromycin, levofloxacin, or rifabutin is not recommended if resistance is present or suspected; however, amoxicillin and metronidazole can be reused.
- Further research is needed to confirm its effectiveness, specifically in patients who have already failed traditional BQT.

Levofloxacin TT

- PPI+amoxicillin+levofloxacin
- The resistance rate of *H. pylori* to levofloxacin in Korea has steadily increased over the past 20 years, reaching 36.0%–**42.9% in recent studies** conducted between 2019 and 2020.

Author	Publication year	Region	Subject (n)	CLR-R (%)	AMX-R (%)	MDZ-R (%)	LVF-R (%)
Kang et al. ⁶	2021	Seoul	257	24.9	7.0	34.6	-
Park et al. ⁵	2020	Seoul	174	28.6	20.0	27.1	42.9
Kim et al. ⁴	2020	Seoul	247	29.6	10.0	23.9	36.0
Lee et al. ⁷	2019	Nationwide	590	17.8	9.5	29.5	37.0

AMX-R, amoxicillin resistance; CLR-R, clarithromycin resistance; LVF-R, levofloxacin resistance; MDZ-R, metronidazole resistance.

Levofloxacin TT

- K-Hp-Reg: **70-80%** success rate
- A Korean study analyzing efficacy by treatment duration in patients who failed both first-line clarithromycin-containing TT and second-line BQT reported ITT eradication rates of **58.3% (7-day), 62.5% (10-day), and 73.7% (14-day).**
- Therefore, levofloxacin TT should be attempted only on a limited basis, considering prior antibiotic history and regional resistance patterns or if susceptibility is confirmed.

순천향대 부천병원 연구 (2016)

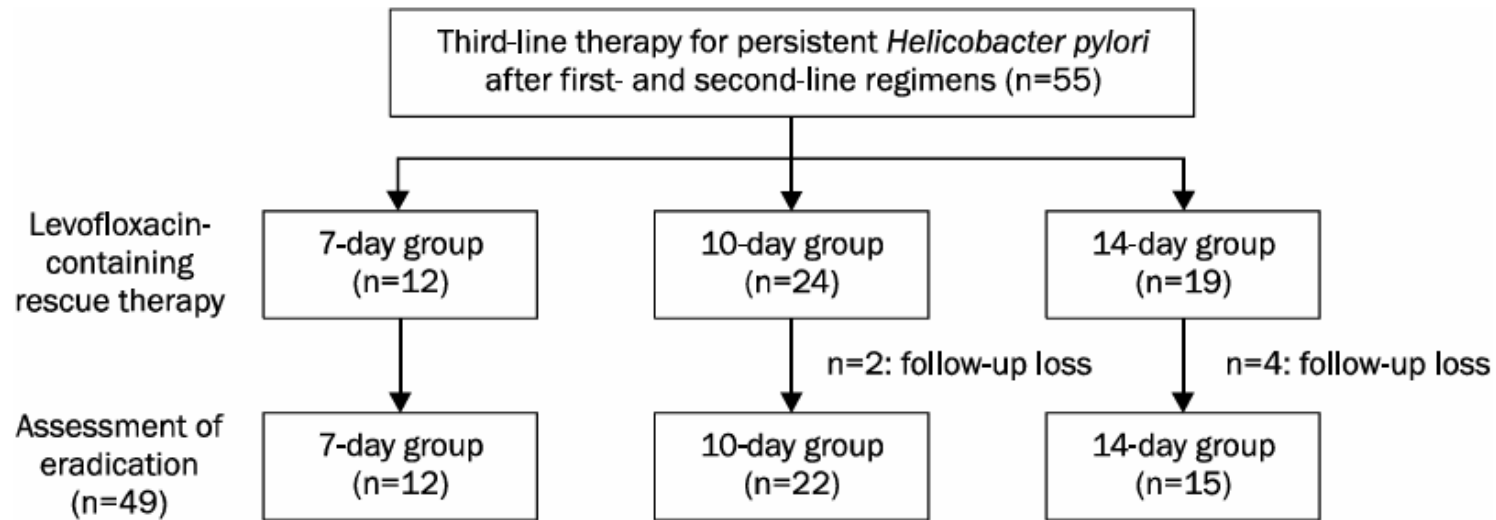


Table 2. Eradication Rate according to Duration of Third-line Rescue Treatment

Treatment duration	Eradication rate	
	Enrolled patients (total, n=55)	Subgroup (follow-up, n=49)
7-day group	58.3 (0.286-0.835)	58.3 (0.286-0.835)
10-day group	62.5 (0.408-0.805)	68.2 (0.451-0.853)
14-day group	73.7 (0.486-0.899) [†]	93.3 (0.660-0.997) [‡]
Total	65.5 (0.513-0.774)	73.5 (0.587-0.846)

Values are presented as % (95% CI).

[†]p=0.447 compared with 7-day group, [‡]p=0.06 compared with 7-day group.

→ Levofloxacin resistance 증가에 따른 영향을 고려 해야 하겠으나, **14일 치료에 대한 data 부족**

Salvage after treatment failure

Statement 9-3. Referral to a specialized H. pylori center capable of antibiotic susceptibility testing-guided tailored therapy is suggested when two or more lines of eradication therapy have failed.

Strength of recommendation: weak; level of evidence: expert consensus

Expert agreement: 81.3% (52/64)

Salvage after treatment failure

- Five regional AST reference hospitals
 - 서울아산병원
 - 인천성모병원
 - 춘천성심병원
 - 경북대병원
 - 고신대병원
- Even after second-line BQT failure, susceptibility-guided therapy can achieve ITT eradication rates of **80%–90%**.

Mono-antibiotic strategy

Table 1. Baseline Characteristics and Demographics (Full Analysis Set)

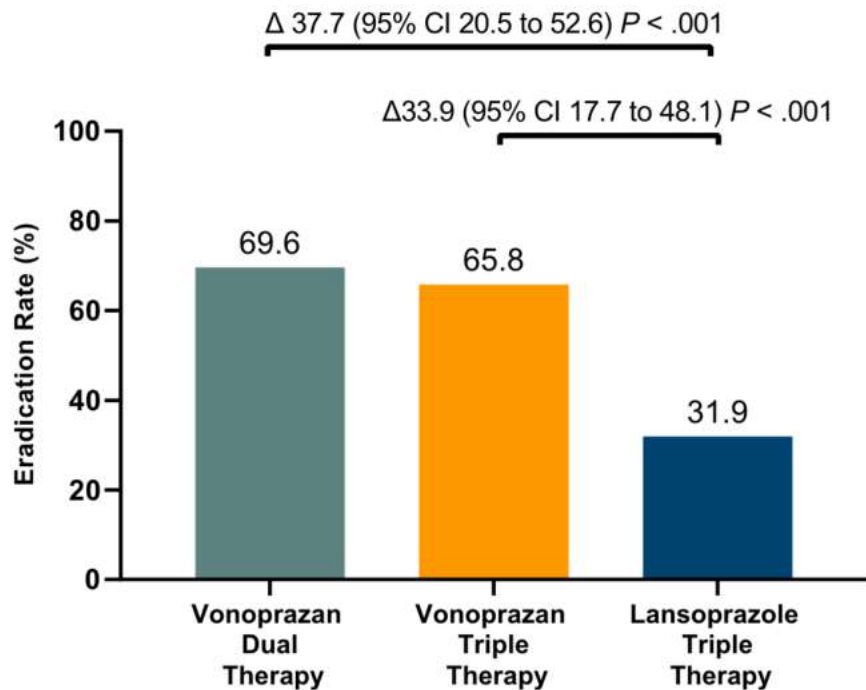
	Vonoprazan dual therapy ^a (n = 324)	Vonoprazan triple therapy (n = 338)	Lansoprazole triple therapy (n = 330)
Antibiotic resistance (n = 907) ^f	n=293	n=308	n=306
Clarithromycin-resistant	56 (19.1)	73 (23.7)	72 (23.5)
Amoxicillin-resistant	3 (1.0)	5 (1.6)	3 (1.0)
Metronidazole-resistant	197 (67.2)	213 (69.2)	218 (71.2)

→ Low Amoxicillin R rate in Western countries

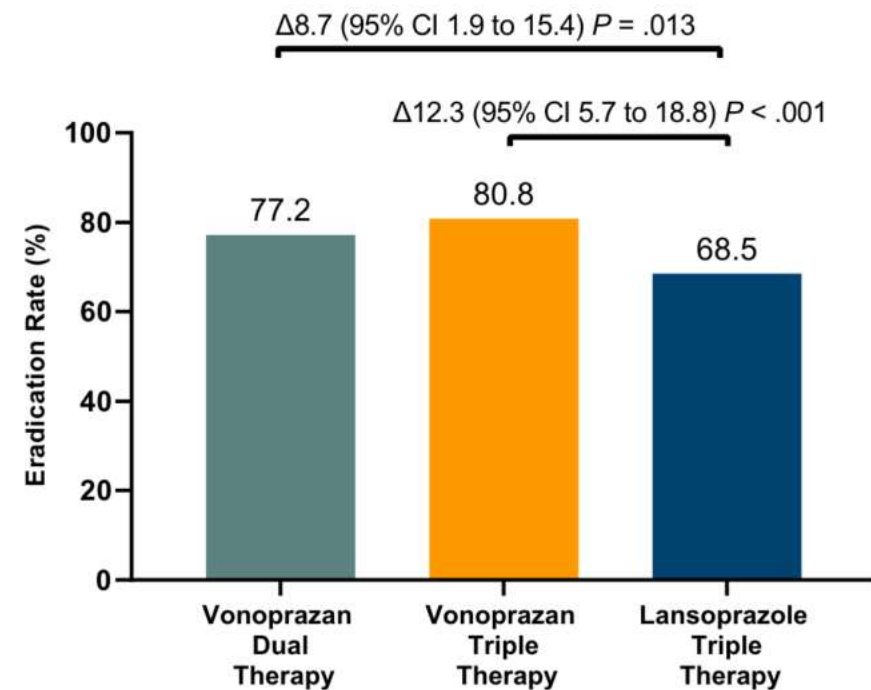
VA vs VAC as first-line in US & Europe

- Phase 3 trial

Patients with Clarithromycin-Resistant Strains



All patients



Vonoprazan 20 mg bid + **Amoxicillin 1 g tid (3000 mg)**
Vono 20/Amox 1g/Clari 500 mg bid for 14 days

ACG Clinical Practice Guideline

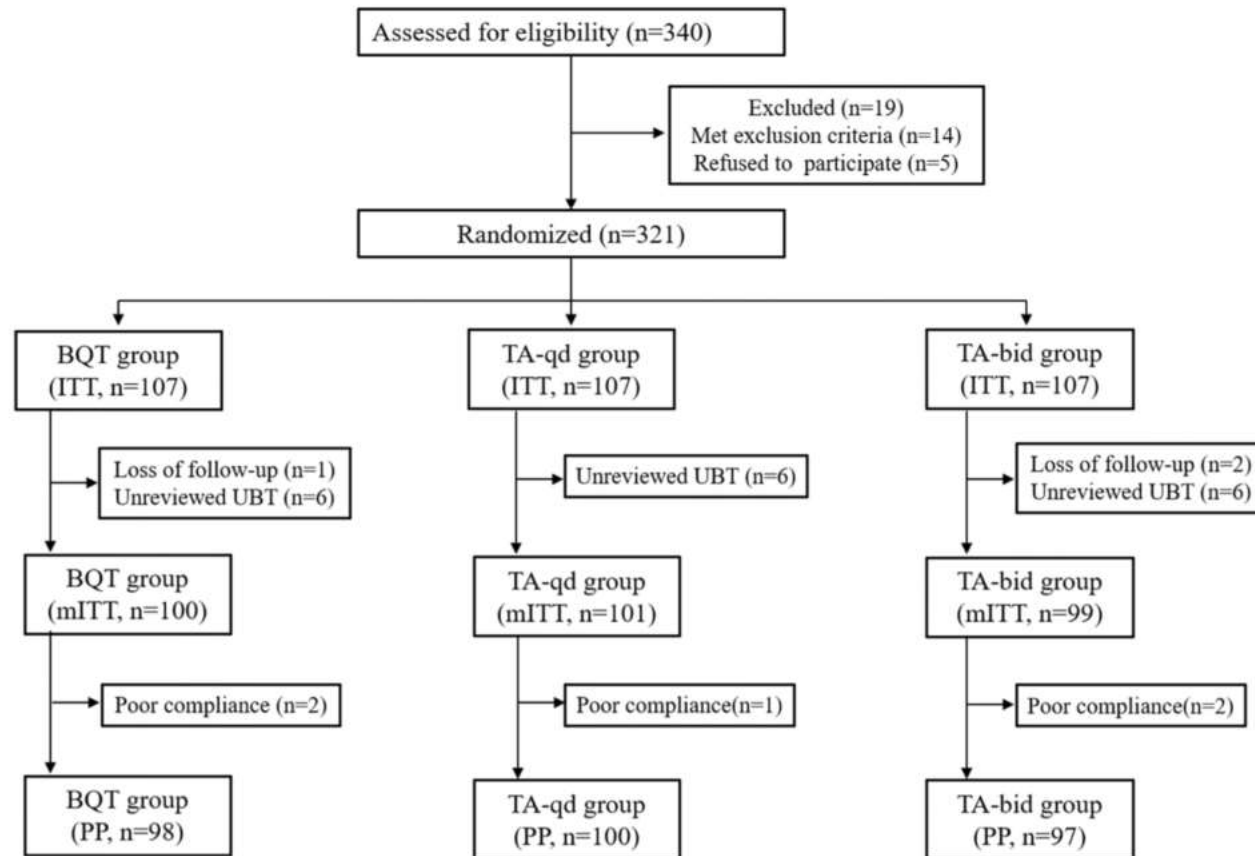
Treatment of <i>H. pylori</i> Infection in North America				
	Treatment Naïve	Treatment-Experienced (Salvage)		Penicillin Allergy
Regimen		Empiric	Proven antibiotic sensitivity	
Optimized Bismuth Quadruple	✓✓✓	✓✓	✓✓	✓✓✓ *
Rifabutin Triple	✓✓	✓✓	✓✓	
Vonoprazan Dual	✓✓	?	?	
Vonoprazan Triple			✓✓	
Levofloxacin Triple			✓✓	

 Recommended
  Suggested
  May be considered when other treatments are not options

* When Bismuth Quadruple Therapy not an option, consider referral for formal penicillin allergy testing and/or desensitization

TA as first line treatment

- Open label multicenter RCT in China (14 days)



BQT: esomeprazole 20 mg twice daily + potassium bismuth citrate 240 mg twice daily + amoxicillin 1 g twice daily + clarithromycin 500 mg twice daily;
 TA-bid: tegoprazan 50 mg twice daily + amoxicillin 1 g thrice daily;
 TA-qd: tegoprazan 50 mg once daily + amoxicillin 1 g thrice daily.

TA as first line treatment

- Open label multicenter RCT in China (14 days)

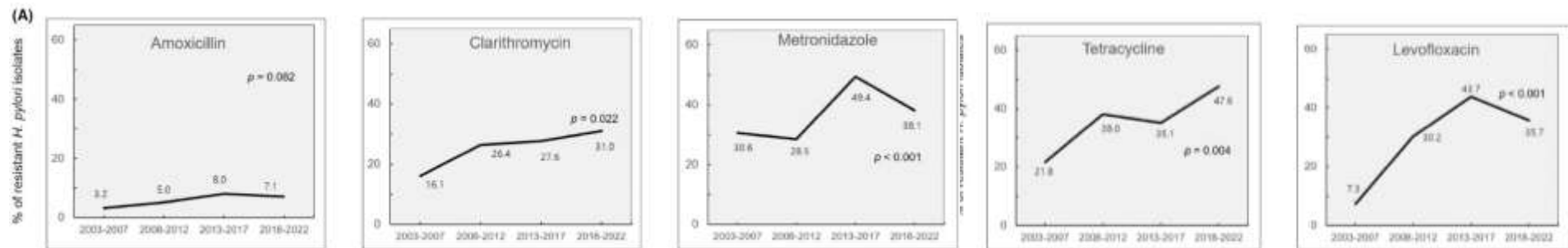
Analysis	BQT	TA-qd	TA-bid
ITT	85.05% (91/107)	85.98% (92/107)	85.98% (92/107)
95% CI	77.10%–90.60%	78.20%–91.30%	78.2%–91.3%
mITT	91.00% (91/100)	91.09% (92/101)	92.93% (92/99)
95% CI	83.80% to 95.20%	83.90% to 95.20%	86.10% 96.50% to
PP	90.81% (89/98)	91.00% (91/100)	93.81% (91/97)
95% CI	83.50% to 95.10%	83.80% to 95.20%	87.20% to 97.10%

Mono-antibiotic strategy

- 국제적으로는 **P-CAB + high-dose amoxicillin dual therapy**가 stewardship 관점에서 높은 관심
- 한국 자료는 아직 부족함
 - 특히 국내 연구는 amoxicillin **2 g/day**를 사용했는데, 국제적으로 말하는 high-dose 기준인 **≥3 g/day**에 못 미침
- 따라서 국내에서 적절한 high-dose P-CAB dual therapy 근거는 아직 충분하지 않음

Antibiotic Resistance (Korea)

- Resistance rates
 - Clarithromycin: 17.8% (MIC > 1 ug/mL)
 - Metronidazole: 29.5% (MIC ≥ 8 ug/mL)
 - Amoxicillin: 9.5% (MIC ≥ 0.5 ug/mL)
 - Tetracycline: 0%(MIC ≥ 4 ug/mL)
 - Levofloxacin: 37.0%(MIC ≥ 1 ug/mL)
 - Ciprofloxacin: 37.0%(MIC ≥ 1 ug/mL)



→ Strong P-CAB과 high dose amoxicillin으로 좋은 제균율 얻을 수 있을지 연구 필요

2025 guideline: what has changed?

Category	2020 Guideline	2025 Guideline
Treatment philosophy	Multiple empirical regimens	Dual-pillar strategy (PCR guided or empirical quadruple)
Tailored therapy	Optional	Preferred first-line
Empirical regimens	TT / ST / CT / BQT	CT / mBQT BQT (selected cases) TT (if AST unavailable & low regional resistance)
Acid suppression	PPI	PPI or P-CAB
Second-line therapy	BQT (10–14 days)	BQT maintained PAMB (if tetracycline unavailable)
Third-line therapy	Limited guidance (levofloxacin TT)	Rifabutin TT / mBQT with unused ABx/ levofloxacin TT (limited) Referral for AST-guided therapy
New indications	—	GC prevention, Hyperplastic polyps

Suggested algorithm

