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Cost-Effectiveness of Tailored vs. Empirical Therapy for *H. pylori*: A Decision-Tree Analysis

Joon Sung Kim[1] | Hankil Lee[2] | Yuri Jeong[3] | Byung-Wook Kim[1]

[1]Department of Internal Medicine, Incheon St. Mary's Hospital, College of Medicine, The Catholic University of Korea, Seoul, Republic of Korea | [2]College of Pharmacy, Ewha Womans University, Seoul, Republic of Korea | [3]Department of Biohealth Regulatory Science, Graduate School of Ajou University, Suwon, Republic of Korea

Correspondence: Byung-Wook Kim (gastro@catholic.ac.kr)

Received: 31 July 2025 | **Revised:** 28 September 2025 | **Accepted:** 7 October 2025

Funding: This research was supported by a grant from the Patient-Centered Clinical Research Coordinating Center (PACEN) funded by the Ministry of Health and Welfare, Republic of Korea (grant number: RS-2019-KH065704).

Keywords: cost-effectiveness analysis | drug resistance | *H. pylori*

ABSTRACT

Background: In Korea, tailored therapy for *H. pylori* based on clarithromycin resistance has been shown to be more effective than empirical therapy. However, the cost-effectiveness of tailored therapy has not yet been fully established.

Aim: This study evaluated the cost-effectiveness of tailored therapy guided by genotypic resistance compared to empirical clarithromycin-based triple therapy.

Methods: A decision-tree model was developed to compare two treatment strategies: empirical therapy and tailored therapy. In the empirical therapy group, patients received clarithromycin-based triple therapy. In the tailored therapy group, patients susceptible to clarithromycin received clarithromycin-based triple therapy, while those with clarithromycin resistance were treated with bismuth-based quadruple therapy. A cost-effectiveness analysis was conducted, and the incremental cost-effectiveness ratio (ICER) was calculated to compare the two strategies.

Results: The estimated costs for empirical and tailored therapies were $173.93 and $249.48, respectively. Compared to empirical therapy, the ICER for tailored therapy was $4.66 per 1% increase in eradication rate, representing the additional cost required to achieve a 1% improvement in eradication. In subgroup analyses, the estimated costs of 7-day empirical and tailored therapies were $157.46 and $233.88, respectively, while the costs for 14-day empirical and tailored therapies were $190.40 and $265.08, respectively. The ICERs for the 7- and 14-day regimens were $3.53 and $7.12, respectively.

Discussion: Tailored therapy guided by genotypic resistance is a cost-effective strategy for *H. pylori* eradication in Korea, particularly in the context of high clarithromycin resistance rates.

1 | Introduction

Traditionally, *Helicobacter pylori (H. pylori)* infection has been treated empirically without antibiotic susceptibility testing [1]. A triple therapy regimen—comprising a proton pump inhibitor, clarithromycin, and amoxicillin—remains the most widely used first-line treatment in many countries. However, increasing resistance to clarithromycin and to levofloxacin, a commonly used second-line antibiotic, has significantly reduced the effectiveness of empirical therapies worldwide [2]. In Korea, one

Joon Sung Kim and Hankil Lee contributed equally as co-first authors.

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study reported primary resistance rates to clarithromycin and levofloxacin exceeding 40%, with eradication rates of regimens including these antibiotics showing a continuous decline [3].

Molecular methods such as real-time PCR now enable the detection of *H. pylori* mutations associated with clarithromycin resistance [4–6]. A recent meta-analysis demonstrated the superiority of susceptibility-guided tailored therapy as a first-line treatment approach [7]. Reflecting this, current guidelines recommend clarithromycin susceptibility testing prior to initiating clarithromycin-based regimens [8, 9]. We recently reported that tailored therapy based on clarithromycin resistance was significantly more effective than empirical therapy in the Korean population [10]. Despite its increasing clinical adoption, tailored therapy is associated with higher upfront costs compared to empirical therapy. Although several studies have compared the costs of these two approaches for primary treatment, they merely focused on the average costs without conducting a comprehensive cost-effective analysis [11–13].

Decision analysis is a quantitative method used to estimate the clinical outcomes of alternative management strategies under uncertainty. A decision-tree model facilitates the identification of the optimal course of action by comparing the potential outcomes of various decisions [14]. In cost-effectiveness analysis, decision-tree models are essential for systematically comparing treatment strategies by clearly mapping out possible outcomes, associated probabilities, and corresponding costs. Despite these advantages, this modeling approach has rarely been applied to assess the cost-effectiveness of *H. pylori* treatment strategies.

Therefore, the aim of this study was to evaluate the cost-effectiveness of tailored therapy guided by genotypic resistance in comparison with empirical clarithromycin-based triple therapy. Additionally, we analyzed the cost-effectiveness of both strategies according to treatment duration and identified key factors influencing economic outcomes.

2 | Methods

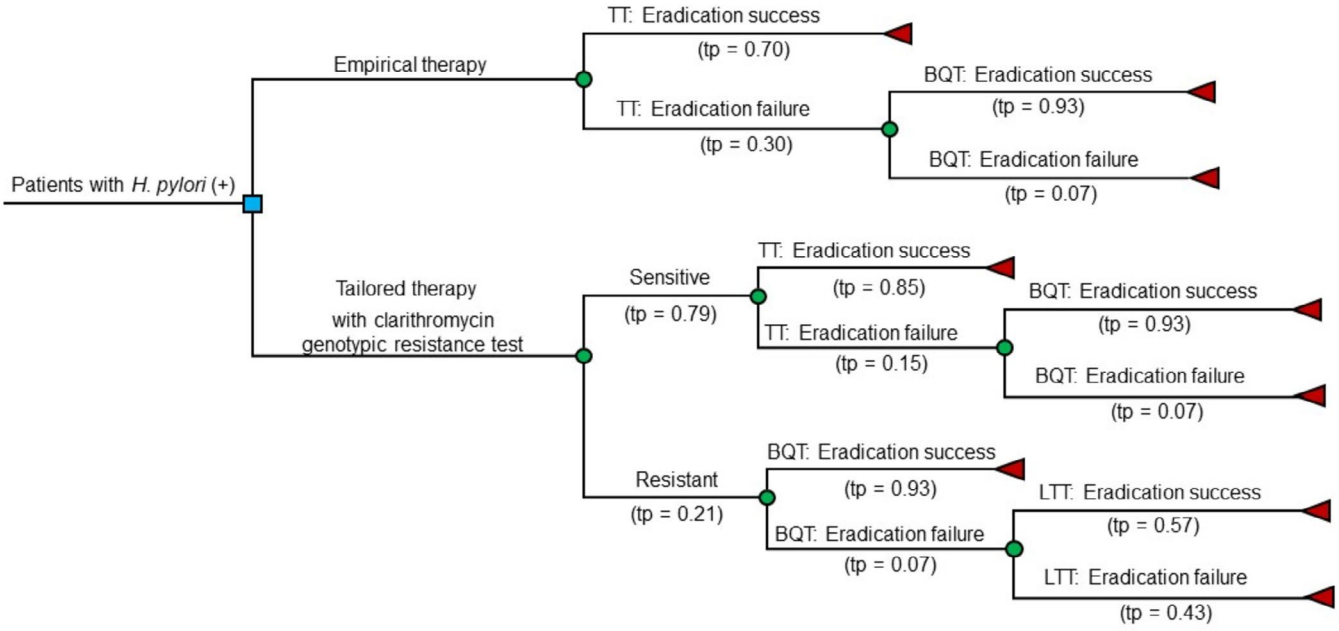
2.1 | Strategies for *H. pylori* Eradication

In this study, a decision-tree model (Figure 1) was developed to conduct a cost-effectiveness analysis assessing the economic value of incorporating tailored therapy based on genotypic resistance for *H. pylori* eradication, compared to empirical therapy. The two treatment strategies evaluated were empirical therapy and tailored therapy. Clinical parameters and treatment outcomes for both strategies were derived from a nationwide, multicenter, randomized study [10]. The model consisted of *H. pylori* treatment-naïve patients diagnosed with *H. pylori* by the urea breath test. Genotypic resistance was detected using the DPO-PCR test (Seeplex ClaR-*H. pylori* ACE Detection; Seegene Institute of Life Science, Seoul, Korea).

Patients in the empirical therapy group received a standard triple therapy (TT), consisting of pantoprazole 40 mg, amoxicillin 1 g, and clarithromycin 500 mg, all administered twice daily. In the tailored therapy group, the treatment regimen was determined based on genotypic resistance identified by PCR testing. Clarithromycin-sensitive patients received the same standard TT, whereas clarithromycin-resistant patients received bismuth quadruple therapy (BQT). The BQT regimen included pantoprazole 40 mg twice daily, metronidazole 500 mg three times daily, and bismuth 300 mg and tetracycline 500 mg, each administered four times daily. *H. pylori* eradication was confirmed using the ^{13}C-urea breath test (UBT) conducted at least 4 weeks after the completion of therapy.

2.2 | Eradication Success Rates

The primary and secondary eradication rates, as well as the clarithromycin resistance rates, were obtained from our previous



BQT: bismuth-based quadruple therapy; LTT: levofloxacin-based triple therapy; TT: triple therapy; tp: transition probability

FIGURE 1 | Decision-tree model for assessing cost-effectiveness of tailored therapy compared to empirical therapy for *H. pylori* eradication.

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nationwide, randomized, controlled study [10]. Eradication success rates differed between the empirical and tailored therapy strategies. In the empirical therapy group, the initial TT regimen achieved an eradication rate of 70.3%.

In contrast, the tailored therapy group demonstrated a higher initial eradication rate compared to the empirical therapy group. The overall eradication rate in the tailored therapy group was 86.5%. Among clarithromycin-sensitive patients treated with TT, the eradication rate was 84.7%. Clarithromycin-resistant patients accounted for 20.9% of the tailored therapy group and were initially treated with BQT, achieving a success rate of 93.1%. These cohort characteristics, resistance rate, and eradication success rates used in the decision-tree model are summarized in Table 1.

2.3 | Cost Estimation

The cost parameters included expenses related to *H. pylori* diagnostic testing and eradication therapy. For empirical therapy, the cost of a single *H. pylori* test—comprising biopsy, rapid urease test (RUT), forceps, and UBT—totaled $103.0. For tailored therapy, the diagnostic cost was $181.2, which included the base cost of diagnostic tests for empirical therapy plus an additional $78.2 for *H. pylori* PCR testing (Table 2).

Eradication therapy costs were estimated based on the 2024 health insurance reimbursement rates in Korea. The medication costs for the 7- and 14-day TT were $31.0 and $62.0, respectively. The costs for BQT were $22.7 for 7 days and $45.4 for 14 days. The administration fees associated with medication dispensing were $23.4 and $25.4 for the 7- and 14-day regimens, respectively. Direct nonmedical costs, such as transportation and caregiving expenses, were excluded from the analysis. A comprehensive breakdown of cost components and their corresponding values is presented in Table 2. All costs are expressed in US dollars (1 USD ≒ 1400 Korean Won).

2.4 | Outcomes

The primary outcome of this study was the Incremental Cost-Effectiveness Ratio (ICER). The ICER was calculated by dividing the difference in total costs between the two strategies by the difference in their *H. pylori* eradication rates as follows. It represents the additional cost required to achieve a 1% increase in eradication rate when using tailored therapy instead of empirical therapy.

$$\mathrm{ICER} = \frac{C_{\mathrm{tailored}} - C_{\mathrm{empirical}}}{E_{\mathrm{tailored}} - E_{\mathrm{empirical}}}$$

2.5 | Analysis

The base-case analysis assessed the cost-effectiveness of empirical and tailored therapies by combining both 7- and 14-day regimens. The analysis focused exclusively on first-line treatment

TABLE 1 | Cohort characteristics and eradication success rate by strategy.

Variables	Value		References
Cohort characteristics			
No. of patients in cohort	40,000[a]		[15]
Age (years)	60.8		[10]
Male (%)	59.5		[10]
Resistance rate for clarithromycin	20.9%		[10]
Eradication success rate (%)	**Empirical therapy**	**Tailored therapy**	**References**
Pooled	70.3	86.5 (Total) 84.7 (Triple) 93.1 (BQT)	[10]
7-day	65.3	87.0 (Total) 85.3 (Triple) 93.1 (BQT)	[10]
14-day	75.5	86.0 (Total) 84.1 (Triple) 93.1 (BQT)[b]	[10]
Subsequent eradication strategy	**Value**		**References**
BQT (14-day)	93.2		[10]
Levofloxacin regimen (10-day)	57.0		[10]

Abbreviation: BQT, bismuth quadruple therapy.
[a]All values were derived from the K-CREATE study [10], except for the number of patients in the cohort, which was obtained from the HIRA database [15].
[b]Assuming the eradication success rate of the 14-day BQT therapy is the same as that of the 7-day BQT therapy.

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TABLE 2 | Estimated costs for diagnosis and treatment of *H. pylori* infection.

Parameters	Value (USD)[a]
Medication cost	
Triple therapy	
7-day	31
14-day	62
Bismuth quadruple therapy	
7-day	22.7
14-day	45.4
Levofloxacin triple therapy	
10-day	34
Diagnosis and eradication confirmation cost	
Biopsy	20.1
RUT	18.6
Forcep	21.2
UBT	43.1
Hp PCR	78.2
Administration cost	
Medical visit cost	
First visit to clinics	13.2
First visit to hospitals	20
Repeated visit to clinics	9.4
Repeated visit to hospitals	15.7
Ratio of healthcare utilization: hospitals vs. clinics[b]	1.7
Prescription cost	
7-day	6
14-day	7.9

Abbreviations: Hp PCR, *Helicobacter pylori* polymerase chain reaction; RUT, rapid urease test; UBT, urea breath test; USD, United States dollars.
[a]All costs are estimated in 2025 values. 1 United States dollar is approximately equal to 1400 Korean won.
[b]The ratio of healthcare utilization is unitless.

outcomes. In the subgroup analysis, the ICERs were compared between the two strategies according to treatment duration (7-day vs. 14-day regimens).

For the sensitivity analysis, the robustness of the results was evaluated by varying key cost parameters, including medication and PCR testing costs. Additionally, the pooled eradication success rates for each strategy were adjusted by ±10% to account for uncertainty in clinical effectiveness and to examine the impact on ICER estimates. All analyses were conducted in accordance with the Consolidated Health Economics Evaluation Reporting Standards (CHEERS) guidelines [16].

TABLE 3 | Base-case results of cost-effectiveness analysis.

Per-patient	Empirical therapy	Tailored therapy	Incremental values
Cost (USD)			
Pooled	173.93	249.48	75.55
7-day	157.46	233.88	76.41
14-day	190.4	265.08	74.68
Effectiveness (eradication rate, %)			
Pooled	70.28	86.5	16.22
7-day	65.31	86.96	21.65
14-day	75.54	86.03	10.49
Incremental cost-effectiveness ratio (USD/%)			
Pooled		4.66	
7-day		3.53	
14-day		7.12	
7-day tailored vs. 14-day empirical		3.81	

Abbreviation: USD, United States dollars.

2.6 | Ethical Considerations

Institutional Review Board approval was waived, as this study was a model-based economic evaluation using only secondary published data.

3 | Results

3.1 | Cost-Effectiveness of First Line Eradication

In the base-case analysis, the pooled expected total cost for empirical therapy was estimated at $173.93, compared to $249.48 for tailored therapy, resulting in an incremental cost of $75.55 (Table 3). The eradication success rates were 70.28% for empirical therapy and 86.50% for tailored therapy, yielding an incremental effectiveness of 16.22%. The ICER was calculated as $4.66 per 1% increase in eradication rate, indicating that an additional $4.66 is required to achieve a 1% improvement in eradication when switching from empirical to tailored therapy (Table 3).

When comparing the 7-day regimens, tailored therapy incurred an additional cost of $76.41 and achieved a 21.65% higher eradication rate than empirical therapy, resulting in an ICER of $3.53. For the 14-day regimens, tailored therapy was associated with an incremental cost of $74.68 and a 10.49% increase in eradication rate, yielding an ICER of $7.12. Additionally, when comparing 7-day tailored therapy with 14-day empirical therapy, the tailored regimen

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resulted in an incremental cost of $43.48 and an 11.42% higher eradication rate, corresponding to an ICER of $3.81 (Table 3).

When comparing tailored therapies between 7- and 14-day regimens, the expected total cost for the 7-day regimen was estimated at $233.88, while the 14-day regimen was $265.08, resulting in an incremental cost of $31.20. The eradication success rates were 86.96% for the 7-day regimen and 88.61% for the 14-day regimen, yielding an incremental effectiveness of 1.65%. Accordingly, the ICER was calculated as $18.89 per 1% increase in eradication rate.

3.2 | One-Way Sensitivity Analysis

As demonstrated in the one-way sensitivity analysis (Figure 2), the pooled eradication rate of the tailored therapy had the greatest impact on the ICER. A 10% decrease in the eradication rate increased the ICER to approximately $10.0 per 1% increase in eradication, while a 10% increase reduced the ICER to around $3.0 per 1%. In contrast, the regimen costs of clarithromycin-based TT and BQT had only a marginal impact on the overall results (Table 4).

4 | Discussion

Tailored therapy based on antimicrobial susceptibility is effective in reducing the unnecessary use of antibiotics and limiting the increase in global antibiotic resistance. A 7-day tailored therapy has demonstrated non-inferior eradication rates compared to a 14-day empirical therapy, suggesting that tailored therapy may allow for a shorter treatment duration without compromising efficacy [10]. However, tailored therapy has the disadvantage of requiring additional resources for antibiotic resistance testing and is also associated with increased costs.

Currently, PCR-based resistance testing for *H. pylori* is reimbursed under the Korean National Health Insurance for certain indications, and approximately 40,000 tests are reported to be performed annually. Several studies have attempted to compare the cost-effectiveness of tailored therapies with that of empirical therapies. One study reported that the total medical costs per successful eradication were higher in the tailored therapy group ($ 120.0) than in the empirical triple therapy group ($ 92.4) [11]. Another study reported that the total per capita medical cost of bismuth-based empirical therapy ($ 406.5) was lower than that of tailored therapy ($ 503.5) [12]. In contrast, tailored therapy has also been reported to be less expensive than empirical triple therapy when shorter treatment durations were used [13]. However, all of these studies focused solely on comparing per-patient medical costs and did not conduct a formal cost-effectiveness analysis.

To our knowledge, this is the first study to compare the ICER of tailored versus empirical therapy for *H. pylori* eradication using a decision-tree model. The decision-tree model is essential for cost-effectiveness analysis, as it allows for a systematic mapping of potential clinical outcomes along with their associated costs and benefits. In our study, the ICER for tailored therapy compared to empirical triple therapy was $4.66, indicating that an additional $4.66 is required to achieve a 1% increase in the eradication success rate at the population level for first-line treatment. When stratified by treatment duration, the ICER decreased to $3.53 for the 7-day regimens but increased to $7.12 for the 14-day regimens. When comparing 7-day tailored therapy to 14-day empirical therapy, the ICER was $3.81. These findings suggest that the ICER tends to increase with longer treatment durations.

Sensitivity analysis revealed that the pooled eradication rates for both tailored and empirical therapies had the greatest impact on cost-effectiveness outcomes, followed by the cost of the PCR test used for genotypic resistance detection. Increases in eradication rates led to marginal reductions in ICER values, whereas decreases in eradication rates resulted in a substantial, nearly twofold increase in ICER.

This study has several limitations. First, the medical cost data used in the cost-effectiveness analysis were based on the Korean health care system; therefore, the findings may not be generalized to other countries with different cost structures. Second, the eradication rates were derived from a single nationwide study conducted in Korea, where the clarithromycin resistance rate exceeds 15%. As a result, this model may not be applicable in countries with lower resistance rates. Third, we were not able to present a willingness-to-pay (WTP) threshold, as an accepted value for the cost of a 1% increase in *H. pylori* eradication has

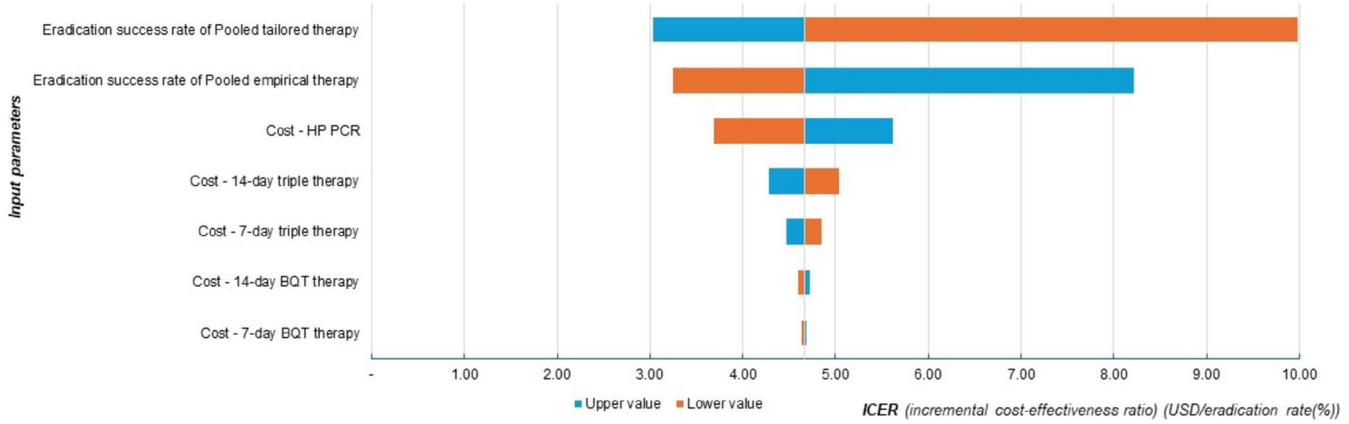


FIGURE 2 | One-way sensitivity analysis.

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TABLE 4 | Sensitivity analysis results.

Parameters	Values		ICERs (USD/%)	Fluctuation (%)
Cost (USD)	**Base-case**	—	**4.66**	**0.00**
7-day TT	Lower	24.80 (−20%)	4.85	4.10
	Upper	37.20 (+20%)	4.47	−4.10
14-day TT	Lower	49.60 (−20%)	5.04	8.21
	Upper	74.40 (+20%)	4.28	−8.21
7-day BQT	Lower	18.16 (−20%)	4.63	−0.63
	Upper	27.24 (+20%)	4.69	0.63
14-day BQT	Lower	36.32 (−20%)	4.60	−1.26
	Upper	54.48 (+20%)	4.72	1.26
Hp PCR	Lower	62.52 (−20%)	3.69	−20.69
	Upper	93.78 (+20%)	5.62	20.69
Eradication success rate (%)				
Pooled empirical therapy	Lower	63.3 (−10%)	3.25	−30.23
	Upper	77.3 (+10%)	8.22	76.49
Pooled tailored therapy	Lower	77.9 (−10%)	9.98	114.31
	Upper	95.2 (+10%)	3.04	−34.78

Abbreviations: BQT, bismuth quadruple therapy; Hp PCR, *Helicobacter pylori* polymerase chain reaction; ICER, Incremental cost-effectiveness ratio; TT, triple therapy; USD, United States dollars.

not yet been established. Fourth, we did not consider culture-based tailored therapy in our analysis as this is not frequently performed in Korea. We did not consider tailored therapy based on other antibiotics such as metronidazole or levofloxacin. We also did not consider the use of other acid-suppressants, such as potassium-competitive acid blockers (P-CABs), which have been reported to be more effective than traditional PPIs. Future studies evaluating tailored therapy guided by resistance to these antibiotics and considering different acid-suppressants are warranted. Lastly, the model did not account for the development of antibiotic resistance in patients with treatment failure and the potential future medical costs associated with managing these cases.

In conclusion, tailored therapy guided by genotypic resistance is a cost-effective strategy for *H. pylori* eradication in Korea, particularly in the context of high clarithromycin resistance rates. Given its high eradication rate and cost-effectiveness, tailored therapy should be preferred over empirical therapy in regions with high clarithromycin resistance. Further cost-effectiveness analyses comparing tailored therapy with empirical treatment regimens other than clarithromycin-based triple therapy will be needed in the future.

Author Contributions

Byung-Wook Kim designed the research study. Joon Sung Kim and Hankil Lee analyzed the data and wrote the manuscript. Yuri Jeong performed a critical review of the manuscript. All authors approved the final version of the manuscript, including the authorship list.

Acknowledgments

This research was supported by a grant from the Patient-Centered Clinical Research Coordinating Center (PACEN) funded by the Ministry of Health and Welfare, Republic of Korea (grant number: RS-2019-KH065704).

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The datasets generated during and/or analyzed during the current study are not publicly available for this specific study but are available from the corresponding author on reasonable request.

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