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ORIGINAL ARTICLE

Randomized Clinical Trial

Efficacy of moxifloxacin-based sequential therapy for first-line eradication of *Helicobacter pylori* infection in gastrointestinal disease

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Abstract

AIM: To evaluate the efficacy of 14-d moxifloxacin-based sequential therapy as first-line eradication treatment of *Helicobacter pylori* (*H. pylori*) infection.

METHODS: From December 2013 to August 2014, 161 patients with confirmed *H. pylori* infection randomly received 14 d of moxifloxacin-based sequential group (MOX-ST group, n = 80) or clarithromycin-based sequential group (CLA-ST group, n = 81) therapy. *H. pylori* infection was defined on the basis of at least one of the following three tests: a positive ^{13}C-urea breath test; histologic evidence of *H. pylori* by modified Giemsa staining; or a positive rapid urease test (CLOtest; Delta West, Bentley, Australia) by gastric mucosal biopsy. Successful eradication therapy for *H. pylori* infection was defined as a negative ^{13}C-urea breath test four weeks after the end of eradication treatment. Compliance was defined as good when drug intake was at least 85%. *H. pylori* eradication rates, patient compliance with drug treatment, adverse event rates, and factors influencing the efficacy of eradication therapy were evaluated.

RESULTS: The eradication rates by intention-to-treat analysis were 91.3% (73/80; 95%CI: 86.2%-95.4%) in the MOX-ST group and 71.6% (58/81; 95%CI: 65.8%-77.4%) in the CLA-ST group (P = 0.014). The eradication rates by per-protocol analysis were 93.6% (73/78; 95%CI: 89.1%-98.1%) in the MOX-ST group and 75.3% (58/77; 95%CI: 69.4%-81.8%) in the CLA-ST group (P = 0.022). Compliance was 100% in both groups. The adverse event rates were 12.8% (10/78) and 24.6% (19/77) in the MOX-ST and CLA-ST group, respectively (P = 0.038). Most of the adverse events were mild-to-moderate in intensity; there was none serious enough to cause discontinuation of treatment

in either group. In multivariate analysis, advanced age (≥ 60 years) was a significant independent factor related to the eradication failure in the CLA-ST group (adjusted OR = 2.13, 95%CI: 1.97-2.29, P = 0.004), whereas there was no significance in the MOX-ST group.

CONCLUSION: The 14-d moxifloxacin-based sequential therapy is effective. Moreover, it shows excellent patient compliance and safety compared to the 14-d clarithromycin-based sequential therapy.

Key words: *Helicobacter pylori*; First-line eradication treatment; Moxifloxacin; Sequential therapy; Eradication rate

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Core tip: This is the first study to evaluate the efficacy of 14-d moxifloxacin-based sequential therapy compared to that of 14-d clarithromycin-based sequential therapy as a first-line eradication treatment of *Helicobacter pylori* infection. Our study showed that the moxifloxacin-based therapy is effective and shows excellent patient compliance and safety compared with the clarithromycin-based sequential therapy. The high eradication rate, excellent compliance, and safety of the moxifloxacin-based sequential therapy suggest its suitability as an alternative to standard triple therapy.

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INTRODUCTION

Helicobacter pylori (*H. pylori*) infection is the single most important factor causing chronic atrophic gastritis, peptic ulcer disease, gastric cancer, and gastric mucosa-associated lymphoid tissue lymphoma[1]. The eradication of *H. pylori* infection effectively reduces the incidence of peptic ulcer and gastric cancer and prevents their recurrence[2]. The most important first-line treatment for eradication of *H. pylori* is currently the standard triple therapy comprising a proton pump inhibitor (PPI), clarithromycin, and either amoxicillin or metronidazole[3,4]. Although many studies have indicated that this therapy is highly effective, the reported eradication rates vary between 70% and 95%[5,6] and have shown a tendency to decrease due to increasing antibiotic resistance[7,8]. Therefore, more effective alternative regimens are needed.

Many alternative, first-line treatment regimens have been studied. Sequential therapy is one alternative regimen, which consists of a PPI and amoxicillin for the first seven days, followed by a PPI plus metronidazole and clarithromycin for another seven days[9]. This regimen is currently recommended as an alternative first-line treatment for *H. pylori* infection in European guidelines[3]. In Korea, a region with relatively high antibiotic resistance, the efficacy of sequential therapy has been reported in several randomized controlled trials, including our previous prospective study[10-12]. These studies initially indicated sequential therapy to be effective, but recent studies have shown less satisfactory results. The main causes of sequential therapy failure are patient non-compliance and antibiotic resistance[13]. Non-compliance is due mainly to patients' complicated schedules[14]. Another key element of treatment failure is bacterial resistance to clarithromycin. Resistance to clarithromycin is relatively high in Korea[15,16] and plays an role in diminishing the effect of sequential therapy[13].

Recently, changing the antibiotic agents that are included in the eradication regimen to improve *H. pylori* eradication therapy efficacy has been studied. The reason for changing antibiotic agents is to overcome resistance to clarithromycin. Among several candidates for new antibiotic agents, moxifloxacin has received attention. Compared with other fluoroquinolones, moxifloxacin has a low incidence of adverse events and small interactions with other drugs. Therefore, we hypothesized that 14-d moxifloxacin-based sequential therapy might increase *H. pylori* eradication as compared to clarithromycin-based sequential therapy in an area with high clarithromycin resistance. A head-to-head comparison between moxifloxacin and clarithromycin regimens has not been addressed in the literature yet.

The aim of the present study was to compare the *H. pylori* eradication rates, patient compliance, and adverse events between first-line moxifloxacin-based sequential therapy and clarithromycin-based sequential therapy.

MATERIALS AND METHODS

Patient selection

This study was conducted at Seoul National University Bundang Hospital between December 2013 and August 2014. A total of 161 patients with *H. pylori* infection were enrolled in this prospective, open-labeled, randomized pilot study. *H. pylori* infection was defined on the basis of at least one of the following three tests: (1) a positive ^{13}C-urea breath test (^{13}C-UBT); (2) histologic evidence of *H. pylori* by modified Giemsa staining in the lesser and greater curvature of the body and antrum of the stomach; or (3) a positive rapid urease test (CLOtest; Delta West, Bentley, Australia) by gastric mucosal biopsy from the lesser curvature of the body and antrum of the stomach. Patients were excluded if they had received PPIs, H_2 receptor

antagonists, or antibiotics in the previous four weeks, or if they had used non-steroidal antiinflammatory drugs or steroids in the two weeks prior to the ^{13}C-UBT. The other exclusion criteria were age below 18 years, previous gastric surgery, or endoscopic mucosal dissection for gastric cancer, advanced gastric cancer, severe current disease (hepatic, renal, respiratory, or cardiovascular), pregnancy, and any condition thought to be associated with poor compliance (*e.g.*, alcoholism or drug addiction).

Study design

This prospective, open-labeled, single-center, randomized pilot study compared 14-d moxifloxacin-based sequential therapy with 14-d clarithromycin-based sequential therapy as a first-line eradication treatment of *H. pylori* infection. All enrolled participants filled in a questionnaire on demographic information, history of comorbidities, body mass index (BMI), smoking habit, and alcohol consumption. Each participant underwent esophagogastroduodenoscopy to confirm clinical diagnosis (such as gastritis or peptic ulcer disease) and to conduct a biopsy for *H. pylori* infection, colonization, atrophic changes, and intestinal metaplasia.

The 161 participants were randomly assigned to one of the two treatment groups using a computer-generated numeric sequence. The 14-d moxifloxacin-based sequential therapy group (MOX-ST group, n = 80) received 20 mg rabeprazole and 1 g amoxicillin twice daily for the first week, followed by 20 mg rabeprazole twice daily, 500 mg metronidazole twice daily, and moxifloxacin 400 mg once daily for the remaining week. Participants in the 14-d clarithromycin-based sequential therapy group (CLA-ST group, n = 81) received 20 mg rabeprazole and 1 g amoxicillin twice daily for the first week, followed by 20 mg rabeprazole, 500 mg metronidazole, and clarithromycin 500 mg twice daily for the remaining one week.

Patient compliance was evaluated by remnant pill counting and direct questions from a physician 1 wk after completion of the treatment. Compliance was defined as good when less than 15% of the pills were unconsumed at remnant pill counting. At the same time, all of the patients were asked about adverse events. Successful eradication therapy for *H. pylori* infection was defined as a negative ^{13}C-UBT test four weeks after the cessation of eradication treatment. The study protocol was approved by the Ethics Committee at Seoul National University Bundang Hospital (IRB number: B-1409/268-103).

^{13}C-Urea breath test

Before the ^{13}C-UBT, the patients were instructed to stop taking medications (*i.e.*, antibiotics for 4 wk, or PPIs for 2 wk) that could affect the result, and fasted for a minimum of 4 h. After patients cleaned their oral cavities by gargling, a pre-dose breath sample was obtained. Then, 100 mg of ^{13}C-urea powder (UBiTkit™; Otsuka Pharmaceutical Co. Ltd., Tokyo, Japan) was dissolved in 100 mL of water and was administered orally, and an additional breath sample was obtained. Breath samples were taken with special breath collection bags while patients were in the sitting position, both before drug administration (baseline) and 20 min after the powder medication. The samples were analyzed using an isotope-selective, non-dispersive infrared spectrometer (UBiT-IR 300®; Otsuka Pharmaceutical Co. Ltd, Tokyo, Japan).

Statistical analysis

The primary and secondary outcomes of the present study were *H. pylori* eradication rates and treatment-related adverse events, respectively. The eradication rates were determined by intention-to-treat (ITT) and per-protocol (PP) analyses. ITT analysis compared the treatment groups, including all patients as originally allocated; the PP analysis compared the treatment groups, including only those patients who had completed the treatment as originally allocated. Mean standard deviations were calculated for quantitative variables. Student's t test was used to evaluate the continuous variables, and χ^2 test and Fisher's exact test were utilized to assess the non-continuous variables. Additionally, univariate and multivariate analyses were conducted to assess the effects of factors on the eradication rate. All statistical analyses were performed using the Predictive Analytics Software 20.0 version for Windows (SPSS Inc., IBM, Chicago, IL, United States). A P value of less than 0.05 was defined as clinically significant.

RESULTS

Characteristics of patients

A schematic diagram of the study is provided in Figure 1. A total of 161 patients with *H. pylori* infection were randomly allocated to the MOX-ST group or the CLA-ST group by 1:1. Of the 161 patients, 155 (96.2%) completed their allocated regimens. The remaining six patients (3.8%) were excluded from study analysis. Therefore, 78 MOX-ST patients and 77 CLA-ST patients were included in the PP analysis. The enrolled patients' baseline demographic and clinical characteristics did not statistically differ between the two groups (Table 1).

Helicobacter pylori eradication rates

Table 2 shows the rates of eradication of *H. pylori* infection according to the ITT and PP analyses. The overall ITT eradication rate was 81.3% (131/161). The final ITT eradication rates were 91.3% [73/80; 95%CI: 86.2-95.4%] in the MOX-ST group and 71.6% (58/81; 95%CI: 65.8-77.4%) in the CLA-ST group (P = 0.014; Table 2). The overall PP eradication rate was 84.5% (131/155), and the final PP eradication

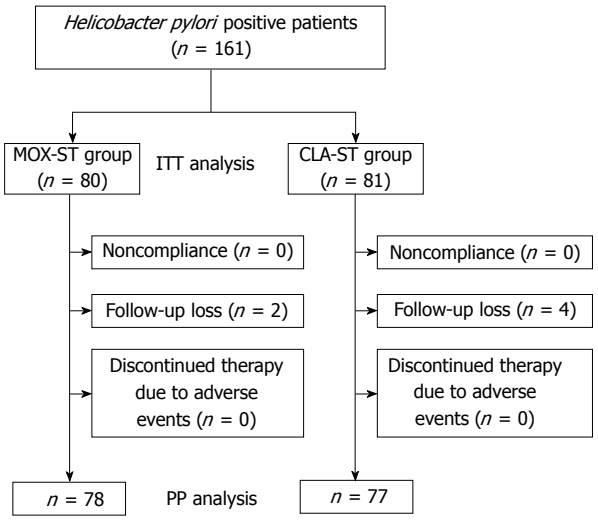

Figure 1 Flow schematic of the study included in intention-to-treat and per-protocol analyses. MOX-ST: 14-d moxifloxacin-based sequential therapy; CLA-ST: 14-d clarithromycin-based sequential therapy; ITT: Intention-to-treat; PP: Per-protocol.

rates were 93.6% (73/78; 95%CI: 89.1%-98.1%) in the MOX-ST group and 75.3% (58/77; 95%CI: 69.4%-81.8%) in the CLA-ST group (P = 0.022; Table 2). The *H. pylori*-eradication rates in the MOX-ST group were significantly higher than those in the CLA-ST group, according to both the ITT (P = 0.014) and the PP analysis (P = 0.022).

Clinical factors influencing H. pylori eradication

To evaluate the clinical factors influencing the efficacy of *H. pylori* eradication, univariate analyses were performed (as listed in Table 3). In the CLA-ST group, the eradication rates of participants over 60 years of age was significantly lower than those of participants under 60 years of age (P = 0.002; Table 3). Other factors in the CLA-ST group did not affect the eradication response. No factors in the MOX-ST group affected the eradication response. The multivariate analysis revealed that age greater than 60 years [adjusted OR = 2.13, 95%CI: 1.97-2.29, P = 0.004] was an independent factor predictive of eradication failure in the CLA-ST group.

Adverse events and compliance

Table 4 lists the adverse events that occurred in the two groups. Adverse events occurred for 10 of 78 patients (12.8%) in the MOX-ST group and for 19 of 77 patients (24.6%) in the CLA-ST group. The difference was statistically significant (P = 0.038). The most common adverse events were bloating/dyspepsia (4/78, 5.1%) and taste distortion (3/78, 3.8%) in the MOX-ST group and epigastric discomfort (5/77, 6.4%) and taste distortion (5/77, 6.4%) in the CLA-ST group. These differences were not statistically significant (P > 0.05). Most of the adverse events were mild-to-moderate in intensity; there was none serious enough to cause discontinuation of treatment in either group. The treatment compliance (as defined as taking at least 85% of scheduled medication doses) was 100% in both groups (Table 4).

Table 1 Demographic and clinical data at baseline (intention-to-treat population) *n* (%)

	MOX-ST	CLA-ST	*P* value
Included in ITT analysis	80	81	NS
Age (yr), mean ± SD	59.3 ± 13.1	59.4 ± 13.1	0.235
Gender (male)	34 (42.5)	33 (40.7)	0.773
BMI (kg/m^2), mean ± SD	22.9 ± 2.2	22.7 ± 2.9	0.352
Current smoker	11 (13.7)	10 (12.3)	0.385
Alcohol drinking	13 (16.2)	9 (11.1)	0.351
Diabetes	5 (6.2)	8 (9.8)	0.125
Hypertension	19 (23.7)	23 (28.3)	0.407
Previous history of peptic ulcer	12 (15.0)	9 (11.1)	0.348
Endoscopic diagnosis			0.624
Gastritis	70 (87.6)	70 (86.6)	
Gastric ulcer	4 (5.0)	5 (6.1)	
Duodenal ulcer	1 (1.2)	1 (1.2)	
Gastric and duodenal ulcer	1 (1.2)	0 (0.0)	
Adenoma	4 (5.0)	4 (4.9)	
Dysplasia	0 (0.0)	1 (1.2)	
Positive CLOtest	59 (73.7)	62 (76.5)	0.955
H. pylori colonization			0.588
Negative	3 (3.7)	5 (6.1)	
Mild	34 (42.5)	36 (44.4)	
Moderate	32 (40.0)	24 (29.6)	
Marked	11 (13.8)	16 (19.9)	
Atrophic change	8 (10.0)	2 (2.4)	0.087
Intestinal metaplasia	10 (12.5)	13 (16.0)	0.761
Drop out	2 (2.5)	4 (4.9)	0.113
Noncompliance	0 (0.0)	0 (0.0)	
Follow-up loss	2 (2.5)	4 (4.9)	
Discontinued therapy due to adverse events	0 (0.0)	0 (0.0)	

MOX-ST: 14-d moxifloxacin-based sequential therapy; CLA-ST: 14-d clarithromycin-based sequential therapy; ITT: Intention-to-treat; SD: Standard deviation; BMI: Body mass index; CLOtest: Rapid urease test; *H. pylori*: *Helicobacter pylori*; NS: Not significant; BMI: Body mass index.

Table 2 *Helicobacter pylori* eradication rates

	MOX-ST	CLA-ST	*P* value
ITT analysis			
Eradication rate	91.3% (73/80)	71.6% (58/81)	0.014
95%CI	86.2%-95.4%	65.8%-77.4%	
PP analysis			
Eradication rate	93.6% (73/78)	75.3% (58/77)	0.022
95%CI	89.1%-98.1%	69.4%-81.8%	

ITT: Intention-to-treat; PP: Per-protocol; CI: Confidence interval; MOX-ST: 14-d moxifloxacin-based sequential therapy; CLA-ST: 14-d clarithromycin-based sequential therapy.

DISCUSSION

To our knowledge, this is the first study that evaluated the efficacy of 14-d moxifloxacin-based sequential therapy compared with 14-d clarithromycin-based sequential therapy as a first-line eradication treatment

Table 3 Univariate analysis of clinical factors influencing the efficacy

	MOX-ST		CLA-ST	
	Eradication rate	*P* value	Eradication rate	*P* value
Age (yr)		0.436		0.002
< 60	97.2% (35/36)		81.1% (30/37)	
⩾ 60	90.4% (38/42)		70.0% (28/40)	
Gender		0.383		0.622
Male	91.1% (31/34)		71.8% (23/32)	
Female	95.4% (42/44)		77.7% (35/45)	
Body mass index		0.651		0.743
< 25	95.2% (20/21)		86.9% (20/23)	
⩾ 25	92.9% (53/57)		70.3% (38/54)	
Smoking		0.585		0.377
(-)	97.0% (65/67)		77.6% (52/67)	
(+)	72.7% (8/11)		60.0% (6/10)	
Alcohol		0.417		0.082
(-)	96.9% (63/65)		77.9% (53/68)	
(+)	76.9% (10/13)		55.5% (5/9)	
Diabetes		0.706		0.107
(-)	94.5% (70/74)		76.8% (53/69)	
(+)	75.0% (3/4)		62.5% (5/8)	
Hypertension		0.322		0.096
(-)	91.6% (55/60)		79.6% (43/54)	
(+)	100.0% (18/18)		65.2% (15/23)	
History of ulcer		0.454		0.828
(-)	92.5% (62/67)		75.0% (51/68)	
(+)	100.0% (11/11)		77.7% (7/9)	
Presence of ulcer		0.352		0.076
(-)	92.6% (63/68)		78.7% (52/66)	
(+)	100.0% (10/10)		54.5% (6/11)	
Positive CLOtest		0.259		0.374
(-)	76.1% (16/21)		63.1% (12/19)	
(+)	100.0% (57/57)		79.3% (46/58)	
Atrophic change		0.111		0.071
(-)	95.7% (67/70)		76.0% (57/75)	
(+)	75.0% (6/8)		50.0% (1/2)	
Intestinal metaplasia		0.270		0.322
(-)	95.5% (65/68)		76.5% (49/64)	
(+)	80.0% (8/10)		69.2% (9/13)	
Bacterial density		0.296		0.507
None	66.7% (2/3)		60.0% (3/5)	
Mild	90.6% (29/32)		67.6% (23/34)	
Moderate	100.0% (32/32)		78.2% (18/23)	
Marked	90.9% (10/11)		93.3% (14/15)	
Compliance		NS		NS
Poor	0.0% (0/0)		0.0% (0/0)	
Good	93.6% (73/78)		75.3% (58/77)	
Adverse events		0.493		0.494
(-)	92.6% (63/68)		77.6% (45/58)	
(+)	100.0% (10/10)		68.4% (13/19)	

MOX-ST: 14-d moxifloxacin-based sequential therapy; CLA-ST: 14-d clarithromycin-based sequential therapy; CLOtest: Rapid urease test; NS: Not significant.

of *H. pylori* infection. In this study, eradication rates in the MOX-ST group (ITT: 91.3%; PP: 93.6%) were higher than those in the CLA-ST group (71.6%/75.3%), with statistically significant differences ($P < 0.05$). These results represented statistically significant differences: namely, markedly higher eradication rates for the MOX-ST group ($P < 0.05$). Moreover, the total adverse-event rate for the MOX-ST group was 12.8% (10/78), which was significantly lower than that for the CLA-ST group (24.6%, 19/77), with statistically

Table 4 Adverse events and compliance *n* (%)

Adverse events	MOX-ST (*n* = 78)	CLA-ST (*n* = 77)	*P* value
Bloating/dyspepsia	4 (5.1)	4 (5.3)	0.383
Taste distortion	3 (3.8)	5 (6.4)	0.316
Epigastric discomfort	2 (2.6)	5 (6.4)	0.296
Nausea	1 (1.3)	1 (1.3)	0.505
Abdominal pain	0 (0.0)	1 (1.3)	0.309
Diarrhea	0 (0.0)	3 (3.9)	0.075
Constipation	0 (0.0)	0 (0.0)	NS
Total	10 (12.8)	19 (24.6)	0.038
Compliance, *n* (%)	78 (100.0)	77 (100.0)	NS

MOX-ST: 14-d moxifloxacin-based sequential therapy; CLA-ST: 14-dclarithromycin-based sequential therapy; NS: Not significant.

differences ($P = 0.038$). The drug compliance was 100% in both groups. Thus, our study showed the 14-d moxifloxacin-based sequential therapy is effective and shows excellent compliance and safety compared with the 14-d clarithromycin-based sequential therapy.

In the clarithromycin-based sequential therapy, the key theoretical basis is the effect of amoxicillin on the bacterial cell wall. Amoxicillin administered in the first half of the regimen damages cell wall of *H. pylori*; this is thought to overcome antibiotic resistance and increase eradication rate by two mechanisms. First, damage to the cell wall damage may ease the penetration of subsequent antibiotics into the *H. pylori* strain. Second, the damaged cell wall cannot develop efflux channels for clarithromycin[17,18]. Several large, multicenter studies have reported high eradication rates with clarithromycin-based sequential therapy[11,19,20]. An earlier Korean study on clarithromycin-based sequential therapy performed in 2008 and 2009 reported a high eradication rate (85.9% by ITT analysis and 92.6% by PP analysis)[21]. However, subsequent studies performed in our institution suggest efficacy of clarithromycin-based sequential therapy is decreasing in Korea. The eradication rate of clarithromycin-based sequential therapy was 79.3% by ITT analysis and 81.9% by PP analysis in 2009 and 2010[10], 75.6% (ITT) and 76.8% (PP) in 2011 and 2012[22], and 71.6% (ITT) and 75.3% (PP) in 2013 and 2014 in these study. These findings imply that resistance to antibiotics in *H. pylori* treatment is increasing, and that clarithromycin-based sequential therapy might already be suboptimal in areas with high prevalence of clarithromycin resistance.

A recent meta-analysis evaluating *H. pylori* strains in Western populations found fluoroquinolone-resistance prevalence in less than 5.0%[15]. Fluoroquinolone resistance in Japan is 15%[23]. In Gyeonggi Province, Korea, the rates of resistance were 5.0% for levofloxacin and moxifloxacin, 5.0% for amoxicillin, 16.7% for clarithromycin, 34.3% for metronidazole, and 8.0% for tetracycline[8]. These results might be related to different patterns of regional and institutional fluoroquinolone use[24]. This explains why a moxifloxacin-based triple

regimen achieved successful eradication in 84%-87% of cases (by PP analysis), as compared with the markedly lower rates recorded for levofloxacin-based triple regimens elsewhere in Asia[25-28]. These results suggest that appropriate *H. pylori*-eradication therapies should be continually adjusted according to local bacterial resistance patterns. Therefore, we could explain that the reason moxifloxacin-based sequential therapy is more effective than clarithromycin-based sequential therapy in Korea is the low resistance to moxifloxacin compared with clarithromycin.

Our study showed that advanced age (≥ 60 years) was a significant independent factor related to the eradication failure in the CLA-ST group, whereas there was no significance in the MOX-ST group in multivariate analysis. Other studies have also reported that advanced age was associated with treatment failure in *H. pylori* eradication therapy[29,30]. However, the mechanisms by which advanced age interfere with eradication remain unclear. Immunity degradation, which is one of the physiological changes of the human body by aging, may be associated with poor treatment response[31]. Further studies are needed to investigate the mechanisms underlying the association between advanced age and poor response to eradication treatment.

The most common adverse events of moxifloxacin are gastrointestinal disturbances, such as diarrhea and nausea. In the present study, the most common adverse events were taste distortion, epigastric discomfort, and abdominal bloating. The total adverse-event rate for the 14-d moxifloxacin-based sequential treatment was 12.8% (10/78), which was significantly lower than that for the 14-d clarithromycin-based sequential treatment (24.6%, 19/77). In both groups, the adverse events were mild to moderate; none was serious enough to require discontinuation or interfered with regular life.

This study has several limitations. First, this study was a single-center pilot study with a relatively small sample size. Larger prospective studies will be needed to confirm our results in regions where different patterns of resistant are present. However, we think our exploratory study would be a good reference for clinicians and researchers to help design new studies on this subject. Second, we could not investigate the antibiotic resistance in each patient. However, this was a pilot study comparing alternative first-line regimens in a Korean population. Moreover, selection bias is ruled out by randomized allocation of the participants, so that the prevalence of primary antibiotic resistance is expected to be equally distributed among the therapeutic groups.

In conclusion, 14-d moxifloxacin-based sequential therapy is a more effective first-line eradication treatment than 14-d clarithromycin-based sequential therapy for *H. pylori* infection. The high eradication rate, excellent patient compliance, and safety of the moxifloxacin-based therapy suggest its suitability as an alternative to standard triple therapy. Further large prospective studies are required to determine the broad application of this regimen in comparison with currently approved first-line therapies.

COMMENTS

Background

A recent meta-analysis reported that the efficacy of sequential therapy for *Helicobacter pylori* (*H. pylori*) infection is modest in Asia, exemplifying the need to find a better regimen.

Research frontiers

The potential role of moxifloxacin as an antibiotic agent useful for eradication treatment in *H. pylori* infection has been suggested by a few animal and human studies.

Innovations and breakthroughs

This is the first randomized controlled study to evaluate the efficacy of 14-d moxifloxacin-based sequential therapy (as compared with 14-d clarithromycin-based sequential therapy) as a first-line eradication treatment of *H. pylori* infection. The high eradication rate, excellent compliance, and safety of the 14-d moxifloxacin-based sequential therapy suggest its suitability as an alternative to the standard triple therapy.

Applications

This pilot study's design and findings could be used to determine sample size for a larger, prospective study aiming to test the efficacy of moxifloxacin-based sequential therapy for *H. pylori* eradication.

Terminology

H. pylori is found in the stomach and is linked to the development of gastritis, peptic ulcers, and stomach cancer. To prevent recurrence in patients with these diseases, it is necessary to eradicate *H. pylori* infection.

Peer-review

This study presents a topic of interest in clinical practice, not often considered in literature. Methods and study population are adequate, and conclusions are reasonable and of possible practical use. This article presents an important issue. This is the first study to compare the efficacy of 14-d moxifloxacin-based sequential therapy with that of 14-d clarithromycin-based sequential therapy.

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