

## ESPS PEER REVIEW REPORT

**Name of journal:** World Journal of Gastroenterology

**ESPS manuscript NO:** 14610

**Title:** The efficacy of moxifloxacin versus clarithromycin-based sequential therapy as first-line eradication regimen for *Helicobacter pylori* infection: A randomized pilot study

**Reviewer code:** 00503571

**Science editor:** Jing Yu

**Date sent for review:** 2014-10-15 10:43

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CLASSIFICATION	LANGUAGE EVALUATION	RECOMMENDATION	CONCLUSION
<input type="checkbox"/> Grade A: Excellent	<input type="checkbox"/> Grade A: Priority publishing	Google Search:	<input type="checkbox"/> Accept
<input type="checkbox"/> Grade B: Very good	<input checked="" type="checkbox"/> Grade B: Minor language polishing	<input type="checkbox"/> Existing	<input type="checkbox"/> High priority for publication
<input checked="" type="checkbox"/> Grade C: Good	<input type="checkbox"/> Grade C: A great deal of language polishing	<input type="checkbox"/> No records	<input type="checkbox"/> Rejection
<input type="checkbox"/> Grade D: Fair	<input type="checkbox"/> Grade D: Rejected	BPG Search:	<input type="checkbox"/> Minor revision
<input type="checkbox"/> Grade E: Poor		<input type="checkbox"/> Existing	<input type="checkbox"/> Major revision
		<input type="checkbox"/> No records	

### COMMENTS TO AUTHORS

Authors from South Korea presented results of a single-centre prospective, open-labelled, randomized pilot study to compare 14-day moxifloxacin-based sequential therapy with 14-day clarithromycin-based sequential therapy as a first-line eradication treatment of *Helicobacter pylori* infection. The design of study corresponds to requirements of such type of the studies. A search in PubMed and Web of Science databases revealed that is the first study that evaluated the efficacy of 14-day moxifloxacin-based sequential therapy compared with 14-day clarithromycin-based sequential therapy. The study has several limitations: study was a single-center pilot study comprising a relatively small sample size and the antibiotic resistance was not investigated in each patient. However, a selection bias was ruled out by randomized allocation of the so that the prevalence of primary antibiotic resistance is expected to be equally distributed among the therapeutic groups. Due to novelty of 14-day moxifloxacin-based sequential therapy as first line of therapy this study could be cited and included into future meta-analyses. Minor remarks: 1) The Introduction section could be shortened. 2) Authors stated that "in Korea, a region with relatively high antibiotic resistance.... the rates of resistance to levofloxacin and moxifloxacin (by agar dilution) were found to be 5.0%". However, literature data on prevalence of resistance of *Helicobacter pylori* to clarithromycin and other antibiotics in Korea was not included (in Discussion section), and this data should be added.

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**Reviewer code:** 00073418

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<input type="checkbox"/> Grade B: Very good	<input checked="" type="checkbox"/> Grade B: Minor language polishing	<input type="checkbox"/> Existing	<input type="checkbox"/> High priority for publication
<input checked="" type="checkbox"/> Grade C: Good	<input type="checkbox"/> Grade C: A great deal of language polishing	<input type="checkbox"/> No records	<input type="checkbox"/> Rejection
<input type="checkbox"/> Grade D: Fair	<input type="checkbox"/> Grade D: Rejected	BPG Search:	<input checked="" type="checkbox"/> Minor revision
<input type="checkbox"/> Grade E: Poor		<input type="checkbox"/> Existing	<input type="checkbox"/> Major revision
		<input type="checkbox"/> No records	

### COMMENTS TO AUTHORS

The efficacy of moxifloxacin versus clarithromycin-based sequential therapy as first-line eradication treatment for *Helicobacter pylori*: A randomized pilot study Hwang JJ et al. The authors describe a single-center, randomized control study of eradication treatment for *H. pylori* infection, involving 161 patients in two groups, comparing moxifloxacin and clarithromycin in similar 14-day, sequential regimens. General comments: Comparing these two antibiotics in a first-line regimen has not been widely studied before, which warrants this study. The study is well presented and the language is close to faultless, adding to the readability. Ethical aspects are covered sufficiently. Specific comments: The title reflects the content of the paper, and the abstract is complete regarding the major points and sufficiently structured. The Materials and Methods section describe the selection of patients and the method used sufficiently for others to reproduce the study. No bacterial culture and *H. pylori* antibiotic resistance testing were performed. This is mentioned in the Discussion section as "we could not investigate the antibiotic resistance", without further explanation. There were 161 patients included in the study, however this number is given as "181" on at least three accounts. The statistical analyses are adequate. The authors show that moxifloxacin is more efficient than clarithromycin in this study, with high compliance and low occurrence of adverse events, although significantly higher in the clarithromycin group. Figure 1 is an excellent example of the use of flow charts to illustrate patient inclusion, etc. Table 1 shows that the groups are comparable, may be in too



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much detail (minor point). Table 2 shows the main results in the study; a significant difference in treatment effect, both in ITT and PP analyses. Univariate analyses (Table 3) show an effect only of age (>60 years) on the treatment outcome. The multivariate analysis is confusing (Table 4). All adjusted ORs have 95% CIs well above 1, yet only age remains with a p value <0.05. This must be clarified or corrected. The study's weakest point is the lack of antibiotic, especially clarithromycin, resistance testing. A high level of clarithromycin resistance may be the explanation for the differences in the two study groups, and may well explain the age effect on treatment outcome. It is not possible to test for *H. pylori* resistance retrospectively, but this point could be discussed somewhat better. The first part of the discussion is a repetition of results in too much detail, and should be simplified. The references are appropriate.

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<input type="checkbox"/> Grade B: Very good	<input checked="" type="checkbox"/> Grade B: Minor language polishing	<input type="checkbox"/> Existing	<input type="checkbox"/> High priority for publication
<input checked="" type="checkbox"/> Grade C: Good	<input type="checkbox"/> Grade C: A great deal of language polishing	<input type="checkbox"/> No records	<input type="checkbox"/> Rejection
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<input type="checkbox"/> Grade E: Poor		<input type="checkbox"/> Existing	<input type="checkbox"/> Major revision
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### COMMENTS TO AUTHORS

The study evaluates the efficacy of 14-day moxifloxacin-based sequential therapy compared with 14-day clarithromycin-based sequential therapy as a first-line eradication treatment of Helicobacter pylori infection in a Korean population. The study is well conducted and shows that MOX-ST Group achieve successful eradication in respect to CLA-ST group, both in intention-to-treat (ITT) analysis and by per-protocol (PP) analysis. The adverse event rates were significantly lower in MOX-ST Group. I think that this study, although single center and not RCT, represents a new finding in the searching a valid H pylori treatment. I have only minor suggestion: In table I substitute the term HPAG with gastritis. Gastric cancer is an exclusion criteria and patient included on CLA-ST should be withdrawn. All the drop-out description should skip since it has been described in Fig 1. Table 4 should be omitted since multivariate analysis reported is already in results section page 9 last para