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Is Otilonium Bromide Really Effective for Treating Asian Patients With Irritable Bowel Syndrome?: Author's Reply

TO THE EDITOR: We do appreciate Dr. Kim for his interest and comments[1] on our publication.[2] Mebeverine has long been an effective antispasmodic to treat the main symptoms of irritable bowel syndrome (IBS). Dr. Kim is correct that most IBS trials have employed mebeverine in the conventional dose of 135 mg t.i.d., which is commonly used and studied among the Korean IBS patients.[3] For the purposes of relieving IBS abdominal pain and global improvement, a meta-analysis indicates no difference between the slow releasing compound with dose of 200 mg b.i.d. and conventional dose of 135 mg t.i.d.[4] However, mebeverine 100 mg tablet t.i.d. is also available in the market including Taiwan and we had studied this dosage in comparison with a calcium channel blocker.[5,6] In fact, mebeverine 100 mg tablet has been marketed and popularly used in our country for decades with a faithful credit. This is why we employed mebeverine 100 mg tablet t.i.d. as the active-controlled agent when the otilonium bromide (OB) study was designed. It is unknown whether this lower dose preparation would exhibit an inferior efficacy compared to the conventional 135 mg tablet used in other countries. With regard to the impact of IBS subgroups on the mebeverine efficacy, he suggested that diarrhea-predominant IBS patients might be treated more effectively.[1] Because mebeverine is recommended to treat IBS main symptoms despite of the characteristic stool consistency,[4,5] we never tried to confirm the subgroup effect. Interestingly, a recent large-scale European multi-national study indicated that OB was safe, well tolerated and superior to placebo in reducing the frequency of abdominal pain, severity of abdominal bloating and even prevented IBS symptom relapse, and this study further addressed that IBS subgroups did not exhibit any obvious impact on OB therapy.[7] As our study already depicted that OB exhibits a efficacy comparable to mebeverine,[2] we do not expect that the IBS subgroups may have a definite impact on 2 studied agents.

The third concern is that almost all our enrolled IBS patients had used rescue agents to treat their troublesome bowel movement (BM) disorders in terms of constipation and diarrhea when the study was conducted. Apart from the main IBS symptoms, IBS subjects are also very concerned about their disordered BM.[8] If an IBS study does not include the rescue agents for the events of intractable diarrhea or constipation, many of them may violate protocol, which would lead to the study failure. Unfortunately, almost all our patients had consumed rescue agents during the trial, which probably means that they might have recorded a better satisfied score on the BM. We recognized that this BM issue has become the concern of investigators, whereas the satisfied response of recorded BM was mostly unreliable. Finally, we do expect that our response has resolved the controversy suggested by Dr. Kim.

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Conflicts of interest: None.