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Davies, CL and Ford, AC (2015) Pinaverium in Irritable Bowel Syndrome: Old Drug, New Tricks? *Clinical Gastroenterology and Hepatology*, 13 (8). pp. 1548-1549. ISSN 1542-3565

<https://doi.org/10.1016/j.cgh.2015.03.007>

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TITLE PAGE

Title: Pinaverium in irritable bowel syndrome: Old drug, new tricks?

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Grant support: None.

Abbreviations:

IBS	irritable bowel syndrome
IBS-D	diarrhea-predominant irritable bowel syndrome
RCT	randomized controlled trial

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Disclosures: CLD: none to declare. ACF: none to declare.

Writing assistance: None

Author contributions: CLD and ACF drafted the manuscript. Both authors have approved the final draft of the manuscript.

Word count: 417

Sirs;

We read with interest the randomized controlled trial (RCT) by Zheng et al. comparing the anti-spasmodic pinaverium with placebo for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D).¹ The authors reported that over 75% of patients receiving pinaverium had either a 30% reduction from baseline in abdominal pain or a 50% reduction in the number of days with at least one stool with a Bristol stool score ≥ 6 at week 4, compared with 33.5% with placebo ($P < 0.001$). The proportion of dual responders, those who achieved both of these endpoints at week 4, was also significantly higher with pinaverium (38.1% vs. 16.7%, $P < 0.001$).

A previous systematic review and meta-analysis suggested that pinaverium was of benefit in IBS,² with a number needed to treat of three, but this was based on only three trials,³⁻⁵ containing 188 patients, which were conducted in the 1970s and 1980s, and which lacked rigorous endpoints. We therefore commend the authors for conducting this RCT using state of the art methodology. Previous experts in the field have pointed out the lack of clarity surrounding the effectiveness of traditional therapies for IBS, due to small underpowered trials, and a failure to assess efficacy using currently accepted endpoints.⁶ This underlines the importance of the current study, which employs an old drug, but judges its effect on IBS symptoms using outcomes that are rigorous and closely mirror those recommended by the Food and Drug Administration.

Patients with IBS-D demonstrate accelerated intestinal transit and reduced terminal ileum diameter on magnetic resonance studies,⁷ which suggests that anti-spasmodic drugs may be of greatest benefit in this patient group but, to date, most studies have failed to examine their efficacy according to IBS subtype. The findings of Zheng et al. therefore allow targeting of antispasmodic therapy towards a specific

IBS subtype, an approach that has been used with almost all novel agents developed for the treatment of IBS since alosetron, another strength of their study.

The major concerns are that the trial was only 4 weeks in duration, and was conducted entirely in China. Whether pinaverium will demonstrate similar efficacy beyond 4 weeks, or in non-Chinese patients with IBS-D, remains to be seen. The authors' assertion that pinaverium can be considered as a first-line treatment for IBS may therefore be premature. Despite this, they are to be congratulated on a rigorous trial, which is an important addition to our growing body of knowledge on the appropriate use of pharmacological therapies in IBS.

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