There are high placebo response rates with a large amount of variability in IBS clinical trials. Recently, more restrictive outcome measures have been developed for IBS trials to distinguish between active treatment response and placebo response. However, a stringent responder endpoint may not accurately convey the degree of clinical improvement based on patient reported outcomes (PRO). The IBS Reduction Evaluation and Safety Trial (IBREST) showed that a novel formulation of peppermint oil (PO) using solid-state microcapsules (PO-SST) to target the small intestine, was an effective IBS therapy at 24 hours, with improved efficacy at 4 weeks. One previous PRO study, IBGACT1, showed an 80% plus response rate.

This post-hoc analysis of IBREST data was done to determine if there was a meaningful response difference between “any improvement” and the high hurdle of “40% improvement” with PO-SST versus placebo. The study was also designed to add to earlier RCT evidence to support the use of PO for IBS.

**Methods**

IBREST subjects met Rome III criteria for IBS-M or IBS-D, had average daily IBS related abdominal pain of ≥4 (0-10 scale), and a total IBS symptom score (TISS) of ≥4 (0-4 scale). Subjects were randomly allocated to PO-SST (180 mg TID) or placebo for 4 weeks. The primary analysis was based on the TISS and a secondary analysis evaluated changes in abdominal pain ≥4 weeks. The stringent “40% improvement” threshold tended to be pronounced within 24 hours in TISS or abdominal pain. Seventy-two patients were evaluable for the 24 hour response population and 71 were evaluable for the 4 week response population.

**Results**

At 24 hours, the response rate for a 40% improvement in TISS was 14% in patients receiving PO-SST vs. 0% receiving placebo (P=0.1678), while 77% receiving PO-SST had “any improvement” vs. 51% receiving placebo (P=0.0172).

At 4 weeks, receiving PO-SST vs. placebo (P=0.017), while 77% receiving PO-SST were “any improvers” vs. 51% receiving placebo (P=0.002).

**Conclusions**

- A higher percentage of patients responded to PO-SST vs. placebo.
- The stringent “40% improvement” threshold tended to be pronounced within 24 hours for TISS and abdominal pain, while differences in “any improvement” were retained at 4 weeks for abdominal pain, supporting a consistent effect on abdominal pain with PO-SST.
- This responder analysis confirmed the high response rates seen with PO-SST in the IBGACT1 trial.

**References**


**Disclosures**

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