

Effect of an Herbal Supplement on Intestinal Methanogenic Overgrowth

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INTRODUCTION

- Intestinal methanogenic overgrowth (IMO) is currently defined by methane (CH₄) levels ≥10 parts per million (PPM) on breath testing
- IMO has been associated with abdominal discomfort, bloating, and constipation. Treatment for IMO is limited to antibiotics which may be ineffective and/or induce adverse effects
- Atrantil® is a nutraceutical purported to reduce CH₄. Atrantil® may reduce symptoms in individuals with IMO

OBJECTIVES

- Determine if Atrantil® (quebracho/horse chestnut/ peppermint oil) is associated with symptom reduction in individuals with IMO**
- Determine if Atrantil® is associated with reduction breath CH₄ levels**
- Determine if there is a correlation between symptom improvement and reductions in breath CH₄ levels**

METHODS

- Successive patients with (+) glucose or lactulose breath tests (CH₄ ≥ 10 ppm) were prospectively recruited from a single academic center. Participants consumed 2 capsules of Atrantil® t.i.d for 4 weeks
- PROMIS GI symptom questionnaires were completed at baseline and on a weekly basis. Abdominal pain, discomfort, bloating and distention were measured daily via 0-10 point Likert scales. Post-treatment breath tests and assessments of adequate relief were performed at 4 weeks
- PROMIS GI t-scores were analyzed using mixed effects regression models with week of treatment as a fixed effect and subject as a random effect
- The threshold for a minimal clinically significant difference was Δt-score ≥5
- Logistic regression was performed for CH₄ levels and adequate relief

RESULTS

- 42 individuals were recruited. 39 (76.9% female, mean age 44.8 years) completed the study. 12.2% were clinically diagnosed with IBS
- Baseline indications for breath testing included: bloating (85%), constipation (46.3%), pain/discomfort (39%)

Effects of Atrantil® on Symptoms:

- Statistically significant improvements in belly pain, gas bloating, constipation, swallowing and nausea/vomiting
- Point estimate improvements in belly pain & gas/bloating suggest a clinically meaningful improvement of 5 points or more
- 56% of subjects reported adequate relief

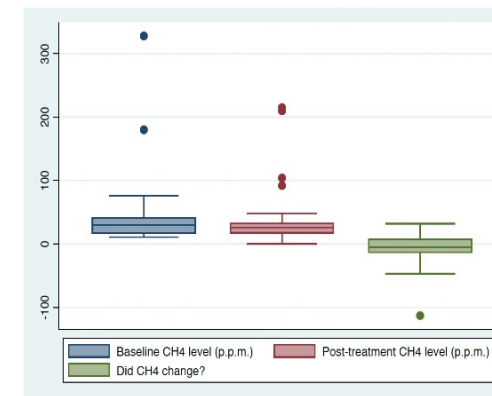
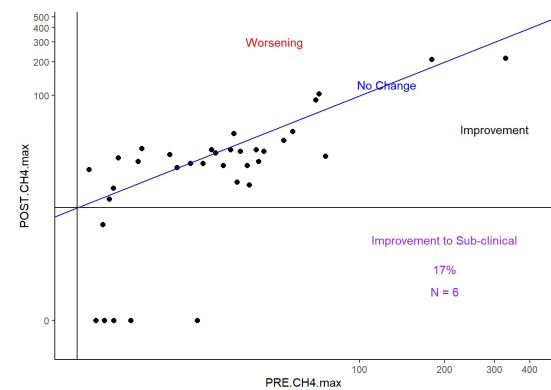
Weekly PROMIS GI t-scores	t-score at baseline (95% CI)	Change at Day 28 (95% CI)
Belly pain	59.1 (56.4-61.7)	-5.8 (-8.5 to -3.1)
Gas/bloating	62.8 (61.1-64.6)	-5.3 (-7.4 to -3.1)
Constipation	53.3 (51-55.7)	-3.7 (-5.5 to -1.9)
Diarrhea	51.2 (48.3-54)	-3.2 (-6.3 to -0.03)
Reflux	46.7 (44.4-49)	-1.6 (-3.6 to 0.35)
Swallowing	46.1 (43.5-48.8)	-2.8 (-4.4 to -1.1)
Nausea/vomiting	49.9 (47-52)	-2.6 (-4.2 to -0.97)

Effects of Atrantil® on CH₄ levels:

- 86.11% of breath tests persistently positive for IMO post-treatment
- Median baseline CH₄ levels decreased from 30 at baseline to 26 post-treatment (median change: -5)
- Weak association between overall reduction of CH₄ and adequate relief (p=0.387)

Figure: Changes in maximum methane level after treatment with Atrantil® (N=35)

Left panel: Dots below the blue line represent decreases in post-treatment CH₄ level; dots below the horizontal black line represent normalization of post-treatment breath tests (CH₄ levels <10 p.p.m.)



ADVERSE EVENTS

- 4 individuals experienced TEAEs: diarrhea (1), bloating (2), belching and stomach burning (1)
- One individual withdrew for bloating

LIMITATIONS

- Pilot study
- Lack of control/placebo arm/blinding
- Heterogeneous enrollment population

CONCLUSIONS

- At 4 weeks, the most robust symptom improvements were belly pain, gas/bloating, & constipation consistent with the presumed effects of Atrantil® in patients with IMO**
- Adequate relief was endorsed by >50% of individuals taking Atrantil®**
- These changes were not significantly correlated with CH₄ levels**
- Atrantil® may be an effective natural treatment for symptoms of IMO**

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