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Is ginger effective for the treatment of irritable bowel syndrome? A double blind randomized controlled pilot trial

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KEYWORDS
Irritable bowel syndrome;
Ginger;
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Summary
Objectives: Ginger is one of the most commonly used herbal medicines for irritable bowel syndrome (IBS) but no data exists about its effectiveness.
Design: Double blind randomized controlled trial.
Setting: University of North Carolina, Chapel Hill, North Carolina, USA.
Intervention: Forty-five IBS patients were randomly assigned to three groups: placebo, 1 g of ginger, and 2 g of ginger daily for 28 days.
Main outcome measures: The IBS severity scale (IBS-SS) was administered, as well as adequate relief of symptoms scale. A responder was defined as having at least 25% reduction in IBS-SS post-treatment.
Results: There were 57.1% responders to placebo, 46.7% to 1 g and 33.3% to 2 g of ginger. Adequate relief was reported by 53.3% on placebo and 53.3% in both ginger groups combined. Side effects were mild and reported by 35.7% in the placebo and 16.7% in the ginger groups.
Conclusions: This double blind randomized controlled pilot study suggests ginger is well tolerated but did not perform better than placebo. Larger trials are needed before any definitive conclusions can be drawn.

Introduction

Irritable bowel syndrome (IBS) is a common chronic condition consisting of abdominal pain with changes in bowel habits. The effectiveness of treatments for IBS are limited and about 40% of patients use alternative medicine to treat their symptoms.[1] The most popular alternative medicine in a large study of 600 IBS patients was ginger.[1]

Ginger root is the rhizome of the perennial plant *Zingiber Officinalis Roscoe*. Ginger contains 1—3% of oils. Ginger dosing is often standardized according to gingerol content which is assumed to have antiemetic, analgesic, sedative, antibacterial and other physiological effects though other non-volatiles may have some of the same effects.[2—4] Ginger is on the American Food and Drug Administration Generally Recognized as Safe list meaning

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that it is considered safe and is exempted from premarket review, approval, and clinical testing before marketing (http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/ucm2006850.htm).

There is some evidence to suggest that ginger can affect IBS symptoms. In Micromedex (an evidence based clinical reference tool for hospitals and physicians; www.micromedex.com) ginger is classified as a broad spectrum antiemetic, and is effective in treating nausea and vomiting associated with pregnancy[5] and surgery.[6] Ginger has also been found to influence pain and gut motility.[2,4] Thus, ginger may be useful in reducing both pain and stool changes in IBS.

Given the known gastrointestinal effects of ginger, its common use among IBS patients and its wide availability and low cost, ginger should be tested as a potential treatment for IBS. The goal of this pilot study was to test the effects of ginger on IBS symptoms through a randomized placebo and dose dependent controlled trial. We chose to run a pilot study to look for signal and magnitude of clinical effect to support the rational and direct the design of a larger study.

Methods

Subjects

Subjects were 45 patients age 18 and older with a physician diagnosis of irritable bowel syndrome (IBS) verified by Rome III criteria. Patients were identified by sending a mass e-mail to all students, staff, and faculty at the University of North Carolina. All participants needed to have symptoms at least once a week severe enough to interfere with daily activities and report being on a stable dose of current medications for IBS for at least 4 weeks. Subjects were excluded if they reported: (a) regular use of ginger (b) ginger allergy/intolerance, (c) history of surgical resection of part of the gastrointestinal tract, (d) being pregnant or planning to become pregnant, or (e) use of cardiotonic or diabetic medications contra-indicated for use with ginger.

The study employed a randomized, controlled, parallel group design in which 15 subjects were randomly assigned to each of three arms: placebo, 1 g ginger daily, or 2 g ginger daily. Treatment duration was 28 days. Most previous trials of gastrointestinal related symptoms, such as nausea/vomiting associated with cancer or pregnancy, have used similar 1—2 g daily doses.[5,7] Given that no previous studies have tested the use of ginger in IBS patients, we have no information to guide power analyses for a trial. Therefore, we chose to run an initial trial with 15 subjects in each arm to look for signal and magnitude of clinical effect to support the rational and direct the design of a larger study.

Study design

All patients completed consent, screening and baseline questionnaires online. More patients expressed interest in participation than the required 45 — only the first 45 were invited to participate. Upon randomization (by a perl-based computer program), a one-month supply of ginger or placebo capsules was sent by mail. Packages included instructions on starting and stopping dates. Patients were contacted within 24 h of ingesting first capsule, and biweekly thereafter to check for compliance and side effects. The study was approved by the Institutional Review Board of the University of North Carolina (approval# 07-1035).

Ginger and placebo capsules

The ginger and placebo capsules were blister packed to ensure blinding,[8] by a compounding pharmacy. The pharmaceutical grade ginger contained 2.29 mg/g of gingerols and 6-shogaols. The placebo contained brown sugar. The pharmacy coded the capsules for blinding and sent a coding key via mail at study completion.

Measures

Irritable bowel syndrome severity scale (IBS-SS)

The IBS-SS[9] measures IBS severity with five items (severity and frequency of pain, abdominal distension, bowel dissatisfaction, and interference with life) rated on a 0—100 scale. A responder was defined as at least a 25% reduction in IBS-SS scores post-treatment.

Adequate relief rating scale (ARRS)

At the end of treatment, patients were asked to respond to the question, ''In the last week, have you had adequate relief of your abdominal pain and other symptoms of IBS (yes or no)?''.[10]

Data analyses

Paired *t*-test was run to compare IBS severity scores before and after treatment. Percentage of responders and ARRS was compared across the three treatment arms with chi square tests.

Results

One-hundred and eighty-one interested patients responded to study notices and completed screening. Of this group the first 45 eligible patients were invited to participate (see Fig. 1 for a CONSORT diagram). No differences between the 3 treatment arms were found in gender, age and IBS-SS scores at baseline. Treatment compliance was acceptable: 97.3% in the placebo group, 98.5% in the 1 g ginger group, and 85.2% in the 2 g ginger group. Side effects were mild and reported by 35.7% in the placebo and 16.7% in the ginger groups. Except for two subjects who reported headaches and tiredness, all side effects were gastrointestinal symptoms including heart-burn, nausea, difficulty passing stool, more frequent stools, loose stools, bloating and hunger suppression.

IBS severity scores before and after treatment are given in Table 1. Placebo and 1 g ginger groups saw a significant reduction in symptoms by 34.8% and 26.4%, respectively. Number of treatment responders across groups was not different (57.1% placebo, 46.7% 1 g ginger, 33.3% 2 g ginger; $p > .05$). Adequate relief was reported by 53.3% in the placebo group and 53.3% in both the ginger groups ($p > .05$).