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Katy N. DeGraw

Philadelphia College of Osteopathic Medicine, Katyde@pcom.edu

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Is Ginger An Effective Treatment For Moderate Or Severe Dysmenorrhea In Females Over The Age Of 18?

Katy N. DeGraw, PA-S

A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

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In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies
Philadelphia College of Osteopathic Medicine
Philadelphia, Pennsylvania

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ABSTRACT

OBJECTIVE: The objective of this selective EBM review is to determine whether or not ginger is a safe and effective treatment for moderate or severe dysmenorrhea in females over the age of 18.

STUDY DESIGN: Review of three randomized controlled studies. All three studies are published in English between 2009-2013.

DATA SOURCES: Three randomized placebo controlled studies found using PubMed and Medline.

OUTCOMES MEASURED: The outcomes that were measured were severity of pain, duration of pain, change in symptoms, and change in severity. This was done by using a visual analogue scale, 5-point Likert scale, Wilcoxon's rank-sum test, and verbal multidimensional scoring system.

RESULTS: The first study, the Jenabi study showed that 29 subjects, 82.85%, reported improvement in their dysmenorrhea symptoms compared to 16 subjects, 47.05%, in the placebo group determined by the five-point Likert scale. In the second study, Ozgoli et al study showed that 62% of subject showed improvement using ginger capsules via a verbal multidimensional scoring system, as compared to 66% of patients using ibuprofen respectively. The third study, Rahnama et al study showed that the ginger group reported 11 hours less pain duration as well as 3 cm less in severity of pain than the placebo group, measured by verbal multidimensional scoring system and visual analogue scale. No serious adverse events were noted in any of the three studies.

CONCLUSIONS: Based on these three trials, ginger is a safe and effective treatment for moderate or severe dysmenorrhea. Each study showed improvement of symptoms or showed it to be as effective as NSAIDs without any serious side effects when using ginger.

KEY WORDS: Ginger, dysmenorrhea

INTRODUCTION

Dysmenorrhea, also commonly referred to as menstrual cramps, can be characterized as throbbing or cramping pains in the lower abdomen that can radiate to the inner thighs just before or during a woman's menstrual cycle with no identifiable pathologic lesion.^{1,5} It is considered moderate or severe when a woman has either moderate or severe pain with influence on daily activities, ineffective use of analgesics, and symptoms such as headache, tenderness, nausea, vomiting, and diarrhea.⁵ This paper evaluates three double blind, randomized controlled trials comparing the efficacy of ginger as an oral medication compared to a placebo or NSAID for improving moderate or severe dysmenorrhea in females over the age of 18.

Dysmenorrhea is relevant to the Physician Assistant profession due to its prevalence, cost to the patients, and amount of lost time from school and work. Dysmenorrhea can have significant effects on patients quality of life. It is extremely common, being one of the most frequent gynecologic disorders, affecting more than half of menstruating women.³ There is an estimation that severe dysmenorrhea results in a loss of 600 million working hours and approximately two billion dollars in lost productivity.^{2,4} The exact number of health care visits due to dysmenorrhea is unknown, however approximately 45.6% of women with severe dysmenorrhea are absent from school or work, resulting in a need for a physician visit and excuse, which is why it is so important for medical providers to aware of this problem.⁴

The exact etiology of the dysmenorrhea is unknown; however, the symptoms are thought to be associated with increased production of prostaglandins in the endometrium which causes increased myometrial contractility, uterine ischemia, and sensitizations of pain fibers.^{4,5} Due to the unknown exact etiology, there is currently no curative treatment.

In most cases of dysmenorrhea, nonsteroidal anti-inflammatory drugs (NSAIDs) are the usual first line therapy.⁶ As the suggested etiology of dysmenorrhea is due to the excess production of prostaglandins, the use of NSAIDs would cause inhibition of prostaglandin synthesis, relieving women of dysmenorrhea.⁶ However, previous studies have showed that up to 25% of women fail the conventional therapy of NSAIDs or may also have contraindications to the use of NSAIDs.⁶ Other methods that are commonly used for dysmenorrhea are combined oral contraceptives. These hormones act by suppressing ovulation and lessening the endometrial lining of the uterus, which in end decrease the amount of prostaglandins.⁷ However, due to many contraindications of the use of combined oral contraceptive pills, such as history of deep venous thrombosis or family history of coagulopathies, some women may not be able to use them as treatment for their dysmenorrhea. Due to the failure rate, limited efficacy, and contraindications of NSAIDs and combined oral contraceptives, the use of ginger may be used as an oral alternative for the relief of dysmenorrhea.

OBJECTIVE

The objective of this systematic review is to determine whether or not ginger is an effective treatment for moderate or severe dysmenorrhea in females over the age of 18.

METHODS

All three studies used in this review required a population of females greater than the age of 18 years old with moderate to severe dysmenorrhea. The intervention was the implementation of ginger tablets, 250 mg or 500 mg, taken three times or four times a day. Comparisons were made between subjects that took a ginger tablet and experimental groups who either took a placebo or ibuprofen. The outcomes measured were severity of pain, duration of pain, and change in severity. All three studies were randomized controlled trails (RCTs) that evaluated

ginger as an effective treatment for moderate or severe dysmenorrhea in females 18 years or older.

Keywords used when searching for articles consisted of ginger and dysmenorrhea, all of which were in English and in peer-reviewed journals. The articles chosen were researched by the author and obtained through either PubMed, Medline, OVID, or Google Scholar. The articles were selected based on the types of studies, the relevance to the clinical question being asked and that the outcomes of the studies mattered to patients. Inclusion criteria for selecting these articles included randomized controlled studies that directly benefit the patient. Exclusion criteria included patients under the age of 18 years old. The statistics that were utilized and reported included relative benefit increase (RBI), absolute benefit increase (ABI), relative risk increase (RRI), absolute risk increase (ARI), numbers needed to treat (NNT), numbers needed to harm (NNH), and p-value. Table 1 displays the demographics and characteristics of the included studies.

Table 1- Demographics & Characteristics of included studies

Study	Type	# of Pts	Age (yrs)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Jenabi ⁴ (2013)	RCT	70	≥ 18 years old	Patients ≥ 18 years old that had moderate to severe dysmenorrhea	Cases of mild dysmenorrhea	1	500 mg of Ginger TID for first 3 days of menstruation
Ozgoli et al ⁵ (2009)	Double blind RCT	150	≥ 18 years old	Patients ≥ 18 years old that had moderate to severe dysmenorrhea	Pre-existing diagnosed disease, history of gestation or taking oral contraceptives, medicinal or herbal sensitivities, BMI <19 or >26, and mild dysmenorrhea	0	250 mg of Ginger QID for first 3 days of menstruation
Rahnama et al ⁶ (2012)	Double blind RCT	120	≥ 18 years old	Patients ≥ 18 years old that had moderate to severe dysmenorrhea; being single, having a menstrual cycle that last from 21 to 35 days with 2-6 days of flow and average blood loss of 20-60 ml.	Diagnosis of a disease, a history of pregnancy or taking oral contraceptives, BMI <19 or >25, and mild dysmenorrhea	15	500 mg of Ginger TID for first 3 days of menstruation

OUTCOMES MEASURED

In Rahnama et al study, the outcomes that were measured were the severity of pain and duration of pain. The way they were measured were by using a verbal multidimensional scoring system, visual analogue scale, and ANCOVA. In Jenabi's study, the outcomes that were measured were severity of pain and change in symptoms, which were measured by a visual analogue, 5-point Likert scale, and Wilcoxon's rank-sum test. In the Ozgoli et al study, the outcome that was measured was change in pain severity, which was measured by using a verbal multidimensional scoring system and 5-point Likert-scale.

RESULTS

All three articles compared the use of ginger with the use of a placebo or ibuprofen for the treatment of moderate or severe dysmenorrhea. Each article consisted of three randomized controlled trails, all presented in continuous data which were then converted into dichotomous data.

The Jenabi study excluded females that had mild dysmenorrhea. The subjects took either a 500mg tablet of ginger TID or a placebo TID, depending on the group they were blindly placed in. This study showed that compared to the baseline, the ginger group had a notably greater reduction in pain compared to that of the placebo group, measure by visual analogue.⁴ The change in pain scores are listed in Table 2, while the change in symptoms is listed in Table 3.

The change in pain score was greater in the ginger group at 3.81 ± 1.17 , while the placebo change in pain score was only 0.48 ± 0.91 , with a p-value of 0.001, showing true significance.

Approximately 83% of subjects in the ginger group reported improvement in symptoms while only 47% of the placebo group reported improvement in symptoms. The relative benefit increase

(RBI) was 77.6%, the absolute benefit increase (ABI) was 36.1%, and the numbers needed to treat (NNT) was 3, all of which point to this being a large treatment effect.

Table 2. Change in Pain Score for Jenabi Study.⁴

Type of Treatment	Before Use (Mean±SD)	After Use (Mean±SD)	Before use- after use
Ginger	7.08 ± 1.02	4.81 ± 1.70	3.81 ± 1.17
Placebo	7.61 ± 1.20	7.11 ± 1.12	0.48 ± 0.91
p-value	0.61	0.001	0.001

Table 3. Change in symptoms for Jenabi Study.⁴

Change in Symptoms	Ginger	Placebo
Much worse	0	0
Worse	0	0
Same	6 (17.4%)	18 (53.5%)
Better	14 (40.0%)	10 (29.0%)
Much Better	15 (42.6%)	6 (17.5%)
n	35	34

Ozgoli et al study excluded females with pre-existing diagnosed disease, history of gestation or taking oral contraceptives, medicinal or herbal sensitivities, BMI <19 or >26, and mild dysmenorrhea.⁵ The subjects took either 250 mg of ginger QID or 400 mg of ibuprofen QID for the first three days of the menstrual cycle. This study showed that ginger was as effective treatment as ibuprofen (NSAID) in the fact that both groups had a decrease in the severity of dysmenorrhea with no differences between the groups in severity of dysmenorrhea, pain relief,

or satisfaction with treatment.⁵ In the group taking ibuprofen, 66% of the subjects said that their pain was either relieved or considerably relieved. In the ginger group, 62% of the subjects said that their pain was either relieved or considerably relieved. Table 4 shows the change in pain severity for both the ibuprofen and ginger groups. The RBI was -6.1%, the ABI was -4% and the NNT was -25, all of which point to a large treatment effect.

Table 4. Change in pain severity for Ozgoli et al.⁵

Change in Pain Severity	Ibuprofen	Ginger
Considerably relieved	18 (36%)	18 (36%)
Relieved	15 (30%)	13 (26%)
Unchanged	17 (34%)	15 (30%)
Worse	3 (6%)	4 (8%)
Considerably worse	0	0

Rahnama et al study excluded subjects based on diagnoses of a disease, a history of pregnancy or taking oral contraceptives, BMI <19 or >25, and mild dysmenorrhea.⁶ The subjects took either 500 mg of ginger TID or a placebo TID for the first three days of the menstrual cycle. There was two different protocols that were done, but for this paper we will focus on protocol 2 which consisted of either 500 mg of ginger TID or a placebo TID given for the first three days of the menstrual period. This study showed that there was a noteworthy difference in severity of pain between ginger and the placebo groups ($p=0.008$), however there was not a significant change in the duration of pain ($p=0.080$).⁶ The ginger group reported a 2.72 ± 2.82 change in severity of pain from before and after use, while the placebo group reported a 1.51 ± 2.77 change in severity of pain from before and after use.⁶ Table 5 and Table 6 show the change in pain severity and duration of pain between the ginger and placebo group. The relative risk increase

(RRI) was -41%, the absolute risk increase (ARI) is -3.6% and the numbers needed to harm (NNH) was 27, all of which point to a large treatment effect.

Table 5. Change in severity of pain for Rahnama et al study. ⁶

	Before Use (Mean±SD)	After Use (Mean±SD)	Before use- after use	p-value
Ginger	7.34 ± 1.1	4.61 ± 2.55	2.72 ± 2.82	0.008
Placebo	7.52 ± 0.93	6.01 ± 2.65	1.51 ± 2.77	

Table 6. Change in duration of pain for Rahnama et al study. ⁶

	Before Use (Mean±SD)	After Use (Mean±SD)	Before use- after use	p-value
Ginger	19.38 ± 16.35	10.88 ± 14.54	8.50 ± 17.77	0.080
Placebo	19.06 ± 22.73	15.57 ± 14.72	3.48 ± 23.08	

DISCUSSION

Ginger is a complex herb that is essentially made up of sesquiterpene, but also includes carbohydrates, free fatty acids, amino acids, proteins, phytoesters, niacin, and nonaromatic compounds. ^{5,8} It has been found that ginger inhibits cyclooxygenase and lipoxygenase pathways in the prostaglandin pathway synthesis as well as have anti-inflammatory effects, which is why they believe ginger improves females dysmenorrhea. ^{5,6} Ginger has also been found to help in other problems including dyspepsia, colic, vomiting, diarrhea, colds, influenza, arthritis, kidney stones, and asthma. ^{4,5}

All three studies analyzed showed a greater improvement in dysmenorrhea with the use of ginger compared to the use of placebo and was considered as adequate as ibuprofen. This review supports the use of ginger in the treatment of dysmenorrhea but there are some limitations in the studies used. Both Rahnama et al and Ozgoli et al studies both made distinct points with the lack

of observation regarding the effects on ginger on the other symptoms that are linked to dysmenorrhea such as nausea, vomiting, etc.^{5,6} Furthermore, in the Rahnama et al study, 13 patients from the placebo group had left the study and no data was available from them. In all three studies there is a strong indication that there is a limitation on the physiology of why ginger helps with improvement of dysmenorrhea. There is a strong suggestion that in order to expand our knowledge and understanding of why ginger works to improve dysmenorrhea, further studies need to be done, as well as knowing the exact etiology of dysmenorrhea.

CONCLUSION

Based on this systematic review and chosen studies, ginger is an effective treatment for moderate or severe dysmenorrhea. The data within these three studies are consistent with the beneficial effects of ginger as well as its overall safety. No serious adverse effects were noted in any of the studies. Therefore it should be considered by healthcare providers to recommend to patients as a treatment of moderate or severe dysmenorrhea. Additional studies investigating the effects of ginger on other symptoms associated with dysmenorrhea, the safety of various doses of ginger, and the exact mechanism of action of ginger should be considered.^{4,5,6}

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