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**Does the use of ginger extract effectively help patient with obesity
loses weight?**

Linh H. Nguyen, PA-S

A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

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 extract (NT) effectively helps obese patient loses weight.

Study Design: Two randomized controlled studies to determine the effectiveness of ginger extract in weight loss and a cross sectional observational study.

Data Sources: Randomized controlled studies published after 2006 relating to ginger extract (NT) and weight loss. Data obtained using PubMed, CINAHL, and OVID databases written in English.

Outcomes Measured: Studies measured weight loss, food intake, and safety such as pulses and blood pressure. Subjects are evaluated at baseline with CMP, CBC and urinalysis weekly.

Results: One randomized controlled studies found a weight loss in the low dose group compared to the placebo “control” group and high dose group. In the same RCT, food intake was significantly decreases in the high dose group. Another randomize controlled studies found the placebo group to have more weight loss than the intervention groups but not statistically different from each other. However, all groups were statistically significant in decreasing food intake. Other outcomes measured were fluctuating within normal ranges and there are no significant differences.

Conclusions: Based on the systematic review of the two randomized controlled trials ginger extract is not an effective method for weight loss in the obesity population. However, according to the observational studies, ginger extract is among the top ten ingredients in weight-loss products. These products are available in retail store in many states. It is generally safe to take and it is believes to have anti-inflammatory and anti-nausea effect.

Key Words: Obesity, weight loss, ginger extract, herbal supplement

Introduction

Obesity is a global epidemic.¹ It has been linked to many chronic diseases such as cancer, hypertension, diabetes, coronary heart disease, myocardial infarction and cerebral vascular accident. A body mass index (BMI) is calculated using the person's weight in pounds and height in inches using the BMI formula. Classification for overweight is a BMI range from 25 – 29.9 and greater 30 is considered obese.² According to the BMI system, currently a worldwide estimation of 937 millions overweight adults and 396 millions obese adults.¹

This is creating a growing health care concerns in the United States for children and adult. Younger generations are seeking health care due to chronic illnesses such as hypertension and diabetes as a result of obesity. Obesity also increases the mortality and morbidity in pre-existing medical conditions. This is one of the most common disorders and a very difficult one to treat or manage.² According to Finkelstein and his colleagues, in 2006, obese patients spent approximately 42 percent more in medical expenses compared to normal weight patients.³ In 2002, it is estimated that Americans spent more than \$2 billion dollars on weight loss supplements.⁴

Obesity is due to many factors such as sedentary lifestyles, increase caloric intakes, genetic predisposition, and other physiologic factors.² The readily availability of fatty foods, sugary drinks and snacks contributed greatly to obesity. Sedentary lifestyles with little or no physical activities also worsen the condition. Genetic played an important role in obesity; children with obese parents are more likely to become obese themselves. Genetic influential has been estimated as high as 40-70% in developing obesity. Women are more likely to be obese than men. Ethnicity such as African American and Mexican-American are more likely to be

obese than other racial ethnic groups. People of lower socioeconomic status are also at risk for developing obesity regardless of their race.²

Methods that had been introduced to treat obesity are conservative therapy, pharmacological therapy, and bariatric surgery. All of the treatments plans have varying degree of effectiveness due to cost, unwanted side effect and compliance issues. Conservative therapy such as exercise, portion control, reduced fatty intakes, reduced caloric intakes and increase energy expenditure. Pharmacotherapies are available in prescription and over-the-counter but the recommendation is for short term use only due to adverse effect. However, the FDA has approved the following for weight loss and they are phentermine, diethylpropion, mazindol, sibutramine and orlistat. Lastly, bariatric surgeries are invasive surgeries for selected patient only. Because of substantial complications associated with bariatric surgeries, the benefit must out weight the risk in each patient. Types of bariatric surgeries are Roux-en-Y gastric bypass and gastric banding. In addition to the above treatment methods, commercial behavioral modification programs are increasingly popular among American.² These behavioral modification programs use different technique to help their clients achieve the weight loss goal. The programs targeted clients based on their lifestyles. For example, Weight Watcher helps clients make healthy food choices and monitor their weight regularly. Nutrisystem provides prepared meal plans that are convenience. Curve's a gym for women only. Others are Jenny's Craig, Sensa, and Atkin's diet. Some will go to the extreme of achieving weight loss by using the starvation diet as well.

In addition to the traditional Western's medicine intervention for obesity, consumers are continually seeking a more natural alternative treatment to achieve the same weight loss goal. Currently herbal supplement that claimed to give weight loss are popular. Some of the well known and well used supplements are green tea, Ginseng, citrus, etc. Adding to the list, ginger

extract (NT) is a natural dietary herbal supplement that may also aid in weight loss. Patient can add this to their exercise regimen to enhance their weight loss result. Studies conducted in China provided successful weight loss result and suppressed appetite in rodents. The herbal supplement has demonstrated to reduce food intake in rodents hence the weight loss result. If successful, ginger extract can aid in weight loss to treat human obesity.

Objectives

The objective of this selective EBM review is to determine whether or not ginger extract (NT) effectively helps obese patient loses weight

Methods

There are specific criteria to be selected for this study. Populations in these studies were female between the ages of 18- 60 years old. Their BMI were between 25 and 35 kg/m² not taking any medications except for birth control or hormone replacement therapy. Interventions were NT extract taking orally in various dosages. Roberts et al mixed NT with gallic acid (GA), a safe substance which has been approved by the FDA to use as antioxidant. Intervention groups were low dose NT with 200 mg GA and high dose NT with 600 mg of GA. Greenway et al used 500mg freeze-dried NT, 250mg bed-dried NT, and 250mg freeze-dried NT. The controls of both studies were a placebo capsule. Two of the most important outcomes measured were weight loss and food intake. Others were blood pressure, pulse rate, complete blood counts (CBC), chemistry panel, liver function and lipids panel. Types of studies included were 2 randomized control studies and a cross sectional observational study.

Literature searches were performed by the author using PubMed, CINAHL, and OVID Medline databases. Literature language was written in English within 2004 to 2011. Key words

used for the search were “obesity”, “weight loss”, “ginger extract” and “herbal supplement”. All articles were published in peer reviewed journals. Inclusions criteria for the articles were human, age between 18-60, randomized, controlled, double blind method, and outcomes measure are patient oriented outcomes (POEMs). Exclusions criteria were animal studies, age under 18 or over 60, pregnancy and lactating. Statistics used in the articles were ANOVA, Chi Square, VAS and p-values using 95% confidence intervals (CIs).

The cross observational study used purposive sampling strategy to select stores to audit. Inclusion of the supplements must claim some weight loss, fat loss, increased metabolism and/or thermogenesis. Exclusions were energy boost, increased muscle mass, and/or reduced water weight. Sharpe and her colleagues determined the top ten ingredients in retail stores. Literature search was conducted for a detailed description of the ingredient, evidence of its efficacy and any adverse effect associated with it.

Table 1: Demographics of included studies

Study	Type	# Pts	Age	Inclusion	Exclusion	W/D	Interventions
Robert ¹ , 2007	RCT, Double blind with three-arm study	105	18-60	BMI between 25-35 kg/m ² , female	Chronic medication other than OCP/HRT	42	Subjects were randomized to receive placebo, low dose NT/GA or high dose NT/GA
Greenway ² , 2006	RCT, cohort, double blind, four-arm study	24	18-60	BMI between 25-35 kg/m ² , female,	Chronic medication other than OCP/HRT, pregnant, lactating	3	Subjects were randomized to receive placebo, oral freeze dried NT, bed-dried NT, or freeze-dried NT

Sharpe ³ , 2006	Cross sectional observational study	73 outlets	N/A	Claimed weight loss, fat loss, increased metabolism, thermogenesis	Energy boost, increased muscle mass, reduced water weight	N/A	N/A
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Outcomes Measured

Roberts and his colleagues measured subjects’ weight as the primary outcomes. In addition, they also checked CBC, blood pressure, pulse rate, chemistry panel, liver function and lipids panel for safety measures at baseline. Measurements were taken at each visit (weeks 0, 2, 4, 8, 12, 16, 20 and 24) and compared from the baseline to the conclusion of the study. Food intakes were also measured at week 0 and 2 using Visual Analogue Scales (VAS) of the subjects’ appetite. Subjects’ had to complete the VAS before and after meal.

Greenway and his colleagues measured subjects’ weight, blood pressure and pulse rate at weekly visit. In addition, they also checked the subjects’ CBC, chemistry panel, urinalysis, and electrocardiogram (EKG) at weeks 6 and 11. Similarly they also measured the amount of food intake from each subjects. They also used the visual analogue scale before and after meal. The outcomes were compared from baseline to the conclusion of the study for any significant changes.

Results

Robert et al used various dosage of intervention in the study. Placebo was compared to low dose NT and high dose NT over the 8 weeks period. As shown in table 2, the placebo group achieved a weight loss of 0.7% body weight; low dose NT achieved a weight loss of 1.2% body

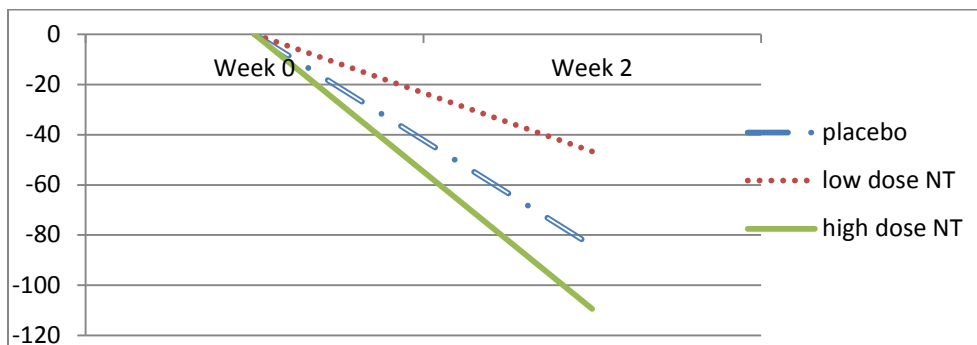
weight; high dose NT achieved a weight loss of 0.6% body weight. When comparing the two NT intervention groups, there was a statistically significant P values = 0.044. However, when comparing the NT intervention groups with the placebo there was no significant differences in weight loss.

Table 2: Efficacy of Ginger Extract on weight loss

Group	Weight loss
Placebo	0.7%
Low Dose NT	1.2%
High Dose NT	0.6%

Food intake was measured at week 0 and 2. Dependent t-test showed a statistically significant decrease of food intake in the high dose group between week 0 and 2. Independent t-test showed that there was no difference in food intake between the placebo and low dose NT with a P value = 0.70 or between the placebo and high dose NT with a P value = 0.73.⁴ As shown in figure 1, high dose group yield a decreased of 109.4 kcal, placebo yield a decreased of 84.3 kcal and the low dose yield the least decreased of food intake with only 46.7 kcal.

Figure 1: Efficacy of Ginger Extract on Food intake



Other outcomes measured such as blood pressure and pulse rate were not statistically significant. Other lab values fluctuated within normal range and none was clinically significant. During each visit pill counting was performed to check for compliance. The placebo group took approximately 93%, low dose NT took 95%, and high dose NT took 92%.⁴ There was no report of adverse effect in the study and the dose mixture was well tolerated.

Greenway et al used four-arm intervention groups. As shown in table 3, weight loss in the placebo group was 1.8 kg, 0.4 kg in the 500 mg freeze-dried NT group, but the 250 mg bed-dried group gained 0.43 kg and the 250 mg freeze dried group gained 0.87 kg. However, they were not statistically significant.

Table 3: Weight loss with NT and placebo

Groups	Weight Changes in Kg
Placebo	- 1.8
500 mg NT	- 0.4
250 mg NT bed-dried	+ 0.43
250 mg NT freeze-dried	+ 0.87

(-)Weight loss; (+) Weight gain

Food intake was compared from baseline to week 4. The placebo group, food intake increased by 12.9 kcal. The 250 mg freeze-dried group, food intake increased by 74 kcal. However, the 250 mg bed-dried group food intake decreased by 49.5 kcal. The 500 freeze-dried mg group food intake decreased by 193.7 kcal. There was a statistically significant between the 250 mg freeze-dried group and the 500 mg freeze-dried group with a P-value < 0.01. When compared the intervention groups with the placebo group there was no significant findings (P values > 0.10).⁵ The VAS scores that was collected after the meal did not differ between groups.

Medication compliance was >95% according to pill counting. As for blood pressure and pulse rate they were fluctuating but all within normal range. There were no EKG changes

throughout the study. Adverse effects report included diarrhea and soft stools (refer to Table 4). There was no diarrhea case reported in the placebo group, but there was 33% case in both the 250 mg bed and freeze dried NT groups, and 67% of the 500 mg group report experienced diarrhea during the course of the study. Soft stools was most prominent in the 500 mg group with a report of 2.83 soft stools per day, whereas both 250 mg groups report 0.6 soft stools per day and placebo group only reported 0.16 soft stools per day.

Table 4: Adverse reactions and NT

Group	Diarrhea	Soft Stools/Day
Placebo	0 %	0.16
250 mg bed-dried	33%	0.60
250 mg freeze-dried	33%	0.60
500 mg freeze dried	67%	2.83

**NNH was not calculated

Observational study conducted by Sharpe and her colleagues identified 402 products containing thousands of ingredients. Products came in the form of capsule, liquid, powder, tea, gum and/or bar. They had identified the top ten most used ingredients and among the list was ginger root extract. The majority of the products claimed to have some weight loss benefits. The literature found on the ginger root extract showed that they had anti-inflammatory and anti-nausea components. However, no literature or studies was found of ginger for weight loss outcomes. The ingredient was generally safe but may interfere with anti-diabetic or heart medications.

Discussion

Ginger extract is a complex herbal supplement. It is widely used around the world for many purposes including weight loss. Because the ingredient is herbal supplement it is not regulated by the FDA, however; many people used it as antioxidant. Both randomized controlled

trials showed a decreased in food intake but not in weight loss. Safety measures for both studies were normal with only one study report adverse effects.

This is a systematic review aimed at determining the efficacy of ginger extract on weight loss for obese patients. The limitation of this review was to select primary, randomized controlled trial in English conducted in the last ten years with human studies only. But there were lacks of human trial studies conducted in the United States hence the limited literature on the topic. More importantly, all the successful rodent studies were conducted in China. This is a country that has been known for their practice of Eastern medicine. They favored and used herbal supplements for the majority of health conditions including obesity.

Obesity, like many other preventable diseases, is better to prevent than to treat. Prevention of obesity should start early in childhood. Parents should teach their children to eat healthy. This includes eating whole grains, fruits, vegetables and decreased on fatty foods, unhealthy snacks and soda drinks. Simple outdoor activities such as playing and walking around every day are recommended. All and all, obesity can be prevented with early intervention.

The limitations on the studies were the small sample size, inclusion and exclusion. The small sample size may yield significant result which can be misleading. Inclusions of the studies were female between the age of 18-60 years old and this does not fully represent the US populations. Male was excluded from the studies make it hard to compare the efficacy between gender. Exclusions of the studies were not chronically ill, pregnancy and lactating. These groups of population may be the population that would benefit the most from weight loss; however, due to unforeseen adverse effect they were excluded from the studies. One study has a withdrawal rate of 42 participants; whereas the other has 3 dropouts due to the reported adverse effects.

Conclusion

Based on this systematic review, ginger extract is not an effective treatment for weight loss in obesity population; however, it can be used as a supplement to decrease food intake as supported by the studies. Ginger extract is generally safe with only one study reported adverse effects of diarrhea and soft stools associated with the high dosage.

There were flaws in the studies that could use some readjustment in the future. The methods in both studies were conducted in a clinic with food provided for participants. Everybody was offered the same type and amount of food. Depend on the individual's caloric intake those normally consumed more calories now consumed less and vice versa which can skew the data. Also, in the studies, there were no modifications in addition to the ginger extract intervention. Because obesity is a growing problem for the welfare of our population, further studies need to be explored. Future study may add ginger extract as a weight loss supplement to behavioral modifications such as exercise. Also, study design should be a larger sample size with both genders: male and female. The study should take at least 20 weeks to have any significant data. All and all, currently ginger extract is not recommended for weight loss and requires more literature research.

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