

Implementing standardised rhodes index to measure the efficacy of ginger extract (*Zingiber officinale*) in pregnancy induced nausea and vomiting

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ABSTRACT

Background: Although nausea and vomiting are natural signs of pregnancy affecting about half the pregnant women during their first trimester of pregnancy, it is unpleasant and difficult symptom to deal with. Considering the fact that medication during pregnancy is not advised, we decided to study the efficacy of a natural product to control nausea and vomiting during early pregnancy. Our study was directed to estimate the efficacy of ginger extract (*Zingiber officinale*) in pregnancy induced nausea and vomiting.

Methods: A total of 30 women with pregnancy of 4-16 weeks, suffering from nausea and vomiting were included in this study (n=30). Subjects were given ginger extract 250mg, to be taken 3 times a day half an hour before food for 1 week. Severity of vomiting was assessed by Rhodes Index of Nausea and Vomiting by the patients. Baseline scores were compared with the score at the end of 7 day. The findings were analysed statistically.

Results: Effect with the ginger extract in pregnancy induced nausea and vomiting was assessed at the end of treatment (day 7) and compared with the baseline values. Four patients reported symptoms of heartburn. Otherwise, there were no other reports of any adverse effects. The results showed significance (p < 0.005).

Conclusions: Ginger extract (*Zingiber officinale*) helps in reducing severity and frequency of pregnancy induced nausea and vomiting. Therefore, we conclude that ginger extract can be used for mild to moderate nausea and vomiting induced by pregnancy during first trimester.

Keywords: Ginger extract, Pregnancy induced nausea and vomiting, Rhodes Index, *Zingiber officinale*

INTRODUCTION

Nausea and vomiting is a commonly encountered problem by women in early pregnancy. Nausea is prevalent in about 50 to 80% of pregnant women, and vomiting and retching in about 50%.¹ Retching or dry heaving, without expulsion of the stomach's contents is a distinct symptom that is increasingly measured separately to vomiting and nausea. The misnomer 'morning sickness', which is colloquially used to describe nausea, vomiting and retching of pregnancy, contradicts the fact that symptoms can occur at any part of the day. Nausea,

vomiting and retching are experienced most often in the first trimester, between six and 12 weeks, but this can continue to 20 weeks and persists after this time in up to 20% of women.¹⁻⁵ Hyperemesis gravidarum, which is characterized by severe and persistent vomiting, is less common, affecting between 0.30% and 3% of pregnant women.^{6,7}

Ketosis is also commonly included as a consequence of hyperemesis gravidarum.^{8,9} However, inpatient hospitalisation is not included in the definition of hyperemesis gravidarum because occasionally, it may be

alleviated or controlled by outpatient interventions.¹⁰ Within the operational definitions of hyperemesis gravidarum, there is generally a focus on the effects of the vomiting like dehydration, ketosis and weight loss. It is important to exclude pathological causes of nausea and vomiting before concluding that it is specific to pregnancy.

Conditions such as peptic ulcers, cholecystitis, gastroenteritis, appendicitis, hepatitis, genito-urinary (e.g. pyelonephritis), metabolic and neurological disorders should be ruled out.¹¹⁻¹³

The main objective of the study was to estimate the efficacy of ginger extract (*Zingiber officinale*) in pregnancy induced nausea and vomiting.

METHODS

Study population were women attending the antenatal clinic.

Inclusion criteria

Women between 4 and 16 weeks of gestation, with pregnancy confirmed by urine pregnancy test and with nausea or vomiting.

Exclusion criteria

Signs of clinical dehydration, known allergy to ginger, Gallstones or any other disease of the gallbladder, Diabetes or on any drugs to control blood sugar levels, cardiovascular disorders and any factor affecting clotting time.

Table 1: Rhodes index of nausea, vomiting and retching.

Patient Initial: _____						
Date: _____						
Day of week: _____						
Time of day: _____						
**Questionnaire given to patient		Scoring provided according to Rhodes Index				
1.	In the last 12 hours, I threw up ____ times.	7 or More	5-6	3-4	1-2	I did not throw up
	score	4	3	2	1	0
2.	In the last 12 hours, from retching and dry heaves, I have felt ____ distress.	No	Mild	Moderate	Great	Severe
	score	0	1	2	3	4
3.	In the last 12 hours, from vomiting or throwing up, I have felt ____ distress.	Severe	Great	Moderate	Mild	No
	score	4	3	2	1	0
4.	In the last 12 hours, I have felt nauseated or sick to my stomach.	Not at all	1 hour or less	2-3 hours	4-6 hours	More than 6 hours
	Score	0	1	2	3	4
5.	In the last 12 hours, from nausea/sickness to my stomach, I have felt ____ distress.	No	Mild	Moderate	Great	Severe
	score	0	1	2	3	4
6.	In the last 12 hours, each time I threw up, I produced a ____ amount.	Very large (3 cups or more)	Large (2-3 cups)	Moderate (1/2-2 cups)	Small (up to 1/2 cup)	I did not throw up
	score	4	3	2	1	0
7.	In the last 12 hours, I have felt nauseated or sick to my stomach ____ times.	7 or more	5-6	3-4	1-2	No
	score	4	3	2	1	0
8.	In the last 12 hours, I have had periods of retching or dry heaves without bringing anything up ____ times.	No	1-2	3-4	5-6	7 or more
	score	0	1	2	3	4

**Patient marked the box in each row that most clearly corresponds to her experience. Scoring done after completion of questionnaire

Women who meet the eligibility criteria were enrolled into the study. Demographic information, general history and history of nausea and vomiting were taken. Health status assessment was conducted for each woman before initiation of the study. They were then requested to fill the Rhodes Index of Nausea and Vomiting Form 2.

The frequency, severity of vomiting and the approximate volume of the vomitus was recorded. They were then asked to complete the Rhodes Index of Nausea and Vomiting Form 2 for 3 days as a baseline before administering the extract. The Rhodes scale is a 5-point Likert scale ranging from 0 to 12, with larger scores indicating more symptoms. A major issue in interpreting and comparing studies on the management of NVP has been the use of numerous different methods to qualify and quantify nausea, vomiting and related symptoms. Different researchers have arbitrarily defined NVP as "mild", "moderate" or "severe" without clear quantitative definitions or biological logic. Often the assessments have been retrospective. In some cases end points were measured dichotomously as success/failure or as percentage preferring one drug over the other (in crossover studies). While these approaches may be reasonable in randomised control trials (RCTs), assuming that all arms of the studies are evaluated similarly, the clinical interpretation of arbitrary endpoints and comparison between studies becomes difficult, if not impossible.

Rhodes Index is a standard, validated tool that will allow comparison among studies to assess nausea and vomiting in pregnancy. It separately scores, as categorical variables, the number of vomiting episodes per day, the size of the vomiting, the degree and length of nausea and retching, as well as the distress associated with the condition (Table 1).

The questionnaire can be administered once or twice a day and, in addition to an overall score, one can report separately on the frequency and changes in nausea, vomiting, retching and stress.⁷ Ginger extract was prepared by Sami Labs (Bangalore) with a certificate of analysis issued that ensures the products were standardized and quality controlled. The study subjects were given the required quantity of ginger extract and instructed to take 250mg, 3 times a day half an hour before food for 1 week. At the end of 1 week the Rhodes Index of Nausea and Vomiting Form 2 was reassessed, and any change in the frequency of nausea and vomiting was recorded at the end of 1 week. Secondary outcomes included the occurrence of any side effects.

Statistical analysis

Statistical data was analysed using SPSS Software Version 18. The hypothesis was tested using paired 't' test to assess the change from baseline. Demographic data are described using Mean and Standard Deviation.

RESULTS

A total of 30 women with pregnancy of 4-16 weeks, suffering from nausea and vomiting were included in this study.

The mean age was 22.17 years (SD 2.230) and means duration of pregnancy was 11.43 weeks (SD 1.716). The Rhodes Index scores at baseline and from days 1 to 7 are shown in Table 2.

Table 2: Rhodes Index Score at baseline and during treatment with ginger extract.

Day of assessment	Minimum score	Maximum score	Mean score	Standard deviation
Baseline	9	22	14.43	3.520
Day 1	6	20	12.13	3.785
Day 2	4	19	10.20	3.537
Day 3	3	15	8.80	3.408
Day 4	2	12	7.17	3.018
Day 5	2	10	5.10	2.796
Day 6	0	7	2.90	1.900
Day 7	0	6	1.17	1.341

The change in the scores from baseline to the end of treatment (day 7) is shown in Figure 1.

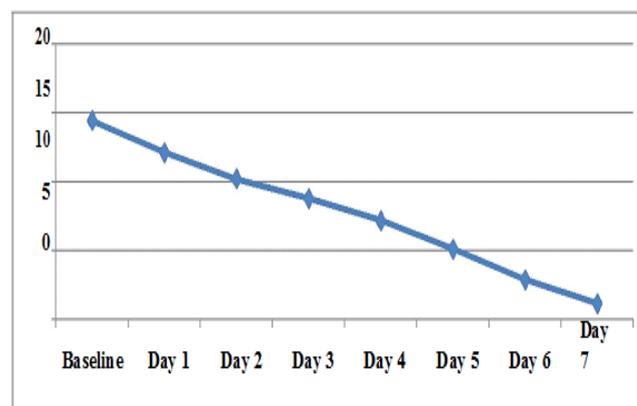


Figure 1: Change in mean Rhodes Index Score from baseline to end of treatment (day 7).

There was a statistically significant effect with the ginger extract in pregnancy induced nausea and vomiting when patients were assessed at the end of treatment (day 7; $p < 0.005$). Four patients reported symptoms of heartburn. Otherwise, there were no other reports of any adverse effects.

DISCUSSION

In our study, 30 pregnant women with nausea and vomiting were treated with ginger extract for a period of one week. They were assessed using the Rhodes Index at

baseline as well as on all the days during the treatment period. There was a significant decrease in the mean Rhodes Index score from baseline (14.43) to end of treatment (1.17; $p < 0.05$). There have been several studies as discussed in the section on 'Review of Literature', comparing the effects of ginger vs. placebo, vitamin B6 and other antiemetics in the management of nausea and vomiting of pregnancy.¹⁴⁻¹⁹ Ginger has been shown to be better than placebo in all these studies, and at least as good as vitamin B6 and other antiemetics like diphenhydramine and metoclopramide. Of the various published studies, three of them used the Rhodes Index to evaluate the efficacy of ginger.¹⁷ In our study also, we used this Index, since it is a self-administered questionnaire, which can be easily filled out by the patient, and also helps in effectively assessing the degree of nausea, vomiting and retching. Ginger seems to be well-tolerated by the woman, as well as no reports of any fetal anomalies. Four patients reported side-effects, which was heartburn in our study. There were no other adverse effects reported. Two studies comparing ginger with vitamin B6 report sedation and heartburn as the most frequent adverse effects. However, there was significant difference between the two treatment groups in their incidence.^{18,19} It is important to note that pregnant women as such tend to suffer from heartburn because of laxity of the gastroesophageal sphincter, and somnolence because of tiredness. Therefore, these adverse effects with ginger may not be significant. The main limitations of our study are that the sample size is small, and that it is a single-arm study, with no comparator. Currently, we are recruiting patients for the placebo arm, and will be comparing the findings with that of the current study.

CONCLUSION

Ginger (*Zingiber officinale*) is one of the more commonly used herbal supplements for various indications. The current study showed that ginger extract is efficacious in the management of nausea and vomiting in pregnancy, similar to findings from previous literature. Although a comparative study with a known drug would be more efficient.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee of CHRI, Chennai

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