Chapter 12

Phytocid (a ginger-based preparation) for nausea-vomiting. A pilot, supplement study in pregnant women

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ABSTRACT

Registry Aim: comparison of the efficacy of ginger or a vitamin B Complex for nausea-vomiting in pregnant women.

Results and conclusions. Phytocid was more effective than a Total B Vit. complex in reducing nausea and vomit. This ginger-based product may be a significant 'natural', soft option for the management of benign nausea-vomiting and 'morning sickness' in otherwise healthy pregnant women. Larger studies – on the basis or our predictive analysis – are still needed, carefully considering dose-finding aspects.

Key Words: ginger, curcumin, vomit, nausea, morning sickness, Phytocid.

INTRODUCTION

Dyspepsia, nausea and vomiting in pregnancy are common complaints, rarely becoming a significant clinical entity. 'Morning sickness' is characterized by nausea and vomiting that occurs during pregnancy. Despite its name, morning sickness can strike at any time of the day or night. Many pregnant women have morning sickness, especially during the first trimester. But some women have morning sickness throughout pregnancy.

Management options include various home remedies, such as snacking throughout the day, sipping ginger ale or taking over-the-counter medications based on ginger to help relieve nausea. Rarely, morning sickness is so severe that it progresses to a condition called hyperemesis gravidarum; nausea and vomiting cause other severe symptoms that may cause severe dehydration or result in the loss of more than 5 percent of pre-pregnancy body weight.

Hyperemesis gravidarum may require hospitalization and treatment with intravenous (IV) fluids, medications and rarely a feeding tube. What causes morning sickness isn't clear, but the hormonal changes may play a role.

Rarely, severe or persistent nausea or vomiting may be caused by a medical condition unrelated to pregnancy — such as thyroid or liver disease.

There's no way to completely prevent morning sickness. However, avoiding triggers such as strong odors, excessive fatigue, spicy foods and foods high in sugar may help.[1,2] OTC and natural products (i.e., ginger extracts) are indicated[4] for this very common condition.[3-4]

In a recent study[3] 126 pregnant women (gestational age of <16 weeks) with nausea and vomiting, required anti-emetics, had no medical complication, and were not hospitalized, were studied. These women received either 650 mg of ginger or 25 mg of vitamin B6 (3 times per day for 4 days). The degree of nausea and vomiting were assessed by three physical symptoms of *Rhode's score:*

- *episodes of nausea,*
- *duration of nausea*
- *vomit episodes.*

These symptoms were recorded 24 hours before treatment for baseline and each subsequent day of treatment. Difference of baseline and post-treatment nausea vomiting scores were calculated for both groups during 4 days of treatment. Ginger and vitamin B6 significantly reduced nausea and vomiting scores. The mean score change after treatment with ginger was greater than with vitamin B6 ($p < 0.05$). There were some minor side effects in both groups ($p=0.795$) respectively, such as sedation, heartburn, arrhythmia. This study shows that both ginger and vitamin B6 are effective for treatment of nausea and vomiting in pregnancy. However, ginger was more effective than vitamin B6. According to this model study we aimed to evaluate a ginger PS Supplement (Phytocid, Alchem, India) in a registry lasting 4 weeks in pregnant women.

PATIENTS/METHODS

Registry: the patients were 22 otherwise healthy pregnant women. The pregnancy had been regular excluding the significant, frequent occurrence of 'morning sickness. Their gestational age at inclusion was >16 weeks.

The symptoms (nausea and vomiting) were frequent and important enough to require management with anti-emetics.

These women had no other medical problems, were not hospitalized and all blood tests (including liver and kidney functional tests) were within normal levels.

Blood pressure had always been within normal limist and the cardiovascular system e was normal. Also fetal ultrasound did not reveal any problem.

The anti-emetic management was used three times/day for 4 weeks.

The degree of nausea and vomiting were assessed using 3 physical symptoms of a modified, simplified **Rhode's score:**

- **episodes of nausea (score 0-3)**
- **duration of nausea (score 0-3)**
- **number of vomit episodes (score 0-3).**

The total score range was 0 to 9.

The symptoms were recorded one week before treatment (as a baseline) and the following weeks of management.

The difference between baseline and post-management nausea and vomiting scores were calculated during the following 4 weeks of treatment.

Phytocyd-GT (Alchem) is a natural product developed to treat dyspepsia, nausea and vomiting; it includes ginger and turmeric and can be used as an anti-emetic; but it also has a significant anti-inflammatory action. Turmeric can modulate excessive peristaltic activity and it has been used for abdominal cramps and irritable bowel syndrome.

Both ginger (50 mg in each capsule) and turmeric (100 mg) are strong anti-oxidants and have e mild antimicrobial action.[3,4]

Phytocid-GT has been previously used against indigestion, motion sickness, oral infections, irritable bowel syndrome, in ulcerative colitis, pregnancy-related nausea and vomiting, in nausea and in vomiting due to gastroenteritis (as a supportive agent) and in chemotherapy-induced nausea and vomiting.

This registry was a pilot, supplement study.

A B complex including Vit. B6 (Total B, RDA, Quarto D'Altino, Italy) was used as a comparative management method.

This product included a total of B6 (3.3 mg), niacin (240 mg), B12 (20 mg).

Statistics.[5-7] At least 10 subjects were considered to be needed to overcame the variability of the measurements. Measurements (scores) results were considered non-parametric and the test scores results were evaluated with the ANOVA with the Bonferroni correction and with Mann-Whitney U-test.

Intra-individual variability of measurements was considered in this model.

Predictive analytics (according to Siegel) was used considering the obained results.[8]

RESULTS

All women competed the study without problems.

The two management groups were comparable.

All women had a single baby and no twin pregnancies were included.

Their BMI was <26. No complications were observed during the pregnancy or just after the delivery.

There was a significant ($p<0.05$) decrease in score (Table 12.I) in the two management groups with a better result ($p<0.05$) with the ginger-product.
Also, the number of vomit and nausea episodes (per week) were significantly decreased in comparison with the pre-management (one week) period ($p<0.05$); the decrease produced by Phytocid was significantly superior ($p<0.05$) to the Total B vit. complex.
No side effects or tolerability problems were reported during the study.
Compliance was very good.
In the accessory safety evaluation (post birth), the rest of the pregnancy progressed in all women to a healthy, uncomplicated conclusion with all newborns without problems (the follow up was up to 3 months after birth).
On the basis of these results a predictive analysis indicated that a larger group (of 60 women) with a follow up of at least 3 months – and, possibly with a dose ranging – would be required to better define the efficacy of Phytocid on a larger, more adequate scale.

TABLE 12.I. THERE WAS A SIGNIFICANT (P<0.05) DECREASE IN SCORE (TABLE 1) IN THE TWO MANAGEMENT GROUPS WITH A BETTER RESULT (P<0.05) WITH THE GINGER-PRODUCT.

Also, the number of vomit and nausea episodes (per week) were significantly decreased in comparison with the pre-management (one week) period ($p<0.05$); the decrease produced by Phytocid was significantly superior ($p<0.05$).

		Inclusion Weeks before Inclusion	End study In 4 weeks on Management	
Phytocid		Age	32.3;2.2	
B Complex			31;0.9	
Score (0-10)				
Phytocid		8.22;0.6	5;0.4*	
B6		8;1.3	5.89;0.7	(P < 0.05).
Number of episodes/week				
Nausea	Phytocid		14.5;2	2.3;0.5*
	B Complex		15;2.4	7.4;2*
Vomit	Phytocid		12.4;3	2;0.3*
	B Complex		12.3;2	5.8;2.3*

The score change with ginger was larger than with the vitamin B complex.
There were no side effects.

CONCLUSIONS

Ginger and a vitamin B complex are effective in managing without drugs or more complex management the common, benign nausea-vomiting in pregnancy.

Ginger-derived Phytocid appears to be significantly more effective than the vitamin B complex on the symptoms.

This pilot supplement registry[9-12] constitute a concept model for a possible, larger study including women with different conditions and characteristics and with a more variable clinical pattern.

No side effects from Phytocid or from the B complex were observed, making these options safe and reliable.

Ginger-derived products confirm their safety and efficacy, in particularly in improving gastric emptying that become faster and more efficient[3,13] with ginger.

The dosage must be well established in future prospective studies.

The dosage of different supplements may be very variable and difficult to predict considering different factors (preparations, absorption, concomitant presence of other elements in the composition).

In conclusion, Phytocid may be a significant 'natural', soft option for the management of benign nausea-vomiting and 'morning sickness' in otherwise healthy pregnant women.

Larger studies – on the basis or our predictive analysis – are still needed, carefully considering dose-finding aspects.

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