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Effects of ginger and vitamin B6 on pregnancy induced nausea and vomiting

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Abstract
Objective: The intention of current research was to estimate the efficiency of vitamin B6 and ginger against nausea and vomiting in expecting females.
Study design: Thirty four expecting females, who had nausea and vomiting, with a gestational age of <17 weeks were included in this study. Pregnant women having other medical disorders that might be associated with these symptoms were excluded in this study. Patients were distributed in 6 groups (T_0, T_1, T_2, T_3, T_4 and T_5) each containing 5 pregnant females who were receiving ginger, B6 and their specific combinations. Two free estimation scales utilized to evaluate the nausea: Likert's scale for vomiting and visual simple scale for nausea. The values were noted before study for baseline and each following day of study. Variance of post-treatment and baseline scores for nausea and vomiting were calculated for groups during 15 days of study. Follow-up and assembling of data took 13 to 14 weeks.
Results: Thirty patients returned to follow-up out of thirty four. There were a considerable reduction in the average of post-therapy minus baseline nausea score in T_3 and T_4 groups with vomiting score from 2.80±1.64 to 0.20±0.44 and 2.60±1.30 to 0.60±0.54 respectively, ($p \leq 0.001$). There was also significant decrease in the mean number of vomiting episodes in T_1 and T_5 groups with nausea score from 7.60±0.54 to 1.20±0.44 and 7.20±1.48 to 0.60±0.54 respectively, ($p \leq 0.001$). While the rest of the treatments also reduced the frequency of vomiting and severity of nausea but their difference did not reach the level of statistical significance.
Conclusion: For handling vomiting and nausea in gestation ginger and B6 both were efficient. Moreover, the combinations of B6 and ginger were more effective than vitamin B6 and ginger alone.

Keywords: Nausea, vomiting, gestation, ginger, vitamin B6, visual analogue scale

1. Introduction
Pregnancy-induced nausea and vomiting (PINV) is a considerable general health problem effecting around 55-90% of expecting women in early pregnancy. Almost 25% of expecting women face nausea and 45-55% face both vomiting and nausea. Indicators usually start from 4th to 9th week of gestation. Extreme signs appear at 12th to 15th week and continue till 20th week of gestational age [1]. Signs and symptoms can appear at several intervals of the day [2]. Symptoms usually resolve after 20 weeks and maximize between 10 and 16 weeks of gestation [3].The most intensive form of vomiting and nausea in gestation is termed as hyperemesis gravidarum (HG) [4].
The precise etiology of nausea and vomiting during pregnancy is unidentified. Increasing levels of hominoid chorionic endocrine elements such as altering levels of thyroid-stimulating hormone, progesterone and estrogen are claimed to increase the severity of PINV [5]. The herbal products in gestation may be used to get rid of gestation associated indications [6]. A lot of alternative therapies and medications presently exist for the management of NVP [7]. Several women are doubtful to take medical drugs for fear of harming the fetus, so accordingly they are frequently attracted in non-medicinal options [8].
Ginger (*Zingiber officinale*) is a perpetual plant native to several African, Asian and European countries [9]. It is used globally as a herbal remedy and a spice for digestive assistance [10]. Fresh ginger rhizome is composed of water (80.7%), carbohydrate (12.3%), protein (2.3%), fiber (2.4%), minerals (1.2%) and fat (1.0%). The minerals present in ginger are calcium, phosphorous, Iron, potassium, sodium and magnesium [11]. The main ingredients therapeutic of ginger are 10-gingerol, 8-gingerol, 6-gingerol and 6-shogaol [12].

Ginger, in proper amounts, is no exception. It needs to be given to the "exact" individual, in the exact dosage, at the exact period, at the exact rate and by the exact technique of management. In USA dehydrated ginger is thought to be escaped in gestation and is therefore frequently drunk as a tea [13]. Use of ginger has been reported to be useful for the management of PINV [14].

Vitamin B6 is commonly used as a first line of management for pregnant women facing vomiting and nausea [15]. Vitamin B6 has been recognized to own antiemetic property since 1942 [16]. The recommended dietary allowance (RDA) for B6 in gestation is 1.9 mg/day [17]. Vitamin B6 is one of the treatments freshly suggested by health specialists to decrease the indications and signs of PINV. But, more investigation is required for determining the defined value for its efficacy or safety in treating PINV [3]. The intention of this study was to compare and evaluate ginger and vitamin B6 for the management of nausea and vomiting in gestation.

2. Materials and Methods

Pregnant women having nausea and vomiting with gestational age less than 17 weeks were included. Those pregnant women were excluded who (1) had additional health complaints such as gastrointestinal diseases or hepatitis that manifest with vomiting and nausea, (2) had taken different drugs in the previous week that may disturb or reduce vomiting and nausea, for example, press tablets, antiemetics, and so forth, (3) were not able to take the solution as recommended, or (4) were not able to return for subsequent visits. General data including age, weight, tallness, occupation, instruction and span of being influenced by the malady were recorded on the Performa, through meeting with the patients.

Fresh ginger roots (*Zingiber officinale)* and vitamin B6 was purchased from local market at Faisalabad. Fresh ginger root were sliced into minor sections, baked at 60ºC for one day and then gound into powder. Specific amounts of ginger powder, vitamin B6 and their definite mixture were weighed and filled into capsules. Patients were distributed in 6 groups or treatments (T_0, T_1, T_2, T_3, T_4 and T_5) each containing 5 pregnant females. Packing of 30 capsules (for 15 days, 2 capsules per day after breakfast and dinner) was given to each woman as per treatment given in table no 1.

Table 1: Treatment plan for pregnant women

Treatments	Concentration of ginger	Concentration of vitamin B6	Dosage
T_0 (Placebo)	-	-	Twice a day
T_1	500mg	0mg	Twice a day
T_2	0mg	30mg	Twice a day
T_3	250mg	30mg	Twice a day
T_4	500mg	15mg	Twice a day
T_5	250mg	15mg	Twice a day

Likert scale (for vomiting) and visual simple scale (for nausea) were used to evaluate as per technique utilized by Ensiyeh and Sakineh [18]. For the visual simple scale, on first day of treatment ladies were asked to review the harshness of nausea in course of recent hours (gauge score) by denoting a bullet comparing to their apparent state on vertical line of 10 cm, from 0 (no sickness) to 10 (sickness as awful as it can be). Over accompanying 15 days of study, the harshness of sickness was noted two times in a day after breakfast and dinner. To acquire goal estimation, the marks on the scale were computed. Day by day and mean sickness values over the 15 days of study for all women was then computed. Likert scale (much more terrible, more awful, same, better, much better) was utilized to survey the quantity of retching scene and treatment reactions. Ladies were likewise examined to record the figure from vomiting scenes in the previous 24 hours at their first appointment before study and after that on every resulting day of study. Patients were requested for return to follow-up. Follow-up and assemble of data took 13 to 14 weeks.

3. Results

Through the period of trial, 34 expecting ladies who matched the standards were involved. They were distributed randomly to take B6, ginger and their specific concentrations. Four ladies randomized to the ginger and B6 did not come back for treatment and as no records were accumulated from those ladies, they were omitted from the trial. This left 30 ladies so they were divided in six groups. In that way each group comprise 5 ladies. There were no statistically alterations in the baseline features (age, weight, height, parity, week of gestation, occupation, and education) among these collections as shown in Table no 1.

Table 1: Baseline characteristics of patients

Features	T_0	T_1	T_2	T_3	T_4	T_5
Age						
mean + SD (year)	23.8+4.1	24.4+3.3	22.6+3.9	24.5+4.1	23.9+3.5	24.7+2.8
Weight						
mean + SD (kg)	51.6+3.7	54.8+5.8	55.1+2.8	49.4+3.5	55.4+6.5	48.8+3.2
Height						
mean + SD (cm)	146.5+3.5	145.7+4.4	146.7+2.3	147.4+4.4	144.4+3.2	150.1+5.5
Parity						
Nulliparous	80%	60%	100%	80%	80%	60%
Multiparous	20%	40%	0%	20%	20%	40%
Education						
Literate	40%	80%	60%	60%	40%	80%
Illiterate	60%	20%	40%	40%	60%	20%
Occupation						
Housewife	100%	80%	80%	80%	60%	60%
Employee	0%	20%	20%	20%	40%	40%

Baseline scores of vomiting, nausea and after treatment scores are shown in Table 2 and 3. Baseline of vomiting and nausea score in the T_0, T_1, T_2, T_3, T_4 and T_5 groups was 2.00±1.22, 2.60±0.54, 2.60±1.14, 1.80±1.64, 2.20±1.30,

1.80±1.09 and 5.40±2.30, 7.60±0.54, 5.60±2.40, 7.40±2.30, 6.00±1.00, 7.20±1.48 respectively.

On follow-up appointments two women in group T_0 and one in group T_2 did not grade their scores on days 10, 11 and 15 of trial. post treatment value of vomiting and nausea score in the T_0, T_1, T_2, T_3, T_4 and T_5 groups was 2.00±0.70, 0.80±0.44, 0.80±0.44, 0.20±0.44, 0.60±0.54, 0.40±0.54 and 5.40±1.14, 1.20±0.44, 1.60±0.54, 1.40±1.14, 1.20±0.83, 0.60±0.54 respectively. When we found the mean values of vomiting periods over 15 days of trial and deducted this from the starting point values for every patient and after that we calculated the complete average variation in the vomiting periods for subjects in all the clusters, there were bigger drop of vomiting periods in T_3 and T_4 groups than in the T_0 group. Though, the alteration not extent to statistical worth ($p \leq 0.001$) (Table 2). The average variation in nausea scores (starting point value minus average post-therapy nausea scores) in the T_1 and T_5 groups were considerably higher ($p \leq 0.001$) than those in T_0 group (Table 3).

Table 2: Change in vomiting score by treatment group

Treatments	Day 0/ pre-treatment values (Mean ± SD)	Day 15/post treatment values (Mean ± SD)	Total Mean value (Mean ± SD)	P values
T_0	2.00±1.22*	2.20±0.70	2.10±0.94	0.838
T_1	2.20±0.54	0.80±0.44	1.50±1.05	0.057
T_2	2.40±1.14	1.40±0.44	1.90±1.25	0.095
T_3	2.80±1.64	0.20±0.44	1.50±1.41	≤0.001
T_4	2.60±1.30	0.60±0.54	1.60±1.26	≤0.001
T_5	1.80±1.09	0.80±0.54	1.30±1.10	0.062

* Mean standard deviance of the alteration (base line minus post treatment).

Table 3: Change in nausea score by treatment group

Treatments	Day 0/ pre-treatment values (Mean ± SD)	Day 15/post treatment values (Mean ± SD)	Total Mean value (Mean ± SD)	P values
T_0	5.40±2.30*	5.60±1.14	5.50±1.78	0.995
T_1	7.60±0.54	1.20±0.44	4.40±3.40	≤0.001
T_2	5.60±2.40	2.60±0.54	3.10±2.67	0.073
T_3	6.40±2.30	2.40±1.14	4.40±3.59	0.060
T_4	6.00±1.00	1.20±0.83	3.60±2.67	0.051
T_5	7.20±1.48	0.60±0.54	3.90±3.63	≤0.001

*Mean standard deviance of the alteration (base line minus post treatment).

Table 4; Nausea effectiveness score

Nausea	Treatment					
	T0	T1	T2	T3	T4	T5
None	3 (0.66%)	26 (5.77%)	14 (3.11%)	15 (3.33%)	14 (3.11%)	31 (6.88%)
Mild	7 (1.55%)	19 (4.22%)	29 (6.44%)	23 (5.11%)	30 (6.66%)	21 (4.66%)
Moderate	45 (10.0%)	15 (3.33%)	21 (4.66%)	22 (4.88%)	21 (4.66%)	17 (3.77%)
Severe	17 (3.77%)	14 (3.11%)	9 (2.0%)	9 (2.0%)	7 (1.55%)	5 (1.11%)
Very severe	3 (5.55%)	1 (0.22%)	2 (0.44%)	6 (1.33%)	3 (0.66%)	1 (0.22%)
Total	75	75	75	75	75	75

Total no of observations =450

0 = none; 2-3 = mild; 4-6 = moderate; 7-8 = severe; 9-10; very severe

Table 5: Vomiting effectiveness score

Vomiting	Treatment					
	T0	T1	T2	T3	T4	T5
Much better	7 (1.5%)	23 (5.11%)	11 (2.44%)	44 (9.77%)	33 (7.33%)	37 (8.22%)
Better	13 (2.88%)	29 (6.44%)	35 (7.77%)	18 (4.0%)	25 (5.55%)	30 (6.66%)
Same	30 (6.66%)	14 (3.11%)	21 (4.66%)	5 (1.11%)	8 (1.77%)	4 (0.88%)
Worse	22 (4.88%)	7 (1.55%)	7 (1.55%)	5 (1.11%)	7 (1.55%)	2 (0.44%)
Much worse	3 (0.66%)	2 (0.44%)	1 (0.22%)	3 (0.66%)	2 (0.44%)	2 (0.44%)
Total	75	75	75	75	75	75

Total no of observations =450

0 = much better; 1 = better; 2 = same; 3 = worse; 4 = much worse

Total numbers of valid observation for nausea were 450 (30 patients* 15 days of treatment), with degree of freedom 20, effects of treatments on pregnancy induced nausea have been presented in table 4. There were only a few reports of severe and very severe nausea among these groups. These groups mostly reported either none or mild nausea. The control treatment T_0 (treated with placebo) did not affect nausea during pregnancy and maximum cases of moderate to severe nausea were reported by the women treated with T_0 (placebo) Overall T_3 treatment 26 (5.77%) and T_4 treatment 31(6.88%) showed optimum results and the symptoms of nausea were significantly decreased in these treatments.

The results for effects of ginger and vitamin B6 on pregnancy induced vomiting have been presented in table 5. Total numbers of valid cases were also 450, with degree of

freedom 20. Overall treatments T_3 44 (9.77%), T_4 33(7.33%) and T_5 37(8.22%) showed optimum results and significantly decreased the vomiting incidence and reported either in the better or much better category of vomiting. There were only few reports of worse and much worse vomiting among these. Maximum observations of worse and much worse vomiting were reported by the women treated with T_0 (Placebo).

No patient in this study took any other prescription for vomiting and nausea. There was one (3.33%) spontaneous abortion in the first or second trimester of ginger group (T_1). Term birth happened in 25/30 (83.2%) patients. There were 2 (6.66%) caesarean deliveries in the T_1 and T_5 group and 1 (3.33%) in the T_2 group. 1 case of slight gastrointestinal abnormalities and 1 case of an inconsequential congenital heart defect were also identified. No new born had any congenital defects and discharged in well situation. Incidences of heartburn was 3/30 (9.9%) in the ginger comprising groups T_1, T_3 and T_4, while there was no heartburn in the vitamin B6 containing groups.

4. Discussion

Despite of substantial studies the reason of vomiting and nausea in initial gestation remains unidentified and probable that one or many gadget included. NVP in initial gestation persist a substantial community healthiness issue that has emotional, physiological economic and social outcomes to ladies, their relatives and culture. Several substitute treatments and prescriptions presently exist for the handling. B6 is used as a chief line management for NVP. Ginger has been valued in various organized studies for the cure of NVP. There are studies that compare the efficiency of B6 to ginger [19].

Sripramote and Lekhyananda disclosed that both B6 (30 mg daily) and ginger (1.5 gm daily) considerably decreased the number of vomiting incidents and grade of nausea. Associating the efficiency, there was no considerably alteration between B6 and ginger for the handling of vomiting and nausea through gestation [20]. Smith and his colleagues revealed that vitamin B6 (75 mg daily) was equivalent to ginger (1.05 gm daily) in, decreasing vomiting (average variance 0.5, 90% CI of 0.0, 0.9) and nausea (average variation 0.2, 90% CI of -0.3, 0.8) in initial gestation. Quantity of ginger was augmented to 1.95 gm per day that is the established secure amount and amount of vitamin B6 was average 45 mg per day and was the same to this trial [19].

This trial was controlled randomized study to compare the effectiveness of ginger, B6 and their definite mixture for the trial of gestation linked vomiting and nausea compared with one another and placebo. Even though this trial did not discover any adversarial consequence of ginger on gestation, associated with vitamin B6 and definite mixture of both, in this trial the number of patients were not huge enough to draw any results about the adversative belongings, especially on inborn irregularities and abortion. Though, it is supportive that this trial, including an accumulative total of 30 ladies, presented that B6 and ginger have no adversative consequences on gestation. These conclusions support earlier outcomes [21].

Handling time of 15 days was preferred in present trial for the reason that a former trial Ensiyeh and Sakineh in 2009 revealed that the results of B6 and ginger were unobvious within a few days of management, and a short day handling period would possibly effect in higher degree of incompliances. In this trial, patients in the B6 and ginger groups reported a development in nausea and vomiting indicators [18].

Outcomes from present trial testing equality are not simply associated with other controlled placebo trials estimating the efficiency of ginger for vomiting and nausea in initial gestation. Our study necessary patient to take the study prescription for 15 days, and our outcomes are less influenced by patient's indicators. Patient's contribution in the study for 15 days could also reveal more precisely patient's usage of these processes to achieve the treatment of their vomiting and nausea. The outcomes of our study presented a considerable progress in average or mean vomiting and nausea scores in ladies who received pyridoxine, ginger and mixture of both compared with those who received placebo. B6, ginger and mixture of both also meaningfully diminish the mean number of vomiting incidents throughout the period of management.

The side effects from ginger were stated to be slight through the 15 days of trial. Though, minor amount of patients and shorter period of treatment may have been lacking to assessment correctly the efficacy of the ginger with respect to gestation results. More research would be require, with enormous subjects to create a certain declaration on the efficacy of ginger in gestation and accompanied by extensive duration of follow-up to identify rare problems like congenital irregularities.

As nutritional variations may be linked with both type of result and treatment, in upcoming researches, nutritional variation outcomes should be definitely controlled. The present study exposed that the mixture of B6 and ginger is additionally proficient than ginger and B6 alone, for relieve the harshness of nausea, and is alike operative for diminish the vomiting episodes in initial gestation.

5. Conclusion

Ginger and B6 both were efficient in relieving the severity of nausea and decreasing the number of episodes of vomiting in pregnant women. Moreover, the combinations of B6 and ginger were more effective than vitamin B6 and ginger alone.

6. References

1. Clark SM, Costantine MM, Hankins GD. Review of NVP and HG and early pharmacotherapeutic intervention. Obstetrics and Gynecology International. 2012; 1(12):8.
2. Firoz T, Maltepe C, Einarson A. Nausea and vomiting in pregnancy is not always nausea and vomiting of pregnancy. Journal of Obstetrics and Gynaecology Canada. 2010; 32(10):970-972.
3. Lacroix R, Eason E, Melzack R. Nausea and vomiting during pregnancy: a prospective study of its frequency, intensity, and patterns of change. American Journal of Obstetrics and Gynecology. 2000; 182(4):931-7.
4. Davis M. Nausea and vomiting of pregnancy: an evidence-based review. The Journal of Perinatal & Neonatal Nursing. 2004; 18(4):312-28.
5. Niebyl JR. Nausea and vomiting in pregnancy. New England Journal of Medicine. 2010; 363(16):1544-1550.
6. Henry A, Crowther C. Patterns of medication use during and prior to pregnancy: the MAP study.

Australian and New Zealand Journal of Obstetrics and Gynaecology. 2000; 40(2):165-72.
7. Willetts KE, Ekangaki A, Eden JA. Effect of a ginger extract on pregnancy-induced nausea: A randomised controlled trial. Australian and New Zealand Journal of Obstetrics and Gynaecology. 2003; 43(2):139-44.
8. Weidner MS, Sigwart K. Investigation of the teratogenic potential of a Zingiber officinale extract in the rat. Reproductive Toxicology. 2000; 15(1):75-80.
9. Borrelli F, Capasso R, Aviello G, Pittler MH, Izzo AA. Effectiveness and safety of ginger in the treatment of pregnancy-induced nausea and vomiting. Obstetrics & Gynecology. 2005; 105(4):849-56.
10. Allaire AD, Moos MK, Wells SR. Complementary and alternative medicine in pregnancy: a survey of North Carolina certified nurse-midwives. Obstetrics & Gynecology. 2000; 95(1):19-23.
11. Jolad SD, Lantz RC, Solyom AM, Chen GJ, Bates RB, Timmermann BN. Fresh organically grown ginger (Zingiber officinale): composition and effects on LPS-induced PGE2 production. Phytochemistry. 2004; 65(13):1937-54.
12. Pertz HH, Lehmann J, Roth-Ehrang R, Elz S. Effects of ginger constituents on the gastrointestinal tract: role of cholinergic M3 and serotonergic 5-HT3 and 5-HT4 receptors. Planta Medica. 2011; 77(10):973-8.
13. Tiran D. Ginger to reduce nausea and vomiting during pregnancy: evidence of effectiveness is not the same as proof of safety. Complementary Therapies in Clinical Practice. 2012; 18(1):22-5.
14. Wichtl M. Herbal drugs and phytopharmaceuticals: a handbook for practice on a scientific basis. Edn 3, Medpharm GmbH Scientific Publishers, Germany, 2004, 566.
15. Jewell D, Young G. Interventions for nausea and vomiting in early pregnancy. The Cochrane Database of Systematic Reviews. 2003; 1(4):CD000145.
16. Matok I, Clark S, Caritis S, Miodovnik M, Umans JG, Hankins G *et al*. Studying the antiemetic effect of vitamin B6 for morning sickness: pyridoxine and pyridoxal are prodrugs. The Journal of Clinical Pharmacology. 2014; 54(12):1429-33.
17. Morris MS, Picciano MF, Jacques PF, Selhub J. Plasma pyridoxal 5′-phosphate in the US population: the National Health and Nutrition Examination Survey, 2003–2004. The American Journal of Clinical Nutrition. 2008; 87(5):1446-54.
18. Ensiyeh J, Sakineh MA. Comparing ginger and vitamin B6 for the treatment of nausea and vomiting in pregnancy: a randomised controlled trial. Midwifery. 2009; 25(6):649-53.
19. Smith C, Crowther C, Willson K, Hotham N, McMillian V. A randomized controlled trial of ginger to treat nausea and vomiting in pregnancy. Obstetrics & Gynecology. 2004; 103(4):639-45.
20. Sripramote M, Lekhyananda N. A randomized comparison of ginger and vitamin B6 in the treatment of nausea and vomiting of pregnancy. Journal of the Medical Association of Thailand= Chotmaihet thangphaet. 2003; 86(9):846-53.
21. Portnoi G, Chng LA, Karimi-Tabesh L, Koren G, Tan MP, Einarson A. Prospective comparative study of the safety and effectiveness of ginger for the treatment of nausea and vomiting in pregnancy. American Journal of Obstetrics and Gynecology. 2003; 189(5):1374-1377.