A Randomized Comparison of Ginger and Vitamin B6 in the Treatment of Nausea and Vomiting of Pregnancy†

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Abstract

Objective : To compare the efficacy of ginger to vitamin B6 in the treatment of nausea and vomiting of pregnancy.

Study design : A randomized double -blind controlled trial.

Setting : The Department of Obstetrics and Gynecology, Bangkok Metropolitan Administration Medical College and Vajira Hospital.

Subjects : Women with nausea and vomiting of pregnancy at or before 16 weeks of gestation, who attended the antenatal care clinic. The subjects requested anti-emetics, had no medical complications, non-hospitalized and were able to attend a one week follow-up visit. From November, 1999 to November 2000, 138 women participated and gave consent for the study.

Method : The subjects were randomly allocated into two groups to take either 500 mg of ginger orally or an identical 10 mg of vitamin B6 one capsule three times daily for three days. Subjects graded the severity of their nausea using visual analogue scales before treatment and recorded the number of vomiting episodes in the previous 24 hours and again during three consecutive days of treatment.

Main outcome measures : The change of nausea scores and the number of vomiting episodes during three days of treatment.

Results : The 64 subjects in each group remained in the study. The demographic data were comparable in both groups. The ginger and vitamin B6 significantly reduced the nausea scores from 5.0 (SD, 1.99) to 3.6 (SD, 2.48) and 5.3 (SD, 2.08) to 3.3 (SD, 2.07) respectively, with $p < 0.001$. The mean score change after treatment with ginger was 1.4 (2.21), less than with vitamin B6, which was 2.0 (2.19) but with no statistically significant difference (95% CI -1.4 to 0.2, $p = 0.136$). The ginger and vitamin B6 also significantly reduced the number of vomiting episodes from 1.9 (2.06) to 1.2 (1.75) and 1.7 (1.81) to 1.2 (1.50) respectively, with $p < 0.01$. The mean number change after treatment with ginger was 0.7 (2.18), more than with vitamin B6, which was 0.5 (1.44) but with no statistically significant difference, ($p = 0.498$). There were some minor side effects in both groups such as sedation (26.6% *vs* 32.8%, $p = 0.439$), and heartburn (9.4% *vs* 6.3%, $p = 0.510$), a non-significant difference.

Conclusion : The nausea score and the number of vomiting episodes were significantly reduced following ginger and vitamin B6 therapy. Comparing the efficacy, there was no significant difference between ginger and vitamin B6 for the treatment of nausea and vomiting during pregnancy.

Key word : Nausea, Vomiting, Pregnancy, Ginger, Vitamin B6

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Nausea and vomiting are the most common symptoms in early pregnancy, with nausea affecting up to 90 per cent of women[1]. About half of pregnant women experience vomiting while as many as 25 per cent require time off work and 10 per cent need medication for this symptom[2,3]. The etiology of nausea and vomiting of pregnancy remains unknown, and it is likely that more than one mechanism is involved. As a consequence, a wide variety of therapies have been studied over the years. However, there is an understandable reluctance to use drugs of any kind during early pregnancy because of the concern for potential teratogenic effects. No anti-emetics for nausea and vomiting of pregnancy have been approved by the United States Food and Drug Administration (FDA), so far. The authors' conclusion on Cochrane Database Systematic Reviews for intervention for nausea and vomiting in early pregnancy: anti-emetic medication appears to reduce the frequency of nausea in early pregnancy[4]. There is some evidence of adverse effects, but there is very little information on the effects on fetal outcome from randomized controlled trials. Pyridoxine (vitamin B6) appears to be more effective in reducing the severity of nausea. Evidence from observational studies suggests no evidence of teratogenicity from any of these treatments[4].

The agent that has been studied alone or in combination with other agents most commonly is vitamin B6 and has been used as an anti-emetic since 1942[5]. The recommended dose as an anti-emetic in pregnancy is 10-25 mg three times daily, although this dose is categorized in category C[6,7]. Vitamin B6 does have some beneficial effect in relieving the severity of nausea and vomiting at or before 17 weeks' gestation[8,9]. Vitamin B6 should be chose first for its safety and low cost. However, a large number of pregnant women require additional drugs, such as meclizine, promethazine, dimenhydrinate, promethazine and hydroxyzine[10,11]. These drugs may cause possible side effects such as sedation, mouth dryness, motor weakness and visual disturbance.

A natural product such as ginger (Zingiber officinale roscoe) would seem to be more acceptable. There is a tradition that dates back centuries of using ginger for symptoms of gastrointestinal distress. Furthermore, the use of ginger is well known in food. The ginger capsule is commercially available in the supermarket of some countries, including the USA. There is no recommended daily allowance dose, but a suggested average adult supplement intake is 1-2 capsules, 550 mg of ginger root, 1-4 times daily. There are no known reports of toxicity in humans from ginger ingestion in normal amounts. So far, two randomized, double-blind, placebo-controlled trials were reported with the use of ginger powder at a daily dose of 750 mg to 1 g at or before 17-20 weeks' gestation showing ginger to be more effective for relieving the severity of nausea and vomiting of pregnancy[12,13]. No adverse effect of ginger on pregnancy outcome was detected. The online search of the National Library of Medicine's MED-LINE database, from 1995-2001, revealed no trial comparing the efficacy of ginger to any anti-emetic for the treatment of morning sickness. The purpose of this

study was to compare the efficacy of ginger to vitamin B6 during 3-days' treatment for nausea and vomiting during pregnancy at the antenatal clinic, in a randomized, double-blind, parallel design.

SUBJECTS AND METHOD

The study was performed from November 1999 to November 2000 at the antenatal clinic, Bangkok Metropolitan Administration Medical College and Vajira Hospital (BMAMC&VH), Thailand. The study was approved by the Ethics Committee for Research involving Human Subjects, BMAMC&VH. The procedures followed were in accordance with the Ethical Principles for Medical Research Involving Human Subjects established by the World Medical Association Declaration of Helsinki of 1975, revised in 2000.

The enrolled subjects were pregnant women before 17 weeks of gestation, had nausea of pregnancy, with or without vomiting and requested anti-emetics. Subjects were excluded if they; 1) had other medical disorders such as hepatitis or gastrointestinal diseases that might manifest with nausea or vomiting; 2) were unable to take the oral capsule as prescribed; 3) were unable to return for a one week follow-up; 4) had taken other medication in the past week that might aggravate or alleviate nausea or vomiting, such as iron tablets or anti-emetics; 5) were mentally retarded; 6) had language or geographic barriers; 7) were hospitalized for hyperemesis gravidarum ; or 8) refused to participate in the trial.

Subjects underwent a general physical examination and routine obstetric evaluation. Those with uncertain last menstrual period or incompatible gestational age and uterine size were confirmed by ultrasonographic evaluation. The consenting subjects were then randomly allocated to receive either a 500 mg capsule of ginger or 10 mg capsule of vitamin B6 orally three times daily before meals for three days. The research nurse explained the research protocol and the participation of the subject simply. They were requested to take one randomized capsule immediately to confirm their ability to swallow the capsule. All were advised to divide their meals into frequent small ones, rich in carbohydrates and low in fat and not to take any medication or other ginger preparation outside the trial. They were asked to return in one week and gave back the capsule envelopes and the record forms. Compliance was assessed by monitoring the attendance at schedule visit, by capsule count, by asking subjects and by observing the subject's self-record on the drug taken or any occurrence of illness.

One pharmacist in a registered herbal factory prepared the ginger and identical-looking vitamin B6 capsules. In summary, fresh middle-aged ginger root was chopped into small pieces, dried in sunlight and ground into powder. The ginger powder was weighed and packed into 500 mg capsules by a capsule machine. The ginger capsules were sterilized by Cobalt 60 gamma ray. The process was performed at the Sterilized Food and Agricultural Product Industry, Office of Atomic Energy for Peace. The aforementioned pharmacist packed the 10 mg vitamin B6 tablet, prepared by the Government Pharmaceutical Organization, identical to the ginger capsule. Both ginger and vitamin B6 capsules were similarly packed in an envelope containing 20 capsules each.

Before the trial began, a pharmacist at BMAMC&VH who was not responsible for patient care used a table of random numbers to prepare the treatment assignment by randomization with a block of four to receive ginger or vitamin B6. The treatment code was concealed by placing the patient's assignments in sequence in sealed opaque envelopes that were drawn in ascending consecutive order. The codes were kept strictly confidential for blinding the physician and subjects and were broken at the end of the study.

The primary outcome was the improvement in nausea symptoms. The degree of nausea was measured using the visual analogue scale (VAS)[14]. The subjects were asked to grade the severity of their nausea by marking an "X" corresponding to their perceived state on a 10-cm horizontal line, ranging from 0 = no nausea to 10 = nausea as bad as it could be. The interval in centimeters between zero to the "X" mark stood for the severity of the nausea. The measurement at the first enrollment to the study was the baseline scores. During the 3-day treatment, the subjects were requested to record the severity of nausea three times daily in the morning, at noon and at bedtime. The average daily nausea scores and the average nausea scores over the 3 days were then calculated. The mean change in the nausea scores (baseline minus post-treatment scores) in the ginger and the vitamin B6 were compared.

The number of vomiting episodes in the 24 hours before treatment and then on each subsequent day of treatment were also recorded. The change in the number of vomiting episodes in the two groups was compared. The other secondary outcomes recorded were the occurrence of side effects such as drowsiness, palpitations, heartburn and mouth dryness.

For the primary outcome, change of the nausea scores after the 3-day treatment, the sample size was calculated. In the pilot study of 11 cases treated with vitamin B6 improvement of nausea was reported with the mean score change of 2.96 cm (SD = 1.44). The authors calculated that if the mean score change of 25 per cent was clinically important, the sample size of 60 subjects per group would be able to detect this difference with a probability of two tailed type I error of 5 per cent and type II error of 20 per cent. To allow for a 10 per cent dropout rate, a total sample of 67 per group was revealed.

The data were analyzed by parametric and non-parametric statistics, using the statistical program SPSS version 9.0. Continuous variables were examined for normal distribution (Kolmogorov-Smirnov test) before using parametric statistics. Differences among continuous variables between the two treatment groups were evaluated with the unpaired *t*-test for variables that were normally distributed, and with the Mann-Whitney *U* tests for variables that were not normally distributed. Differences among continuous variables within the same subjects (pre- and post- treatment) were evaluated appropriately with paired *t*-test, or Wilcoxon Signed Ranks test. Categorical variables were evaluated appropriately with Chi squared (χ^2) test, or Fisher's exact test. The primary outcome measure was considered significant only when $p \leq 0.05$. The significance of all secondary outcomes was $p \leq 0.001$ to account for multiple testing, a conservative approach. Analysis was performed by excluding those who were lost to follow-up. In addition, the effectiveness was assessed by intention-to-treat analysis.

RESULTS

During the study period, 138 pregnant women who suited the criteria were enrolled in the study. They were randomly allocated to receive ginger in 68 cases and vitamin B6 in 70 cases. Four cases (5.9%) in the ginger group and six cases (8.6%) in the vitamin B6 group did not return for follow-up, leaving 64 in each group who were evaluable. The baseline characteristics of those who were lost to follow-up were similar to the main study cases. All subjects who returned for follow-up took the first eight tablets during the 3-day treatment. The demographic baseline data of both groups of subjects were similar as shown in Table 1.

The baseline nausea scores and post-treatment scores are shown in Table 2. Both groups showed improvement of nausea symptom during the 3-day treatment. Comparing the baseline score and average score in the same group, the mean score change in the

Table 1. Baseline characteristics.

Characteristics	Ginger (n = 64) Mean (SD)	%	Vitamin B6 (n = 64) Mean (SD)	%
Age (yr)	27.5 (5.63)		26.7 (5.44)	
Gestational age (wk)	10.1 (2.74)		10.3 (2.95)	
Number of nulliparae	27	42.2	34	53.1
Body mass index (kg/m^2)	21.7 (3.93)		21.9 (2.75)	
Baseline nausea scores (cm)	5.0 (1.99)		5.3 (2.08)	
Baseline episodes of vomiting in previous 24 h [median (range)]	1 (0-10)		1 (0-10)	
Smoking				
Never	61	95.3	63	98.4
Quit during pregnancy	3	4.7	1	1.6
Education				
No/primary school	32	50	32	50
Secondary school	22	34.4	24	37.5
University	10	15.6	8	12.5
Occupation				
Employee	34	53.1	38	59.4
Housewife	23	35.9	18	28.1
Merchant	6	9.4	7	10.9
Civil servant	0	0.0	1	1.6
Undergraduate	1	1.6	0	0.0

ginger group was 1.4 (SD, 2.22), which was significantly different, ($p < 0.001$). Also in the vitamin B6 group, the score change from baseline was 2.0 (SD, 2.19), $p < 0.001$. The score changes on day 1-3 in the vitamin B6 group were larger than those in the ginger group, but without statistical significance. The difference of average score change when comparing the two groups was 0.6 with 95 per cent CI of -1.4 to 0.2, a non-significant difference, ($p = 0.136$). Intention-to-treat analysis was not performed since the effect observed in the vitamin B6 group was greater than that observed in the ginger group although with non-significant difference. Assuming that the missing subjects in the vitamin B6 group had the best outcome would further increase the efficacy of vitamin B6.

The baseline number of patients with vomiting of at least one time in the previous 24 hours, in the ginger group was 47 in 64 (73.4%) compared to 43 in 64 (67.2%) in the vitamin B6 group ($p = 0.562$). Comparing baseline (pre-treatment) to average vomiting episodes after the 3-day treatment, both groups showed reduction in vomiting episodes. The mean episode change in the ginger group was 0.7 (SD, 2.18), which was significantly different, ($p = 0.003$). Also in the vitamin B6 group, reduction of the vomiting episodes was 0.5 (SD, 1.44), $p = 0.008$. After the 3-day ginger treatment, the number of patients with vomiting was less than those in the vitamin B6 group, 28 in 64 (43.8%) *versus* 38 in 64 (59.4%), ($p = 0.146$). Both groups showed reduction of the number of vomiting episodes during the 3-day treatment as shown in Table 3. The difference between the two groups was not statistically significant.

The occurrence of drowsiness and heartburn in the ginger group and the vitamin B6 group was 17/64 (26.6%) *versus* 21/64 (32.8%), $p = 0.439$ and 6/64 (9.4%) *versus* 4/64 (6.3%), $p = 0.510$. These side effects were reported to be minor and did not

Table 2. Baseline and post-treatment nausea scores.

Nausea score	Ginger (n = 64) Mean (SD)	Vitamin B6 (n = 64) Mean (SD)	P-value
Baseline	5.0 (1.99)	5.3 (2.08)	0.613[1]
Post-treatment			
Day 1	3.9 (2.42)	3.9 (2.25)	0.939[1]
Day 2	3.8 (2.70)	3.4 (2.01)	0.322[2]
Day 3	3.2 (2.54)	3.0 (2.42)	0.494[1]
Average	3.6 (2.48)	3.3 (2.07)	0.435[2]
Change in nausea score			
Day 1	1.1 (2.21)	1.4 (2.23)	0.331[1]
Day 2	1.2 (2.35)	1.9 (2.18)	0.057[1]
Day 3	1.8 (2.41)	2.3 (2.53)	0.209[2]
Average	1.4 (2.21)	2.0 (2.19)	0.136[2]

[1] Mann-Whitney *U* test, [2] unpaired *t*-test.

Table 3. Baseline and post-treatment number of vomiting episodes.

Number of vomiting episodes	Ginger (n = 64) Mean (SD)	Vitamin B6 (n = 64) Mean (SD)	P - value[1]
Baseline	1.9 (2.06)	1.7 (1.81)	0.622
Post-treatment			
Day 2	1.2 (1.84)	1.3 (1.70)	0.384
Day 3	1.1 (2.03)	1.1 (1.40)	0.328
Average	1.2 (1.75)	1.2 (1.50)	0.314
Change in vomiting episode			
Day 2	0.7 (2.26)	0.4 (1.53)	0.423
Day 3	0.8 (2.39)	0.6 (1.46)	0.396
Average	0.7 (2.18)	0.5 (1.44)	0.498

[1] Mann-Whitney *U* test.

preclude them from taking their prescribed medication. No other adverse events were observed in both groups during the one week follow-up.

DISCUSSION

Two randomized controlled trials reported the efficacy of ginger for nausea and vomiting during pregnancy[13,14]. In one study, powdered root of ginger in a daily dose of 1 g during 4 days was better than placebo in diminishing or eliminating the symptoms of hyperemesis gravidarum of 30 hospitalized pregnant women[13]. In another study, involving 70 non-hospitalized women with less severe manifestation of nausea and vomiting of pregnancy at or before 17 weeks' gestation, ginger at a daily dose of 1 g during 4 days was effective for relieving the severity of nausea and vomiting[14]. In both studies, no adverse effect of ginger on pregnancy outcome was detected.

In the present study, the authors used vitamin B6 as the positive control instead of placebo for ethical consideration. The other reason was the effect of lactose which may not be an inert ingredient for some subjects. The authors chose the 30 mg daily dose of vitamin B6, the minimum effective dose reported for safety. Vitamin B6 was taken for three days because the previous study[9] showed that vitamin B6 significantly reduced the number of vomiting episodes during the first 3-day treatment, the beneficial effects appeared to diminish over time and too long a study period will only result in a higher rate of subject noncompliance and loss to follow-up. However, 20 capsules were given to each woman to cover seven days of follow-up appointment. The authors chose the ginger dose of 0.5 g three times daily as recommended in the foreign market.

The ginger capsules and vitamin B6 capsules were alike externally. However, the vitamin B6 capsule was lighter and less compact. This could cause drug contamination by interchanging the capsule between the subjects. However, this did not happen during interviewing on the follow-up visit.

In the present study, both ginger and vitamin B6 significantly reduced the degree of nausea and the number of vomiting episodes. Considering the degree of nausea which was the primary outcome, the nausea score changes in the ginger group were 0.6 or 30 per cent less than those in the vitamin B6 group, but without statistical significance. The authors calculated the power of study and revealed only 33 per cent which reflected the small sample size. This was affected by the larger SDs (pooled SD of 2.22 compared to 1.44 in the pilot study) and the smaller effect size. The sample size should be 220 for each group to yield the power of 80 per cent at the same SD and effect size. However, this small score difference was not of clinical importance and should not need such a large sample size.

In the present study, the duration of ginger treatment was very short and the dosage used was very low. The dose of 1.5 g daily did not exceed the amount prescribed in recipes for cakes or tarts (amounting to 30 g)[12]. A larger dose of ginger may be more effective. Further studies with large power are needed to evaluate the optimal dose of ginger and to detect the small effect size. The present study showed no significant side effects in both treatment groups. However, the number of subjects was not sufficiently large enough to exclude the possibility of uncommon adverse effects. Ginger is a potent thromboxane synthetase inhibitor; it may affect testosterone receptor binding in a fetus possibly affecting sex steroid differentiation of the fetal brain[15]. Further studies with large power or meta-analysis to detect uncommon complications, such as certain congenital anomalies, are needed.

In Thailand, ginger has long been recommended as folklore treatment for nausea and vomiting during pregnancy. It is reassuring that two previous aforementioned randomized trials including the present study consistently showed that there were no significant side effects. Anti-emetics are not available in many places of Thailand. Food containing ginger should be encouraged, although the optimal amount of fresh or powdered ginger to relieve the symptoms of nausea and vomiting of pregnancy is unknown.

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เปรียบเทียบขิงกับวิตามินบี 6 ในการรักษาภาวะคลื่นไส้อาเจียนในสตรีตั้งครรภ์†

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วัตถุประสงค์ : เพื่อศึกษาประสิทธิผลของขิงเปรียบเทียบกับวิตามินบี 6 ในการลดอาการคลื่นไส้อาเจียนในสตรีตั้งครรภ์

ชนิดของการวิจัย : วิจัยเชิงทดลองแบบ randomized double –blind controlled trial

สถานที่ทำการวิจัย : ภาควิชาสูติศาสตร์–นรีเวชวิทยา วิทยาลัยแพทยศาสตร์กรุงเทพมหานครและวชิรพยาบาล

กลุ่มตัวอย่าง : สตรีตั้งครรภ์อายุครรภ์น้อยกว่าหรือเท่ากับ 16 สัปดาห์ ที่มีอาการคลื่นไส้ อาเจียน แต่ไม่รุนแรงจนต้องนอนโรงพยาบาล มีความต้องการยาแก้คลื่นไส้อาเจียน ไม่มีโรคหรือความผิดปกติทางอายุรกรรม และสามารถมารับการตรวจซ้ำภายใน 1 สัปดาห์ได้ สมัครใจเข้าร่วมในโครงการวิจัย ในช่วงระหว่างเดือนพฤศจิกายน พ.ศ. 2542 ถึงเดือนพฤศจิกายน พ.ศ. 2543 มีสตรีสมัครใจเข้าร่วมโครงการวิจัย จำนวน 138 ราย

วิธีดำเนินการวิจัย : แบ่งผู้ป่วยเป็น 2 กลุ่มโดยการสุ่ม แต่ละกลุ่มกินแคปซูลบรรจุขิง (500 มิลลิกรัม) หรือวิตามินบี 6 (10 มิลลิกรัม) ที่บรรจุในแคปซูลลักษณะเดียวกัน โดยให้ครั้งละ 1 เม็ด วันละ 3 เวลา เป็นเวลา 3 วัน บันทึกระดับความรุนแรงของอาการคลื่นไส้ตาม visual analogue scale และบันทึกจำนวนครั้งของ การอาเจียนเป็นเวลา 3 วัน นัดผู้ป่วยมาตรวจอีก 7 วัน นำผลการรักษามาเปรียบเทียบกัน

ตัววัดที่สำคัญ : คะแนนความคลื่นไส้ และจำนวนครั้งของการอาเจียนที่เปลี่ยนแปลงหลังได้รับยา

ผลการวิจัย : สตรีที่กลับมาตรวจตามนัดมีกลุ่มละ 64 ราย ข้อมูลพื้นฐานของสตรีทั้ง 2 กลุ่มใกล้เคียงกัน ขิงและวิตามินบี 6 สามารถลดคะแนนความคลื่นไส้อย่างมีนัยสำคัญทางสถิติ จาก 5.0 (SD 1.99) เหลือ 3.6 (SD 2.48) และ 5.3 (SD 2.08) เหลือ 3.3 (SD 2.07) ตามลำดับ, $p < 0.001$ คะแนนความคลื่นไส้เฉลี่ยหลังได้ขิงลดลง 1.4 (2.21) ซึ่งน้อยกว่าหลังได้วิตามินบี 6 ซึ่งลดลง 2.0 (2.19) แต่ความแตกต่างไม่มีนัยสำคัญทางสถิติ (95% CI –1.4 ถึง 0.2, $p = 0.136$) ขิงและวิตามินบี 6 สามารถลดจำนวนครั้งของการอาเจียนอย่างมีนัยสำคัญทางสถิติ จาก 1.9 (2.06) เหลือ 1.2 (1.75) และ 1.7 (1.81) เหลือ 1.2 (1.50) ตามลำดับ, $p < 0.01$ จำนวนครั้งของการอาเจียนเฉลี่ยหลังได้ขิงลดลง 0.7 (2.18) ซึ่งมากกว่าหลังได้วิตามินบี 6 ซึ่งลดลง 0.5 (1.44) แต่ความแตกต่างไม่มีนัยสำคัญทางสถิติ ($p = 0.498$) มีอาการข้างเคียงเล็กน้อยที่เกิดขึ้นขณะได้รับยาขิงและวิตามินบี 6 คือ อาการง่วงซึม (26.6% และ 32.8%, $p = 0.439$) และแสบร้อนในอก (9.4% และ 6.3%, $p = 0.510$) ซึ่งแตกต่างกันอย่างไม่มีนัยสำคัญทางสถิติ

สรุป : ขิงและวิตามินบี 6 ลดคะแนนความคลื่นไส้ และจำนวนครั้งของการอาเจียนในสตรีตั้งครรภ์อย่างมีนัยสำคัญ เมื่อเปรียบเทียบประสิทธิผลของยาทั้งสองชนิด พบว่าไม่แตกต่างกัน

คำสำคัญ : คลื่นไส้, อาเจียน, สตรีตั้งครรภ์, ขิง, วิตามินบี 6

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