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A RANDOMIZED COMPARISON OF GINGER AND NAVIDOXINE IN THE TREATMENT OF NAUSEA AND VOMITING FOR PREGNANCY

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ABSTRACT
The experiment was conducted to compare the effectiveness of ginger and Navedoxine for treatment of nausea and vomiting in pregnancy. Samples were taken in Privet clinic at Baghdad /Iraq between July 2008 and February 2009 there were 57 women randomized to ginger and 51 women to Navidoxine, women with nausea or vomiting were eligible for the trial if they were between 8 and 16 weeks pregnant, with dates confirmed by ultrasound. Women were randomly allocated to receive either ginger or Navidoxine in a blinded fashion, they were instructed to take water extract of ginger root (500 mg) or 1 tablet of Navidoxine (50 mg) two times a day for two weeks. Patients 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 using the drugs. The results show that the number of vomiting episodes decreased in both groups. In the ginger group, 10/29 women (34.5%) reported an improvement (+ve) in nausea symptoms, compared with 19/29 women in the Navidoxine group. While 40/63 women reported an improvement (++ve) in nausea symptom in the ginger group compared with 23/63 women in the Navidoxine group. The total response was 52.8% in the ginger group, and 47.2% in the Navidoxine group. The difference in outcome between the two groups was not significant. The results showed thatnpowdered ginger root and Navidoxine tablet in the dose used was found to be effective in reducing nausea and vomiting induced by pregnancy. Comparing the efficacy ginger was comparable to Navidoxine tablet.

KEYWORDS: Nausea, Vomiting, Pregnancy, Ginger, Navidoxine.

INTRODUCTION

Nausea and vomiting are common symptoms experienced by women in the first trimester of pregnancy and affect 50–80% of pregnant women.[1]Women often seek help from professionals and try numerous strategies to alleviate their symptoms, few of which suppress their symptoms to their satisfaction. There is a tradition of using ginger, an antiemetic herb in Chinese and Ayurvedic medicine, to treat nausea and vomiting. Many complementary medicines are perceived as being safe and natural, and many pregnant women choose to use these products or therapies during pregnancy [(2)] Ginger (Zingiber officinale Roscoe, Zingiberaceae) is a medicinal plant that has been traditionally used both as a popular food ingredient and a medicinal herb all over the world. Its multisystemic effects have been claimed and reviewed from time to time [(3)].In recent years, clinical trials and research have shown that ginger can be used successfully in the treatment of a number of conditions, both gastrointestinal and non-gastrointestinal. Ginger has been used for a wide array of unrelated ailments such as arthritis, rheumatism, sprain, muscular ache, pain, sore throat, cramp, constipation, indigestion, vomiting, hypertension, dementia, fever, infection and helminthiasis.[(4)] The National Center for Complementary and Alternative Medicine (NCCAM) in United States has evaluated the results of available studies on ginger and classified them as "suggestive" (for short-term use of ginger in pregnant related nausea and vomiting), "mixed" (for nausea caused by motion sickness, chemotherapy, or surgery) [(5)]. Navidoxine (Meclizine Hydrochloride 25 +Vitamin B6 (Pyridoxine Hydrochloride) 50mg). Pyridoxine hydrochloride is used in treatment of sideroblastic anemias; it is readily absorbed from the gastrointestinal tract following oral administration and is converted to the active forms, pyridoxal phosphate and pyridoxamine phosphate, which are stored mainly in the liver where there is oxidation to 4-pyridoxic acid and other metabolites that are excreted in the urine. It is involved in amino acid as well as carbohydrate and fat metabolism. It is used in a variety of disorders, including the treatment of depression and other symptoms [(6)]. Meclezine hydrochloride a 1- phenylmethyl] -4-(3-methylbenzyl) piperazine dihydrochloride, is yellow or yellowish-white, crystalline powder. This piperazine derivative is antihistamine with antimuscarinic and central sedative properties. It is used in the prevention and treatment of nausea and vomiting associated with variety of conditions including motion sickness and for the symptomatic treatment of vertigo caused by Meniere's disease and other vestibular disorders .[(6,7).] Our objective of this study was to compare the efficacy of Ginger to Navidoxine in the treatment of nausea and vomiting of pregnancy.

MATERIALS AND METHODS

There were 57 women randomized to ginger and 51 women to Navidoxine. The trial took place at privet clinic in Baghdad /Iraq between July 2008 and February 2009.

Study protocol was approved by the ethics committee of the institution. Informed consent of all patients was taken before inclusion in the study. Women with nausea or vomiting were eligible for the trial if they were between 8 and 16 weeks pregnant, with dates confirmed by ultrasound. Women could continue to use any existing medication or other measures other than ginger or Navidoxine during the trial, and a record of use was made at the start and end of the trial. Women were randomly allocated to receive either ginger or Navidoxine in a blinded fashion, they were instructed to take water extract of ginger root (500 mg) or 1 tablet of Navidoxine (50 mg) two times a day for two weeks. Patients 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 using the drugs.

Sample size was calculated with the assumption that ginger is as effective as Navidoxine as an antiemetic and consider Navidoxine as control. Type I error probability associated with the test of null hypothesis is 0.05,results revealed that we will need to study 45 experimental subjects and 45 control subjects to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. All calculations were accomplished by using PS program.

Statistical Analysis

Data were analyzed by using SAS program and the difference in the incidence of nausea and vomiting between the two treatments groups were tested using Chi-square test. Probability P≤ 0.05 was considered statistically significant. Descriptive statistics were summarized as percentage.

RESULTS

Table (1) show that the number of vomiting episodes decreased in both groups. In the ginger group, 10/29 (34.5%) women reported an improvement (+ve) in nausea symptoms, compared with 19/29 (65.5%) women in the Navidoxine group and the difference between them was significant (Chi-Square value 5.324, d.f. 1, P=0.021) Table (2). While 40/63 (63.5%) women reported an improvement (++ve) in nausea symptom in the ginger group compared with 23/63 (36.5%) women in the Navidoxine group and the difference between them was significant (Chi-Square value 6.964, d.f. 1, P=0.008) Table (2). The total response was 52.8% in the ginger group, and 47.2% in the Navidoxine group. The difference in these outcomes between the two groups was not significant (Chi-Square value 0.667, d.f. 1, P=0.414).

TABLE 1: Response * type Cross tabulation

Response * type Cross tabulation					
			type		Total
			Navidoxine	Ginger	
Response	-ve	Count	9	7	16
		% within Response	**(9/16)**56.3%	**(7/16)**43.8%	100.0%
		% within type	17.6%	12.3%	14.8%
	+ve	Count	19	10	29
		% within Response	**(19/29)**65.5%	**(10/29)**34.5%	100.0%
		% within type	37.3%	17.5%	26.9%
	++ve	Count	23	40	63
		% within Response	**(23/63)**36.5%	**(40/63)**63.5%	100.0%
		% within type	45.1%	70.2%	58.3%
Total		Count	51	57	108
		% within Response	**(51/108)**47.2 %	**(57/108)**52.8 %	100.0%
		% within type	100.0%	100.0%	100.0%

TABLE 2: Comparison between types

Response	Chi-Square value	df	P
- ve	0.614	1	0.433
+ ve	5.324	1	0.021
++ ve	6.964	1	0.008

DISCUSSION

It is well known that ginger has a beneficial effect in people with dyspepsia, nausea and vomiting. The present study is consistent with other trials showing that ginger is an effective treatment for nausea and vomiting in pregnancy. Comparing the efficacy ginger was the same as Navidoxine as it significantly reduced nausea and vomiting symptom during the two weeks of treatment. In functional bowel disorders, ginger is also reported to be one of the most common complementary and alternative medicines[8]. Many scientists are interested in proving its effect and action on nausea and vomiting in pregnancy and there are trials that compare the effectiveness of ginger to vitamin B6[9,10,11]. The author concluded that the use of ginger is a safe and effective option comparable to vitamin B6[12]. The mechanism of the action of ginger on nausea

and vomiting has not been fully identified. Two possible mechanisms are enhanced intestinal and Central Nervous System (CNS)activity, Ernst E, and Pittler MH reported that with studies in humans indicating that the latter is more likely[13]. While Jednak MA,*et al*[14] suggested that symptoms of nausea and vomiting during pregnancy improved in direct correlation to the improvement in pregnancy induced gastric dysrhythmias . Levine ME *et al*[15] suggest that ginger cause significant decrease in gastric dysrhythmia when the gastric myoelectrical activity was recorded. Therefore, ginger-induced reduction of pregnancy symptoms may be due to a direct effect of the drug on the gastrointestinal tract. [10]. The side effects from ginger were reported to be minor and did not need any treatment [10]. Meclozine is a derivative of benzhydrylpiperazine,it has anti-emetic, sedative, anticholinergic and H1 antihistamine properties[16]. The mechanism by which meclizine exerts its antiemetic, anti–motion sickness, and antivertigo effects is not precisely known but may be related to its central anticholinergic actions. It diminishes vestibular stimulation and depresses labyrinthine function. An action on the medullary chemoreceptive trigger zone may also be involved in the antiemetic effect[17]. Epidemiological studies in a large number of pregnant women have not shown that Navidoxine increases the risk of malformation when administered during pregnancy [18].

Ginger has the potential to offer not only a cheaper natural alternative to conventional agents, but also one with significant lower side effects [4, 19] Ginger has not been associated with any significant adverse events in trials. In some cases, gastrointestinal upset is reported. Doses as high as 1 g/kg have been used in rats with no signs of toxicity or teratogenicity [20]. Based on these results, it was concluded that ginger and Navidoxine were significantly reduce nausea and vomiting induced by pregnancy ,and **there** was no significant difference between ginger and Navidoxine for the treatment of nausea and vomiting during pregnancy.

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