



The Association of Vanilla Ice Cream in Symptomatic Relief of Nausea and Vomiting in Management of Hyperemesis Gravidarum: A Cohort Study

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Abstract

Aim: To determine the association of vanilla ice cream in symptomatic relief of nausea and vomiting in management of hyperemesis gravidarum as measured by modified Pregnancy-Unique Quantification of Emesis (PUQE) score.

Methods and Material: An observational study was carried out on the patients admitted for hyperemesis gravidarum during first trimester over a period of 1.5 years in a tertiary care Hospital. A cohort of pregnant women having vanilla ice cream was compared with the cohort who did not take it for the symptoms. All the patients admitted were treated using a standard treatment protocol based on the ACOG Practice Bulletin No.153. Modified PUQE scores of both the groups were compared at the time of admission and after 48 h.

Statistical Analysis Used: The data was analyzed and Relative Risk (RR) was calculated for variables.

Results: All participants except two in the control group remained in the study. Patients who were taking vanilla ice cream had a better recovery and better modified PUQE scoring at 48 h. The mean modified PUQE scores of post-therapy decreased significantly in the vanilla group (3.95) compared with the control group (2.57).

Conclusion: The consumption of Vanilla ice cream during pregnancy can be used as an adjuvant therapy for treatment of hyperemesis gravidarum.

Keywords: Hyperemesis gravidarum; Vanilla; PUQE score

Introduction

Nausea and vomiting of pregnancy is a common condition which can adversely affect the health of a pregnant woman and her fetus. The pregnant women commonly resort to trial with Complementary and Alternative Medicine (CAM) and household remedies before consulting an obstetrician. Nausea and Vomiting of Pregnancy (NVP) has prevalence rates for nausea of 50% to 80% and for vomiting and retching of 50% [1]. Hyperemesis gravidarum appears to represent the extreme end of the spectrum of nausea and vomiting of pregnancy [2]. Pregnancy-Unique Quantification of Emesis (PUQE) scoring system is quite a reliable tool for assessing the severity of NVP based on three physical symptoms: Nausea, vomiting, and retching over the previous 12 h. It was modified and validated to a 24-h scale to account for the time spent sleeping [3,4]. Despite the fact that several medications are available for the treatment of NVP, the treatment gets delayed as most of pregnant women are cautious of medicines for fear of harming the fetus [5]. Over the years, ginger has been used extensively and found to provide significant relief in vomiting in women suffering from hyperemesis gravidarum [1,6]. In recent years, Complementary and Alternative Medicines (CAM) is getting popular and use of non-pharmacological medicines and herbal extracts during pregnancy has been observed with high frequency [7]. The use of ginger and its impact as an antiemetic has been extensively investigated for at least 30 years [8]. Recently, it was found that over 28% of participating women of a multinational study used herbals medicines for nausea and vomiting of pregnancy. The popular herbs were ginger and cranberry accounting for almost 46% with valerian and raspberry among other choices [9]. During interactions and patient education program we observed that certain group of women was benefitted by taking vanilla ice cream for the symptoms of nausea and vomiting during pregnancy. In order to validate this association an

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observational study over a period of 2 years in tertiary care hospital was carried out on the patients admitted for hyperemesis gravidarum during first trimester.

Material and Methods

During clinical practice we observed that some pregnant subjects with hyperemesis gravidarum reported reduced symptoms of nausea and vomiting by taking vanilla ice cream on advice of their peers. Based on the above, we planned an observational study to find the association, if any, between eating vanilla ice-cream and reduction in symptoms of nausea and vomiting as measured by modified PUQE. The algorithm of the study protocol is given in Figure 1. The Institutional Ethics Committee approved the study protocol. Women with nausea and vomiting of pregnancy, who reported at antenatal clinic and were admitted with a diagnosis of hyperemesis Gravidarum during first trimester having any of these criteria (modified PUQE score >7, clinical signs of dehydration, ketonuria or weight loss) were invited to participate in the study.

Written informed consent was taken from all the women who participated in the study. A cohort of pregnant women having vanilla ice cream was compared with the cohort who was not taking it for symptoms. The study was conducted over a period of 2 years in Tertiary Care Hospital. All the admitted patients were treated using a standard treatment protocol based on ACOG Practice Bulletin No.153 [10]. The women who had started taking vanilla ice cream and continued to do so were considered as exposed cohort and the women not taking it as unexposed cohort. Gestational age was calculated from Last Menstrual Period (LMP) and in cases of unsure date; it was confirmed by first trimester ultrasonography. A pretested interviewer administered questionnaire was used to collect the data on demography, parity, gestational age, vanilla ice cream consumption (amount, duration and number of times in a day), symptoms of nausea and vomiting (modified PUQE, IV fluids, additional medication) and follow up till outcome of pregnancy. The admission criteria and management plan for patients was outlined using the modified 24-h PUQE score and the NVP assessment algorithm. The exclusion criteria included multiple pregnancy, molar pregnancy, gastrointestinal diseases (reflux oesophagitis, gastritis, cholecystitis), peptic ulceration, infection including *Helicobacter pylori*, hepatitis), and urinary tract infection, participants on opioids drugs and iron supplements or other medical disorders like migraine, thyrotoxicosis, eating disorders etc were also excluded from the study.

Medical history and investigations including Complete Blood Count (CBC), Serum electrolytes, BUN, liver function test and thyroid function test were obtained from all patients. Other medical and surgical causes were ruled out before labeling a patient suffering from Hyperemesis gravidarum. The patients were treated for the correction of hypovolemia, electrolyte imbalances and ketosis and anti-emetic medication. Thiamine supplementation and thromboprophylaxis was individualized as per requirement for the patient [11]. Isotonic saline and crystalloids were used for fluid replacement and 5% dextrose was avoided [12]. For grading the severity of nausea and vomiting scoring was done using "24 h modified PUQE score" at the time of admission and again during consecutive days while taking treatment till the time of discharge from hospital [13]. In our experiences, as one of the criteria for admission was dehydration, more than 60% cases required correction with IV fluids. The patient once started tolerating oral fluids and food without vomiting with Urine ketones negative were discharged from hospital. Appropriate antiemetic and folic acid

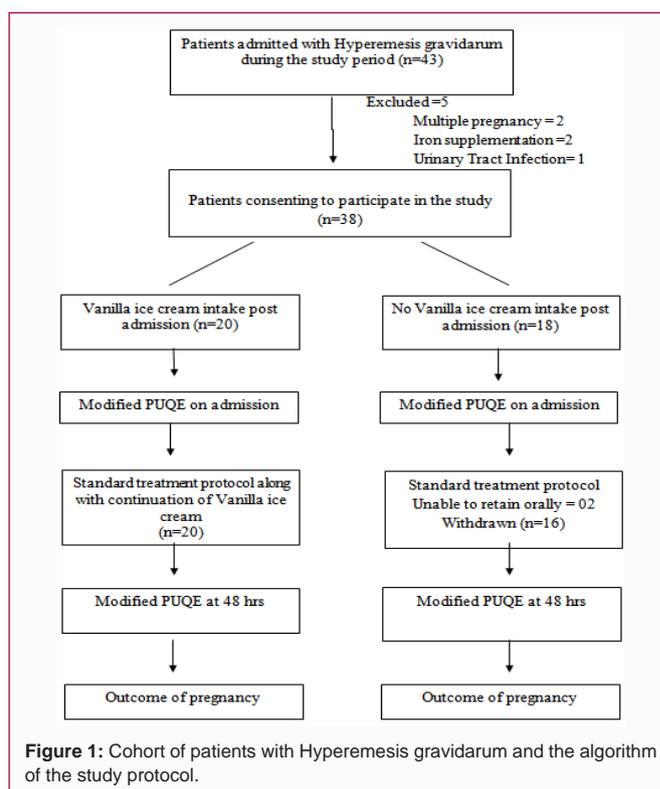


Figure 1: Cohort of patients with Hyperemesis gravidarum and the algorithm of the study protocol.

prescription were provided along with advice on diet.

Results

Between March 2016 and September 2017, a total of 43 women were admitted for hyperemesis gravidarum at or before 14 weeks' gestation. Thirty eight women meeting the eligibility criteria had consented to participate in the study (Figure 1). The consenting women were evaluated for severity of hyperemesis gravidarum using modified PUQE score. All eligible women who agreed to participate in the study were briefed about the study design. Twenty women of exposed cohort took vanilla ice cream two to three times a day during stay in hospital. The same brand was used throughout the study. Patients were evaluated daily with modified PUQE by a paramedic who was blinded for the study. There was no significant difference between the mean age of the women in the exposed cohort 24.75 (\pm 2.29) and the unexposed cohort 23.62 (\pm 3.28). Other baseline characteristics of cohorts on hospitalization, during treatment, modified PUQE score at baseline, modified PUQE at 48

Table 1: Baseline characteristics of cohorts at hospitalization and during treatment.

| | Vanilla Ice cream | n | Mean |
|-----------------------------|-------------------|----|-------|
| Age | Yes | 20 | 24.75 |
| | No | 16 | 23.63 |
| Period of Gestation | Yes | 20 | 9.36 |
| | No | 16 | 10.11 |
| PUQE at baseline | Yes | 20 | 10.65 |
| | No | 16 | 11.94 |
| PUQE at | Yes | 20 | 6.70 |
| | No | 16 | 9.37 |
| Duration of hospitalisation | Yes | 20 | 3.30 |
| | No | 16 | 4.50 |

Table 2: RR values of various variables.

| Various Variables and Their Impact | | | | | | | |
|------------------------------------|-----|-----------|-----------|------|--------|-------|---------|
| Variable | | PUQE 48hr | | RR | 95% CI | | P value |
| | | <7 (n=19) | >7 (n=17) | | Lower | Upper | |
| Vanilla | Yes | 14 | 6 | 2.5 | 1.14 | 5.47 | 0.007 |
| | No | 5 | 11 | | | | |
| Previous Pregnancy | Yes | 6 | 3 | 1.3 | 0.76 | 2.54 | 0.33 |
| | No | 13 | 14 | | | | |
| PUQE on Admission | >11 | 15 | 10 | 1.65 | 0.71 | 3.84 | 0.21 |
| | <10 | 4 | 7 | | | | |
| Oral intake | Yes | 12 | 12 | 0.86 | 0.46 | 1.6 | 0.64 |
| | No | 7 | 5 | | | | |
| Vomiting | >7 | 16 | 9 | 2.4 | 0.86 | 6.4 | 0.04 |
| | <6 | 3 | 8 | | | | |
| Ketone | Yes | 10 | 11 | 0.8 | 0.43 | 1.46 | 0.46 |
| | No | 9 | 6 | | | | |
| Doxinate | Yes | 10 | 11 | 0.8 | 0.43 | 1.46 | 0.46 |
| | No | 9 | 6 | | | | |
| IV Fluids | Yes | 8 | 14 | 2.16 | 1.2 | 4 | 0.01 |
| | No | 11 | 3 | | | | |
| Addl drugs | Yes | 15 | 14 | 0.9 | 0.44 | 1.8 | 0.79 |
| | No | 4 | 3 | | | | |

h and outcome of pregnancy were compared (Table 1). The RR value for various variables was calculated and it was found that intake of vanilla during hyperemesis gravidarum has significant impact when compared with other confounding factors (Table 2).

This being a pioneer study the sample size could not be calculated. However Post-Hoc power for the two outcome variables was estimated. Post-Hoc power modified PUQE at 48 h was 0.99 and for the duration of hospitalization was 0.94. The study was adequately powered to find the difference between two groups. No subjects in this study took any medications other than those prescribed in the protocol. All participants except two in the control group (unable to tolerate orally) remained in the study. Patients in the vanilla ice cream cohort had a better recovery and better modified PUQE scoring after 48 h. The mean duration of hospitalization in vanilla cohort (mean = 3.3 days) was also significantly different from the unexposed cohort (mean = 4.5 days) (Table 1).

Discussion

The vanilla ice cream intake for hyperemesis gravidarum along with the standard treatment decreases the severity of symptoms as well as duration of hospital stay. Nausea and vomiting of pregnancy is a common condition which can adversely affect the health of the pregnant woman and her fetus. Nausea and vomiting of pregnancy has prevalence rates for nausea of 50% to 80% and for vomiting and retching of 50%. Hyperemesis gravidarum appears to represent the extreme end of the spectrum of nausea and vomiting of pregnancy. Other causes should be considered because hyperemesis gravidarum is a diagnosis of exclusion. In population-based studies from California and Nova Scotia, the hospitalization rate for hyperemesis gravidarum was 0.5% to 0.8% [14]. Up to 20% of those hospitalized in a previous pregnancy for hyperemesis will again require hospitalization

[15]. The etiopathogenesis of hyperemesis gravidarum is likely multifactorial and certainly is enigmatic. It appears to be related to high or rapidly rising serum levels of pregnancy-related hormones. It is presumed that Human Chorionic Gonadotropin (hCG), estrogens, progesterone, leptin, placental growth hormone, prolactin, thyroxine, and adrenocortical hormones are likely to be involved [16]. In an attempt to quantify nausea and vomiting severity a Pregnancy-Unique Quantification of Emesis and Nausea (PUQE) scoring index was proposed [17]. The severity of the condition should be assessed using the modified 24-h PUQE (Pregnancy Unique Quantification of Emesis and Nausea) score [18]. The pregnant women commonly resort to trial with Complementary and Alternative Medicine (CAM) and household remedies before consulting the obstetrician. Vanilla is regarded as the world's most popular aroma and flavor and is widely used compound for foods and beverages. It is the most well-liked ice cream flavor. Vanilla ice cream can be used as an adjuvant therapy for treatment of hyperemesis gravidarum.

Conclusion

In conclusion, based on the evidence of this observational study, vanilla ice cream can be used as an adjuvant therapy for treatment of hyperemesis gravidarum. However further studies are necessary to reach any conclusion. The results from these studies could be used to optimize the design for clinical trials to test the efficacy of vanilla ice cream in the management of hyperemesis gravidarum.

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