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A Randomized Controlled Trial of the Effectiveness of Peppermint Aromatherapy on Nausea in Women Post C-section

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200 word abstract containing: (a) purpose of study, without detailed background; (b) design of study; (c) methods used; (d) findings; and (e) conclusions.

Abstract:
Purpose of Study: This study examined the effect of spirits of peppermint on postoperative nausea in women following a scheduled C-section.

Design of Study: A randomized control trial using a pretest-posttest research design with three treatment groups was used. Group 1 inhaled spirits of peppermint, Group 2 received standard antiemetics, and Group 3 inhaled an inert placebo.

Methods Used: Women were recruited for this study using a convenience sampling method, and were randomly assigned to one of three groups on admission. If they became nauseated, nurses on the mother-baby unit assessed their nausea (baseline), administered the assigned treatment, and then reassessed their nausea two- and five-minutes later. Nurses assessed participants' nausea by asking them to rate it using a 6-point nausea scale.

Findings: Thirty-five participants became nauseated post-operatively. Participants in all three treatment groups had similar levels of nausea at baseline. The nausea levels of participants in the peppermint group were significantly lower than those of participants in the other two groups at two- and five-minutes post treatment.

Conclusions: Spirits of peppermint may be a useful adjunct in the treatment of post-operative nausea. This study should be replicated with greater numbers of participants and using alternate aromatherapies as placebos.

200 words counting headings

A Randomized Controlled Trial of the Effectiveness of Peppermint Aromatherapy on Nausea in Women Post C-section

Women in the postoperative period following a C-section often experience the discomfort of nausea. Vagal, or sympathetic stimuli, severe pain, visceral trauma, medications, and anesthesia can stimulate receptors in the medulla resulting in post operative nausea and vomiting (Huether, 2006). Nausea is frequently treated with pharmacologic therapies in order to improve patient comfort and decrease the incidence of vomiting, which may place stress on the surgical wound. Traditionally, in our community hospital promethazine (Phenergan) had been used intravenously to treat post operative nausea. However, promethazine was removed from the formulary for intravenous use due to concerns about phlebitis and severe tissue damage. This resulted in the use of Ondansetron (Zofran) for the treatment of post op nausea. Zofran's safety has not been established in breast feeding women and its effect can last up to eight hours (Deglin and Vallerand, 2009). These standard drug therapies can be problematic in postpartum women because they can result in sedation and interfere with breast feeding.

The lack of effective medications for short term acute nausea that did not cause sedation or interfere with breast feeding presented a challenge to the nurses on the post partum unit; this resulted in a search for alternative ways to relieve nausea. A registered nurse on the post partum unit who specializes in alternative therapies suggested that aromatherapy with spirits of peppermint be explored as an alternative treatment that might quickly and safely relieve nausea without the side effects of sedation. A review of the literature revealed two studies that used peppermint oil aromatherapy for treating post operative nausea (Anderson, 2004; Tate, 1997). However, no studies were found that used spirits of peppermint, which combines peppermint

with an aromatic ethyl alcohol base. The purpose of this study was to examine the effect of spirits of peppermint on post op nausea in women following a scheduled C-section.

LITERATURE REVIEW

Peppermint (Mentha piperita) is an aromatic herb that is classified as a carminative that can relieve stomach and intestinal disorders and relieve nausea and vomiting (Martindale, 2009; Longe, 2005). Peppermint is also commonly used as a flavoring in food, teas, lotions, and medications. The menthol in Peppermint is thought to calm the stomach through relaxing the stomach muscle and acting as an anesthetic to the stomach wall which decreases or reduces nausea and vomiting (Longe, 2005). Peppermint is also thought to have an emotional calming effect (Cassileth, 1998). Information on Peppermint aromatherapy's physiological effect to decrease nausea and vomiting is primarily historical and anecdotal. Peppermint is generally thought to be a relatively safe aromatic herb for treating GI discomfort (Ebadi, 2002). Since, Peppermint is not an FDA regulated product, scientific studies on pregnant and nursing women appear to be absent. A limited number of controlled studies have evaluated peppermint's effect on nausea using the administration technique of aromatherapy.

Two articles were noted in the literature that examined the use of peppermint oil aromatherapy to treat nausea (Anderson, 2004;Tate, 1997). Anderson (2004) in a randomized controlled trial compared the effect of peppermint oil, isopropyl alcohol, and a placebo on nausea in 33 surgical patients in a post anesthesia care unit. All three therapies were found to be equally effective. The researchers attributed the decrease in nausea levels among the three interventions to the deep breathing that the subjects were instructed to perform during the inhalation of the peppermint oil, isopropyl alcohol, or isotonic saline. Tate (1997) in a study of post operative nausea in 18 gynecological patients compared the effect of no therapy, peppermint essence, and

peppermint oil. Subjective data and the decreased use of antiemetics in the experimental group suggested that the peppermint oil might be useful as a nausea treatment in women following a gynecological procedure.

Inhalation of isopropyl alcohol is believed to disrupt the emetic response by affecting the transmission of nausea sensations along neural pathways (Wang, Hofstadter, and Kain, 1999). Spencer (2004) in a review of the literature found a number of studies that demonstrated the effectiveness of isopropyl alcohol in reducing nausea/vomiting related to surgery (Anderson et al (2004); Langvein & Brown 1997; Merrit, Okyere, & ;Jasinski (2002); Wang et al., 1999; Winston et al., 2003).

A review of the literature revealed a very limited number of studies on the use of peppermint aromatherapy in post operative nausea. No study used peppermint spirits which contains an aromatic ethyl alcohol base. Isopropyl alcohol inhalation has been shown to decrease nausea/vomiting in several studies. However there were no studies that used ethyl alcohol. This experimental study was designed to capture the possible synergistic effect of both peppermint and alcohol which has not been done in previous studies.

RESEARCH QUESTION

Will women who receive spirits of peppermint aromatherapy (experimental group) experience a greater decrease in nausea than women who receive either sterile water (placebo group) or standard antiemetics (control group) post treatment?

Design

A randomized control trial using a pretest-posttest research design was used to examine the treatment effects. The three treatment groups consisted of peppermint spirit (ethyl alcohol

82%, peppermint oil, purified water, peppermint leaf extract), standard anti-emetics, and an inert placebo (sterile water/green food coloring).

Participants and Setting

Women were recruited for this study using a convenience sampling method. Women were eligible to participate in this study if they were scheduled for a C-section, English speaking, at least 18 years of age, a non-smoker, and became nauseated post C-section. Women were invited to participate in this study by phone. Those who agreed to participate were sent an enrollment package and consent form. Women were excluded from the study if they had an allergy to peppermint, had been diagnosed with hyperemesis, had a wound infection, or were receiving magnesium sulfate therapy.

The setting for this study was a women's center of a community hospital located in the metropolitan area of a large city in the southeastern USA. This hospital primarily provides services to an underserved minority community.

Ethical Protections

Approval to conduct this study was obtained from the medical center's Institutional Review Board.

Data Collection and Analysis Processes and Procedures

Recruitment flyers were sent to obstetrician's offices and posted in classrooms used for child birthing classes. The project recruiter telephoned women who were scheduled for a C-section and invited them to participate in the study. Participants were told they would be assigned to one of three treatment groups. An enrollment package and consent form was then

sent to the women. The signed consent forms were brought to the hospital admissions department on the day of the participant's admission to the hospital.

The coordination of three departments was required to assure inclusion of the participants in the study. The admission department performed random assignment, Labor and Delivery verified participation, and the Mother/Baby unit conducted the assessments and implemented the treatment. Staff in the admissions department assigned participants to treatment groups per protocol using a blocked systematic random assignment method. Participants were assigned to treatment groups in blocks of three, one to each group, to foster equal sample sizes in the three groups. A color coded round label designating participants' treatment group assignment was placed on the front of each participant's chart.

Staff in the labor and delivery asked each participant if she were participating in the peppermint study. If the participant said yes, the labor and delivery staff verified that the participant understood the purpose of the study and that the consent form was signed, and on the chart. They also verified the placement of the color sticker, signifying group assignment, on the chart.

When the post C-section participants was transferred to the mother/baby unit the assigned nurse checked to see if the patient was in the study and noted the label color the on the chart, indicating participant's treatment group assignment. Whenever participants became nauseated, the nurse assessed their nausea levels using the nausea scale (baseline), administered the assigned treatments, and reassessed their nausea levels at two and five minutes post treatment. Nurses assessed participants' nausea by asking them to rate it using a 6-point ordinal nausea scale.

Administration of Intervention and Placebo

When a participant in the intervention or placebo group became nauseated the nurse went to the medication room and obtained an administration packet. Each packet consisted of a cotton ball inside of a mini ziplock bag, a syringe containing either the spirits of peppermint or sterile water with green food coloring**.** In the medication room the nurse inserted the contents of the syringe into the cotton ball and closed the zip lock bag. The zip lock bag was taken to the patient's room where they were instructed to hold the open zip lock bag under their nose and inhale deeply three times. The mother did not hold her baby during the inhalations.

Instruments/Measurements

An ordinal nausea scale adapted from one used by Tate (1997) was used to measure the patient's subjective perceptions of nausea and vomiting. The six item scale ranged from 0-6 and consisted of the descriptors of "No Nausea," "Slightly Nauseated," "Moderately Nauseated," "Extremely Nauseated," "About to Vomit," and "Vomited." It took participants less than five seconds to identify their nausea levels. A background form was developed by the researchers and used to collect demographic, alternative therapy use, and pregnancy-related information.

Data Analysis

The data were analyzed using descriptive and inferential statistics. Descriptive statistics, including means, standard deviations, and/or frequencies were used to analyze data from the background form and nausea scale. Inferential statistics in the form of Chi-square analyses were conducted to answer the research question. The overall significance level was set at p=0.05.

Methodological Limitations

The major methodological limitations were the small and unequal sample sizes. There were multiple causes for both the small and the nonequivalent sample sizes. Some patients were not recognized as participants upon admission and were not assigned to a treatment group. Also, not all nurses on the nursing unit implemented the research protocol. Although all the reasons for this were unclear, some nurses felt uncomfortable administering a placebo. A small number of patients that had consented to be in the study refused to participate when they could not be in the peppermint group. Attrition numbers were also affected by patients that delivered early, had an emergency C-section or related complications. Another problem was data could not be used if the nausea scale had not been completed at all 3 collection points. As a result the recruitment goal of 84 participants, 28 per treatment group with complete data collected, was not met.

RESULTS

Thirty-five of the eligible women became nauseated during the study. The mean age for the participants was 30.9, 50% were black, 12.5% Hispanic, and 25% were Caucasian, the majority were married (72%) and had received spinal anesthesia (93.1%). Thirty-six per cent (n=8) reported they were often nauseated during their pregnancy. Most of the participants were between 38-39 weeks gestation (42.3%). Slightly more than half delivered male babies 54.1%). There were 62.6% (n=22) of the patients in the peppermint group, 22.8% (n=8) in the placebo group, and 14.2% (n=5) in the standard therapy group. Twenty of the women did not experience nausea; of the women who reported their baby's gender in this group, 82% (n=17) had been pregnant with boys. All of the 35 women in the study who became nauseated reported

they had used alternative therapies for nausea. The most common alternative therapy reported was deep breathing.

Within Groups Comparisons of Nausea Levels (Research Questions 1-3)

At baseline women in the Peppermint group experienced nausea levels ranging from slight to about to vomit. Almost all of these women, 19, felt that they were either extremely nauseated or about to vomit at this time point. At two minutes more than half of these women, 14, experienced none-slight levels of nausea. Another six were experiencing moderate levels of nausea at this time point, yielding 20/22 experiencing none to slight nausea at this time point. At five minutes more than half of these women, 12, experienced no nausea, and another five experienced slight nausea. This yields 17/22 experiencing none-slight levels of nausea five minutes post treatment.

At baseline all five women in the Control group felt that they were either extremely nauseated or about to vomit. Their nausea was unchanged at two minutes. At five minutes the nausea level of one of the five women had decreased to moderate. None of these women had their nausea reduced to none or slight levels at either two minutes or five minutes post treatment.

At baseline five of the eight women in the Placebo group felt that they were either extremely nauseated or about to vomit. At two minutes post treatment six of these women felt that they were either extremely nauseated or about to vomit and one woman vomited. At five minutes post treatment seven of these eight women continued to experience either extreme nausea or thought that they were about to vomit. Just as occurred with the women in the Control group, none of the women in the Placebo group had their nausea reduced to none or slight levels at either two minutes or five minutes post treatment.

Between Groups Comparisons of Nausea Levels (Research Questions 4-8)

Baseline

Participants in all three treatment groups had similar levels of nausea at baseline. Almost all of the women, 29/35, felt that they were either extremely nauseated or about to vomit. There were no significant differences between women in these 3 groups at the .01* level (χ^2 = 5.829, df=6, p=0.443).

2 minutes

There were significant differences in nausea levels 2 minutes after baseline between women in these 3 groups at the .01* level (χ^2 = 26.697, df=10, *p*=0.003). There were significant differences in the decrease in nausea levels from baseline to 2 minutes between women in these 3 groups at the .01* level (χ^2 = 35.000, df=12, *p*=0.000).

5 minutes

There were significant differences in nausea levels 5 minutes after baseline between women in these 3 groups at the .01* level (χ^2 = 21.869, df=8, *p*=0.005). There were significant differences in the decrease in nausea levels from baseline to 5 minutes between women in these 3 groups at the .01* level (χ^2 = 28.398, df=12, *p*=0.005).

. Participants in all three treatment groups had similar levels of nausea at baseline. When their levels of nausea were measured again, two and five minutes later, their levels of nausea were significantly different. The nausea levels of participants in both the Control and Placebo groups did not decrease much. For example, 0/5 women in the Control group and 0/8 women in the Placebo group experienced either no or slight levels of nausea at 2 and 5 minutes post treatment respectively. The nausea levels of participants in the Peppermint group decreased

significantly. For example, 7/22 and 12/22 women experienced no nausea at 2 minutes and 5 minutes post treatment respectively.

Implications of Findings

The study results support the use of spirits of peppermint aromatherapy as a useful adjunct treatment for post-operative nausea following a C-section. This study was unique because it used a combination of peppermint and alcohol, instead of the previous studies that examined peppermint oil and/or alcohol as separate aromatherapy agents. Limitations of the study were related to the small sample size and methodological issues. This study should be replicated with larger sample sizes at other facilities in male and female patients undergoing a variety of surgical procedures. Using the aromatherapy as the placebo or as a complementary therapy in conjunction with standard therapies may help to improve implementation of the protocol. The findings of the study are useful for nursing because peppermint aromatherapy improved nausea symptoms without causing sedation which can interfere with breast feeding and bonding time with the baby. The lessons learned from the study involve the importance of staff buy-in and involvement with a project. Many staff members did not want to administer a placebo. Patients also in general wanted to be in the intervention group that received peppermint aromatherapy. Involving fewer people and departments in the project and minimizing the number of data collection forms may have been useful in preventing lost information.

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