ORIGINAL ARTICLE

Effectiveness of oral peppermint as treatment of postoperative nausea after gynecological surgery

Teresa Scobee-King[1], Morgan Kuhns[2], Brandy Snowball[1], Kimberly Breault[1], Ashley Peacock[1], Peggy Ward-Smith*[2]

[1] *Nursing Department, North Kansas City Hospital, North Kansas City, MO, United States*
[2] *School of Nursing and Health Studies, University of Missouri-Kansas City, Kansas City, MO, United States*

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ABSTRACT

Objective: The aim of this study was to determine the effectiveness of an oral peppermint lozenge as a treatment for postoperative nausea and vomiting among females undergoing a gynecological operative procedure under general anesthesia.
Methods: Prospective design with consented subjects randomly assigned to either the control or the intervention group. A total of 132 subjects were assigned to the intervention group. Postoperative nausea was assessed upon admission to the post-anesthesia care unit using the Aldrete Scoring System and the Discomfort and Intervention Assessment Measure. The intervention was administered to subjects when the assessment indicated nausea. Data was collected from subjects in the control group for comparison purposes.
Results: Demographically, there were minor variances between the control and intervention groups, none of which were statistically significant. Of the 12 subjects who required the intervention, it successfully treated their postoperative nausea 9 times, with 3 of the subjects requiring the administration of an antiemetic.
Conclusions: Consideration for oral peppermint, as treatment of postoperative nausea, should be explored. The results of this study demonstrate its ability to resolve the experience with no adverse effects noted, and decreasing the need for an antiemetic drug.

Key Words: Postoperative; Nausea; Vomiting; Peppermint lozenge; Gynecological surgery

1. INTRODUCTION

Post-operative nausea and/or vomiting (PONV), while rarely life-threatening, is an unpleasant sensation which impacts the patient's experience and prolongs the length of stay in the post-anesthesia unit. While incidences of post-operative nausea are difficult to capture, data from the American Society of PeriAnesthesia Nurses Strategic Work Team[1] and Smith and colleagues[2] estimate the approximate prevalence at 30% among all patients with an 80% rate among high-risk patients. Research has identified an increase in PONV among females[3] and those undergoing gynecological procedures.[4] The impetus for this study included the knowledge that women are at higher risk for postoperative nausea, gynecological procedures have been associated with higher rates of postoperative nausea, and data documenting an openness toward complementary treatments among women[5] and gynecological surgeons.[6] There is a plethora of research exploring the use of non-pharmacological, or complementary treatments for postoperative nausea.[7] These studies primarily focus on the use of peppermint oil or aromatherapy, rather than an oral intervention. This study explores a new area

*Correspondence: Peggy Ward-Smith; Email: wardsmithp@umkc.edu; Address: Emeriti Faculty, UMKC, 4324 NE Hideaway Drive, Lees Summit, MO 64084, United States.

of research, the effect an oral intervention has as treatment for PONV among females undergoing gynecological surgery under general anesthesia.

Apfei and associates[9] report that the combination of being a woman and undergoing gynecological surgery increases the prevalence of PONV threefold. The use of general anesthesia has been associated with a 34.5% prevalence rate for PONV[9] Smith, Smith, and Smith[2] conclude that PONV increases the time required for care in the post anesthesia care unit (PACU), which increases overall hospital costs. Pharmaceutical treatment for post-operative nausea can be provided using preventative or incidence-specific measures.[10] These include administering an antiemetic at the conclusion of the procedure or upon an initial complaint. Peppermint lozenges, which serve as the intervention in this study, do contain a small amount of sugar, which may elevate blood glucose levels. While prolonged elevated glucose levels have been associated with adverse outcomes, results from a systematic review of the literature[11] determined that blood glucose levels are elevated in conjunction with the surgery itself and should not be attributed to a single dose of any treatment that includes sugar. Therefore, it was not necessary to exclude diabetics from study participation.

The availability of an all-natural ingredient, certified Non-GMO, Vegan (does not contain animal products), Gluten-Free, and Kosher (prepared in adherence with traditional Jewish dietary law) peppermint lozenge decreased cultural reasons for non-participation. Recent use of nicotine and/or cannabis, operationalized as within the previous six months, prevented study participation based on their ability to alter absorption of medications and supplements.[12,13] Guided by the review of the literature, and the effort to add to the state of the science, one study population and one intervention, with blinded randomization to the two treatment arms formed the framework of the study. The aim of this study was to determine the effectiveness of an oral peppermint lozenge in reducing PONV after gynecological surgery under general anesthesia will allow the results of future replication research to be directly compared, building an evidence-based practice intervention.

2. METHODS

2.1 Study design

Data for this two-arm, blinded prospective study were collected from self-consented subjects who met the study inclusion criteria. The consent was available in English and Spanish, reflective of the demographics of the intended study population. All study activities were approved by the Institutional Review Board utilized at the study site (#11938). Results from a power analysis (G*Power) using a two-arm approach (standard care and intervention) indicate that a sample size of 132 subjects in each study arm was necessary to determine a moderate effect size (0.03), with a 0.05 error of probability, and a 0.95 confidence level.

The study intervention was a commercially available Simply Mints^{TM} peppermint lozenge. The contents of this lozenge are (1) cane sugar, (2) peppermint oil, and (3) calcium stearate. They are vegan, non-GMO, and contain nothing artificial. As a lozenge, the intervention dissolves in the oral cavity and does not rely on a working gastro-intestinal system for absorption.

2.2 Study subjects

Study participation was available to patients who met study inclusion criteria and undergoing a planned gynecological procedure, under general anesthesia, at the study site. A study screening tool was used to determine eligibility. This tool verified the age of the patient, documented the surgical procedure and the use of a general anesthetic, and determined eligibility guided by the inclusion/exclusion criteria.

2.2.1 *Exclusion criteria*

Exclusion criteria included a self-reported allergy to peppermint, the use of nicotine and/or cannabis in any format within the previous six months,[12,13] any known extreme reaction to anesthesia, hyperemesis, pregnancy, or under the age of 21 years. If the results of this assessment determined that the patient was not appropriate, the document was placed in the study box, located at the nursing station, and no further study activities were implemented. Potential study participation was presented after all procedure-related consents were completed, ensuring that care would not be compromised regardless of the patient's decision.

2.2.2 *Method of allocation*

Guided by the consent form, the study was explained to all potential subjects by the admitting nurse (RN). Implicit in the study consent are the risks and benefits associated with study participation including an explanation that, despite consenting, the random placement into the control group will result in not receiving the intervention, even if clinically indicated, but that standard care will be provided; their PONV will receive treatment. In addition, an exact description of what study participation entails, the estimated time study participation will require, and what data will be collected as a part of study participation will be stated. Each qualifying patient will then have the option of participating in the study, with the explicit awareness that (1) study participation may be rescinded by them at any point or cancelled by and member of the healthcare team if participation will endanger their health and (2) the care they receive, or any financial responsibility

for this study will not be altered in any way. Each subject received a copy of the consent form, in the language of their preference.

Once consented, the study coordinator located in the post-anesthesia area was notified, the signed consent was handed to this person, and the subject underwent the planned surgical procedure. During the procedure, the study coordinator accessed the unlocked study treatment folder box labeled "Study Data." This box contains sealed envelopes which determine the treatment arm the subject will be in (control or intervention). The study coordinator randomly selected an envelope and placed it in the PACU area where the patient will be transferred once the surgical procedure is completed. This prevents delays in initiating the study activities for those in the intervention study group or standard care for those in the control group. The study packet is opened by the RN who will provide care to the subject while in the PACU. This is when the study sub-group placement is known.

Consented participants placed in the control group will receive standard treatment for PONV. This includes the provision of any anti-emetic medication prescribed by the surgeon and/or anesthesiologist, with routine re-assessments per PACU protocol. Study data for this population is thus limited to their age, results of the initial PONV scores, and length of stay in the PACU.

Once the subject in the intervention group is received in the PACU, the initial assessment includes the identification of any PONV. If/when the subject complains of nausea, the intervention will be initiated. The study protocol contains the caveat such that orals agents, inclusive of peppermint lozenges, are not/will not be administered to patients with a DISAIM nausea score of 3. This adheres to the recommendations of the authors of the tool.[14] An assessment result of 3 or more must be treated with a pharmacological intervention. The study intervention consists of administering an oral peppermint lozenge upon initial complaint of PONV and a re-assessment 5-10 minutes later. Dependent upon assessment results, the scenario may be repeated once, for a total of two interventions. If the second lozenge is ineffective when re-assessed 5-10 minutes later, a pharmacological intervention is provided. Thus, the study subject will not endure PONV for longer than 10-20 because of study participation. If the subject declines repeating the intervention or requires pharmacological treatment for their PONV at the conclusion of the study activities, their data set will be included in the study results, with the acknowledgement that the intervention was halted or ineffective. Study participation ceased 5-10 minutes after the second assessment for PONV, before the subject was transferred from the PACU.

2.2.3 *Data collection and ethics*

Prior to each study participant leaving the PACU area, the study coordinator collected all study materials, place these back in the envelope provided, and place the sealed envelope in the locked study data file labeled "completed." The study data sheets contain no personal health information (PHI) in compliance with IRB mandates. Bi-monthly, all study folders (those that failed to meet study inclusion criteria, those that were in the control group, and those that were in the intervention group) were handed to the study data manager. This person was then responsible for entering the data into a password protected study specific SPSS file. Three study files were created, (1) those that failed to meet study inclusion criteria or opted out of participation, (2) those placed in the control group, and (3) those placed in the intervention group. All study data were hand-entered into the appropriate SOSS file and checked for accuracy. All study data is maintained within the locked private office of the study data manager and will be deleted as dictated by IRB policy.

2.2.4 *Study population*

There were 460 potential subjects identified for study participation. Study enrollment was continuous until the study sample size was reached. This required 16 months. Figure 1 displays the flow chart/decision tree for placement of each potential participant.

2.3 Intervention

2.3.1 *Standard postoperative care*

Each study subject underwent their planned surgical procedure under general anesthesia. Routine operative and perioperative care were provided. Study activities began when the subject was admitted to the PACU and guided by the study group placement and described within the Methods Section.

Clinical assessment – the Aldrete Scoring System

Upon admission to the PACU, standardized care included completion of the Aldrete and DISAIM nausea scales The Aldrete Scoring System[15] originally consisted of 5 clinical indicators which assess physiological recovery from anesthesia. The revised scoring system[16] includes an assessment of consciousness and oxygenation within the 5 clinical indicators. These variables were of importance in this study and used to guide the appropriateness of administering an oral intervention to a subject who demonstrates a deficiency in their level of consciousness or respiratory system. An Aldrete score of 8 or higher demonstrates physiological stability and suitability for discharge from the PACU. The results of this clinical assessment assured that the subject's overall clinical condition was stable, and there were no unintended consequences from the intervention.

Measurement of DIScomfort and Intervention Assessment Measure (DISAIM) and Administration of Peppermint

The DISAIM is a study-specific 4-point nausea assessment tool[14] which combines patient evaluation and nurse observation to determine nausea status while receiving care in the PACU. The tool focuses specifically on nausea and vomiting. Using a 3-point response scale, from 0, which indicates no nausea and not vomiting, to 3, which correlates to severe nausea and recurrent vomiting. The subject describes their present condition, which is visually clinically verified by the RN. As recommended by the authors,[14] oral agents, of any type, were not administered if the DISAIM score was 3. This tool was used to describe the intensity of PONV and to determine the effectiveness of the intervention.

2.4 Statistical analysis

Descriptive statistics, specifically means, ranges, and standard deviations were calculated separately for each study group (control and intervention), then compared. All analyses were performed on SPSS software, version 29.0 (IBM Inc.). Sample Size Results from a power analysis (G*Power) using a two-arm approach (standard care and intervention) indicate that a sample size of 130 individuals in each study arm is necessary to determine a moderate effect size (0.03), with a 0.05 error of probability with a .95 confidence level.

3. RESULTS

3.1 Study population

Of the 460 patients screened for study participation, 109 patients were determined to be ineligible. Ineligibility was due to recent use of nicotine and/or cannabis for 97 patients, 9 reported a known history of hypertension, and 3 due to an allergy to peppermint. There were 84 patients who declined to participant; 15 stated that they had a dislike of peppermint and 4 reported the desire to not receive complementary treatment. No study data were collected from these patients. This resulted in 267 patients being consented. The second group consisted of the 131 subjects who were randomly placed in the control group. The third group consisted of the 132 subjected who were randomly placed in the intervention group. Within this group, there were 4 subjects who were removed from the study prior to being transferred to the PACU due to conflicts between the care required and available staffing within the PACU. Thus, data were collected from 132 subjects in the intervention group (see Figure 1).

Demographically, the age mean, range, and standard deviation for the control and intervention were similar, as were the results from the two nausea assessment tools. The PACU length of stay mean was similar for the control and intervention groups, with an increased time identified among those within the intervention group who received the intervention. Table 1 displays the range, mean, and standard deviation scores, by study group, for each of the outcome variables.

3.2 Control group

Demographically, the control group mirrors the intervention group. Thus, the study populations may be assumed to be homogeneous. Assessment results among subjects placed in the control group achieved a full range of scores for the Aldrete scale and a decreased range of scores for the DISAIM tool. The range of possible scores is from 0 to 4; there were no scores above 3 within this group. Despite the condensed scoring, the mean scores on the DISAIM tool were 0.24 for the control group and 0.26 for the intervention group, indicating that no one in the control group encountered unintended consequences as a result of study participation.

3.3 Intervention group

Of the 132 subjects in the study intervention group, guided by DISAIM scores, 12 required the study intervention. This calculates to a 9.09% prevalence rate, which is below the 19.7% rate reported by Ahmed and Jaffar.[17]

Within the study population that required an intervention, PONV occurred among subjects of all ages, supporting the necessity of routine assessment. While Echeverria-Villalobos and associates[4] note that those undergoing gynecological procedures have a greater risk for PONV, the phenomenon appears to have no age-preference. The use of oral peppermint appears to have some benefit as a treatment for PONV. For the 12 subjects whose postoperative assessment indicated a need for the intervention, PONV was resolved for two after one dose, with seven requiring two doses to resolve their PONV. One subject requested an injectable antiemetic after one dose of the study intervention, and two required an injectable antiemetic after receiving two doses of the study intervention. The clinical progression for these subjects is displayed in Figure 1.

3.4 Study populations comparison

Table 1 displays a comparison of the results among the 12 subjects who received the intervention (a sub-group of the Intervention Group). The results document efficacy of the intervention, for the Aldrete mean scores are higher (2.71 versus 1.88, indicating a higher physiological stability) and the DISAIM mean scores are higher (0.67 versus 0.26, reflective of the need for the intervention). The mean length of stay in the PACU for this subgroup was longer, at 139.83 minutes, when compared with the intervention group as a whole, at 120.51 or the control group, at 123.85 minutes. It may be concluded that PONV does not statistically increase

the PACU length of stay (3.34 minutes), but the intervention did increase the PACU length of stay among the Intervention subjects (19.32 minutes). These data are necessary to avoid application of these results to a different population and to guide replication studies. Evidence-based care must be specific to a population, which provides direct comparison of results.

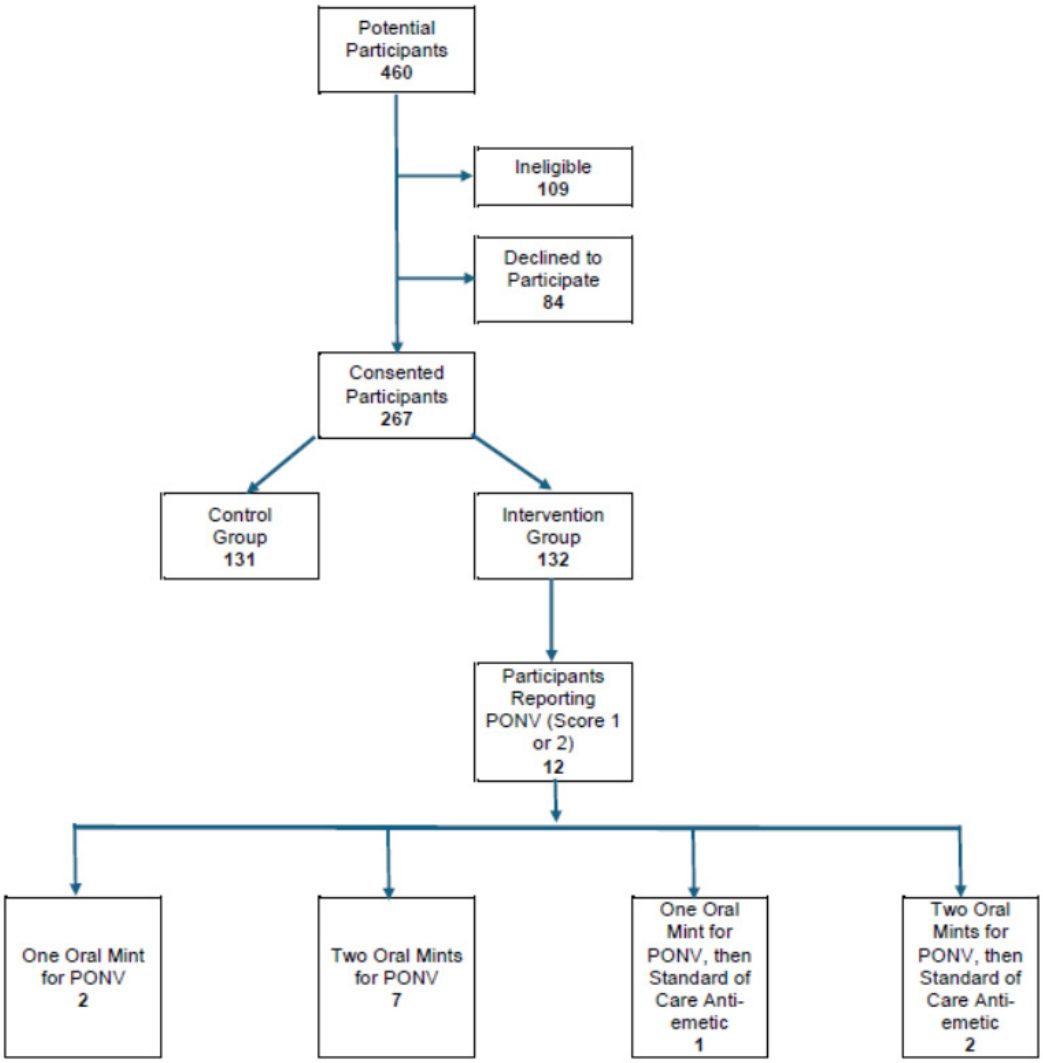

Figure 1. Study enrollment

Table 1. Quantitative results by study group and those that received the intervention

Variable	Control Group (n = 131)	Intervention Group (n = 132)	Those in the Intervention Group that Received the Intervention (n = 12)
Age in years (range, mean ± SD)	21-91, 50.39 ±16.55	21-87, 48.51 ± 14.99	21-81, 46.67 ± 16.00
Aldrete score (range, mean ± SD)	0-10, 7.05 ± 1.94	0-10, 6.78 ± 1.88	0-10, 6.92 ± 2.71
DISAIM score (range, mean ± SD)	0-3, 0.24 ± 0.927	0-3, 0.26 ± 1.15	0-3, 0.67 ± 0.985
Total PACU time (in minutes) (range, mean ± SD)	50-594, 123.85 ± 59.64	7-294, 120.51 ± 39.12	91-199, 139.83 ± 39.28

Note. DISAIM = DIScomfort and Intervention Assessment Measure; PACU = Post anesthesia care unit

4. Discussion

Ethical concerns surrounding collecting data from patients immediately after surgery, when their level of consciousness may be affected, need to be implicit. For this study, the study was explained and consent was secured prior to any medical intervention. Each potential participant had the opportunity to participate, and understood that, even if consent was granted, there was a possibility of being placed in the control group, where the intervention, if necessary, would not be provided, but standard care would be provided. All study activities were reviewed and supported by members of the surgical, anesthesia, and management team at the study site. Each member of the research team completed an on-line research training program, and these certificates of completion were submitted to the IRB with the application. These steps, combined with IRB approval as a research study, addressed all known ethical concerns.

While cases of PONV are infrequent, oral peppermint was capable of relieving PONV in nine instances, or 75% of the time. Mohr and colleagues[18] posit that incorporating holistic patient decisions enhances the healthcare experience. The presence of PONV does increase the length of stay in the PACU.[19] This finding is supported by the results of this study. The PACU length of stay for intervention subjects in this study who experienced PONV required an additional 16 to 19 minutes of care. This increases nursing workload and overall hospital costs. Routine assessment and treatment may mitigate these outcomes. Further research, including replication studies, is recommended to identify patient groups at risk for PONV and who will benefit from an oral agent as treatment.

Data from the Centers for Disease Control and Prevention's National Center for Health Statistics[20] most recent report that almost 4 in 10 American adults have used complementary medicine in the previous 12 months. Rates of complementary medicine have been reported to be highest among young adult women; Barqawi and colleagues[21] concluded that among young women undergoing surgery, the prevalence ranges from 40% to 66%. The use of complementary interventions in healthcare is increasing worldwide. Research which investigates potential interactions between complementary and conventional treatments will ensure that these treatment options are integrated safely. Including research in the implementation of complementary medicine provides the ability to determine the efficacy of any complementary treatment.

Limitations

Data for this study was obtained at one study site and from one health population. While this enhances specificity of the results, it limits generalizability. Further research is needed. People who used nicotine and/or cannabis were excluded from the study population. For this study, that represents 97, or 21% of the potential study subjects. The prevalence of these lifestyle activities indicates that research, specifically for this population, is warranted.

5. Conclusion

Interventions, as treatment for PONV, appears to have popularity among females undergoing gynecological surgery. When indicated, the use of oral peppermint displays some efficacy in treating PONV, but does increase the length of stay in the PACU. The cost of the additional time should be considered prior to implementing this intervention as a routine option for patients. The desire to provide a healthcare plan that is wholistic should include complementary, or non-pharmacological interventions. Funding for these interventions needs to be explored. As a commercially available intervention, peppermint lozenge will not be reimbursable by insurance companies to the hospital. Although the peppermint lozenge used in this study was not expensive, it was a controlled usage scenario. Funding for any complementary therapy, provided in an inpatient in a healthcare facility, must be secured prior to widespread application. Further research using this intervention among different patient populations and varying surgical procedures is warranted.

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Authors Contributions

TSK, BS, and KB conceived the research idea and secured physician and administrative support. AP and PWS developed the study framework and oversaw research approval activities. Study data were collected by TSK, MK, and KB. PWS performed the computations, with AP and TSK verifying the results. All authors contributed to the final manuscript and required edits, which were supervised by AP. Each author has provided approval for the final manuscript to be published.

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Conflicts of Interest Disclosure

The authors have no conflicts of interest to declare.

INFORMED CONSENT

Obtained.

ETHICAL STATEMENT

The study was approved by the Institutional Review Board contracted with the Healthcare Organization. Approval number #13150.

ETHICS APPROVAL

The Publication Ethics Committee of the Sciedu Press. The journal's policies adhere to the Core Practices established by the Committee on Publication Ethics (COPE).

PROVENANCE AND PEER REVIEW

Not commissioned; externally double-blind peer reviewed.

DATA AVAILABILITY STATEMENT

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

DATA SHARING STATEMENT

The data can be requested from the corresponding author.

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