



# The effect of peppermint essential oil on postoperative nausea, vomiting, and pain in rhinoplasty patients: a randomized clinical trial

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**Background:** The present study aims to determine the effect of peppermint essential oil on postoperative nausea, vomiting, and pain in rhinoplasty patients.

**Materials and methods:** This randomized clinical trial included 80 patients aged 18–65 randomly assigned to either the peppermint or the control group. The peppermint group received 20 oral drops of 2% peppermint essence 30 minutes before surgery, while the control group received an equal amount of distilled water. Blinding was maintained for recovery staff and patients. Nausea, vomiting, and pain were assessed at three intervals: upon entry into the recovery room, upon ward admission, and one-hour post-admission, using the Visual Analogue Scale (VAS) and observational methods.

**Results:** The evaluation of pain and vomiting in patients during recovery, upon ward admission, and one-hour post-admission did not reveal a statistically significant difference between the two intervention groups (those administered with peppermint essence and the control group) ( $P > 0.05$ ). However, a statistically significant association was observed between nausea at different measurement times and the groups under study ( $P < 0.001$ ). Specifically, at all three measurement times, the incidence of nausea was significantly lower in patients who were administered mint compared to those in the control group. Nevertheless, intra-group comparisons did not reveal a significant difference in the occurrence of nausea across different measurement times ( $P > 0.05$ ).

**Conclusion:** The application of peppermint essential oil is efficacious in mitigating postoperative nausea following rhinoplasty. Consequently, peppermint can be considered a safe and effective antiemetic intervention in the surgical setting.

**Keywords:** mint, nausea, pain, rhinoplasty, vomiting

## Introduction

Rhinoplasty, despite its inherent complexities, is one of the most frequently performed surgical procedures globally, with a rising trend in the number of candidates opting for such interventions<sup>[1,2]</sup>. Despite the potential complications associated with the procedure, the pursuit of optimal functional and aesthetic outcomes has sustained rhinoplasty's position as one of the predominant cosmetic procedures<sup>[3–5]</sup>. The surgical approach to

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## HIGHLIGHTS

- The evaluation of pain and vomiting in patients during recovery, upon ward admission, and one-hour post-admission did not reveal a statistically significant difference between the two intervention groups (those administered with peppermint essence and the control group) ( $P > 0.05$ ).
- A statistically significant association was observed between nausea at different measurement times and the groups under study ( $P < 0.001$ ).
- At all three measurement times, the incidence of nausea was significantly lower in patients who were administered mint compared to those in the control group.
- Nevertheless, intra-group comparisons did not reveal a significant difference in the occurrence of nausea across different measurement times ( $P > 0.05$ ).
- The application of peppermint essential oil is efficacious in mitigating postoperative nausea following rhinoplasty. Consequently, peppermint can be considered a safe and effective antiemetic intervention in the surgical setting.

rhinoplasty can be either open or closed, with the open method gaining significant popularity in recent decades<sup>[6]</sup>. In terms of the prevalence of cosmetic procedures, particularly rhinoplasty, Iran appears to occupy a leading position worldwide when compared to its total population, although precise statistics regarding these procedures remain elusive<sup>[7]</sup>.

Nausea and vomiting represent common, and at times distressing, postoperative side effects that patients may experience following discharge<sup>[8,9]</sup>. These side effects pose inconvenience to both the medical practitioner and the patient, often resulting in an extended recovery phase<sup>[10]</sup>. Postoperative nausea and vomiting are frequent complications associated with anesthesia, with an overall incidence reported to be 30%, and up to 70% in high-risk patients<sup>[11]</sup>. Despite advancements in anesthetic and antiemetic medications, postoperative nausea and vomiting persists as a discomforting issue for patients. It is linked with delayed hospital discharge, increased utilization of resources and equipment, diminished patient satisfaction, dehydration, and an elevated risk of aspiration<sup>[11]</sup>.

Pain, a protective physiological response to harmful stimuli, is an unpleasant sensation often triggered by intense or damaging stimuli. It serves as a crucial symptom and is significantly associated with an individual's health and overall functionality<sup>[12]</sup>. Similar to nausea and vomiting, pain is one of the most prevalent postoperative side effects; research indicates that approximately 80% of patients experience acute pain following surgery<sup>[13]</sup>. The incidence of pain among rhinoplasty patients is estimated to be between 20% and 40%<sup>[14]</sup>. Post-rhinoplasty pain can be attributed to the mucosal incision, manipulations on the nasal cartilaginous blade, and osteotomy of the nasal blade and floor, as well as the nasal packing inserted post-procedure<sup>[15]</sup>. Alleviating postoperative pain can expedite the patient's recovery process and facilitate an earlier return to physical activity<sup>[16]</sup>.

Mint, a member of the mint family, is an edible plant. Peppermint has been found to reduce calcium flow via its impact on neuronal calcium channels, a mechanism that contributes to pain reduction<sup>[17]</sup>. The utilization of medicinal plants in traditional and complementary medicine has seen substantial growth in recent years, supplementing conventional medical practices<sup>[18]</sup>. Presently, there is an expanding public interest in the application of complementary and alternative medicine treatment methods<sup>[19]</sup>. While the development and discovery of new drugs have advanced patient care, these methods are accompanied by several complications such as intestinal paralysis, intestinal obstruction, nausea, and vomiting. Contemporary strategies to control nausea and vomiting often draw from traditional and complementary medicine, which offers numerous advantages including diversity, flexibility, accessibility, cost-effectiveness, global availability, high acceptance among the majority of individuals in developing countries, reduced technological dependence, and growing economic significance<sup>[20]</sup>. The mint plant, with over four thousand species across two hundred genera, has been utilized for medicinal and culinary purposes for two millennia<sup>[21]</sup>. Peppermint essential oil is highly regarded for its beneficial effects on the digestive system<sup>[22]</sup>. Using peppermint essential oil as an alternative treatment can avoid the adverse reactions typically associated with most antiemetics<sup>[23]</sup>. It is effective in relieving postoperative nausea and vomiting, thereby improving patient satisfaction and empowerment<sup>[24,25]</sup>. The oil is well-documented for its anti-spasmodic, analgesic, anti-inflammatory, and antioxidant properties<sup>[26]</sup>. The analgesic effects of peppermint are primarily due to its main components, such as carone, limonene, and menthol<sup>[27]</sup>.

Given the significance of postoperative complications, particularly nausea, vomiting, and pain, and considering the studies that have separately examined the use of aromatherapy in complementary medicine for one of these indicators, there is a dearth of research on the application of essential oils, medicinal plants,

or herbal supplements, specifically peppermint, for the treatment of nausea and vomiting. No study has been identified that concurrently investigates the impact of peppermint essence on nausea, vomiting, and pain in patients who have undergone rhinoplasty. In light of the importance of these variables, this study was undertaken to explore the influence of peppermint essential oil on postoperative nausea, vomiting, and pain in rhinoplasty patients.

## Methods

### Study design

The present investigation is a randomized clinical trial executed from 30 April 2023 to 30 January 2024. The cohort for this research comprised all individuals who were prospective candidates for septoplasty and rhinoplasty procedures, to be performed under general anesthesia, within the geographical confines of Rasht, Iran. The study adhered to CONSORT criteria<sup>[28]</sup> (Supplementary File 1, available at: <http://links.lww.com/MS9/A733>).

### Ethics consideration

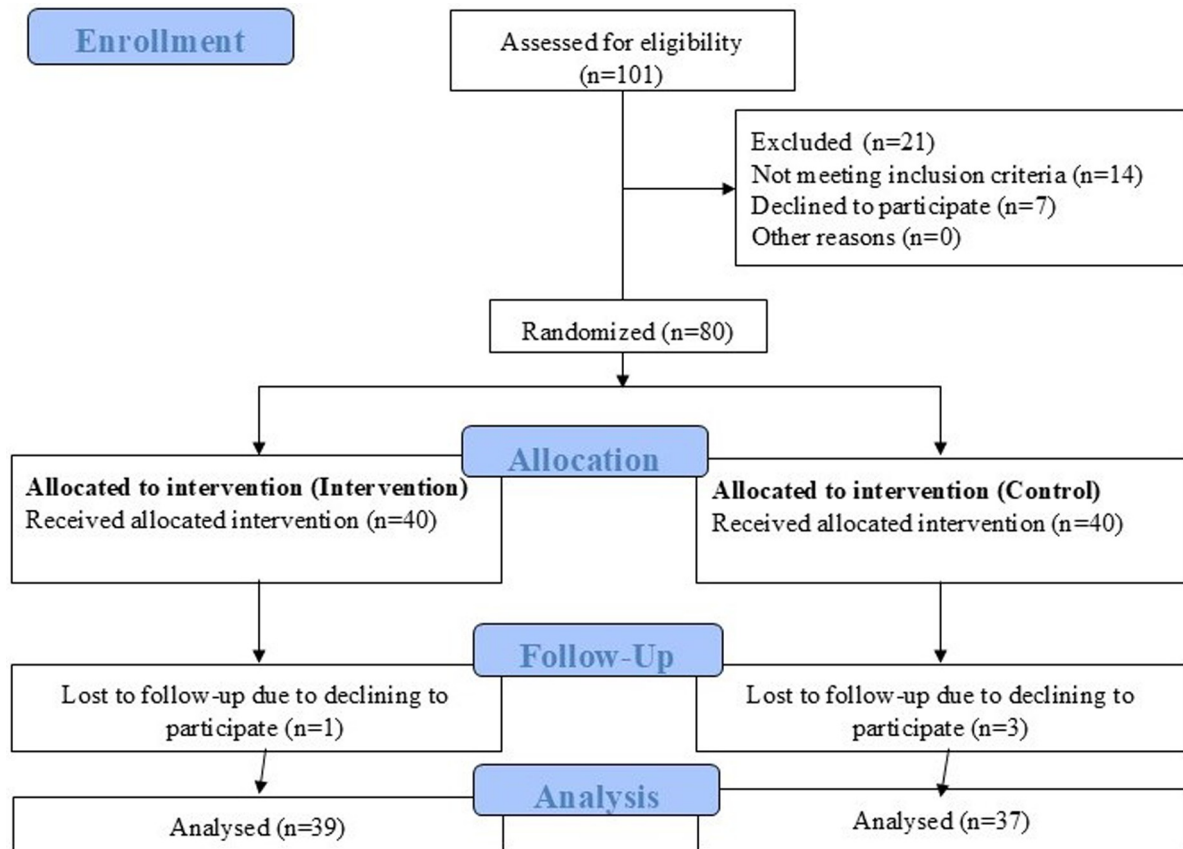
Ethical approval for this investigation was secured from the Ethics Committee of Guilan University of Medical Sciences. The study was also registered in the Iranian Clinical Trials Registration Center. All participants furnished informed consent after a thorough explanation of the study's aims. It was explicitly communicated to them that they possessed the right to withdraw their participation at any point, should they choose to do so.

### Participants

Patients deemed eligible for the study were continually referred and, upon obtaining informed written consent, were randomly assigned to one of two intervention groups: one with peppermint essence and a control group. The allocation sequence was established using a block method with a volume of 4. An online software tool was employed for the random allocation of samples across the two intervention groups and the control group. Codes "A" for the peppermint essence group and "B" for the control group were enclosed within envelopes. In this approach, a total of 20 envelopes, each marked with a number from 1 to 20 on the exterior, were opened at the time of the patient's visit. Based on the code contained within the envelope as determined by the software, the sequence of patient visits and the corresponding code was established, thereby assigning the patients to one of the two groups (Fig. 1). The prerequisites for participation in the study encompassed an age range of 18 to 65 years, absence of olfactory disorders, elective rhinoplasty, and septorhinoplasty procedures, no known allergies to mint, non-smoking and non-sedative status, patients classified under ASA class I or II, and no breastfeeding individuals. Criteria for exclusion from the study included non-adherence to the anesthesia protocol, administration of anti-emetic medication before or during anesthesia, and a lack of willingness to cooperate.

### Sample size

The requisite sample size was ascertained by the study's findings conducted by Maghami *et al.*<sup>[23]</sup> with the nausea severity score equal to 4.61 (SD = 2.85) and 2.43 (SD = 2.84) in the control and intervention groups, respectively, in the first four hours after the



**Figure 1.** Flow diagram of participants.

operation. This determination factored in a test power of 90%, a type 1 error of 5%, and an anticipated attrition rate of 10%. Consequently, the sample volume for each group was consistently established at 40 eligible individuals.

### Intervention

In this investigation, patient evaluations were conducted at three distinct time intervals. The initial assessment occurred upon the patient's entry into the recovery room, where the patient researcher examined the patient for symptoms of nausea, vomiting, and pain. Subsequent evaluations were performed in the ward, one-hour post-admission, by nurses who were blinded to the study groups. At this stage, the patient's nausea, vomiting, and pain were reassessed.

Data collection was facilitated through a demographic information questionnaire, and vomiting was investigated via direct observation and evaluation of nausea based on nursing reports and patient testimonials. Pain was assessed using the Visual Analogue Scale (VAS). Patients in the experimental group were administered 20 oral drops of 2% peppermint essence, produced by Alice Company, half an hour before surgery<sup>[29]</sup>. The control group received 20 drops of distilled water, which bore a similar color to the original drug, to maintain blinding as much as possible. Although we tried to keep the patients blind to the

intervention, however, the odor of the essential oil might have interfered with the blindness of the patients. However, the statistician how performed the data analysis was blind to the groups and only knew the groups as group A or B. No placebo intervention was applied due to characteristic odor of peppermint oil. Therefore, blinding of researchers and patients to study groups could not be achieved.

Post-surgery, patients were transferred to recovery by the surgical and anesthesia staff, where monitoring and recovery care were provided routinely. All personnel in the recovery department were kept unaware of the patients' group assignments. Information about vomiting was recorded through observation and questionnaire responses from patients (yes/no). The severity of nausea was classified according to nursing reports and patient testimonials into mild (nausea without treatment), moderate (nausea requiring treatment), and severe (nausea resistant to treatment)<sup>[30]</sup>.

The induction of anesthesia was achieved using Midazolam (1 mg), Fentanyl (2–3 µg/kg), Lidocaine (1 mg/kg), Propofol (2 mg/kg), and Atracurium (0.5 mg/kg). Maintenance of anesthesia was ensured with Propofol (50–150 µg/kg) and Remifentanyl (0.1–0.5 µg/kg). After the operation, reversal was induced by administering Neostigmine (0.04 mg/kg) and Atropine (0.02 mg/kg). Pain levels were measured using the VAS scale, which ranges from 0 (no pain) to 10 (maximum pain). If the VAS score

exceeded 3 and the patient experienced severe nausea or vomiting, pharmacological therapy was initiated via Pethidine (0.04 mg/IV).

### Statistical analysis

The analysis of data was executed using the SPSS software (version 16.0, SPSS Inc., Chicago, IL, USA). Descriptive statistics were presented, including means (Standard Deviation) for continuous variables and frequencies (percentages) for categorical variables. The comparative analysis of data about the individual factors of the two groups was performed using the chi-square test, t-test, Mann–Whitney test, and Fisher’s exact test. Analyses using Fisher’s and Mann–Whitney tests were conducted to verify the scores of pain, nausea, and vomiting in patients across the two intervention groups (peppermint essence and control). Additionally, intra-group comparisons were carried out using Friedman’s test. A significance level of less than 0.05 was considered for all the tests.

## Results

### Participants

As delineated in Table 1, a total of 80 patients were examined, of which 4 patients were excluded from the study due to declining to participate. Among these patients, 39 were allocated to the intervention group, while 37 were in the control group. A significant proportion of the participants, precisely 55.26%, were aged above 30 years. The study population was predominantly female, accounting for 84.21%. Half of the participants were single, and 52.63% were not engaged in any form of employment. Educational attainment varied among the participants, with 40.79% holding a diploma. A vast majority, 98.68%, reported no addiction. Other individuals were addicted to marijuana. Regarding the American Society of Anesthesiologists (ASA) physical status classification, 61.84% of the patients were classified as ASA grade one. The participants’ health indicators were also recorded, with the average systolic pressure being 107.28 (SD = 11.09), the average diastolic pressure being 65.50 (SD = 10.59), and the mean arterial blood oxygen saturation being 98.24% (SD = 1.33). Additionally, apart from the mean diastolic pressure, which exhibited a statistically significant difference ( $P = 0.049$ ), there were no significant disparities observed in the other demographic and clinical variables between the intervention and control groups ( $P > 0.05$ ).

### Pain, vomiting, and nausea in rhinoplasty patients

As depicted in Table 2, the pain intensity experienced during recovery, upon ward admission, and one-hour post-admission did not significantly differ between the intervention and control groups ( $P > 0.05$ ). However, within the intervention group, a significant variation in pain intensity was observed across the three time periods ( $P = 0.046$ ).

Regarding the incidence of vomiting, no significant difference was found during recovery, upon ward entry, and one hour after entry between the intervention and control groups ( $P > 0.05$ ). Similarly, no significant difference was noted within the control and intervention groups across the three time periods ( $P > 0.05$ ).

Additionally, the results demonstrated that at all three measurement times, nausea was significantly lower in the mint group compared to the placebo group ( $P < 0.001$ ). However, intra-group comparisons did not reveal a significant difference in the

**Table 1**

**Individual and clinical characteristics of the participants (N = 76)**

		Groups		
	Total (N = 76)	Control (N = 37)	Intervention (N = 39)	P value
Age				
< 30	42 (55.26)	19 (51.35)	23 (58.97)	0.504 <sup>a</sup>
≥ 30	34 (44.74)	18 (48.65)	16 (41.03)	
Sex				
Male	12 (15.79)	7 (18.92)	5 (12.82)	0.466 <sup>a</sup>
Female	64 (84.21)	30 (81.08)	34 (87.18)	
Marital status				
Single	38 (50.00)	19 (51.35)	19 (48.72)	0.730 <sup>b</sup>
Married	37 (48.68)	17 (45.95)	20 (51.28)	
Divorced	1 (1.32)	1 (2.70)	0 (0)	
Job				
Unemployed	40 (52.63)	18 (48.65)	22 (56.41)	0.664 <sup>b</sup>
Employed	31 (40.79)	17 (45.95)	14 (35.90)	
Student	5 (6.58)	1 (2.70)	3 (7.69)	
Education				
High school	18 (23.68)	9 (24.32)	9 (23.08)	0.128 <sup>b</sup>
Diploma	31 (40.79)	11 (29.37)	20 (51.28)	
Bachelor's degree	25 (32.89)	15 (40.54)	10 (25.64)	
Master and above	2 (2.63)	2 (5.41)	0 (0)	
Addiction				
Yes	1 (1.32)	1 (2.70)	0 (0)	0.487 <sup>b</sup>
No	75 (98.68)	36 (97.30)	39 (100)	
History of surgery				
Yes	37 (48.68)	19 (51.35)	18 (46.15)	0.650 <sup>a</sup>
No	39 (51.32)	18 (48.65)	21 (53.85)	
Clinical characteristics in patients				
Clinical characteristics in family				
ASA				
1	47 (61.84)	22 (59.46)	25 (64.10)	0.667 <sup>a</sup>
2	29 (38.16)	15 (40.54)	14 (35.90)	
Systolic BP in recovery	107.28 (SD = 11.09)	105.54 (SD = 11.18)	108.92 (SD = 10.88)	0.185 <sup>c</sup>
Diastolic BP in recovery	65.50 (SD = 10.59)	63.05 (SD = 11.00)	67.82 (SD = 9.75)	0.049 <sup>c</sup>
Arterial blood oxygen saturation in recovery	98.24 (SD = 1.33)	98.30 (SD = 1.29)	98.18 (SD = 1.37)	0.453 <sup>d</sup>

Values are given as a number (percentage) for categorical variables and mean (SD) for continuous variables.

<sup>a</sup>P value was obtained with a chi-square test.

<sup>b</sup>P value was obtained with a Fisher exact test.

<sup>c</sup>P value was obtained with an independent t-test.

<sup>d</sup>P value was obtained with a Mann–Whitney U test.

occurrence of nausea across the different measurement times ( $P > 0.05$ ).

## Discussion

Peppermint essential oil has been widely studied for its therapeutic properties, particularly in reducing symptoms such as nausea, vomiting, and pain. One of the primary mechanisms of action of peppermint oil is its antispasmodic effect on smooth muscles. Menthol, the major component of peppermint oil, acts on calcium channels in smooth muscle cells<sup>[31]</sup>. Nausea and vomiting, particularly in postoperative settings, are frequently

**Table 2**  
**Pain, vomiting, and nausea in the intervention and control groups (n = 76)**

	Control (n = 37)	Intervention (n = 39)	P value
Pain			
In recovery	1.62 (SD = 1.59)	1.41 (SD = 1.45)	0.603 <sup>a</sup>
Upon entering the ward	1.76 (SD = 1.12)	1.97 (SD = 1.80)	0.792 <sup>a</sup>
One hour after entering the ward	1.73 (SD = 1.04)	1.74 (SD = 1.41)	0.572 <sup>a</sup>
P value	0.623 <sup>b</sup>	0.046 <sup>b</sup>	
Vomiting			
In recovery			
Yes	0 (0)	1 (2.56)	0.999 <sup>c</sup>
No	37 (100)	38 (97.44)	
Upon entering the ward			
Yes	1 (2.70)	0 (0)	0.487 <sup>c</sup>
No	36 (97.30)	36 (100)	
One hour after entering the ward			
Yes	2 (5.41)	0 (0)	0.234 <sup>c</sup>
No	35 (94.59)	39 (100)	
P value	0.368 <sup>b</sup>	0.368 <sup>b</sup>	
Nausea			
In recovery			
No	12 (32.43)	32 (82.05)	<0.001 <sup>c</sup>
Mild	25 (67.57)	6 (15.36)	
Moderate	0 (0)	1 (2.56)	
Upon entering the ward			
No	10 (27.03)	32 (82.05)	<0.001 <sup>c</sup>
Mild	25 (67.57)	7 (17.95)	
Moderate	2 (5.41)	0 (0)	
One hour after entering the ward			
No	13 (35.14)	31 (79.49)	<0.001 <sup>c</sup>
Mild	23 (62.16)	8 (20.51)	
Moderate	1 (2.70)	0 (0)	
P value	0.407 <sup>b</sup>	0.607 <sup>b</sup>	

Values are given as a mean (SD) for continuous variables.

<sup>a</sup>P value was obtained with an independent t-test.

<sup>b</sup>P value was obtained with a Friedman test.

<sup>c</sup>P value was obtained with a Fisher exact test.

mediated through serotonin (5-hydroxytryptamine or 5-HT) receptors, particularly the 5-HT<sub>3</sub> subtype. Peppermint oil has shown potential as a natural antiemetic by acting as a 5-HT<sub>3</sub> receptor antagonist, which reduces the vomiting reflex<sup>[32,33]</sup>. Menthol also activates transient receptor potential melastatin 8 (TRPM8), a cold receptor channel that triggers a cooling sensation and mild analgesia. TRPM8 activation helps reduce the sensation of pain by modulating pain pathways in both the peripheral and central nervous systems<sup>[34]</sup>.

The comprehensive results of this study indicate that the mean pain scores of patients in the recovery room, upon ward admission, and one-hour post-admission did not significantly differ between the two groups. However, intra-group comparisons within the mint group demonstrated a statistically significant variation in average pain scores at different time points, although this difference was not clinically substantial. Specifically, the mean pain score increased upon ward admission but decreased one hour later, returning to levels similar to those observed in the recovery room. Additionally, there was no

statistically significant association between the incidence of vomiting across the three measurement points (recovery room, ward admission, and one-hour post-admission) and the treatment groups. Intra-group comparisons similarly failed to identify any significant associations.

In contrast, the severity of nausea at different time points exhibited a statistically significant association with the treatment groups. At all three measurement points, nausea was significantly less prevalent among patients who received mint than those in the placebo group. However, intra-group comparisons did not reveal a significant difference in the occurrence of nausea between different measurement times.

Several studies support the effectiveness of these interventions in reducing nausea across diverse patient populations. For example, Briggs *et al* reported similar findings in their research, "Inhalation of Peppermint Oil on Postoperative Nausea in Heart Surgery Patients"<sup>[24]</sup>. Additionally, Ahmadi *et al* demonstrated that aromatherapy with mint helped reduce nausea in patients<sup>[35]</sup>. A study by Ertürk *et al* investigating the effects of peppermint essential oil on nausea, vomiting, and belching in cancer patients undergoing chemotherapy found that applying a drop of peppermint oil on the philtrum three times a day for five days post-chemotherapy reduced the frequency of nausea, vomiting, and belching<sup>[36]</sup>. These findings align with the present study regarding reducing nausea, although the current study did not observe an effect on vomiting.

Similarly, Maghami *et al* found that inhalation of peppermint essential oil reduced nausea and vomiting following open-heart surgery<sup>[23]</sup>. While these results are consistent with the present study regarding nausea reduction, the effect on vomiting was not observed in this research. Most studies that align with the present findings underscore the impact of peppermint essential oil on nausea, suggesting its potential role in further investigations and nursing care as a complementary therapeutic option.

Kiani *et al*, in their study evaluating the effect of super mint (mint essence) on the satisfaction of both patients and the colonoscopy team during pediatric colonoscopy, found that super mint drops significantly reduced pain during the procedure<sup>[17]</sup>. Contrary to the present findings, their study supported the hypothesis that peppermint essential oil is effective in lowering post-cesarean section pain<sup>[12]</sup>. Furthermore, Shavakhi *et al* showed that peppermint capsules effectively reduced pain during colonoscopy<sup>[37]</sup>, a finding inconsistent with the present study.

The discrepancies observed between these studies and the current research can be attributed to several factors, including differences in sample populations, the intensity of the medical procedures involved, the dosage and concentration of the essential oil used, and variations in intervention methodologies.

### Limitations

A notable constraint of this study pertains to the aromatic characteristic of peppermint essential oil, which posed challenges in maintaining blinding conditions for the investigator. To mitigate this issue, a variety of strategies were employed to preserve the integrity of the study's blinding process. First, concerted efforts were made to prevent participants from recognizing their own group allocation. Patients were not informed of the specific intervention being tested or the treatment received by others in the study. Furthermore, measures were taken to reduce the chance of participants encountering each other during the

study period, such as staggering the timing of sample collection. This prevented cross-contamination of information among patients and minimized the risk of participants discussing their experiences, which could inadvertently reveal details about their group assignment. In addition to these precautions, operating room personnel were involved in the sampling and administration of the essential oil. Their participation helped to further maintain blinding by isolating the patients from the investigators conducting the study. Operating room staff were trained to ensure that they followed a standardized procedure when administering the treatment or placebo, further ensuring that no identifying cues were given to the participants. While the aromatic nature of peppermint essential oil presented a significant constraint in maintaining full blinding, these proactive measures helped minimize the potential for unintentional bias, thus preserving the scientific validity of the study's results.

### **Clinical implementation**

Consequently, it is proposed that healthcare professionals, including nurses, consider the application of peppermint essential oil in patients undergoing surgeries similar to those examined in this study. The aromatic nature of peppermint essential oil, coupled with its demonstrated efficacy in alleviating nausea, makes it a viable non-pharmacological intervention. Its ease of administration, cost-effectiveness, and non-invasive nature further enhance its suitability. However, it is crucial to ensure that the use of peppermint essential oil does not contravene any existing clinical guidelines or individual patient contraindications.

### **Recommendations for future research**

In light of the study's findings, it is recommended to undertake more comprehensive research on the oral administration of peppermint essential oil. Future studies should consider a larger sample size and explore the effects of varying the concentration of peppermint essential oil. This could provide more robust evidence on the efficacy and optimal dosage of peppermint essential oil for managing postoperative nausea.

### **Conclusion**

In summary, the findings of this research underscore the beneficial impact of peppermint essential oil on patient nausea. Given the positive effects of peppermint essential oil, its use is recommended for patients who align with the criteria of the research units in this study. It should be regarded as a non-invasive, easily implementable, cost-effective, and efficacious intervention for nausea.

### **Ethical approval**

The ethics committee of Guilan University of Medical Sciences has given its approval to this study (IR.GUMS.REC.1402.033; available at: <https://ethics.research.ac.ir/PortalProposalListEn.php?code=IR.GUMS.REC.1402.033&title=&name=&stat=&isAll=>).

Also, this study was registered in the Iranian Registry of Clinical Trials Database (IRCT20210927052608N2). The participants gave informed consent after being informed of the current study's goals. It was made clear to participants that

they could leave the study at any time (available at: <https://irct.behdasht.gov.ir/trial/69793>).

### **Consent**

Written informed consent was obtained from the patient for publication and any accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal on request.

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### **Author's contribution**

All the authors contributed to the study concept and design, data acquisition, data interpretation, drafting the manuscript, and revision of the manuscript, and approved the final version of the manuscript.

### **Conflicts of interest disclosure**

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

### **Research registration unique identifying number (UIN)**

None.

### **Guarantor**

Dr Soudabeh Haddadi.

### **Provenance and peer review**

Not commissioned, externally peer-reviewed.

### **Data availability statement**

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

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