

Effects of Ginger Extract plus Ondansetron on Postoperative Nausea and Vomiting in Patients Undergoing Cesarean Section with Spinal Anesthesia Supplemented by Intrathecal Morphine: A Randomized Controlled Trial

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ABSTRACT

Objective: To evaluate the efficacy of oral ginger extract plus ondansetron in preventing postoperative nausea and vomiting (PONV) induced by intrathecal morphine (ITM) in parturients undergoing cesarean section.

Materials and Methods: This double-blind, randomized, placebo-controlled trial included 40 parturients scheduled for elective cesarean under spinal anesthesia with ITM who were randomized to receive either ginger extract capsules (1,000 mg per dose, cumulative dose 3,000 mg) or placebo capsules at three time points. The primary outcome was PONV severity assessed using a visual analog scale (VAS) at 0, 6, 12, and 24 hours postoperatively. Secondary outcomes included PONV incidence, rescue antiemetic use, and adverse events.

Results: The ginger group showed a non-significant trend toward reduced PONV severity at 12 and 24 hours postoperatively and slightly reduced antiemetic use (50% vs. 55%, $p=0.515$). No statistically significant differences were observed in vomiting incidence, total vomiting episodes, ondansetron consumption, or adverse effects between groups.

Conclusion: Oral ginger extract did not provide additional benefit in reducing ITM-induced nausea and vomiting beyond standard ondansetron treatment. Although the severity of PONV and antiemetic use were modestly lower in the ginger group, the differences were not statistically significant. Further studies with larger sample sizes are warranted.

Keywords: Cesarean section; Ginger; Intrathecal morphine; Postoperative nausea and vomiting; Spinal anesthesia

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Intrathecal morphine (ITM) is widely used for neuraxial analgesia in cesarean delivery, providing effective and prolonged postoperative pain control with minimal sedation. However, ITM use is often associated with dose-dependent adverse effects, particularly postoperative nausea and vomiting (PONV), which affect 60% to 67% of patients receiving

ITM^(1,2). Uncontrolled PONV may lead to dehydration, electrolyte disturbances, pulmonary aspiration, surgical wound dehiscence, and prolonged hospital stay⁽³⁾. The pathophysiology of PONV is multifactorial, involving central and peripheral mechanisms such as stimulation of the chemoreceptor trigger zone (CTZ), vagal inputs from the gastrointestinal tract, vestibular system activation, and higher cortical centers^(4,5). These signals converge on the medullary vomiting center, modulated by various neurotransmitter receptors,

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What is already known about this topic?

Ginger has shown anti-nausea effects in pregnancy, chemotherapy, and postoperative settings, with good safety.

What does this study add?

This study evaluates the use of ginger extract plus ondansetron for preventing nausea and vomiting after cesarean section under spinal anesthesia with ITM. Although not statistically significant, the findings suggest that ginger may be a safe and well-tolerated adjunct in reducing postoperative nausea and rescue antiemetic use. It supports the potential role of ginger as part of a multimodal antiemetic strategy in obstetric anesthesia.

including dopaminergic (D_2), serotonergic ($5-HT_3$), and histaminergic (H_1) receptors⁽⁶⁾. Current pharmacologic treatments for PONV, such as metoclopramide and ondansetron, target these pathways but are associated with side effects, including sedation, dry mouth, dizziness, and extrapyramidal symptoms^(2,4-6).

Ginger (*Zingiber officinale*), a traditional remedy, has shown potential as an antiemetic in pregnancy, chemotherapy, and postoperative settings^(5,7-19). Its mechanisms are thought to involve $5-HT_3$ receptor antagonism and modulation of gastrointestinal motility⁽⁸⁾. Ginger is classified as GRAS by the FDA for up to 4 grams daily, although the optimal dose for PONV prevention remains unclear⁽⁷⁾. Previous studies have demonstrated that ginger extract at a dose of 1,000 mg effectively reduces PONV with minimal side effects⁽¹⁻³⁾.

The present study aims to evaluate the efficacy of oral ginger extract plus ondansetron in preventing PONV induced by ITM in parturients undergoing cesarean section under spinal anesthesia. The primary outcome is the severity of PONV, with secondary outcomes including the incidence of nausea, vomiting, need for rescue antiemetics, and adverse effects.

MATERIAL AND METHODS

The present study was approved by the Ethics Committee of Srinakharinwirot University on July 6, 2022 (SWUEC-038/2565F) and registered at the Thai Clinical Trials Registry, TCTR20250319003. The study protocol was approved by the Institutional Ethics Committee before participant enrollment, and all participants provided written informed consent. Trial registration in the Thai Clinical Trials Registry was completed retrospectively after study completion because of an administrative oversight. No changes were made to the study protocol, primary outcome, or statistical analysis plan after recruitment had commenced.

The present study included parturients aged 18-45 years with American Society of Anesthesiologists (ASA) physical status II-III undergoing elective cesarean section under spinal anesthesia with ITM at HRH Princess Maha Chakri Sirindhorn Medical Center, Srinakharinwirot University, between October 2022 and May 2023. Patients were excluded if they have 1) allergy to ginger, ondansetron, morphine, or bupivacaine, 2) pre-pregnancy body mass index of more than 35 kg/m², 3) history of PONV, motion sickness disease, chronic nausea and vomiting, vestibular diseases, 4) antiemetic or prokinetic drugs usage during 24 hours before surgery, 5) history of

smoking, alcohol dependence, or illicit drug abuse, 6) use of anticoagulant drugs or aspirin, 7) History of cardiac, gastrointestinal, hepato-pancreato-biliary surgery, 8) Any contraindication to spinal anesthesia e.g., coagulopathy, and or infection at the suspected injection site, 9) Patients with inadequate spinal anesthesia necessitating conversion to general anesthesia, 10) Patients who receiving fentanyl, midazolam, ketamine, Methylergonovine maleate during perioperative period were also excluded.

The present study was a prospective randomized double-blind placebo-controlled clinical trial.

Following approval from the institutional review committee and written informed consent, 40 healthy parturients (ASA II-III) with gestation >37 weeks, undergoing elective cesarean section with spinal anesthesia, were enrolled from October 2022 to May 2023. Each participant received 0.2 mg ITM mixed with 9 to 11 mg of 0.5% hyperbaric bupivacaine. Participants were randomly assigned to two groups (20 patients each). Group G received ginger extract capsules containing 500 mg per capsule, while Group P received identical placebo capsules. Participants in both groups took two capsules per administration (equivalent to 1,000 mg of ginger extract per dose in Group G) at three predefined time points: 10:00 p.m. on the night before surgery, 2-6 hours postoperatively, and 6-10 hours postoperatively. Postoperative doses were administered within predefined time windows according to the participants' postoperative recovery status and clinical readiness for oral intake. The cumulative total dose of ginger extract administered was 3,000 mg.

Preoperative assessments were conducted to screen for heartburn, belching, abdominal discomfort, motion sickness, previous PONV, and any history of antiemetic treatment or prior anesthesia exposure. Participants were also questioned about drug allergies, previous surgeries, and any ongoing medications. A general physical examination, systemic examinations, and airway assessments were performed.

Participants fasted for 8 hours prior to surgery. Standard monitoring equipment, including an electrocardiogram (ECG), pulse oximetry, non-invasive blood pressure, and capnography, was attached, and baseline parameters were recorded. An intravenous preload of 10 mL/kg of balanced salt solution was administered.

Spinal anesthesia was performed in the lateral decubitus position using a 27-gauge Quincke spinal needle at the L3/4 or L4/5 intervertebral space. After confirming free-flow of cerebrospinal fluid (CSF), a

mixture of 1.8-2.2 mL of 0.5% hyperbaric bupivacaine and 0.2 mg preservative-free morphine was injected intrathecally by an anesthetist not involved in the study. The parturient was positioned in a left lateral tilt to prevent aortocaval compression and hypotension. Continuous monitoring of oxygen saturation, ECG, and non-invasive blood pressure was performed. Measurements were recorded every minute during the first 10 minutes post-injection, then every 5 minutes thereafter. If hypotension (a systolic blood pressure <100 mmHg or >20% drop from baseline) occurred, ephedrine (6-9 mg) or norepinephrine (5-10 mcg) was administered. If bradycardia (heart rate <50 bpm) occurred, atropine (0.6 mg) was given. Surgery was initiated following identification of the anesthetized segment using a pinprick test. After delivery, all participants received ondansetron 8 mg and oxytocin 10-20 IU intravenously.

The primary outcome was the severity of PONV, measured using a visual analog scale (VAS) at 0, 6, 12, and 24 hours following spinal morphine administration. The VAS consisted of a 10-centimeter horizontal line, with 0 cm indicating no nausea and 10 cm representing the worst imaginable nausea. Patients marked a point on the scale to indicate their nausea severity. Scores were categorized as mild (1-3 cm), moderate (4-6 cm), and severe (7-10 cm).

Secondary outcomes included the incidence of PONV, time to first rescue antiemetic administration, total dose of rescue antiemetics, and the presence of adverse effects potentially related to oral ginger (e.g., abdominal discomfort, diarrhea, headache, drowsiness, and heartburn).

Patients who reported a VAS score >3 or experienced vomiting despite receiving intraoperative prophylactic antiemetics were administered 10 mg intravenous metoclopramide. Those with persistent moderate to severe nausea, ongoing vomiting, or who requested additional treatment received intravenous dexamethasone (0.15 mg/kg) followed by ondansetron (4 mg IV), repeated at 6-hour intervals as needed.

A total of 40 participants were randomly assigned to one of two groups (ginger or placebo) using a web-based randomizer (<https://www.randomizer.org>). Randomization was performed with block sizes of 4 and a 1:1 allocation ratio. The randomization sequence was sealed in an opaque envelope. This study employed a double-blind design: participants were unaware of their group assignment, and a nurse, not involved in the study, administered the interventions. The anesthesiologist conducting postoperative evaluations was also blinded to group allocation.

Sample Size Calculation and Statistical Analysis

Data analysis was performed by an independent statistician using Stata, version 14 (StataCorp LP, College Station, TX, USA). The sample size was initially calculated based on the study by Zeraati et al.⁽²⁰⁾, targeting a statistical power of 90% ($\beta=0.10$) and a two-sided significance level of 5% ($\alpha=0.05$). Accounting for a predicted 20% dropout rate, a total of 40 participants were required and randomly assigned, with 20 participants per group. The categorical variables were described as numbers and percentages and compared using the Pearson chi-square test or Fisher's exact test. Continuous variables were summarized as mean $\pm$ standard deviation (SD) or median with interquartile range (IQR), as appropriate based on data distribution. Comparisons between groups for continuous variables were performed using one-way analysis of variance (ANOVA) or repeated-measures ANOVA, as appropriate. A p-value of less than 0.05 was considered statistically significant, with a 95% confidence interval.

RESULTS

Demographic Data

A total of 46 parturients were screened for the study. Six were excluded: three had a history of PONV, two had a BMI >35 kg/m², and one was an active smoker. As a result, 40 patients consented to participate and were randomly assigned to either the ginger or placebo group (20 patients each). Four patients in the ginger group were excluded: one due to inadequate spinal anesthesia, two for receiving Methylergonovine maleate during the perioperative period, and one who declined participation. Therefore, 36 participants (16 in the ginger group and 20 in the placebo group) were included in the final analysis (**Figure 1**). No significant differences were observed in demographic characteristics or procedural details between the two groups (**Table 1**).

Primary Outcome

Repeated-measures ANOVA demonstrated a significant time effect ($p=0.0002$), indicating that nausea severity decreased over time. However, there was no significant group effect ($p=0.7303$) or time $\times$ group interaction ($p=0.1597$). Although not statistically significant, the ginger group reported lower mean VAS scores at 12 and 24 hours compared to the placebo group (0.25 vs. 1.05 and 0.00 vs. 0.50, respectively) (**Table 2**).

Secondary Outcomes

The cumulative incidence of postoperative

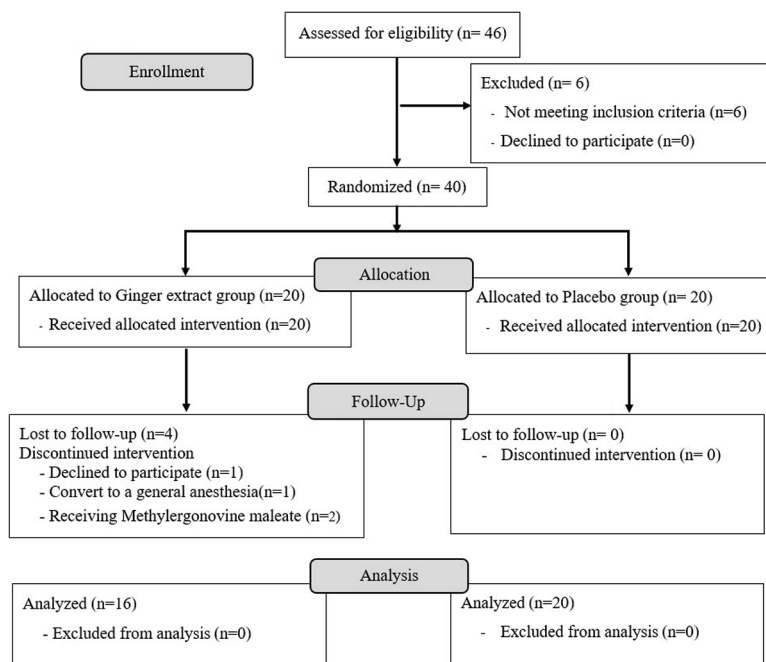


Figure 1. CONSORT flow diagram.

Table 1. Patients and clinical characteristics between the studied groups

Characteristic	Study group	
	Ginger group (n=16)	Placebo group (n=20)
Age (years); mean±SD	31.56±5.33	31.40±4.87
ASA physical status class; n (%)		
II	12 (75.0)	11 (55.0)
III	4 (25.0)	9 (45.0)
Prepregnancy BMI (kg/m ²); median (IQR)	28.75 (20-34)	24.60 (19-39)
Gestation; mean±SD	38.19±0.75	38.35±0.58
Gravida; mean±SD	2.50±1.54	2.19±0.91
Parity; n (%)		
0	5 (31.2)	3 (15.0)
1	8 (50.0)	9 (45.0)
2	6 (37.5)	5 (25.0)
>2	1 (6.2)	1 (5.0)
Estimated intraoperative blood loss (mL); mean±SD	450±240.14	540±202.35
Operation duration (minutes); mean±SD	92.50±24.96	101.75±27.16
Use of uterotonic; n (%)	9 (56.5)	7 (35.0)
Use of vasopressor; n (%)	14 (87.5)	2 (10.0)

SD=standard deviation; IQR=interquartile range; ASA=American Society of Anesthesiologists; BMI=body mass index

vomiting in the PACU (up to 1 hour after surgery) and in the ward (1-24 hours after surgery) was higher in the placebo group. However, the total number of vomiting episodes within 24 hours was similar: 7 (43.75%) in

Table 2. Postoperative nausea scores at different postoperative time points in the ginger and placebo groups and repeated-measures ANOVA results

Time point (hours)	Mean±SD	
	Ginger group (n=16)	Placebo group (n=20)
0	2.56±3.93	1.85±2.81
6	2.63±2.86	1.75±2.07
12	0.25±0.77	1.05±1.84
24	0.00±0.00	0.50±1.19
Repeated measures ANOVA		p-value
Group		0.7303
Time		0.0002
Group*Time		0.1597

SD=standard deviation

* SD is not applicable due to zero variance at this time point

the ginger group vs. 9 (45%) in the placebo group.

No significant differences were observed in the time to the first dose of ondansetron, total ondansetron consumption over 24 hours, or the use of rescue antiemetic medications (ondansetron, metoclopramide, dexamethasone) between the groups (Table 3).

The use of specific rescue antiemetics (ondansetron, metoclopramide, dexamethasone) did not differ significantly between the groups (Table 4).

There were no significant differences in adverse events between the groups (Table 5).

Table 3. Secondary outcome: the incidence of nausea, vomiting, time to first dose of ondansetron, cumulative ondansetron use during the first 24 hours, and use of rescue antiemetic

Variable	Study group		p-value
	Ginger group (n=16)	Placebo group (n=20)	
Incidence of nausea/vomiting; n (%)	7 (43.75)	9 (45.00)	0.9 ¹
Time to first dose of ondansetron (hours); mean±SD	5.0±1.96	7.0±1.94	0.136 ²
Cumulative ondansetron used during the first 24 hours (mg); mean±SD	4.0±2.59	4.0±2.00	0.767 ²
Use of rescue antiemetic; n (%)	8 (50.0)	11 (55.0)	0.515 ¹

SD=standard deviation

¹ Chi-square test, ² Independent t-test**Table 4.** Details of the rescue antiemetic used

Rescue antiemetic	Study group; n (%)		p-value†
	Ginger group (n=16)	Placebo group (n=20)	
Ondansetron	2 (12.50)	3 (15.00)	0.742
Metoclopramide	5 (31.25)	7 (35.00)	0.803
Dexamethasone	1 (5.00)	1 (6.25)	0.898

† Chi-square test

Table 5. Secondary outcome: incidence of adverse effects

Variables	Study group		p-value†
	Ginger group (n=16)	Placebo group (n=20)	
Participants who had an SAE, n (%)	1 (5%)	0 (0.0)	-
Heartburn	1	0	0.303
Abdominal discomfort	0	0	-
Diarrhea	0	0	-
Headaches	0	0	-
Drowsiness	0	0	-

SAE=serious adverse event

† Chi-square test

DISCUSSION

In this randomized controlled trial, we evaluated the effectiveness of oral ginger extract plus ondansetron in preventing PONV in parturients undergoing cesarean section under spinal anesthesia with ITM. Although the ginger group demonstrated numerically lower nausea scores at 12 and 24 hours postoperatively, no statistically significant differences were detected between groups in nausea severity, rescue antiemetic use, or overall incidence of PONV.

The present study is consistent with the findings of Zeraati et al., who reported reduced nausea and vomiting with ginger extract during cesarean section under spinal anesthesia, although no statistically significant differences in nausea severity were observed between groups at 2 and 4 hours postoperatively⁽²⁰⁾.

Similarly, our findings demonstrated a trend toward lower nausea severity in the ginger group during the later postoperative period, although statistical significance was not achieved. This lack of significance, however, should be interpreted with caution; given the relatively small sample size, the trial may have been underpowered to detect clinically meaningful differences, thereby increasing the possibility of a type II error.

The dosing regimen in the present study was selected based on previous literature evaluating ginger for PONV prevention and was intended to maintain therapeutic exposure during the peak period of ITM-related nausea, which may persist for up to 24 hours postoperatively. Therefore, repeated dosing was utilized rather than a single preoperative administration. The cumulative ginger dose administered in this study remained within the generally recognized safe daily intake range.

Several previous studies conducted in postoperative, chemotherapy-related, and pregnancy-associated nausea and vomiting settings have demonstrated the potential antiemetic properties of ginger⁽²¹⁻²⁴⁾. For instance, Apariman et al. reported no significant reduction in nausea scores at 2 hours after gynecologic laparoscopy but observed significantly lower nausea severity and vomiting rates at 6 hours in patients receiving ginger compared with placebo⁽²³⁾. This observation suggests that the antiemetic effect of oral ginger may be delayed but remains clinically relevant, particularly in patients receiving opioid-based analgesia. In contrast, Visalyaputra et al. and Eberhart et al. reported no significant benefit of ginger, which might be attributed to differences in dosing strategies, timing of administration, and outcome assessment methods^(25,26).

Interestingly, a substantially higher proportion of participants in the ginger group required vasopressor treatment for intraoperative hypotension compared with the placebo group. Because hypotension during

cesarean section under spinal anesthesia is a recognized contributor to nausea and vomiting, this hemodynamic imbalance acted as a significant confounding factor. Despite this disadvantage, the delayed postoperative nausea scores in the ginger group remained numerically lower than those in the placebo group. While this exploratory finding warrants further investigation with a larger, more balanced sample size, it suggests a potential protective or stabilizing effect of ginger against hypotension-induced emesis.

Despite the absence of statistically significant differences, ginger extract was well tolerated with no reported adverse events, suggesting it may still hold value as part of a multimodal antiemetic strategy. However, because all participants in this study received prophylactic intravenous ondansetron as part of standard institutional care, the additional antiemetic effect attributable to ginger alone may have been obscured by a ceiling effect of the standard prophylactic regimen.

LIMITATION

The present study has several limitations that should be acknowledged. First, the sample size was relatively limited, with only 36 participants completing the study protocol. A post-hoc power analysis based on the primary outcome at 12 hours demonstrated an actual statistical power of 23.4%. Consequently, the trial may have been underpowered to detect small but clinically meaningful differences between groups, increasing the possibility of a type II error. Therefore, these findings should be interpreted cautiously and considered exploratory in nature.

Second, all participants received prophylactic intravenous ondansetron after delivery as part of standard institutional care. This concomitant antiemetic administration may have acted as a potential confounding factor, making it difficult to isolate the independent antiemetic effect of ginger extract.

Third, a substantially higher proportion of participants in the ginger group required vasopressor treatment for intraoperative hypotension compared with the placebo group. Because intraoperative hypotension during cesarean delivery under spinal anesthesia is a recognized contributor to nausea and vomiting, this imbalance may also have influenced postoperative nausea outcomes.

Fourth, the relatively strict exclusion criteria used to maintain a homogeneous study population may limit the generalizability of the findings to broader obstetric populations, particularly patients at higher risk for PONV.

Lastly, the timing, pharmacokinetics, and individual bioavailability of oral ginger extract may not have been fully optimized to achieve maximal therapeutic effect during the postoperative period.

Future well-powered multicenter studies incorporating alternative dosing regimens and different multimodal antiemetic strategies are warranted to further clarify the potential role of ginger in preventing PONV in obstetric anesthesia.

CONCLUSION

The present study found that oral ginger extract was safe but did not provide additional benefit in reducing ITM-induced nausea and vomiting beyond standard ondansetron treatment after cesarean section under spinal anesthesia. Although reduced nausea severity and rescue antiemetic use were observed in the ginger group, the differences were not statistically significant. These results are consistent with prior studies suggesting ginger's potential efficacy for PONV prevention. Future research with larger sample sizes, varied dosing regimens, and comparative trials against standard antiemetics is needed to further evaluate ginger's clinical utility. Given its safety profile, ginger remains a promising candidate in the development of multimodal approaches to PONV prevention.

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Authors Contributions

WC, VK, and DS conceived and designed the study. VK, NG, and PP collected the data. VK and DS performed the statistical analysis and drafted the manuscript. All authors contributed to the revision of the manuscript and approved the final version.

Clinical Trial Registration

This study was registered with the Thai Clinical Trials Registry (TCTR) under registration number TCTR20250319003.

Conflicts of Interest

The authors declare no conflict of interest.

Data availability statement

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request. The data are not publicly available because they contain information that could

potentially compromise the privacy of the study participants.

Ethics Approval and Consent to Participate

The present study was approved by the Ethics Committee of Srinakharinwirot University on July 6, 2022 (SWUEC-038/2565F). Participants were fully informed about the research objectives, methods, and safety precautions prior to enrollment. All procedures adhered to ethical standards, ensuring the protection of participants' rights and confidentiality. Written informed consent was obtained from each participant, who was also informed of their right to withdraw from the research at any time, for any reason, without consequence.

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Use of Artificial Intelligence

The authors take full responsibility for the content of the manuscript. ChatGPT (OpenAI) was used solely for English language editing.

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