



Effects of ginger and ondansetron on intra and postoperative nausea and vomiting in cesarean section under spinal anesthesia: A double-blinded randomized clinical trial

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ABSTRACT

Introduction: The occurrence of nausea and vomiting following anesthesia and surgery is a prevalent and distressing issue, ranking second only to pain. In this study, the effects of ginger and ondansetron in mitigating these symptoms in patients who underwent cesarean section surgery were compared.

Methods: This double-blinded randomized clinical trial included 150 eligible patients who were randomly assigned to one of three groups: ginger, ondansetron, and control. The ginger group was given one 1000 mg ginger capsule, the ondansetron group was given one 16 mg ondansetron capsule, and the control group was given one placebo capsule. Participants took their designated capsules with 30 mL of water one hour before their scheduled surgery. Nausea intensity and vomiting frequency were assessed throughout the surgical procedure and at post-operation intervals of 0.5, 1, 2, and 4 hours.

Results: Compared to the control group, the ginger group had significantly less severe nausea during the surgery ($P=0.03$) and one hour after surgery ($P=0.01$). The ginger group also had significantly fewer vomiting episodes during the surgery ($P=0.007$) and half an hour after surgery ($P=0.001$). There was no significant difference between the ginger and ondansetron groups regarding the severity of nausea and the number of vomiting ($P>0.05$).

Conclusion: The administration of ginger was found to be successful in alleviating the severity of nausea and vomiting both during and after spinal anesthesia for cesarean section procedures. It could be a viable alternative to ondansetron.

Implication for health policy/practice/research/medical education:

This clinical trial showed that ginger might be useful in preventing nausea and vomiting caused by cesarean section as a possible natural remedy.

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Introduction

Cesarean delivery is a medical procedure that involves delivering the fetus by making incisions in both the abdominal and uterine walls (1). Today, many cesarean sections are performed using local anesthesia, such as epidural or spinal anesthesia, which minimizes the risk of harm to both the mother and fetus from anesthetic agents. Among these, spinal anesthesia is known for its simplicity,

reliability, and fast-acting properties (2).

Postoperative nausea and vomiting (PONV) is characterized by the presence of nausea, vomiting, or retching within the first two days following surgery among hospitalized patients (3). Nausea and vomiting are considered to be the second most prevalent and distressing symptoms after surgery and anesthesia, second only to pain. In some cases, nausea and vomiting can be

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more frequent than pain and result in greater suffering for patients, regardless of whether the surgery was minor or major (4). PONV can be a common occurrence among hospitalized patients, affecting around 30% of patients and up to 70-80% of at-risk patients within the first 24 hours following surgery. These symptoms may persist for up to 24-48 hours after the surgery has been completed (5). PONV is a difficult condition to treat due to its complex mechanisms, which may involve multiple factors related to the anesthetic, surgical, and patient characteristics (6). There is currently no universally accepted standard for the treatment of PONV, as the effectiveness of antiemetics can be impacted by patient characteristics (7). To address the common issue of postpartum nausea and vomiting during surgery, studies have investigated a range of treatment options, including medication and non-medication approaches such as ginger, acupuncture, acupressure, droperidol, metoclopramide, and ondansetron (8). Ondansetron can be effective in reducing cesarean section-related nausea and vomiting; however, its impact may not be fully complete. In an investigation patients who underwent cesarean sections under epidural anesthesia still experienced vomiting despite receiving prophylactic 4 mg ondansetron (9). Frequently observed adverse effects associated with the use of ondansetron include headaches, tiredness, dry mouth, general discomfort, and constipation. Additional infrequently reported effects may manifest as central nervous system symptoms like drowsiness and sedation, as well as localized reactions at the injection site and itchiness (10). Due to the limited efficacy of antiemetic drugs and their side effects, other techniques are being sought for the treatment of PONV (11). Alternative and complementary therapies to medications are being more routinely used in the treatment of PONV (12).

Ginger (*Zingiber officinale* Roscoe) has been used as a spice and natural remedy for ages. Recent research has shown that ginger has antioxidant, anti-inflammatory, antimicrobial, and anticancer properties and may help prevent or manage various conditions such as neurodegenerative diseases, cardiovascular disease, diabetes, obesity, chemotherapy-induced nausea and vomiting, and respiratory illnesses (13). Ginger increases intestinal movements, inhibits gastric contractions, and removes free radicals that stimulate nausea and vomiting; because it contains antagonists of galanolactone, 5-hydroxytryptamine-3, and serotonin-3 receptors. Ginger can promote intestinal motility, suppress gastric contractions, and reduce the effects of free radicals that trigger nausea and vomiting. These effects are due to ginger's antagonistic properties against galanolactone, 5-hydroxytryptamine-3, and serotonin-3 receptors. Ginger root is a well-known spice that the Food and Drug Administration (FDA) recognizes as a dietary supplement with no known complications or interactions

with other medications, as noted in the Commission E monograph. (14). While several randomized clinical trials have examined ginger's antiemetic effects in different conditions, its antiemetic activity is not yet fully understood (15,16).

Nausea and vomiting are frequently encountered postoperative complications in patients who undergo cesarean delivery, and can negatively impact their comfort and well-being after the procedure. While ondansetron is the most commonly used medication to manage these symptoms during surgery, few studies have compared its effectiveness to oral ginger in surgical settings. Our research is the inaugural study to directly compare the preventative impacts of ginger and ondansetron against PONV, both during and following cesarean section surgery, with the aim of identifying safe and effective treatment options for patients.

Materials and Methods

Our research investigation was designed as a double-blind clinical trial and took place at Hamadan Fatemeh hospital between August and October 2022. Prior to commencing the study, we obtained written permission from the Research Vice-Chancellor of Hamadan University of Medical Sciences, with the ethical code of IR.UMSHA.REC.1401.316. We recruited 150 participants between the ages of 20 and 40 who had undergone cesarean surgery with spinal anesthesia and had reached full gestational age with a singleton pregnancy for our study. Sampling began after we had thoroughly explained the study methods to the participants and received written informed consent from all patients involved in the study. The subjects were assigned to one of three groups in a random manner. To ensure blinding, both the patients and the surgeon were unaware of the type of intervention or which group the patients were assigned to.

To be eligible for the study, participants had to meet several inclusion criteria, including a willingness to participate, absence of high-risk anesthesia (classified as III and IV according to the American Society of Anesthesiologists), no history of mental disorders or gastrointestinal disease, absence of pre-eclampsia or eclampsia, no use of antiemetic drugs or nausea-inducing medication within 24 hours before the operation, and no allergy to ondansetron or ginger. To maintain the integrity of the study, we excluded participants who met either of the following criteria: unwillingness to continue participating in the study or conversion from spinal anesthesia to general anesthesia during the surgical procedure. The samples were assigned randomly to one of the three groups: ginger, ondansetron, and control, in equal proportion using a simple random sampling procedure that adhered to the study criteria. The "Random Allocation Software" program was used to perform the randomization process. According to previous studies (17,18) and the capsule

brochure, the dose of ginger used to prevent surgery-induced nausea and vomiting was 1000 mg, and according to *Lexi-Comp's Drug Information Handbook* (19) and the brochure of ondansetron tablets, its effective dose was 16 mg. Therefore, the preparation of ginger capsules (1000 mg), ondansetron capsules (16 mg), and placebo capsules (containing rice flour) was carried out by the pharmacology laboratory at Hamadan University of Medical Sciences with similar shape, color, and size under the supervision of a pharmacist. Following coordination with the anesthesia and gynecological surgery teams and one hour prior to spinal anesthesia, the participants ingested their designated capsules along with 30 mL of water.

Spinal anesthesia was administered via an intrathecal injection using a 24–26-gauge needle, with 3–3.5 mL of 0.5% bupivacaine. To maintain hydration during the operation, patients were given Ringer's solution. Following the delivery of the baby, an intravenous infusion of 60 units of syntocinon was administered. After the surgery, women were transported to the recovery room using stretchers to minimize the impact of their movements on nausea and vomiting. The same approach was then followed as in the gynecology ward. Furthermore, the surgeon and anesthesiologist were the same for all patients.

The severity of nausea and the number of vomiting were recorded during surgery (15 minutes after the start of the operation) and 0.5, 1, 2, and 4 hours after the end of surgery. The participants were instructed on how to use a visual analog scale tool (VAS) with a 10-cm line to rate the severity of their nausea. The recorded nausea scores were classified into five distinct categories, namely no nausea, mild, moderate, severe, and very severe nausea, corresponding to the scores of 0, 1–3, 4–6, 7–9, and 10, respectively (20) (Figure 1). The checklists related to the number of vomiting after spinal anesthesia were based on questions from the patients or their companions. The number of vomiting was classified into three levels: mild (occurring less than 3 times), moderate (between 3 and 5 times), and severe (more than 5 times) (2). Each retching was recorded as one vomiting episode. If patients experienced difficulty in tolerating nausea and vomiting, they were administered antiemetic medication (ondansetron 2 mg IV as needed).

Statistical data analysis

The statistical analysis of the data was conducted using

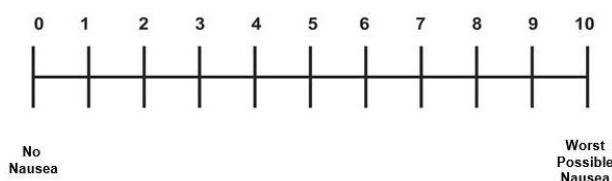


Figure 1. Visual analog scale.

the software SPSS version 23. The normality of the distribution of both nausea and vomiting scores was assessed using the Kolmogorov-Smirnov test. The purpose of this was to decide whether to use parametric or non-parametric tests. The demographic and clinical characteristics of the samples were compared using One-way ANOVA analysis. To compare the mean levels of nausea and vomiting among the ginger, ondansetron, and control groups, the Kruskal-Wallis test was employed. Furthermore, the Mann-Whitney U test was utilized to perform pairwise comparisons between the groups. The requirement for antiemetic medication during the study was assessed using the Chi-square test. A significance level of $P < 0.05$ was used to assess statistical significance in all tests. Drawing from the research investigation carried out by Sedighmaroufi et al (20), which reported the incidence of vomiting in the ondansetron and ginger groups four hours after intervention as 22% and 5%, respectively, and considering a confidence interval of 95%, $\alpha = 0.05$, and a power of 70%, the sample size for each study group was set at 50 individuals to achieve sufficient statistical power.

Results

Among the 198 eligible patients evaluated for this study, a total of 36 individuals were excluded due to inadequate inclusion criteria and other reasons (Figure 2). No statistically significant differences were found among the study groups (ginger, ondansetron, and control) in relation to age, body mass index (BMI), mean arterial pressure, heart rate, and saturation of peripheral oxygen (SPO₂). Although there existed a statistically significant difference in the duration of surgery among the groups, the difference was deemed clinically insignificant as it was too small to be considered significant from a practical perspective (Table 1).

According to Table 2, the mean intensity of nausea had a trend to decrease in the ginger and ondansetron groups during surgery and at half an hour, one hour, two hours, and four hours post-surgery, compared to the control group. However, the statistical analysis revealed that only one hour after the surgery, there was a significant difference among the three groups ($P=0.04$). Significant differences were observed in the paired comparison between the ginger group and the control group during the surgery ($P=0.03$) and one hour after the surgery ($P=0.01$). Despite the fact that the mean intensity of nausea in the ginger group was lower than that of the ondansetron group at all evaluation times, the difference was not statistically significant ($P>0.05$). Furthermore, there was no statistically significant difference observed between the ondansetron group and the control group at any of the evaluation times ($P>0.05$). In relation to the incidence of vomiting, the ondansetron and ginger groups exhibited a lower average compared to the control group during the surgical procedure, half an hour, one hour, two

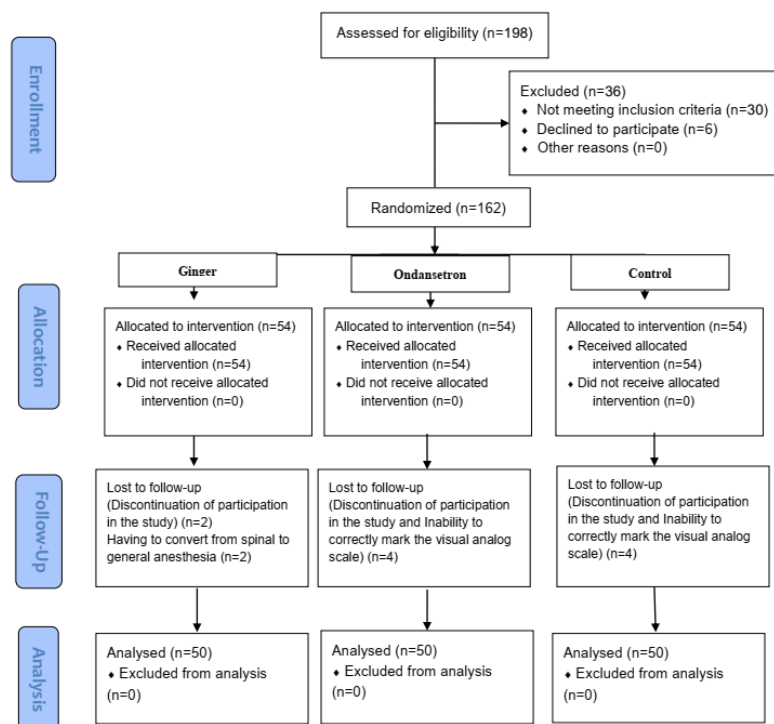


Figure 2. Consort flowchart of the study.

hours, and four hours after surgery. However, the statistical significance of the difference among the three groups was observed only during ($P=0.007$) and half an hour after the surgery ($P=0.001$). Significant differences were observed in the paired comparison between the ginger and control groups during the surgery ($P=0.003$) and half an hour after the surgery ($P=0.001$). At all evaluation times, the mean number of vomiting episodes in the ginger group was lower than that of the ondansetron group, but the difference was not statistically significant ($P>0.05$). Furthermore, a significant difference was observed between the ondansetron and control groups half an hour after the surgery ($P=0.01$). None of the women in the ginger group experienced vomiting four hours after the surgery. Meanwhile, in the ondansetron group, the mean number of vomiting episodes was 0.19 ± 0.04 at this time. The chi-square test indicated that the need for antiemetic

drugs during the study was not statistically significant. Specifically, 9 women (18%) in the control group, 4 women (8%) in the ondansetron group, and 3 women (6%) in the ginger group required antiemetic drugs ($P=0.11$). Furthermore, none of the patients reported any side effects from the administered medications.

Discussion

This study aimed to assess the impact of orally administered ondansetron and ginger on nausea and vomiting in patients undergoing cesarean sections. The findings of the study revealed that there was a significant difference among the groups with respect to the mean nausea severity one hour following the surgery. The ginger group showed a notable difference in the intensity of nausea both during and one hour after surgery, compared to the control group. However, there was no significant

Table 1. The demographic and clinical characteristics of the participants in three groups of ginger, ondansetron, and control

Variables	Ginger group	Ondansetron group	Control group	P value
Age (year)	29.98 \pm 4.69	28.84 \pm 5.06	30.22 \pm 6.57	0.41
BMI (kg/m ²)	28.96 \pm 0.46	92.02 \pm 0.44	28.98 \pm 0.60	0.86
Mean arterial pressure (mm Hg)	87.82 \pm 1.33	87.64 \pm 1.38	88.02 \pm 1.49	0.40
Heart rate (per minute)	92.8 \pm 2.98	93.16 \pm 2.22	93.2 \pm 3.45	0.75
SPO ₂ (%)	98.3 \pm 1.01	97.94 \pm 1.26	98.22 \pm 1.02	0.24
Duration of surgery (min)	35.26 \pm 2.98	36.92 \pm 2.58	35.48 \pm 2.76	0.006

The means \pm standard deviations were used to present the data.
BMI, body mass index; SPO₂, saturation of peripheral oxygen.

Table 2. The mean severity of nausea and the number of vomiting in three groups and pairwise comparison of them at each evaluation time

Variables	Time	Ginger group	Ondansetron group	Control group	P value	G & O* (P value)	G & C** (P value)	O & C*** (P value)
Nausea	During surgery	1.62 ± 0.30	1.97 ± 0.31	2.82 ± 0.39	0.08	0.40	0.03	0.15
	Half an hour	1.70 ± 0.28	1.92 ± 0.31	2.88 ± 0.39	0.21	0.82	0.10	0.17
	1 hour	1.17 ± 0.25	1.76 ± 0.30	2.22 ± 0.33	0.04	0.16	0.01	0.29
	2 hours	0.63 ± 0.19	0.69 ± 0.18	0.91 ± 0.25	0.91	0.65	0.80	0.88
	4 hours	0.31 ± 0.12	0.45 ± 0.15	0.52 ± 0.16	0.47	0.25	0.30	0.99
Vomiting	During surgery	0.20 ± 0.09	0.26 ± 0.07	0.68 ± 0.15	0.007	0.20	0.003	0.50
	Half an hour	0.18 ± 0.06	0.30 ± 0.08	0.64 ± 0.11	0.001	0.29	0.001	0.01
	1 hour	0.10 ± 0.04	0.22 ± 0.06	0.34 ± 0.10	0.19	0.15	0.07	0.66
	2 hours	0.06 ± 0.03	0.06 ± 0.03	0.14 ± 0.05	0.26	1.00	0.18	0.18
	4 hours	0.00 ± 0.00	0.04 ± 0.02	0.04 ± 0.02	0.36	0.15	0.15	1.00

The means ± standard deviations were used to present the data.

* Ginger and ondansetron groups.

** Ginger and control groups.

*** Ondansetron and control groups.

contrast in this aspect between the ginger group with ondansetron and the ondansetron group with the control. There was a significant difference in the average number of vomiting episodes during and 30 minutes after surgery between the groups, and the ginger group differed significantly from the control group in terms of the number of vomiting episodes during these two evaluation periods. The ondansetron and control groups showed significant differences in nausea and vomiting levels only 30 minutes after surgery. Although, the ginger group displayed lower mean levels of nausea and vomiting in comparison to the ondansetron group throughout the evaluation intervals, the difference in this regard was not considered statistically significant.

Some studies have shown results that are in line with our findings (2,14,20, 21), while a few studies have reported contradictory results (18,22). In a research study carried out by Sedighmaroufi and colleagues (20), it was discovered that the severity of nausea did not significantly differ among the three groups of ginger, ondansetron, and placebo. Nevertheless, a notable distinction in the frequency of vomiting was observed among the groups one and two hours after the surgery. As a result, the study concluded that ginger could be considered a more advantageous alternative to ondansetron due to its effectiveness, safety, and lower cost. The difference between our study and the one mentioned above is the type of surgery and anesthesia used. Their study was conducted during eye surgery under general anesthesia, while ours was done during cesarean surgery, which is a type of abdominal surgery under spinal anesthesia. However, the final outcome of both studies was similar. Amouee et al (14) conducted a study aimed to explore the impact of ginger versus a placebo in reducing nausea and vomiting following cesarean section surgery under spinal

anesthesia. Their study found that ginger significantly reduced the severity of vomiting during surgery and 30 minutes after surgery, which is consistent with the findings of the current study. However, unlike the present study, which compared ginger with ondansetron and control groups, Amouee et al measured the effect of ginger alone. They concluded that ginger could effectively reduce the incidence and severity of PONV that occur in patients undergoing cesarean section surgery, and may also decrease the need for antiemetic drugs. Soltani et al (21) performed an investigation to compare the efficacy of oral ginger and intravenous ondansetron in reducing PONV following laparoscopic cholecystectomy surgery. Their study found that taking 500 mg of ginger one hour before surgery was safe and well-tolerated, and significantly reduced the severity of nausea compared to ondansetron. However, the frequency of vomiting was not significantly different between the two groups except 16 hours after surgery. Although their study and the current study had similar results, there were differences in treatment dosage, administration method, and type of surgery.

Cesarean surgery involves more abdominal manipulation and hormonal changes, which may contribute to more severe nausea and vomiting during surgery. Therefore, additional research is required to ascertain the appropriate treatment dose for different types of surgery. Pakniat et al (2) found ginger was as effective as metoclopramide in reducing nausea and vomiting in cesarean section patients under spinal anesthesia. Their investigation did not demonstrate a notable dissimilarity in the incidence and intensity of nausea and vomiting between the ginger and metoclopramide groups, both during the surgical procedure and at 2 and 6 hours following the surgery. Although their study lacked a control group and metoclopramide was administered intravenously, the

results of their research was in line with the outcomes of the present study. Kalava et al (18) conducted a study that compared powdered ginger with placebo in elective cesarean section patients who received combined spinal epidural anesthesia. Their study found that ginger reduced the number of nausea episodes during surgery but did not influence the occurrence of PONV. This may be attributed to the loss of effectiveness of ginger over time and insufficient dosage. In contrast, the present study showed a significant difference between the three groups during surgery and the immediate postoperative period. This is in line with Kalava and colleagues' suggestion that ginger's effectiveness in preventing PONV may diminish over time, and the dosage may not have been sufficient in their study. However, additional research is necessary to identify the ideal dose and duration for maximum efficacy of ginger treatment for preventing PONV in elective cesarean section patients. Eberhart et al (22) reported that ginger was not effective in decreasing the incidence of PONV after gynecologic laparoscopies. This may be attributed to the use of general anesthesia or the different type of surgery compared to the present study. It is worth noting that different types of surgery and anesthesia may have varying effects on PONV, and the effectiveness of ginger may differ depending on the specific circumstances of each case.

One limitation of the study was that some patients were initially unwilling to participate or lacked cooperation, which could have potentially introduced patient selection bias. However, the researchers were able to address this issue by providing detailed information about the potential complications of cesarean section and the importance of preventing them, which helped to encourage patients' participation.

Conclusion

The study's findings suggest that both ginger and ondansetron are effective in reducing nausea and vomiting in individuals undergoing cesarean section surgery with spinal anesthesia, and can help decrease the need for additional antiemetic drugs. Ginger was found to be particularly effective in reducing the severity of nausea and vomiting and is a more cost-effective and readily available alternative to ondansetron. However, it is important to note that further research with increased sample sizes and different surgical procedures is needed to confirm the efficacy of ginger compared to ondansetron. Nonetheless, the study's results indicate that ginger could potentially be used as a substitute for ondansetron in preventing PONV in cesarean section patients under spinal anesthesia.

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Authors' contributions

SA took part in the data collection, transcribed the data, and wrote the manuscript. BI took part in supervision, guidance on the writing of the manuscript, and proofreading the manuscript. SK took part in the data analysis and in proofreading the final version of this manuscript. PH took part in the validation, supervision, and proofreading of the final version of this manuscript.

Conflict of interests

There is no conflict of interest to declare.

Ethical considerations

The Vice-Chancellor for Research of Hamadan University of Medical Sciences approved this study, and the relevant Ethics Committee provided the ethics code (IR.UMSHA.REC.1401.316). All research procedures were conducted following the ethical standards of the Institutional and National Research Committee and with the 1964 Helsinki Declaration. The protocol was registered in Iranian Center for Clinical Trials (Identifier: IRCT20220614055172N1; <https://www.irct.ir/trial/64269>).

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