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Original Research

The Combination of *Bunium persicum* (Boiss.) B.Fedtsch. and *Rhus coriaria* L. as Complementary Medicine to Prevent Postoperative Nausea and Vomiting in Surgical Patients: A Randomized, Double-Blind Clinical Study

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Abstract

Unwanted side effects such as postoperative nausea and vomiting (PONV) remain a significant clinical challenge for surgical patients. Research on antiemetic strategies is therefore critical for the development of novel pharmacological agents and more effective treatment modalities. The present study was designed to formulate and evaluate the efficacy of a herbal preparation containing extracts of *Bunium persicum* (Boiss.) B.Fedtsch. and *Rhus coriaria* L. in preventing postoperative nausea and vomiting among patients admitted to the Department of Surgery at Pastor Hospital, Bam, Iran. Following the formulation, a double-blind randomized controlled trial was conducted involving 120 patients. Eligible participants who provided informed consent were enrolled and randomly assigned to one of two groups. Both groups received pretreatment consisting of 500 mg capsules, containing either the ethanolic extract or corn starch as a placebo, respectively, administered twice daily for 24 hours before surgery. Postoperatively, once patients regained consciousness, the frequency and severity of nausea and vomiting were assessed at 0, 4, 8, 16, and 24 hours. Postoperative vomiting scores were significantly lower in the intervention group (0.43 ± 0.23) compared to the control group (0.72 ± 0.55) ($p < 0.001$). The administration of an herbal preparation containing extracts of *B. persicum* and *R. coriaria* as an adjunctive (complementary) therapy demonstrated effectiveness in reducing postoperative nausea and vomiting among patients.

Keywords: Traditional Persian Medicine; Herbal medicine; Traditional medicine; Cumin; Sumac

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Introduction

Postoperative nausea and vomiting (PONV) represent a major clinical concern, affecting approximately 30% of patients during the early postoperative hours according to available statistics [1]. The adverse consequences of this complication include electrolyte imbalances (such as hypocalcemia, clinical hypochloremia, and hyponatremic metabolic alkalosis), dehydration, esophageal rupture, wound dehiscence, and hematoma formation beneath skin flaps following abdominal or ocular surgery. Consequently, PONV remain one of the principal challenges faced by anesthesiologists. Several factors, including sex, smoking history, age, and surgical duration, have been identified as predictors influencing the incidence of PONV [2]. Predictors of PONV, supported by meta-analyses and systematic reviews, indicate that female sex after puberty, non-smoking status, prior history of PONV or motion sickness, childhood after infancy, young adulthood, prolonged surgical duration, and exposure to volatile anesthetics, nitrous oxide, high-dose neostigmine, or intra- and postoperative opioids are well-established risk factors [3].

Given the multifactorial etiology of PONV, the development of novel antiemetic strategies is critical. Although herbal medicines have been widely employed in the management of gastrointestinal disturbances, including nausea and vomiting, the available body of evidence remains insufficient. *Zingiber officinale* Roscoe (ginger) has been extensively studied for the treatment of PONV, with several trials demonstrating its superiority over placebo [4,5], although contradictory findings have also been reported [6]. While other medicinal plants may offer potential benefits, few have undergone rigorous clinical evaluation.

Bunium persicum (Boiss.) B. Fedtsch. (Apiaceae), commonly known as black cumin, and *Rhus coriaria* L. (Anacardiaceae), widely known as sumac, are emphasized in Traditional Persian Medicine for their efficacy in alleviating nausea and vomiting. *B. persicum* has demonstrated notable antimicrobial, antioxidant, anti-inflammatory, antiulcer, and gastroprotective properties, underscoring its considerable potential for applications in both the medical and food industries. Additionally, it has been traditionally employed in the management of digestive and urinary disorders, diabetes, and obesity.

Rhus coriaria L. has been recognized for its antimicrobial and stomach-tonic effects and has been utilized in the treatment of diarrhea, dysentery, ulcers, hemorrhoids, hemorrhage, wound healing, hematemesis, and hemoptysis [7-9]. This plant is rich in polyphenols, flavonoids, tannins, organic acids, and essential oils. Its principal bioactive constituents include gallic acid, quercetin, syringic acid, protocatechuic acid, caryophyllene, α-pinene, and β-caryophyllene, which collectively contribute to its strong antioxidant, anti-inflammatory, and antimicrobial activities [10].

A randomized controlled trial assessing *B. persicum* syrup demonstrated a faster return of bowel motility and a shorter hospital stay, with no reported adverse effects, supporting its safe gastrointestinal stimulatory effects in post-cesarean patients [11]. Furthermore, a combination of *B. persicum* and *R. coriaria* was evaluated in a randomized clinical trial among cancer patients undergoing chemotherapy. The findings revealed a significant reduction in both the intensity and frequency of nausea and vomiting, likely mediated through the antioxidant and neuromodulatory actions of active compounds such as cuminaldehyde and terpenoids [12]. Collectively, these data provide preliminary evidence that the active components of these medicinal herbs exert pharmacological effects- including antioxidant, anti-inflammatory, gastroprotective, and neuromodulatory activities- that may underlie their antiemetic potential. Accordingly, the present study was designed and conducted to formulate and evaluate the efficacy of herbal capsules containing combined extracts of sumac and cumin- hereafter referred to as "*Busu"*- for the prevention of postoperative nausea and vomiting.

Materials and Methods

Preparation of the Busu Formulation

Cumin seeds (*B. persicum*) and sumac fruits (*R. coriaria*) were collected from cultivated fields and authenticated by a professional herbalist. Voucher specimens were deposited in the Herbarium Center of the Faculty of Pharmacy, Kerman University of Medical Sciences, Iran, under the accession voucher numbers KF-1141 for *B. persicum* and KF-1500 for *R. coriaria*. Hydroalcoholic extracts (30% w/w) were obtained using the maceration method. The dried and milled extracts were encapsulated in size "00" capsules, with each capsule containing 500 mg of extract in an 80:20 weight ratio of sumac to cumin.

Standardization of herbal preparations

Quality control testing was conducted in accordance with the *US Pharmacopoeia* [13]. Microbial challenge tests were performed to confirm microbiological safety. In addition, the phenolic profile of the preparation was standardized using the tannic acid equivalence (TAE) method, with a calibration curve ranging from 50 to 500 ppm (R^2 = 0.996) [14].

Trial design

The study was designed as a double-blind, randomized, placebo-controlled clinical trial with an allocation ratio of 1:1. It was carried out from December 2022 to August 2023 at Bam University of Medical Sciences, Bam, Iran. The protocol was reviewed and approved by the Ethics Committee of Bam University of Medical Sciences (IR.MUBAM.REC.1401.028), and the trial was registered with the Iranian Registry of Clinical Trials (IRCT20220912055947N1).

Participants
The study population consisted of patients referred for surgical procedures at Pastor Hospital in Bam City, Kerman Province, Iran. Eligible participants were between 18 and 65 years of age, free from underlying medical conditions such as diabetes, cardiovascular disease, renal or hepatic disorders, Mallory-Weiss disease, and gastrointestinal ulcers, and without intestinal obstruction or known sensitivity to herbal medicines. Only patients who provided written informed consent were enrolled. Patients were excluded if they were unwilling to continue, failed to respond to the intervention, developed allergic reactions or other complications during treatment, or had Parkinson's disease. Patients using opioids or opioid-containing analgesics and those who had received prophylactic antiemetic drugs before surgery were also excluded.

Sampling
The sample size was calculated using STATA software, which indicated a requirement of approximately 60 patients in each group (Power = 0.96; $\alpha = 0.05$; $1–\beta = 0.90$).

Randomization and blinding
Patients who met the inclusion criteria were randomly assigned to either the intervention or placebo group using a computer-generated block randomization method, with each block consisting of four patients. Both groups received the allocated medication in the form of capsules. Corn starch was employed in the formulation of the placebo. To maintain blinding integrity, the placebo and intervention capsules were identical in size, color, and opacity, rendering their contents visually indistinguishable. To mask the characteristic herbal odor, both capsule types were polished using a cloth moistened with cumin essential oil (five drops). The final preparations were packaged in identical containers and uniformly labeled with coded identifiers. Neither the participants nor the researchers were aware of the group allocations, thereby ensuring strict double-blind conditions throughout the study.

Intervention
The study population was divided into two groups of 60 participants each, comprising an intervention group and a control group. Patients in the intervention group received one capsule containing 500 mg of the herbal preparation; while patients in the control group received a placebo capsule of the same size and appearance. Both groups were instructed to take the capsules with a glass of cold water, twice daily before meals, beginning 24 hours before surgery. All patients underwent surgery under general anesthesia, and propofol was administered as the induction agent in all cases. The evaluation of postoperative nausea and vomiting was performed by the anesthesiologist at standardized intervals of 0, 4, 8, 16, and 24 hours following recovery of consciousness. If patients were asleep during an assessment point, they were not disturbed, and if discharged earlier than 24 hours postoperatively, follow-up was conducted via telephone. Vital signs were monitored during the recovery period and up to 24 hours post-surgery. In cases where patients experienced nausea and vomiting requiring treatment, 4 mg of ondansetron was administered by intravenous injection.

Outcome assessment
The primary outcome was the severity of nausea and frequency of vomiting episodes during the first 24 hours post-surgery. Nausea intensity was assessed at 0, 4, 8, 16, and 24 hours after recovery of consciousness using a visual analog scale (VAS). The VAS consisted of a 100-mm horizontal line, anchored at the left end with "0 = no nausea" and at the right end with "10 = unbearable nausea"[15].

Statistical analysis
All statistical analyses were conducted using SPSS software. Qualitative variables were summarized using frequencies and percentages, while quantitative variables were expressed as means and standard deviations. The normality of continuous variables was assessed before selecting statistical tests. Sex distribution between the intervention and placebo groups was compared using the Chi-square test. Age was analyzed using the independent t-test, and body mass index (BMI) was compared between groups using the independent Mann–Whitney test. The relationship between BMI and the number of vomiting episodes, as well as between anesthesia duration and the number of vomiting episodes, was examined using Spearman's correlation coefficient. Repeated measures analysis of variance (ANOVA) was applied to compare VAS scores across different time points between the two groups, with the type of surgery included as a confounding factor. All statistical tests were two-sided, and a p value < 0.05 was considered statistically significant.

Results

Standardization of herbal preparations
The microbial quality assessment and the quantification of polyphenolic compounds in the final herbal formulation "Busu" were conducted. Results of microbial analysis are presented in table 1, and the total polyphenolic content expressed as tannic acid equivalence is presented in table 2.

Intervention results

Baseline data
A total of 120 patients completed the designed study (Figure 1). The patients' baseline demographic and clinical characteristics, summarized in table 3, demonstrate that the majority of the participants in both groups were male.

Table 1. Microbial quality of the prepared herbal product *'Busu'*

Results (cfu/g)	Acceptance limit (cfu/g)	Method/Test Reference	
N≤10^3	N≤10^3	Monograph 61, USP 40	Total aerobic microbial count (g)
N≤10	N≤10	Monograph 61, USP 40	Total combined mold and Yeast count (g)
Negative	Negative	Monograph 61, USP 40	Escherichia coli (g)
Acceptance criterion for microbiological quality			Final Result

Table 2. Evaluation of polyphenolic compounds of the prepared herbal product "Busu."

	Method/Test Reference	Test Results	Unit
Total polyphenol Content as Tannic acid equivalent	UV/ In-House	102.67± 3.99	Mg/g

No statistically significant differences were observed between groups at baseline ($p > 0.05$).

The Post-Intervention Data

Following 24 hours of pretreatment with 500 mg capsules administered twice daily, the mean number of vomiting episodes was significantly lower in the intervention group compared to the placebo group (0.43 ± 0.23 vs. 0.72 ± 0.55, $p < 0.001$, Independent Sample *t*-test; confirmed by Mann-Whitney test).

Gender-specific analysis demonstrated no significant differences in the number of vomiting episodes within either group (male: 0.48 ± 0.055, $p = 0.615$; female: 0.50 ± 0.057, $p = 0.389$, Independent Sample *t*-test). Similarly, there was no significant correlation between BMI and the number of vomiting episodes ($p = 0.998$). In contrast, a significant positive correlation was observed between the duration of anesthesia and the number of vomiting episodes (r = 0.950, $p = 0.038$), indicating that longer anesthesia was associated with increased vomiting frequency.

As illustrated in figure 2, the mean nausea intensity scores in the intervention group decreased consistently over time, regardless of the type of surgery. Repeated measures analysis revealed that nausea severity, as measured by VAS, significantly declined across time points ($p < 0.0001$), and this reduction was comparable between abdominal and non-abdominal surgeries. No significant differences were observed in mean VAS scores across surgical types independent of time ($p = 0.932$).

According to figure 3, the mean frequency of ondansetron administration as a rescue antiemetic within 24 hours postoperatively was significantly higher in the control group compared with the intervention group ($p < 0.001$).

As shown in figure 4, nausea intensity measured immediately after surgery (VAS1) and at 4 hours postoperatively (VAS2) was higher in the control group compared with the intervention group. However, between 4 and 16 hours after surgery, no significant differences in nausea intensity were detected between groups.

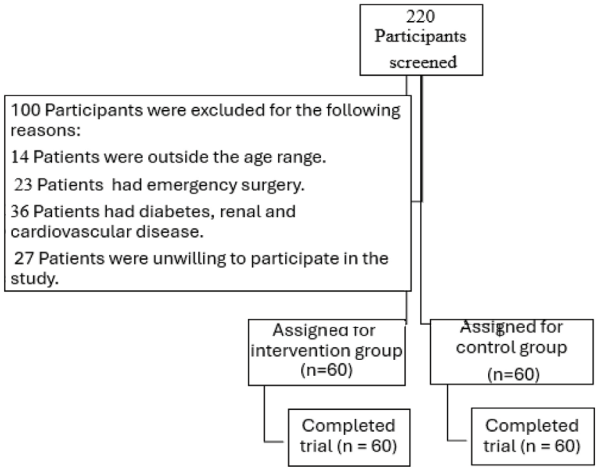

Figure 1. The flowchart illustrates the trial design comparing the efficacy of the *Busu* formulation and the placebo.

Table 3. Baseline demographic characteristics of the study

Characteristics		Groups		
		Control n=60 (Frequency (%))	Intervention n=60 (Frequency (%))	P- value
Gender[a]	Male	75.0%	78.3%	0.7
	Female	25.0%	21.7%	
Age [b] (years)		31.0±12.0	34.0± 14.0	0.2
BMI [b] (kg/m^2)		26.5 ±3.0	27.0± 2.6	0.3

.[a] Chi-square test applied

.[b] Mann–Whitney and t-test applied

Discussion

The present study demonstrated that, over a 24-hour postoperative period, both the intensity and frequency of nausea and vomiting differed significantly between the intervention and control groups. Additionally, no sig-

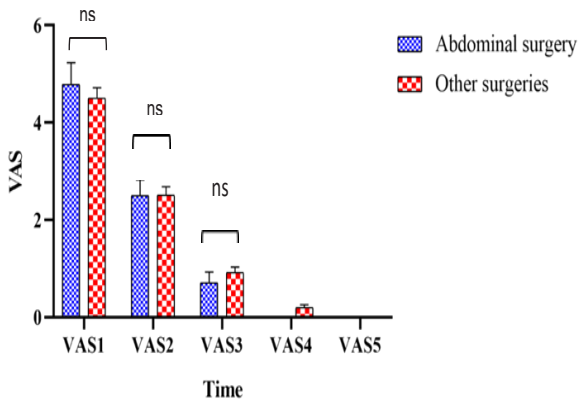

Figure 2. The mean scores of the intensity of nausea in different surgeries (0,4,8,16, and 24 hours) in the intervention group

Notes: There was no significant difference in the mean nausea intensity scores between abdominal and non-abdominal surgeries during the 24-hour postoperative period. A one-way repeated measures ANOVA was applied as the comparison test.

VAS1 represents the mean nausea intensity score immediately after surgery (0 hours).

VAS2 represents the mean nausea intensity score at 4 hours postoperatively.

VAS3 represents the mean nausea intensity score at 8 hours postoperatively.

VAS4 represents the mean nausea intensity score at 16 hours postoperatively.

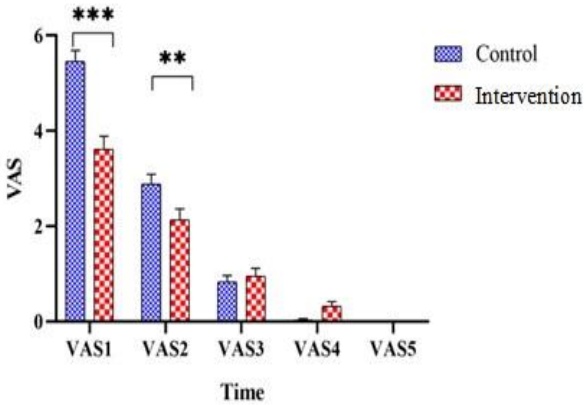

Figure 4. Intensity of nausea after surgery in the control and intervention groups.

*** and ** illustrate that the mean nausea intensity differed significantly between the two groups immediately after surgery and at 4 hours postoperatively, as confirmed by one-way repeated measures ANOVA (***p value: 0.001, and ** p value:0.01).

VAS1 represents the mean nausea intensity score immediately after surgery (0 hours).

VAS2 represents the mean nausea intensity score at 4 hours postoperatively.

VAS3 represents the mean nausea intensity score at 8 hours postoperatively.

VAS4 represents the mean nausea intensity score at 16 hours postoperatively

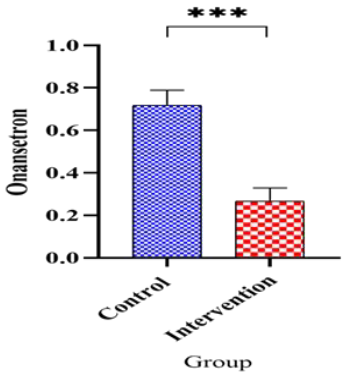

Figure 3. The mean scores of receiving ondansetron between the control and intervention groups.

: A significant difference was observed in the mean frequency of ondansetron administration between the control and intervention groups 24 hours postoperatively, as indicated by the Spearman correlation coefficient. (: p <0.001)

nificant differences in VAS scores were observed across different types of surgery, indicating that time influenced postoperative nausea similarly regardless of the surgical procedure. Gender also had no significant effect on mean VAS scores, suggesting that the passage of time reduced nausea intensity equally in both men and women. Furthermore, the number of vomiting episodes was positively correlated with the duration of anesthesia (p = 0.038), indicating that longer anesthesia is associated with increased postoperative vomiting.

Recent research on medicinal plants has highlighted their potential efficacy in treating gastrointestinal disorders, including nausea and vomiting [16]. A 2022 systematic review and meta-analysis of randomized controlled trials indicated that ginger significantly reduced postoperative nausea at 2, 6, and 12 hours after surgery compared to control groups [17]. Evidence suggests that ginger may be particularly effective in laparoscopic and obstetric/gynecological procedures, although some studies have reported no significant difference compared to the placebo. While most research has focused on ginger, these findings underscore the importance of evaluating other herbal agents with potential antiemetic effects [18]. In 2017, Nazari et al. investigated an herbal product containing cumin and sumac for chemotherapy-induced nausea in breast cancer patients. Their findings demonstrated a significant reduction in the frequency and severity of nausea and vomiting in both acute and delayed phases, except for the acute-phase severity [12]. Consistently, the current study showed that patients receiving the "Busu" formulation experienced significantly lower nausea scores than those in the control group.

A 2024 review of 19 clinical trials reported that herbal medicines administered post-laparoscopic surgery re-

duced both the severity and frequency of nausea and vomiting compared to placebo, with effects comparable to conventional antiemetics. Importantly, patients receiving herbal therapy experienced fewer side effects than those treated with conventional medications [19]. Several mechanisms have been proposed to explain the antiemetic effects of phytoconstituents. These include the acceleration of gastric emptying and the stimulation of gastric antral contractions [20]. Additionally, antispasmodic effects may occur through the relaxation of gastrointestinal smooth muscles and the blockade of calcium channels. The anti-inflammatory and antioxidant properties of these compounds are attributed to their ability to inhibit pro-inflammatory cytokines and cyclooxygenase (COX) enzymes. Moreover, modulation of neurotransmitter systems particularly the 5-HT_3 receptor has been observed, contributing to the reduction of nausea and vomiting [21,22]. Furthermore, dopamine receptor antagonism has been identified as another effective mechanism in the prevention and management of PONV [23].

R. coriaria extracts particularly hydroalcoholic, ethanolic, and aqueous extracts [24], are abundant in phenolic compounds, which are closely associated with anti-inflammatory and anticancer properties [25-28]. One potential mechanism underlying these therapeutic effects is the inhibition of COX production.

B. persicum contains a diverse array of bioactive constituents, including monoterpenes, sesquiterpenes, phenylpropenes, phenolic compounds, fatty acids, and carbohydrates. Its essential oil is particularly rich in γ-terpinene, cumin aldehyde, *p*-cymene, and limonene, which confer strong antimicrobial and antioxidant properties [29]. Beyond these, *B. persicum* exhibits a wide spectrum of pharmacological activities, including analgesic, anti-inflammatory, acetylcholinesterase inhibitory, anticonvulsant, 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase inhibitory, anticancer, antidiabetic, antihistamine, antidiarrheal, antispasmodic, antihematotoxic, antityrosinase, and antimicrobial effects [30]. Notably, its acetylcholinesterase inhibitory activity may enhance gastrointestinal motility and accelerate gastric emptying, potentially contributing to the antiemetic effects observed with the *"Busu"* formulation. Moreover, the *"Busu"* capsules contained substantial amounts of tannic acid (102.67 ± 3.99 mg/g). Previous studies have shown that tannic acid at concentrations of 0.01–1 mg/mL can enhance transepithelial resistance in human gut epithelial cells and inhibit calcium-activated chloride secretion. It also mitigates tumor necrosis factor (TNF)-α-induced disruption of epithelial barrier function, which may contribute to its protective and antiemetic properties [31].

Several limitations should be acknowledged. Patients undergoing emergency surgery were excluded due to insufficient time to administer the herbal preparation before surgery. Moreover, the study population was restricted to elective surgeries, and participants were not monitored in the hospital for 24 hours before surgery. Patients who did not adhere to the prescribed medication regimen were excluded, which slowed the recruitment process.

Despite these limitations, the study possesses notable strengths. The selection of *B. persicum* and *R. coriaria* was informed by evidence from Traditional Persian Medicine, in contrast to most prior studies, which have predominantly focused on ginger. Comparable clinical trials suggest the potential efficacy of various herbal agents in preventing and managing PONV. Consequently, the observed effectiveness of "Busu" as a post-surgical intervention warrants further investigation in future research.

Conclusion

The findings of the present study demonstrate that the "Busu" herbal formulation, comprising extracts of *B. persicum* and *R. coriaria*, effectively reduces both the intensity and frequency of PONV. These results underscore the potential utility of this herbal preparation as a safe and efficacious alternative or adjunct to conventional antiemetic therapies in surgical patients.

In conclusion, administration of the combination of *B. persicum* and *R. coriaria* as a complementary therapy demonstrated efficacy in reducing PONV in patients receiving propofol anesthesia. Nevertheless, comprehensive characterization of the bioactive compounds within these herbal medicines remains limited, and further studies are required to elucidate their precise mechanisms of action and full therapeutic potential.

Conflict of Interests

None.

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None.

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