

# BMJ Open Chinese herbal medicine as adjuvant treatment for postoperative nausea and vomiting in patients undergoing laparoscopic surgery: a protocol for systematic review and meta-analysis

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## ABSTRACT

**Introduction** Postoperative nausea and vomiting (PONV) is a distressing symptom that patients often complain of even after less invasive surgery such as laparoscopic surgery (LS). If PONV is not well managed, patient recovery and postoperative quality of life are adversely affected. Although various drugs have been administered to prevent PONV, their effectiveness is limited, and adverse effects are numerous. Although herbal medicines have been widely used to manage various gastrointestinal symptoms, including nausea and vomiting, scientific evidence of their effects is lacking. This protocol is intended for a systematic review to analyse the efficacy and safety of Chinese herbal medicines for PONV after LS through a meta-analysis.

**Methods and analysis** Randomised controlled trials, reported until June 2022, will be retrieved from electronic databases such as Medline, EMBASE and Cochrane Library. We will compare the effects of herbal medicine in patients presenting with PONV after LS with those of Western medicine, placebo and no treatment. If sufficient studies are identified, we will evaluate the combined effects of herbal and Western medicine. The incidence of nausea and vomiting will be considered the primary outcome. Secondary outcomes will include the intensity of complaints, quality of life and incidence of adverse events. Two independent reviewers will collect data based on the Preferred Reporting Items for Systematic Review and Meta-Analyses statement, evaluate the quality of each study using the Cochrane risk-of-bias tool and synthesise the results via meta-analysis, if possible.

**Ethics and dissemination** Ethical approval is not required for this review. The results of this study will be disseminated to peer-reviewed journals and posters.

**PROSPERO registration number** CRD42022345749.

## INTRODUCTION

Postoperative nausea and vomiting (PONV) is a frequent complication of anaesthesia or surgery and significantly affects patient discomfort and morbidity.<sup>1</sup> Nausea and vomiting are observed in 20%–30% of patients undergoing surgery,<sup>2</sup> with an incidence of

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This systematic review protocol will critically follow the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols to ensure transparency and fairness in the process.
- ⇒ This review will explore the safety and efficacy of not only Chinese herbal medicine but also its co-administration with Western medicine for nausea and vomiting after laparoscopic surgery.
- ⇒ Two independent reviewers will screen the titles, abstracts and full-text articles obtained from various databases in this systematic review.
- ⇒ Grading of recommendation assessment, development and evaluation systems will be employed to assess the quality of evidence to interpret review results in the fields of clinical medicine.
- ⇒ An insufficient number of well-designed randomised controlled trials may be a limitation of this study.

approximately 60% in those undergoing gynaecological laparoscopic surgery (LS).<sup>3</sup>

The laparoscopic approach for surgeries, such as splenectomy, cholecystectomy and oesophageal surgery, allows for minimal invasion, which results in a better quality of life, less pain and faster recovery than open surgery;<sup>4</sup> however, 40%–77% of patients experience PONV following LS.<sup>3</sup>

PONV can be attributed to various aetiologies, including patient conditions (eg, age, body mass index and underlying diseases), type of surgery, anaesthesia-related factors and postoperative factors (eg, pain intensity and use of opioid analgesics).<sup>1</sup> PONV requires appropriate management as it can delay discharge from the hospital, prolong patient recovery and increase medical costs. The use of anaesthetics and analgesics that make patients prone to vomiting should be avoided to reduce the risk of PONV. For these reasons, the administration of prophylactic

antiemetics is recommended to accelerate the patient's recovery process.<sup>5</sup> However, antiemetic drugs, such as metoclopramide, droperidol and ondansetron, have been effective in alleviating vomiting in only 20% of patients; they may also cause adverse effects, such as headache, constipation and dizziness, or contribute to drug interactions. Therefore, the risk must be minimised by selecting the appropriate drug and dose according to the patient's health status and risk level.<sup>5</sup>

Herbal medicine has long been used to treat gastrointestinal symptoms such as nausea and vomiting. Many studies have explored the effectiveness of ginger (*Zingiber officinale*) in the treatment of nausea.<sup>6,7</sup> In some studies, ginger was more effective than placebo in preventing PONV after gynaecological surgery.<sup>8,9</sup> Furthermore, two randomised controlled trials (RCTs) demonstrated the therapeutic effect of ginger as an antiemetic agent after laparoscopic cholecystectomy and nephrectomy.<sup>10,11</sup> In relevant reviews, ginger has been reported to safely improve the severity of PONV, thus reducing the need for antiemetics and substituting their use.<sup>12-14</sup> However, some studies identified no significant difference in reducing the incidence of PONV between the ginger and placebo groups.<sup>15,16</sup> Considering the overall results of previous studies, scientific evidence to recommend herbal medicine for the treatment of PONV after LS remains limited.

To date, as studies on herbal medicines for PONV are limited to the use of ginger, more comprehensive research is required. Thus, in this review, we will search for studies on Chinese herbal medicine, including ginger and other herbs, to evaluate the safety and efficacy of complementary medicine in managing patients undergoing surgery. This review will focus on LS, which can cause more nausea and vomiting through directly affecting the abdominal organs. We aimed to explore the safety and effectiveness of herbal medicine and its co-administration with Western medicine, offering an alternative treatment option to counteract the side effects of antiemetics.

This review aims to investigate the effectiveness and safety of Chinese herbal medicine in patients with PONV after LS.

## METHODS AND ANALYSIS

### Study design and registration

This systematic review protocol is registered in the PROSPERO database (registration ID: CRD42022345749). The study will be performed following the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P).<sup>17</sup> We have not yet begun the final data extraction stage of the review.

### Eligibility criteria

We used population, intervention, comparison, outcome and study design as a framework to develop the search strategy as well as the inclusion and exclusion criteria for our systematic review as follows: population (patients experiencing PONV after LS), intervention (Chinese

herbal medicine), comparison (herbal medicine vs control group (no herbal medicine)), outcome (incidence of nausea and vomiting) and study design (RCTs).

### Types of studies

This review will include RCTs, such as multiarm trials, involving eligible interventions. Animal experiments, case studies, study protocols and commentary articles will be excluded.

### Types of participants

We will review studies involving patients with complaints of nausea and vomiting after LS, with no restrictions on sex, age or race. Patients with nausea or vomiting attributable to conditions other than LS, such as pregnancy, will be excluded.

### Types of interventions

Studies on the use of herbal medicines to prevent and treat nausea and vomiting after LS will be included (any dose, dosing time, frequency or duration). Only studies involving the oral route of administration will be considered for inclusion, and those that used aromatherapy and herbal decoction enemas will be excluded. All dosage forms of herbs, such as powders, granules and extracts, will be considered experimental interventions. We will exclude studies using herbal decoctions or extract granules with no details on the composition and administration information. We will include studies with Western medicine, placebo, and no treatment as comparator groups.

### Types of comparisons

We will include studies involving the following types of comparisons: herbal medicine versus comparators (Western medicine, placebo and no treatment). If sufficient studies are identified, we will compare the efficacy of combination therapy (herbal and Western medicine) for nausea and vomiting with that of conventional Western medicine.

### Types of outcome measures

The primary outcome will include the cumulative incidence of patients with nausea and/or vomiting over time postoperatively (eg, 3, 6, 12 and 24 hours post-LS). The secondary outcomes will include the frequency and intensity of both nausea and vomiting, time to symptom improvement, frequency of rescue antiemetic requirements and incidence of adverse events.

### Data source and search strategy

#### Database resources

The following 11 electronic databases will be searched for articles published from inception until June 2022, without any language restrictions: the English databases, including the Allied and Complementary Medicine Database, Cochrane Central Register of Controlled Trials, EMBASE and Medline via PubMed; the Korean databases, including KoreaMed, Korean Medical Database,

**Table 1** Search strategy used in Medline via PubMed.

No.	Search items
#1	Laparoscopy(MH) OR Laparoscop*(TW) OR Celioscop*(TW) OR Peritoneoscop*(TW) OR 'Laparoscopic Surger*(TW) OR 'Laparoscopic Assisted Surger*(TW) OR 'Surgical Procedures, Laparoscopic'(TW) OR 'Procedures, Laparoscopic Surgical'(TW) OR 'Surgery, Laparoscopic'(TW) OR 'Surgeries, Laparoscopic'(TW) OR 'Surgery, Laparoscopic Assisted'(TW) OR 'Surgical Procedure, Laparoscopic'(TW)
#2	'Minimally Invasive Surgical Procedures'(MH) OR 'Minimally Invasive Surgical Procedure*(TW) OR (Minimal*(TW) AND ('Invasive Surg*(TW) OR 'Surgical Procedu*(TW) OR 'Access Surg*(TW))) OR 'Surgical Procedure, Minimal'(TW) OR 'Surgical Procedures, Minimal'(TW) OR 'Surgeries, Minimally Invasive'(TW) OR 'Surgery, Minimally Invasive'(TW)
#3	'Cholecystectomy, Laparoscopic'(MH) OR 'Cholecystectomies, Laparoscopic'(TW) OR 'Laparoscopic Cholecystectom*(TW) OR 'Celioscopic Cholecystectom*(TW)
#4	'Surgery, Computer-Assisted'(MH) OR 'Surgery, Computer Assisted'(TW) OR (('Computer-Assisted'(TW) OR 'Computer-Aided'(TW) OR 'Image-Guided' OR 'Computer Assisted'(TW) OR 'Computer Aided'(TW) OR 'Image Guided') AND Surg*(TW)) OR 'Surgical Navigation'(TW) OR 'Navigation, Surgical'(TW)
#5	'Hand-Assisted Laparoscopy'(MH) OR ('Hand Assisted'(TW) OR 'Hand-Assisted'(TW)) AND (Laparoscop*(TW) OR 'Laparoscopic Surger*(TW) OR 'Laparoscopy, Hand-Assisted'(TW) OR Surg*(TW) AND ('Hand-Assisted'(TW) OR 'Hand Assisted'(TW))
#6	'Nephrolithotomy, Percutaneous'(MH) OR 'Percutaneous Nephrolithotom*(TW) OR 'PCNL'(TW) OR 'percutaneous kidney stone removal'(TW)
#7	#1 OR #2 OR #3 OR #4 OR #5 OR #6
#8	'Postoperative Nausea and Vomiting'(MH) OR 'Postoperative Nausea and Vomiting'(TW) OR PONV(TW) OR ('Postop*(TW) OR 'Post-op*(TW)) AND (Nausea(TW) OR Vomiting(TW) OR Emesis(TW) OR 'nausea and vomiting'(TW))
#9	Nausea(MH) OR Nausea(TW) OR (postpro*(TW) OR postsurg*(TW)) AND nausea OR 'Nausea, Postoperative'(TW)
#10	Vomiting(MH) OR Vomiting(TW) OR Emesis(TW) OR 'post-procedure vomiting'(TW) OR 'vomiting, postoperative'(TW)
#11	#8 OR #9 OR #10
#12	#7 AND #11
#13	'Herbal Medicine'(MH) OR 'Plants, Medicinal'(MH) OR 'Medicine, Traditional'(MH) OR 'Drugs, Chinese Herbal'(MH) OR herb*(TIAB) OR plant(TIAB) OR plants(TIAB) OR phytomedicine(TIAB) OR botanical(TIAB) OR weed*(TIAB) OR algae(TIAB) OR fungi(TIAB) OR fungus(TIAB) OR (traditional(TIAB) OR chinese(TIAB) OR herbal(TIAB)) AND medicine(TIAB) OR (oriental(TIAB) OR chinese(TIAB)) AND tradition*(TIAB)
#14	#12 AND #13

MH, MeSH (Medical Subject Headings) terms; TW, text words; TIAB, title/abstract.

Korean Studies Information Service System, National Digital Science Library and Oriental Medicine Advanced Searching Integrated System; the Chinese database China National Knowledge Infrastructure; and the Japanese database Citation Information by NII.

If possible, additional data from registries, such as the Clinical Research Information Service and ClinicalTrials.gov, will be searched. We will check the relevant grey literature, such as ongoing research and committee reports, using Google Scholar and OpenGrey.

### Search strategy

We will use the search terms 'nausea and vomiting' and 'herbal medicine', which are indicative of the disease and intervention, respectively. The search strategy for Medline is presented in [table 1](#), and its modified versions will be applied according to the instructions of each database.

### Data collection and assessment

#### Study selection

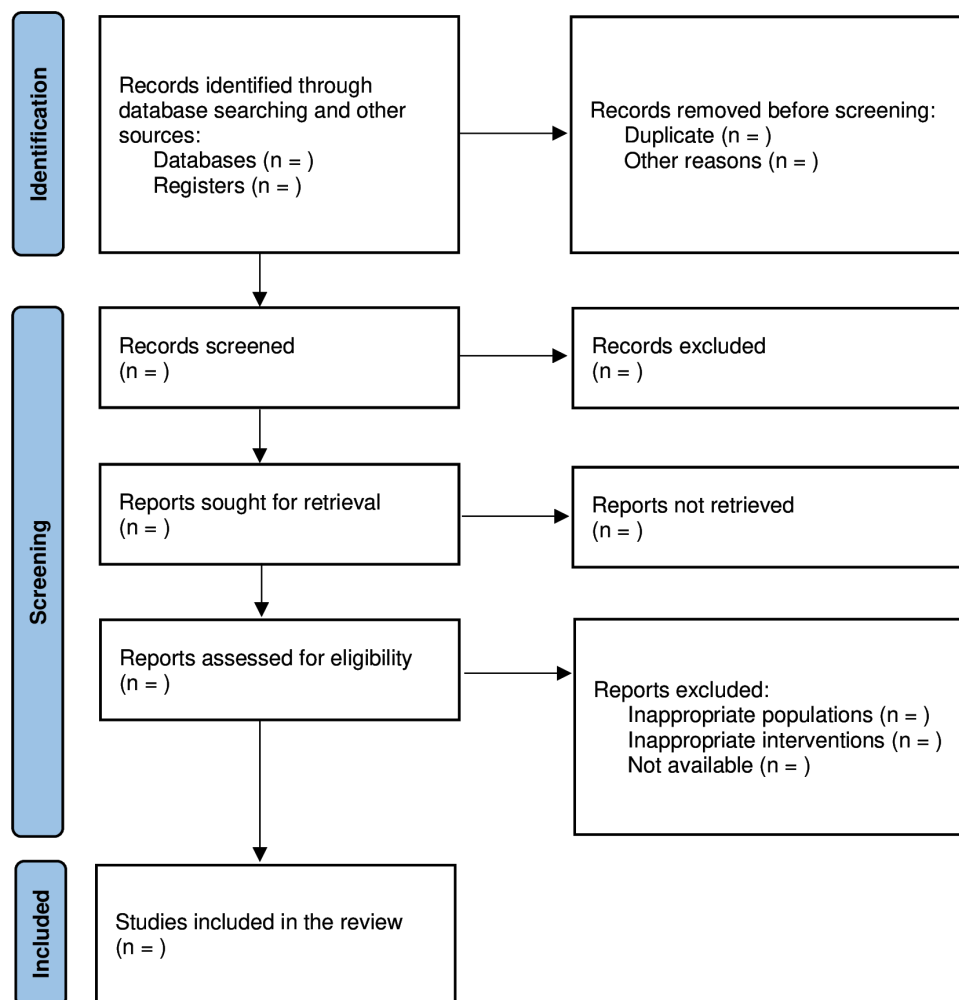
Two independent reviewers (N-YH and M-JP) will screen the titles and abstracts to determine the eligibility of the articles for this review. Articles will be collected and sorted using EndNote 20 (Clarivate Analytics, London, UK). After screening, investigators will independently review

the full-text articles to exclude irrelevant articles. Any disagreement between the two researchers throughout the review process will be arbitrated by a third party (JK). The details of this procedure are presented in the PRISMA flow diagram ([figure 1](#)).<sup>18</sup>

#### Data extraction

Two researchers will independently collect and manage the necessary research data through a predesigned standard data extraction form using Microsoft Excel (2019). The collected data will be verified by the third author, and the translation will be validated by an independent professional translator consultant. We will extract the following information: basic information of the study, including the first author, publication year, country and study design; characteristics of participants, including the mean age, sex distribution and sample size; interventions, including name, formulation and composition of prescription, control type, dosage and administration period; and outcomes, including outcome measures, results and statistical differences.

In the case of missing data, we will contact the corresponding author of the article by email to supplement the details.



**Figure 1** Flowchart of the search process.

### Quality assessment

The methodological quality of the included studies will be assessed using a revised version of the Cochrane tool to assess the risk of bias in randomised trials. Two independent reviewers will evaluate the risk of bias for each study. Disagreements among reviewers will be reconciled through discussion, assisted by an arbitrator, if necessary. The five domains of bias are as follows: bias arising from the randomisation process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in outcome measurement and bias in selection of the reported result. The assessments of bias for each domain are 'low risk of bias', 'some concerns' or 'high risk of bias'.<sup>19</sup>

The Grading of Recommendation Assessment, Development and Evaluation (GRADE) approach will be employed to assess the quality of evidence and interpret the results of this systematic review using the GRADEpro GDT software, which will be based on the categories of study limitations: inconsistency of results, indirectness of evidence, imprecision and reporting bias.<sup>20</sup>

### Data analysis and synthesis

#### Analysis and synthesis procedure

Data will be pooled using the Review Manager software (V.5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014). The outcomes will be presented as the risk ratio for discrete outcomes (eg, incidence rate of nausea) and mean difference for continuous outcomes (eg, intensity of nausea) with a 95% CI. Quantitative synthesis will be applied if methodological similarities are guaranteed between more than two RCT reports; otherwise, a narrative summary and tabulation will be presented.

#### Assessment of heterogeneity

Statistical heterogeneity among the articles will be quantified using  $I^2$  statistics for the meta-analysis. The outcomes will be treated under a random-effects model with significant heterogeneity ( $I^2 > 50\%$  may represent substantial heterogeneity); otherwise, a fixed-effects model will be applied.

#### Sensitivity analysis

Sensitivity analysis will be conducted to assess the robustness of the results via deleting studies with a high overall bias in methodological quality (high: any trial evaluated as 'high risk of bias' for more than three domains).

### Assessment of publication bias

A funnel plot will be used to assess publication bias if more than 10 relevant studies are identified.

### Analysis of subgroups

A subgroup analysis will be performed according to the type of surgery and Chinese herbal medicine. Variables, such as dosage and formulation of herbal medicine and treatment period, may also be considered in the subanalyses if sufficient data are available.

## ETHICS AND DISSEMINATION

Ethical approval is not required for this review because it is aimed to analyse the results of previous trials in which participants have already consented to the purpose of the study. The results of this study will be disseminated to peer-reviewed journals and posters.

## PATIENT AND PUBLIC INVOLVEMENT

The patients and public were not involved in the design process, data research or preparation for this study.

## DISCUSSION

PONV is a subjective discomfort experienced by approximately one-third of patients undergoing surgery.<sup>1,21</sup> It can lead to dehydration, electrolyte imbalance and aspiration pneumonia.<sup>22</sup> Patients with PONV spend 30% more time in the postanaesthesia care unit postoperatively, extending from 3 to 4 hours on average, compared with those without it. Additionally, the total cost of postoperative recovery was approximately 14% higher in patients with than in those without PONV (\$730 vs \$640, respectively). With the failure to manage the symptoms of PONV, the treatment period is prolonged, thus increasing the economic cost and adversely affecting patients' quality of life.<sup>21</sup> Nevertheless, PONV management has been considered less important than pain management.

LS is less invasive than open surgery and has the advantages of lower blood loss and fewer complications.<sup>23–24</sup> Thus, LS is preferred as a surgical practice; however, the high incidence of PONV after LS remains a cause of concern for both patients and surgeons.<sup>4</sup> A possible explanation for PONV is intestinal ischaemia caused by increased intra-abdominal pressure, which triggers the release of serotonin.<sup>25</sup> Well-defined management guidelines for PONV using various antiemetic drugs should be established to prevent and treat PONV, and drug-related adverse effects and postoperative complications must be properly managed for the rapid recovery of patients undergoing surgery.<sup>5, 26</sup>

Studies on the prevention of PONV have been conducted using complementary and alternative medicines, such as Chinese herbal medicine, to overcome the limitations of these treatment options. A single botanical drug, ginger, significantly improved both nausea and

vomiting compared with placebo according to a recent meta-analysis based on two RCTs with 212 participants after obstetrical/gynaecological surgery;<sup>27</sup> however, the evidence is still insufficient to clarify its effect.<sup>28</sup> In addition, as combination prescriptions containing multiple herb species are prescribed more frequently than single herbs in clinical fields, synthesising various herbal preparations and analysing their overall effectiveness in PONV are necessary.

This systematic review aims to analyse the effects of Chinese herbal medicine compared with placebo or Western medicine for treating PONV caused by LS. This study will investigate whether the quality of life and complications of surgical patients can be managed and improved with concurrent administration of herbal and Western medicines compared with the discrete use of Western medicine. We will search multiple databases with a reproducible search plan and include both published and unpublished papers to cover all possible outcome variables.

A potential limitation that may affect the final conclusions of this study is the poor methodological quality of the included studies. However, to the best of our knowledge, this review will be the first to comprehensively assess and synthesise clinical evidence of the preventive and therapeutic effects of Chinese herbal medicine and combination therapy on nausea and vomiting after LS. These future findings will facilitate the decision making of patients, clinicians and policymakers through establishing evidence for the management of PONV related to LS with herbal medicine and providing guidelines for its use. Therefore, we plan to submit the results of this systematic review for publication in a peer-reviewed journal and disseminate the clinical data on reasonable request.

**Contributors** This study was first conceptualised by N-YH and M-JP. The protocol was designed by N-YH and JK. N-YH and M-JP conducted the data search and investigation in this study. The original draft of this manuscript was written by N-YH and finally confirmed by JK. All authors read and approved the final version of this article.

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**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

**Patient consent for publication** Not applicable.

**Provenance and peer review** Not commissioned; externally peer reviewed.

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