



Review Article / 총설

위암 수술 후 항암치료를 병행한 한의치료의 유효성 및 안전성: 체계적 문헌고찰 및 메타분석 프로토콜

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Efficacy and Safety of Combination Treatment of Traditional Korean Medicine after Gastric Cancer Surgery: A Systematic Review and Meta-analysis Protocol.

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ABSTRACT

Objectives : Gastric cancer is a malignant tumor of the digestive tract that not only has a high mortality rate, but also affects quality of life. In Traditional Korean Medicine, acupuncture and herbal medicines can increase the survival rate for Gastric cancer and improve the quality of life. Traditional Korean Medicine treatment played an important role when used alone or in combination with chemotherapy. However, there is still insufficient evidence to support

the efficacy and safety of Traditional Korean Medicine in patients undergoing chemotherapy after surgery. Therefore, the purpose of this study is to systematically evaluate the effect of oriental medicine treatment on patients as a complementary therapy for Gastric cancer.

Methods : 2 researchers will search using EMBASE, Pubmed, CNKI, Cochrane Library, CiNii, KMBASE, KISS, OASIS, RISS, ScienceON. The search period of the database is from inception until June 2022. This study will include a randomized controlled trial of GC for acupuncture and herbal treatment. Primary outcomes include anti-cancer effects. Secondary outcomes evaluate survival rates and improvements in quality of life. The data uses Review Manager Software 5.4.

Results : This study will provide a systematic evaluation by synthesizing the anti-cancer effect, survival rate and quality of life of Gastric cancer when Traditional Korean Medicine is combined with chemotherapy.

Conclusion : The conclusion of this study will provide a basis for determining whether Traditional Korean Medicine treatment for Gastric cancer treatment is an effective and safe treatment method in clinical practice.

Key-words : Gastric cancer, Traditional Korean Medicine, Integrative oncology, Acupuncture, Herbal medicine, Systematic review Protocol.

1. Introduction

In 2020, gastric cancer (GC) was responsible for over 1 million new cases and 769,000 deaths worldwide. GC is the fourth leading cause of cancer death and the fifth most common cancer globally. Men are affected at twice the rate of women ¹⁾. GC mainly refers to adenocarcinoma arising from glandular cells (gland cells) of the gastric mucosa. Gastric adenocarcinoma can be further classified into several types based on the morphology of the cancer cells ²⁾. In addition to gastric adenocarcinoma, there are rare lymphomas arising in lymphoid tissue of the stomach, gastrointestinal tumors originating from stromal cells of the stomach, and sarcoma, a malignant tumor originating from non-epithelial cells ³⁾. The treatment approach for GC is determined by its progression and can be broadly categorized into biologic therapeutic agents, radiotherapy, chemotherapy, and surgical resection ⁴⁾. Furthermore, patients may experience psychological distress following a cancer diagnosis, side effects from chemotherapy, and post-surgical complications. As a

result, the quality of life after surgery is often severely deteriorated due to these psychological and physiological changes ⁵⁾. According to one study, patients after gastric cancer surgery face many challenges, including physical discomfort, economic hardship, and how to deal with unemployment ⁶⁾. Therefore, it is important to improve the quality of life and prolong the survival of patients with advanced GC.

Traditional Korean Medicine (TKM) is a complementary and alternative medicine that can improve the quality of life of cancer patients and it includes therapeutic modalities such as acupuncture and herbal medicine ⁷⁾. Research has shown that TKM enhances the therapeutic effects of conventional cancer treatments and increases survival rates through comprehensive care ⁸⁾. TKM can also help with the postoperative complications of GC and reduces the side effects of radiation therapy and chemotherapy ⁹⁾. Some studies have found that combining chemotherapy with acupuncture can help improve gastrointestinal symptoms and quality of life in gastric cancer patients ^{10,11)}. Another study found

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that herbal medicine prescription can increase immunity for cancer patients, inducing cell death through apoptosis^{12,13}. However, there has not yet been a systematic review to standardize the effect of the combination treatment method of TKM and GC. Therefore, this study aims to use a meta-analysis to assess the efficacy and safety of postoperative herbal combination therapy for GC, providing clinical evidence.

2. Material and methods

This protocol has been registered on PROSPERO (CRD 42022354133) and will be according to the guidelines of Preferred Reporting Items for Systematic Reviews and Meta-analysis¹⁴.

2.1 Selection criteria

2.1.1 Type of studies

Selection Criteria: Randomized controlled trials (RCTs) that evaluated the efficacy and safety of (electro) Acupuncture and herbal medicine in the treatment of GC will be included. Documents written in Korean, Chinese, and English will be included.

Exclusion Criteria: All cases where the study was designed with non-human animal subjects, a preclinical study, case studies without a control group during clinical studies, Observational research and cross over design will be excluded.

2.1.2 Types of patients

Patients with gastric cancer, including those with

early-stage, advanced, and late-stage gastric cancer, will be included. Cases of gastric cancer with no specific cause will also be included.

2.1.3 Types of interventions and comparisons

The treatment group should be a combination of chemotherapy and TKM (acupuncture, electroacupuncture, acupressure, auricular acupuncture, herbal medicine) or TKM alone after surgery. Studies in which TKM treatment is not included as an intervention in the treatment group are excluded. The control group is based on studies using no treatment, conventional western medicine alone, and a placebo group without the use of TKM.

2.1.4 Types of outcomes

The primary outcome is the anti-cancer effect. The anticancer effect will be evaluated by using any tool. Secondary outcomes include improved survival rates and quality of life measured by using any tool.

2.2 Search strategy

As a search engine, domestic web databases KMBASE, KISS, OASIS, RISS, ScienceON and overseas web databases EMBASE, Pubmed, CNKI, Cochrane Library, and CiNii will be used for searching. The search period is from their inception to June 2022. Table 1 and 2 show the search strategy for the PubMed database, which will be searched in the corresponding database. This research is only focused on the aforementioned electronic searches.

Table 1. Search Strategy (Herbal Medicine)

Number	Search terms	Search result
#1	“gastrointestinal neoplasms”[Mesh] or “stomach neoplasms”[Mesh]	
#2	(carcin* or cancer* or neoplas* or tumour* or tumor* or cyst* or growth* or adenocarcin* or malig* or neoplasm* or metastas*)	
#3	(gastr* or stomach*)	
#4	#2 and #3	
#5	#1 or #4	
#6	gastrectomy[Mesh]	
#7	“gastric cancer surgery”[tiab] or “gastric cancer operation”[tiab] or gastrectomy[tiab]	
#8	laparoscopy[Mesh]	
#9	laparoscopy[tiab] or laparoscopic[tiab]	
#10	#6 or #7 or #8 or #9	
#11	#5 and #10	
#12	"Plants, Medicinal"[Mesh]	
#13	"Plant Extracts"[Mesh]	
#14	"Drugs, Chinese Herbal"[Mesh]	
#15	"Plant Preparations"[Mesh]	
#16	"Herbal Medicine"[Mesh]	
#17	"Medicine, East Asian Traditional"[Mesh]	
#18	"Medicine, Korean Traditional"[Mesh]	
#19	"Medicine, Chinese Traditional"[Mesh]	
#20	"Medicine, Traditional"[Mesh]	
#21	Phytotherapy[Mesh]	
#22	“Plant Extracts”[tiab] OR “Herbal Medicine”[tiab]	
#23	(Chinese adj3(medic* or herb* or drug* or formul* or plant* or prescri*)[tiab]) OR (herb*[tiab] OR plant*[tiab] OR phytodrug*[tiab])	
#24	#12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23	
#25	randomized controlled trial [pt]	
#26	controlled clinical trial [pt]	
#27	randomized [tiab]	
#28	placebo [tiab]	
#29	RCT [tiab] or (random* [tiab] AND allocat* [tiab]) or (random* [tiab] AND assign* [tiab])	
#30	trial [tiab]	
#31	group [tiab]	
#32	#25 or #26 or #27 or #28 or #29 or #30 or #31	
#33	animals [mh] NOT humans [mh]	
#34	#32 NOT #33	
#35	#11 and #24 and #34	



Table 2. Search Strategy (Acupuncture)

Number	Search terms	Search result
#1	“gastrointestinal neoplasms”[Mesh] or “stomach neoplasms”[Mesh]	
#2	(carcin* or cancer* or neoplas* or tumour* or tumor* or cyst* or growth* or adenocarcin* or malig* or neoplasm* or metastas*)	
#3	(gastr* or stomach*)	
#4	#2 and #3	
#5	#1 or #4	
#6	gastrectomy[Mesh]	
#7	“gastric cancer surgery”[tiab] or “gastric cancer operation”[tiab] or gastrectomy[tiab]	
#8	laparoscopy[Mesh]	
#9	laparoscopy[tiab] or laparoscopic[tiab]	
#10	#6 or #7 or #8 or #9	
#11	#5 and #10	
#12	acupuncture [Mesh]	
#13	acupuncture therapy [Mesh]	
#14	auriculotherapy [Mesh]	
#15	acupuncture [tiab] or auriculotherapy [tiab] or electroacupuncture [tiab] or electro-acupuncture [tiab]	
#16	acupunct*[tw] or acupress*[tw] or acupoint*[tw] or electroacupunct*[tw] or electro-acupunct*[tw] or auriculotherap*[tw] or auriculoacupunct*[tw]	
#17	#12 or #13 or #14 or #15 or #16	
#18	randomized controlled trial [pt]	
#19	controlled clinical trial [pt]	
#20	randomized [tiab]	
#21	placebo [tiab]	
#22	RCT [tiab] or (random* [tiab] AND allocat* [tiab]) or (random* [tiab] AND assign* [tiab])	
#23	trial [tiab]	
#24	group [tiab]	
#25	#18 or #19 or #20 or #21 or #22 or #23 or #24	
#26	animals [mh] NOT humans [mh]	
#27	#25 NOT #26	
#28	#11 and #17 and #27	

2.3 Study selection and data extraction

2.3.1 Selection of studies

Two researchers will conduct searches based on the research criteria and strategies, managing the references using the Endnote version 20 program¹⁵⁾. Two researchers will independently evaluate the titles and abstracts of the studies and select them for

further evaluation. The next step involves reading the full-text, and the selection results will be cross-checked by the two reviewers. Any disagreement will be resolved by consensus. The further argument will be handled by the third reviewer. Excluded studies are recorded with reason. The process for thesis topic selection will be outlined.

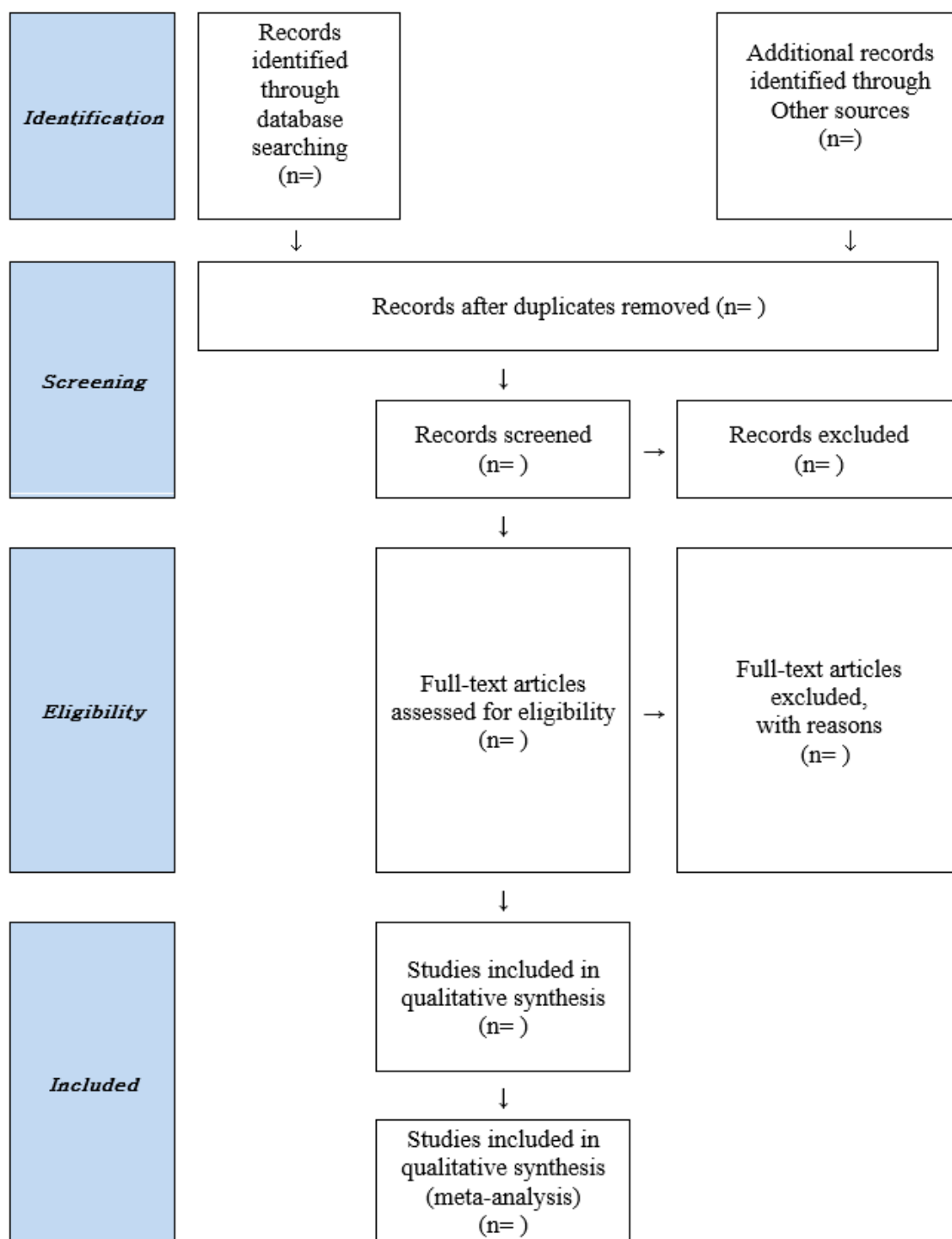


Figure 1. PRISMA flowchart



2.3.2 Data extraction

Data will be extracted by two independent researchers. Extracted data will include first author, the year of study publication, study period, participants, comparison, interventions in treatment and control groups, outcome and adverse event. If there are any missing data, the team will discuss it, and the first author may be contacted by e-mail for clarification.

2.3.3 Assessment of risk of bias

We will use the Cochrane Risk of Bias (ROB) to assess the selected literature data (16). The risk of trial bias is assessed through 7 items: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data addressed, selective reporting, and other bias. The evaluation will be conducted by selecting one of three responses: “Low risk”, “High risk” or “Unclear risk”. A high risk of bias can be ruled out by evaluating the quality of the literature. Two reviewers will input these data into the RevMan software.

2.3.4 Data synthesis

Review Manager Software 5.4 will be used to generate all data results. Efficacy data will be classified based on patient characteristics, treatment, control, and outcome assessment. The data will be synthesized and examined based on the degree of statistical heterogeneity. If the heterogeneity tests reveal minimal or no statistical heterogeneity in these trials, the fixed-effects model will be applied to the pooled data. If significant heterogeneity is discovered (I^2 value greater than 50%), the random-effects model will be used for data synthesis. Meta-analysis will not be performed if the trials are highly heterogeneous.

2.3.5. Measurement of treatment effect

In this study, the risk ratio (RR) with 95% confidence interval (CI) is used to measure

dichotomous data. For continuous data, the mean difference (MD) with a 95% CI will be used when measuring treatment outcomes on the same scale. Standard mean differences (SMD) will be used when measuring treatment outcomes on different scales.

2.3.6. Unit of analysis issue

Before statistical analysis, the units of each outcome from different trials will be converted to the International System of Units.

2.3.7 Dealing with missing data

Reviewers will contact the first author of the study to obtain any missing data. Data will be excluded if information cannot be obtained.

2.3.8 Assessment of heterogeneity

Heterogeneity will be calculated using Higgins' I^2 . If the study heterogeneity is less than $P=.05$ and the I^2 is less than 50%, it is determined that there is no heterogeneity between the two studies, and the fixed effect model is used for meta-analysis. If I^2 exceeds 50%, it is determined that there is heterogeneity and the random effect model is applied.

2.3.9 Assessment of reporting bias

A funnel plot will be used to detect reporting bias when more than 10 studies are included.

2.3.10 Sensitivity analysis

Sensitivity analysis will be performed to assess the reliability of the primary decisions made throughout the review process. Various decision nodes, such as small studies, methodological flaws, and missing data, will be considered during the systematic review process to conduct a sensitivity analysis.

2.3.11 Evaluation of the evidence quality

Two researchers will use the Grading of Recommendations Assessment, Development, and Evaluation to assess the quality of evidence. The quality of evidence will be evaluated based on five

factors: study design, literature quality, volume of evidence, consistency of evidence, and directness of evidence. It will be categorized as high, moderate, low, or very low quality ¹⁷⁾.

2.4 Ethics and dissemination

This study does not require ethical approval as it has not been linked to developing patient data.

3. Discussion

GC has a high morbidity and mortality rate worldwide, which underscores the ongoing need for new treatment methods ¹⁸⁾. Factors predisposing individuals to gastric cancer encompass non-modifiable attributes such as ethnicity, age, and sex, along with other contributors like infection from *Helicobacter pylori* bacteria, consumption of foods rich in nitrates and nitrites, and tobacco usage. Beyond these, elements like genetic predispositions, past medical records, and malignant anemia also play roles in the manifestation of stomach cancer ¹⁹⁾. Standard treatments for gastric cancer span from surgical interventions and radiotherapy to chemotherapy. However, instances of relapse and adverse reactions are not uncommon ²⁰⁻²¹⁾. Moreover, patients might grapple with emotional distress stemming from tumor identification, post-surgical complications, and treatment aftermaths ²²⁾. Chemotherapy drugs routinely employed in addressing gastric cancer, like Oxaliplatin, are often accompanied by side effects including nausea, vomiting, diarrhea, and diminished appetite ²³⁾. Notably, supplementary chemotherapy doesn't consistently enhance survival outcomes ²⁴⁾. Gastric cancer management, encompassing surgical and chemotherapeutic avenues, not only incurs substantial expenses but also inflicts pain, poses societal challenges, and crucially, compromises patients' life quality. As a result, refining gastric cancer treatments stands as a pressing concern ²⁵⁾. Among various treatments for gastric cancer, TKM is performing its

role as a therapeutic agent by reducing the side effects of conventional chemotherapy, improving patient quality of life, and inhibiting cancer cell proliferation ^{26,27)}. Acupuncture and herbal medicine are the major therapeutic modalities that helps with side effects of gastric cancer surgeries and method of improving quality of life of cancer patient comprehensively ²⁸⁻³²⁾. Despite the fact that there are numerous randomized clinical trials evaluating TKM's therapeutic effects on gastric cancer management, systematic reviews on TKM for the treatment of gastric cancer are still lacking. As a result of reviewing and meta-analyzing the results of various RCTs, it is expected to develop ideal treatment strategies for gastric cancer patients while also evaluating their efficacy and safety. The study's limitations include the various stages and types of gastric cancer, as well as the various types of treatment methods. It may increase heterogeneity; however, because this study evaluates the efficacy and safety of TKM as it is, it is expected to draw some meaningful clinical recommendations.

Author contributions

Conceptualization: Jonghee Kim

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Methodology: Jonghee Kim, Soodam Kim,
Eunbin Kwag

Supervision: Hwa-Seung Yoo, Sojung Park

Writing – original draft: Jonghee Kim,
Eunbin Kwag

Writing – review & editing: Eunbin Kwag

Funding source: No such involvement

Abbreviations

GC = gastric cancer, TKM = Traditional Korean Medicine, RCTs = randomized controlled trials, ROB = Cochrane Risk of bias, RR = risk ratio, CI = confidence interval, MD = mean differences, SMD = Standard mean differences.

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Data Availability

The data used to support the findings of this study are included within the article.

Conflicts of interest

The authors have no conflicts of interest to disclose.

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