

Efficacy and safety of American ginseng-based therapies for cancer: a systematic review and meta-analysis

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ABSTRACT

Introduction To systematically evaluate the efficacy and safety of American ginseng (AG, *Panax quinquefolius* L.)-based cancer therapies and assess the certainty of the available evidence. **Methods** We searched the China National Knowledge Infrastructure, Wanfang, Chinese Scientific Journals Database, SinoMed, PubMed, Embase, and the Cochrane Library databases from inception until December 8, 2025, and updated the search through June 30, 2026, for randomized controlled trials (RCTs) evaluating AG-based therapies for malignant tumors. Two reviewers independently selected studies, extracted data, assessed risk of bias using the Cochrane Risk of Bias 2 tool, and assessed evidence certainty using the Grading of Recommendations Assessment, Development and Evaluation (GRADE)pro guideline development tool. Disagreements were resolved by consultation with a third reviewer. Meta-analyses, data visualization, and sensitivity analyses were performed using R software. **Results** The meta-analysis included 15 RCTs involving 1415 participants (intervention group: 857 participants; control group: 558 participants). Pooled analyses of traditional Chinese medicine (TCM) formulations containing AG suggested a higher objective response rate (ORR) when combined with conventional medical treatment (CMT) (risk ratio [RR] = 1.39, 95% confidence interval [CI]: 1.04, 1.85) and a higher disease control rate (DCR) when administered alone or in combination with CMT (RR = 1.21, 95% CI: 1.10, 1.33). A higher proportion of patients receiving AG-containing TCM formulations met the study-defined criterion for improved Karnofsky Performance Status (KPS) (RR = 2.62, 95% CI: 1.63, 4.21). Pooled estimates also favored AG-containing TCM formulations plus CMT for chemotherapy-related leukopenia, gastrointestinal reactions, hepatic dysfunction, and alopecia, although several of these estimates were based on a small number of studies. The certainty of evidence across outcomes was low or very low. **Conclusion** Although several pooled estimates favored AG-containing TCM formulations, the certainty of the available evidence was low to very low certainty. Therefore, our findings should be considered exploratory rather than confirmatory.

Registration This study was registered with the International Prospective Register of Systematic Reviews (<https://www.crd.york.ac.uk/PROSPERO/>, CRD420261419243).

KEYWORDS

American ginseng, cancer, objective response rate, disease control rate, randomized controlled trial, systematic review, meta-analysis

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1. Introduction

The global burden of cancer continues to increase, with approximately 20 million new cancer cases and 9.7 million cancer deaths estimated worldwide in 2022.¹ Traditional Chinese medicine (TCM) is used in supportive cancer care to alleviate symptoms, reduce treatment-related adverse effects, and maintain quality of life.^{2,3} American ginseng (AG, *Panax quinquefolius* L.), a perennial species of the family Araliaceae, has also been used in supportive care for patients with cancer and replenishes qi and nourishes yin while clearing heat and generating fluids in TCM.⁴

AG has also been evaluated in contemporary oncology. Based on evidence from randomized controlled trials (RCTs), the American Society of Clinical Oncology (ASCO) lists AG among interventions that may be considered for cancer-related fatigue.^{5,6} Its major constituents include ginsenosides and polysaccharides, and preclinical studies have reported antitumor activity for

several ginsenosides, including Rg2 and Rg3, as well as other dammarane-type saponins.⁴ Experimental and clinical studies have also suggested possible effects on the chemotherapy response, immune regulation, and treatment-related toxicity.⁷⁻⁹

However, existing reviews in oncology have largely focused on fatigue or broader ginseng-containing preparations rather than comprehensively evaluating AG-based cancer therapies across cancer types and clinical outcomes.¹⁰ Thus, the overall efficacy and safety of AG-based therapies in patients with cancer remain uncertain. To our knowledge, no previous systematic review and meta-analysis has comprehensively evaluated these therapies across multiple cancer types. Therefore, we systematically evaluated RCTs of herbal formulas or proprietary medicines in which AG was the principal component, as well as single-ingredient AG preparations, administered either alone or in combination with conventional medical treatment (CMT). We evaluated antitumor efficacy, safety, functional outcomes, and selected immune indicators and, where appropriate, quantitatively synthesized comparable outcomes.

2. Methods

This review was planned, conducted, and reported in accordance with the

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Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRIS-MA) 2020 statement.¹¹

2.1. Eligibility criteria

2.1.1. Participants

Eligible trials enrolled patients with confirmed malignant tumors. Eligibility was not restricted by tumor site, disease stage, comorbidities, ethnicity, nationality, geographical region, age, or disease duration.

2.1.2. Interventions and comparators

Eligible experimental interventions were centered on AG and comprised (I) tablets or capsules containing AG as the sole herbal ingredient, (II) multi-herb decoctions in which AG was designated as the principal herb, and (III) proprietary Chinese medicines in which AG was the principal ingredient. These interventions could be given alone or in combination with CMT. Comparator groups received CMT (chemotherapy, radiotherapy, or both), placebo, or no additional treatment. The eligibility criteria did not include dose and treatment course.

2.1.3. Outcomes

The primary outcomes were short-term efficacy indicators, including objective response rate (ORR) and disease control rate (DCR) for solid tumors. Included studies were required to report tumor responses according to World Health Organization (WHO) criteria¹² or the Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1.¹³ Response categories included complete response (CR), partial response (PR), stable disease (SD), and progressive disease (PD). ORR was defined as CR + PR and DCR as CR + PR + SD. Secondary outcomes covered three domains. First, functional status was evaluated using the Karnofsky Performance Status (KPS), including the proportion of participants meeting the improvement definition adopted by the original trial (a post-treatment increase of > 10 points) and the absolute change in KPS score.¹⁴ The > 10-point criterion was treated as a trial-defined response threshold rather than as a validated minimal clinically important difference. Second, safety outcomes included leukopenia, gastrointestinal reactions, hepatic dysfunction, and alopecia during treatment. Third, immune outcomes included post-treatment changes in the percentages of CD3⁺ T cells, CD4⁺ T cells, and natural killer (NK) cells among lymphocytes.

2.1.4. Study design

RCTs published in Chinese and English were eligible.

2.2. Exclusion criteria

Studies were excluded if they (I) had incomplete or duplicate data, (II) were unavailable in full text, or (III) were ineligible research types, such as conference abstracts, case reports, or narrative reviews.

2.3. Search strategy

The China National Knowledge Infrastructure (CNKI), Wanfang Data, Chinese Scientific Journals Database (VIP), SinoMed, PubMed, Embase, and Cochrane Library databases were searched from their inception to December 8, 2025 (The initial database searches and management of retrieved records were carried out by ZYL and SYS), and the search was updated through June 30, 2026. Chinese search terms included “yangshen,” “xishen,” “huaqishen,” and “Guangdong renshen,” and English search terms included “American ginseng,” “*Panax quinquefolius*,” and “ginseng.” The complete database-specific search strategies are provided in Appendix 1.

2.4. Screening process and data extraction

Two reviewers (TXL and YKS) independently screened all retrieved records. Records were first deduplicated using NoteExpress (Beijing Aegean Software, Beijing, China), after which titles and abstracts were screened and

potentially relevant reports underwent full-text assessment. Disagreements were resolved through discussion or consultation with a third reviewer (KL).

Data were independently extracted by two reviewers (TXL and YL) using a predefined form and checked by a third reviewer (KL). Extracted data included: (I) study characteristics (first author, publication year); (II) participant characteristics (sample size, age, diagnostic criteria, tumor type and stage, disease duration, and baseline comparability); (III) intervention details (formula name, main components, route of administration, dosage, treatment course, and co-interventions); (IV) comparator details; (V) outcome data; and (VI) information relevant to risk-of-bias assessment. For duplicate publications, the report with the most complete information or largest sample size was retained.

Studies were eligible for quantitative synthesis if they reported the same prespecified outcome using a compatible measurement definition, involved clinically comparable patient populations and comparator types (e.g., an AG-based intervention vs. CMT or placebo), or provided extractable numerical data. Studies meeting these criteria were pooled for meta-analysis.

2.5. Risk-of-bias and certainty-of-evidence evaluation

Risk of bias was independently assessed by two reviewers (TXL and YKS) using the Cochrane RoB 2 (RoB 2) tool.¹⁵ The assessment considered bias arising from the randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result. Each domain and the overall trial were classified as low risk of bias, some concerns, or high risk of bias.

The certainty of evidence for each outcome was independently assessed by two reviewers (TXL and YL) using the Grading of Recommendations Assessment, Development and Evaluation GRADEpro Guideline Development Tool (GRADEpro GDT).¹⁶ Certainty was rated as high, moderate, low, or very low based on risk of bias, inconsistency, indirectness, imprecision, and publication bias. Disagreements were resolved through discussion with a third reviewer (KL).

2.6. Statistical analysis

Statistical analyses and data visualization were performed using R software (R Foundation for Statistical Computing, Vienna, Austria), primarily with the *meta* and *robvis* packages. Although the review included several forms of AG-based therapies, trials of single-ingredient AG did not provide data that contributed to the pooled efficacy, KPS, chemotherapy-related toxicity, or immune analyses. Therefore, the quantitative syntheses were based on AG-containing TCM formulas or proprietary Chinese medicines in which AG was the principal component, administered either alone or with CMT.

Meta-regression was not performed because too few studies contributed to each outcome to support reliable regression analyses. Because clinical heterogeneity was anticipated across formulations, comparators, and patient characteristics, random-effects models were used for all meta-analyses. Risk ratios (RRs) with 95% confidence intervals (CIs) were used to summarize binary outcomes, whereas mean differences (MDs) with 95% CIs were used for continuous outcomes. For three-arm trials,^{8,17} only arms relevant to the prespecified contrast were analyzed, and shared control groups were not counted twice within a pairwise synthesis. Between-study heterogeneity was assessed using the Cochran Q test and the *I*² statistic. Leave-one-out sensitivity analyses were conducted for the primary outcomes to evaluate the robustness of the findings. Funnel plots and Egger's regression test were planned only for outcomes represented by at least 10 studies. All statistical tests were two-sided, and statistical significance was set at *P* < 0.05.

3. Results

3.1. Study selection

A total of 61 273 records were identified. After deduplication, records

underwent title/abstract screening and full-text eligibility assessment. After excluding ineligible records (e.g., inappropriate study design⁷ or insufficient data¹⁸), 15 studies^{5,8,9,17,19–29} were included, comprising 12 Chinese-language^{8,9,19–28} and three English-language publications^{5,17,29}. The study selection process is shown in Figure 1.

3.2. Characteristics of the included studies

The 15 included RCTs enrolled 1415 participants (857 in the intervention groups and 558 in the control groups) and were published between 1997 and 2024. The trials included a range of malignancies, including lung and esophageal cancers. The characteristics of the included studies are summarized in Table 1. The predominant comparison was AG-containing TCM formulations plus CMT versus CMT alone, whereas fewer studies compared AG-containing TCM formulations with CMT alone. Thirteen distinct AG-based intervention regimens were identified, as detailed in Appendix 2. The report-

ed outcomes included ORR, DCR, KPS improvement, and changes in KPS score, leukopenia, gastrointestinal reactions, hepatic dysfunction, alopecia, and selected immune function indicators.

3.3. Risk-of-bias assessment

Risk of bias was assessed for all 15 RCTs using the RoB 2 tool (Figure 2). Overall, one study⁵ was rated as having a low risk of bias, seven^{9,17,22,23,24,25,28} as having some concerns, and seven^{8,19,20,21,26,27,29} as having a high risk of bias, indicating substantial methodological limitations in the included evidence base.

Regarding the randomization process, only two studies^{5,17} explicitly reported computer-generated random allocation one of which also reported trial registration information⁵; both were rated as having a low risk of bias in this domain. Two studies^{19,27} provided insufficient information regarding the basis for random allocation and were rated as having a high risk of bias. The remaining studies reported only that participants were randomly allocated

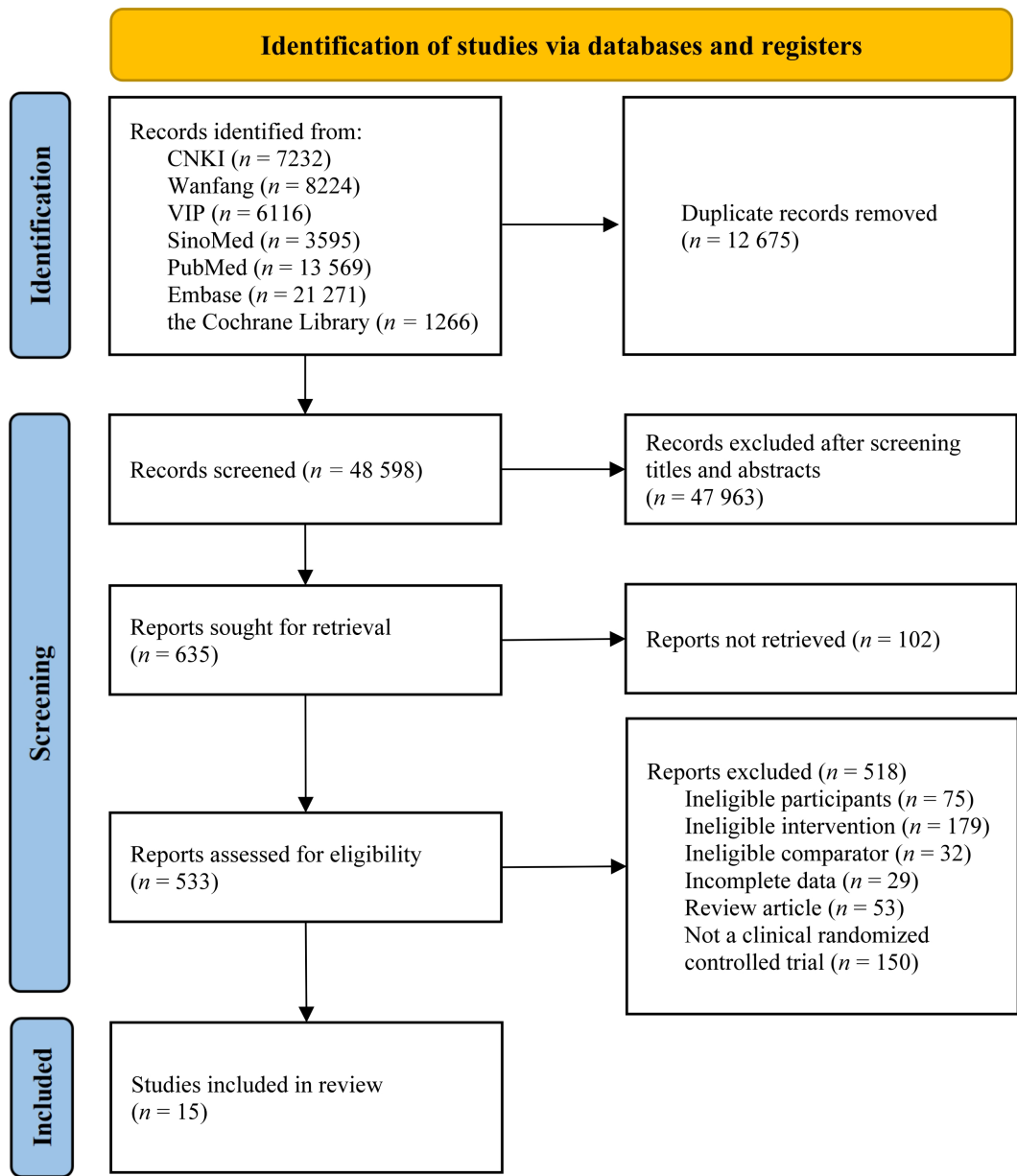


Figure 1 PRISMA flow diagram for the study selection process

Notes: CNKI: China National Knowledge Infrastructure; n: number; PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses; VIP: Chinese Scientific Journals Database.

Table 1 Characteristics of included studies

Study ID	Disease/condition	Sample size		Sex (M/F)		Age, y, (mean [SD], or range)		Treatment		Course (d)	Outcomes
		CG	IG	CG	IG	CG	IG	CG	IG		
Barton DL (2013) ⁵	Cancer-related fatigue	171	170	42/128	33/138	55.9 (11.8)	55.3 (12.7)	Placebo capsules; 2000 mg each time, twice daily	AG capsules; 2000 mg each time, twice daily	56	No quantitatively poolable outcomes
Wang J (2018) ⁸	Advanced esophageal adenocarcinoma	A: 30	B: 30; C: 30	A: 19/11	B: 18/12; C: 20/10	A: 45-76	B: 42-75; C: 45-75	A: Chemotherapy (FOLFOX4); FOLFOX4 biweekly regimen: oxaliplatin 85 mg/m ² , IV over 2 h (day 1); leucovorin 400 mg/m ² , IV over 2 h (days 1-2); 5-FU 400 mg/m ² , IV bolus then 600 mg/m ² continuous infusion over 22 h (days 1-2)	B: AG- <i>Hedyotis diffusa</i> decoction + chemotherapy (FOLFOX4); C: AG- <i>Hedyotis diffusa</i> decoction (monotherapy); Same as group A plus AG- <i>Hedyotis diffusa</i> decoction (AG 20 g, <i>Hedyotis diffusa</i> 15 g) 100 mL orally twice daily	84	ORR, DCR, KPS improvement rate, leukopenia rate, GI reaction rate, hepatic dysfunction rate
Yang CX (2007) ⁹	Cisplatin-induced renal injury	19	19	15/4	11/9	32-70	31-69	Chemotherapy (cisplatin) Cisplatin-based chemotherapy 30 mg/m ² ; basic supportive treatment + oral oxidized starch 10 g three times daily. 1 course = 1 month for both groups	Chongcao Yangshen capsule + chemotherapy (cisplatin) Cisplatin-based chemotherapy 30 mg/m ² + Chongcao Yangshen capsules 0.067 g/(kg • d) orally, 4 capsules three times daily	30	No quantitatively poolable outcomes
Barton DL (2010) ¹⁷	Cancer-related fatigue	D: 69	A: 70; B: 72; C: 71	D: 24/45	A: 24/46; B: 25/47; C: 23/48	D: 62 (13)	A: 58 (11); B: 60 (12); C: 62 (11)	placebo; placebo capsules daily	A: AG capsules 750 mg; B: AG capsules 1000 mg; C: AG capsules 2000 mg	56	No quantitatively poolable outcomes
Wang SL (2014) ¹⁹	Esophageal cancer	45	45	30/15	28/17	56-74	53-77	Chemotherapy (5-FU + cisplatin); 5-FU 500 mg/m ² on days 1-2, repeated every 3 weeks; cisplatin 30 mg/m ² on days 1-3, repeated every 3 weeks; comprehensive evaluation after three cycles	Shenqi Tongyou decoction + chemotherapy Take the decoction twice a day in the morning and evening for 14 days, after that cease for 7 days; concurrent with chemotherapy; one cycle = 3 weeks; comprehensive evaluation after three cycles	45	ORR, DCR, KPS score change, leukopenia rate
Qin Y (2016) ²⁰	Cervical cancer	30	30	0/30	0/30	49.74 (6.52)		Chemotherapy (paclitaxel + irinotecan) / (mitomycin + cisplatin + 5-FU); Chemotherapy / TACE	Fuzheng Guben decoction + chemotherapy (paclitaxel + irinotecan) / TACE (mitomycin + cisplatin + 5-FU); Chinese herbal decoction one pack per day, regular preparation, taken decoction warm twice daily + chemotherapy / TACE	180-360	ORR, DCR, KPS score change, GI reaction rate, hepatic dysfunction rate, alopecia
Wu B (2009) ²¹	Leukopenia	35	45	20/15	21/24	41	43	Batyl alcohol 50 mg, three times daily	Fuzheng capsule; two capsules each time, three times daily	28	No quantitatively poolable outcomes

(To be continued on the next page)

(Continued)

Study ID	Disease/condition	Sample size		Sex (M/F)		Age, y, (mean [SD], or range)		Treatment		Course (d)	Outcomes
		CG	IG	CG	IG	CG	IG	CG	IG		
Liu Z (2005) ²²	Non-small cell lung cancer	29	36	19/10	25/11	44-75	42-72	Chemotherapy (vinorelbine + carboplatin / paclitaxel + carboplatin / gemcitabine + carboplatin); vinorelbine + carboplatin / paclitaxel + carboplatin / gemcitabine + carboplatin	Compound Zaofan pill + chemotherapy; 9 pills each time, three times daily, for 9-10 weeks + at least two cycles of chemotherapy	70	Leukopenia rate
Piridon (2023) ²³	Laryngeal cancer	34	34	28/6	31/3	59.70 (6.58)	60.59 (5.84)	Postoperative limited-field radiotherapy (60-66 Gy); (1) modified vertical partial laryngectomy under general anesthesia: exposure of thyroid cartilage lamina, resection of tumor with 1 cm margin, vocal cord, laryngeal muscles, inner perichondrium, and thyroid cartilage, reconstruction of phonation, closure; (2) Limited-field radiotherapy 60-66 Gy starting on postoperative day 28. 1 cycle = 21 days, two cycles in total	Huangqi Baizhu and AG oral liquid + postoperative radiotherapy; one vial each time, three times daily	42	KPS improvement rate
Li X (2024) ²⁴	Radiation pneumonitis	50	50	32/18	33/17	60.48 (3.31)	60.51 (2.23)	Placebo herbal decoction + radiotherapy; one pack daily (placebo) + 6 MV linear accelerator conventional irradiation of primary lesion and regional lymphatics, 1.8-2.0 Gy each time, 5 times per week, at a total dose of 60-66 Gy	Modified Xiyangshen Baihe Maidong decoction + radiotherapy; one pack daily + radiotherapy	60	No quantitatively poolable outcomes
Zhou YF (2005) ²⁵	Non-small cell lung cancer	B: 30	A: 30; C: 30	B: 17/13	A: 18/12; C: 16/14	B: 58.5	A: 60.46; C: 60.46	B: NP chemotherapy regimen; Vinorelbine (NVB) 25 mg/m ² , IV on days 1 and 8; cisplatin (DDP) 40 mg, IV on days 1-3	A: Xiaoliu formula; C: Xiaoliu formula + NP chemotherapy; Twice daily	60	ORR, DCR, KPS improvement rate, CD3, CD4, CD4/CD8, NK
Wen HY (2006) ²⁶	Liver cancer	30	32	17/13	20/12	29-68	28-72	TAE; Selective hepatic artery chemoembolization (TAE) via femoral artery using Seldinger technique; chemotherapy drugs: THP 50-70 mg, MMC 10-20 mg, 5-FU 1.0-1.25 g or carboplatin 300-500 mg; lipiodol 10-20 mL; antiemetic: ondansetron 8 mg. Each patient received 1-6 TAE sessions (mean 2-3), interval 1-3 months.	Fuzheng Kangai formula + TAE; one pack per day + TAE	28	ORR, DCR, CD ₃ , CD ₄ , CD ₄ /CD ₈ , NK

(Continued)

Study ID	Disease/condition	Sample size		Sex (M/F)		Age, y, (mean [SD], or range)		Treatment		Course (d)	Outcomes
		CG	IG	CG	IG	CG	IG	CG	IG		
Qiao XL (1997) ²⁷	Gastric cancer	43	267	176/91		29–88		Chemotherapy; chemotherapy + vitamins B and C	Chinese herbal formula + chemotherapy; Chinese herbal decoction taken during chemotherapy for 2–4 weeks; decoction taken in warm twice per day; 1 course = 50 packs; 4-week interval between courses. Included if ≥ one course completed alongside chemotherapy (range 1–5 courses, at an average of three courses)	150	Hepatic dysfunction rate, alopecia
Fu YJ (2013) ²⁸	Small cell lung cancer	14	16	19/11		38–70		Chemotherapy (carboplatin + etoposide); CE regimen: carboplatin 400 mg/m ² , IV on day 1; etoposide 100 mg/m ² , IV on days 3–6; 1 cycle = 28 days; efficacy evaluated after 2–4 cycles	Yangshen Erchong powder + chemotherapy; herbal powder 5 g three times daily + chemotherapy	84	ORR, DCR, KPS improvement rate, leukopenia rate, GI reaction rate
Guglielmo M (2020) ²⁹	Cancer-related fatigue	15	17	9/6	13/4	35–79	34–73	Placebo; 1000 mg per day	AG tablets; 1000 mg per day	56	No quantitatively poolable outcomes

Notes: AG: American ginseng; CD: cluster of differentiation; CE: carboplatin + etoposide; CG: control group; d: day; DCR: disease control rate; DDP: cis-diamminedichloroplatinum(II); F: female; FOLFOX4: folinic acid, fluorouracil, and oxaliplatin regimen 4; FU: 5-fluorouracil; GI: gastrointestinal; Gy: Gray; h: hour; IG: intervention group; IV: intravenous; KPS: Karnofsky Performance Status; M: male; MMC: mitomycin C; MV: megavolt; NK: natural killer; NP: navelbine + platinol; NVB: Navelbine; ORR: objective response rate; SD: standard deviation; TACE: transcatheter arterial chemoembolization; TAE: transcatheter arterial embolization; THP: 4'-O-Tetrahydropyranyladriamycin; y: year. Ingredients: Baihe: *Lilium brownii* F. E. Brown var. *viridulum* Baker; Baizhu: *Atractylodes macrocephala* Koidz.; Hedyotis diffusa: *Hedyotis diffusa* Willd.; Huangqi: *Astragalus membranaceus* (Fisch.) Bge. var. *mongholicus* (Bge.) Hsiao; Maidong: *Ophiopogon japonicus* (L. f.) Ker-Gawl.; Xiyangshen: *Panax quinquefolium* L.

without further details and were therefore judged as having some concerns because baseline characteristics appeared comparable between groups.

Regarding deviations from intended interventions, only three studies^{5,17,24} used a double-blind or sham-controlled design; the remaining studies did not adequately describe blinding procedures. Most studies had short treatment periods and complete follow-up and were therefore considered to have low risk due to missing outcome data; however, one study²⁷ was rated as having high risk of bias because the analysis population was not clearly defined.

Regarding outcome measurement, tumor response and serological and immunological endpoints were relatively objective. However, subjective outcomes such as KPS and symptom improvement were generally assessed without reported blinding, resulting in ratings of some concern for this domain in most studies. Regarding selection of the reported result, only one study⁵ was rated as having low risk because it had a registered protocol with clearly specified primary outcomes and assessment time points. The remaining studies lacked preregistered protocols or statistical analysis plans and were considered potentially at risk of selective reporting.

3.4. Meta-analysis results

Five studies^{8,19,20,25,28} contributed to the ORR analysis. The pooled estimate favored AG-containing TCM formulations plus CMT over CMT alone (RR = 1.39, 95% CI: 1.04, 1.85; Figure 3A), with low between-study heterogeneity

($I^2 = 0\%$, $P = 0.857$), indicating consistent findings across studies.

Six studies^{8,19,20,25,26,28} contributed to the DCR analysis. Participants receiving an AG-containing TCM formulation, either alone or with CMT, were more likely to achieve disease control than participants in the corresponding control groups (RR = 1.21, 95% CI: 1.10, 1.33; $P = 0\%$, $P = 0.442$; Figure 3B). Subgroup analyses according to treatment strategy yielded pooled RRs of 1.26 (95% CI: 1.10, 1.44) for TCM formulations containing AG plus CMT and 1.17 (95% CI: 1.03, 1.33) for TCM formulations containing AG administered without concomitant CMT. The test for subgroup differences was not statistically significant ($P = 0.451$). Given the small number of studies in each subgroup, however, this comparison was exploratory and should not be interpreted as establishing equivalence between treatment strategies.

Six studies^{8,19,20,23,25,28} assessed functional status using KPS, four of which^{8,23,25,28} reported KPS improvement rates. AG-containing TCM formulations, administered either alone or in combination with CMT, were associated with a higher KPS improvement rate than the corresponding control groups (RR = 2.62, 95% CI: 1.63, 4.21; $P = 0\%$; Figure 4A). Three studies^{8,19,20} reported absolute changes in KPS score; AG-containing TCM formulations plus CMT were associated with greater increases in KPS than the control group (MD = 14.85 points, 95% CI: 12.66, 17.04; $P = 0\%$; Figure 4B).

Subgroup analyses according to treatment strategy yielded RRs of 2.61 (95% CI: 1.42, 4.78) for AG-containing TCM formulations plus CMT and 2.67 (95% CI: 1.13, 6.34) for AG-containing TCM formulations without con-

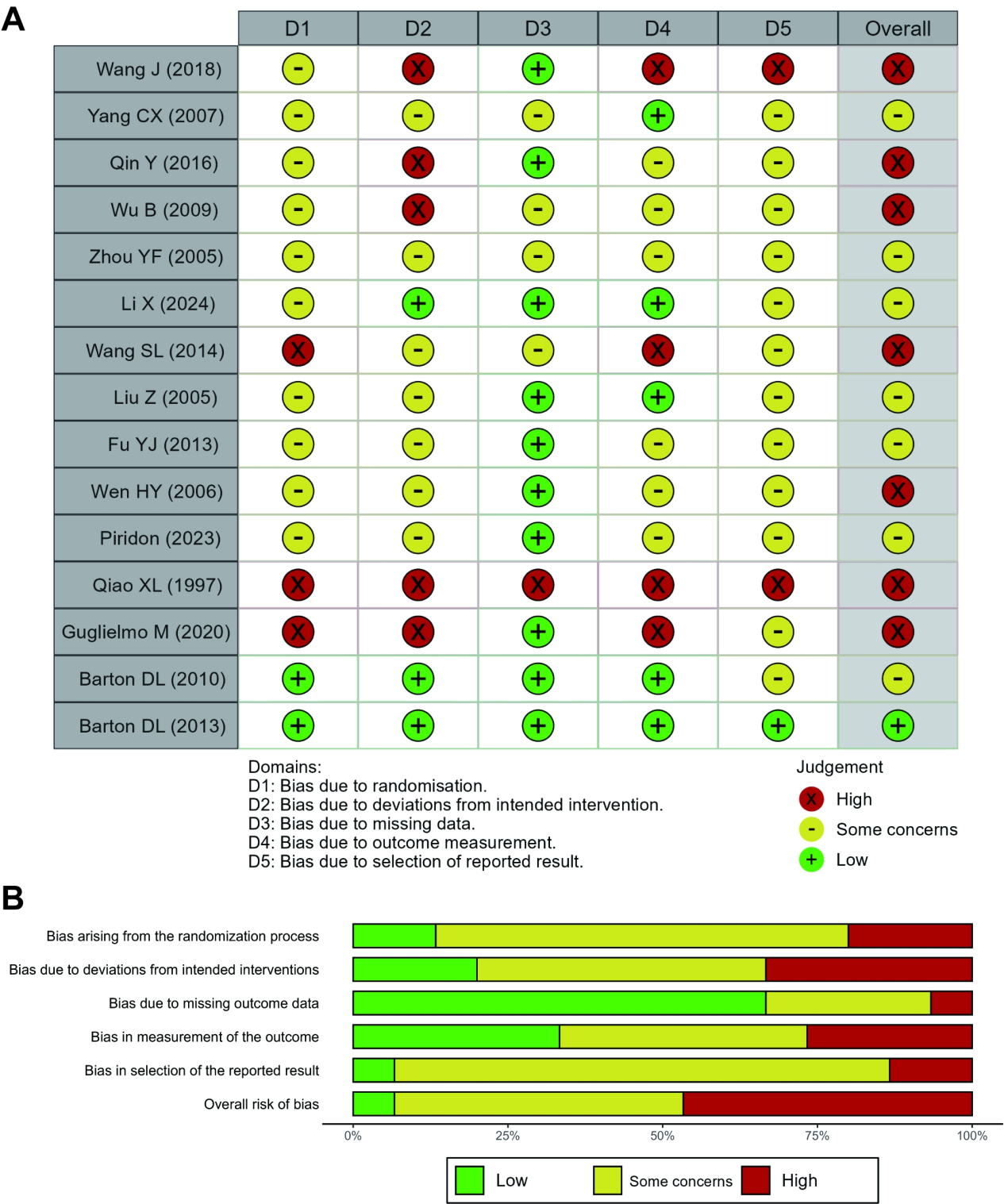


Figure 2 Risk-of-bias assessment: (A) traffic-light plot (red, high risk; yellow, some concerns; green, low risk; (B) summary plot

comitant CMT. The test for subgroup differences was not statistically significant ($P = 0.965$); however, the small number of studies precluded reliable assessment of differences between treatment strategies.

3.5. Chemotherapy-related adverse events

Five studies^{8,19,20,22,27} reported chemotherapy-related leukopenia. The pooled

estimate favored AG-containing TCM formulations plus CMT over CMT alone ($RR = 0.47$, 95% CI: 0.25, 0.86; Figure 5A), although between-study heterogeneity was substantial ($I^2 = 90.6\%$, $P < 0.001$). Leave-one-out analyses preserved the direction of the pooled estimate, although its magnitude varied appreciably depending on the study excluded. Therefore, the leukopenia estimates should be interpreted with caution.

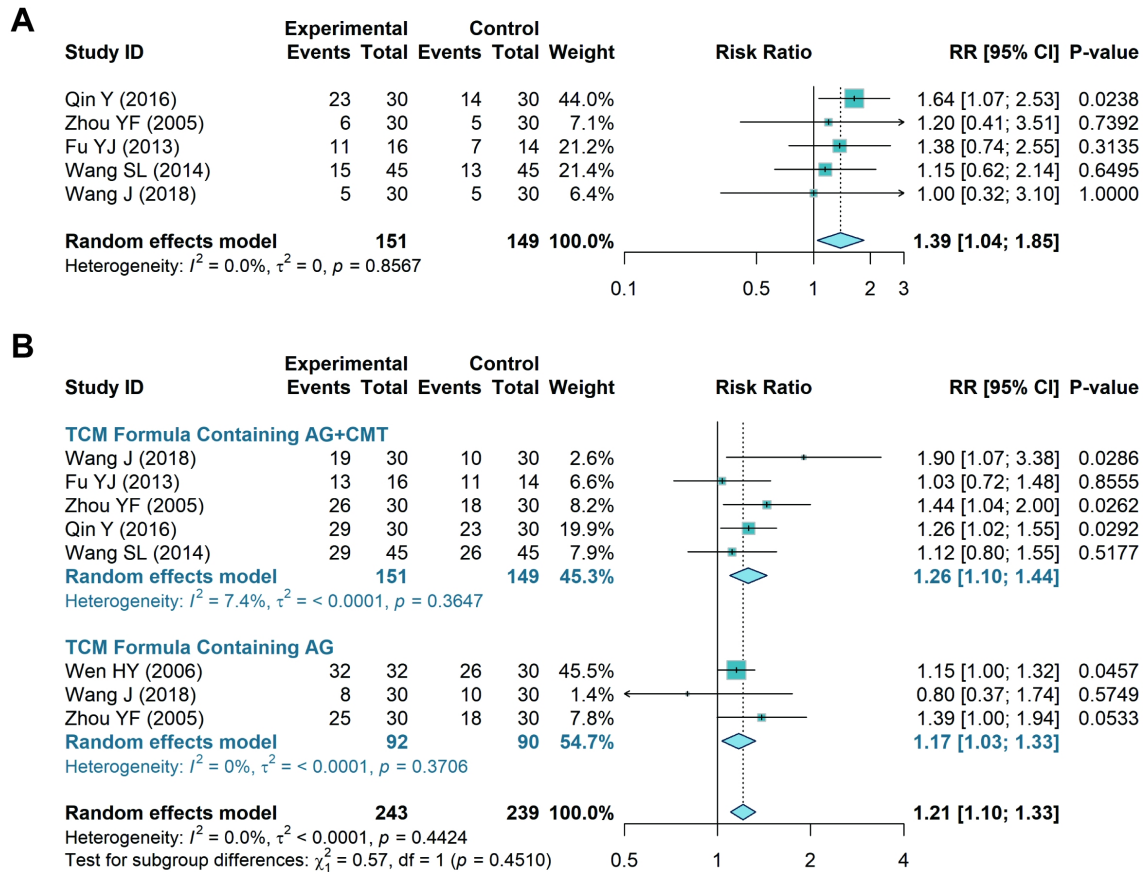


Figure 3 Forest plot of objective tumor response outcomes: (A) objective response rate; (B) disease control rate

Notes: AG: American ginseng; CI: confidence interval; CMT: conventional medical treatment; P: probability; RR: risk ratio; TCM: traditional Chinese medicine.

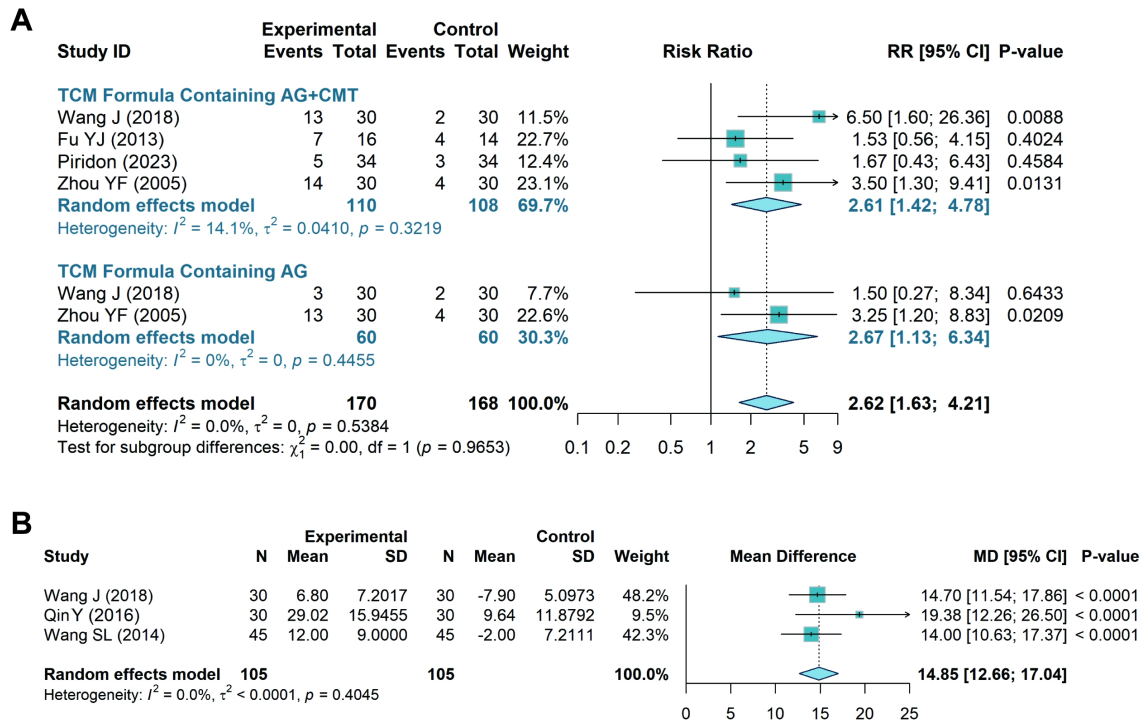


Figure 4 Forest plots of Karnofsky Performance Status outcomes: (A) KPS improvement rate; (B) change in KPS score

Notes: AG: American ginseng; CI: confidence interval; CMT: conventional medical treatment; KPS: Karnofsky Performance Status; MD: mean difference; SD: standard deviation; P: probability; RR: risk ratio; TCM: traditional Chinese medicine.

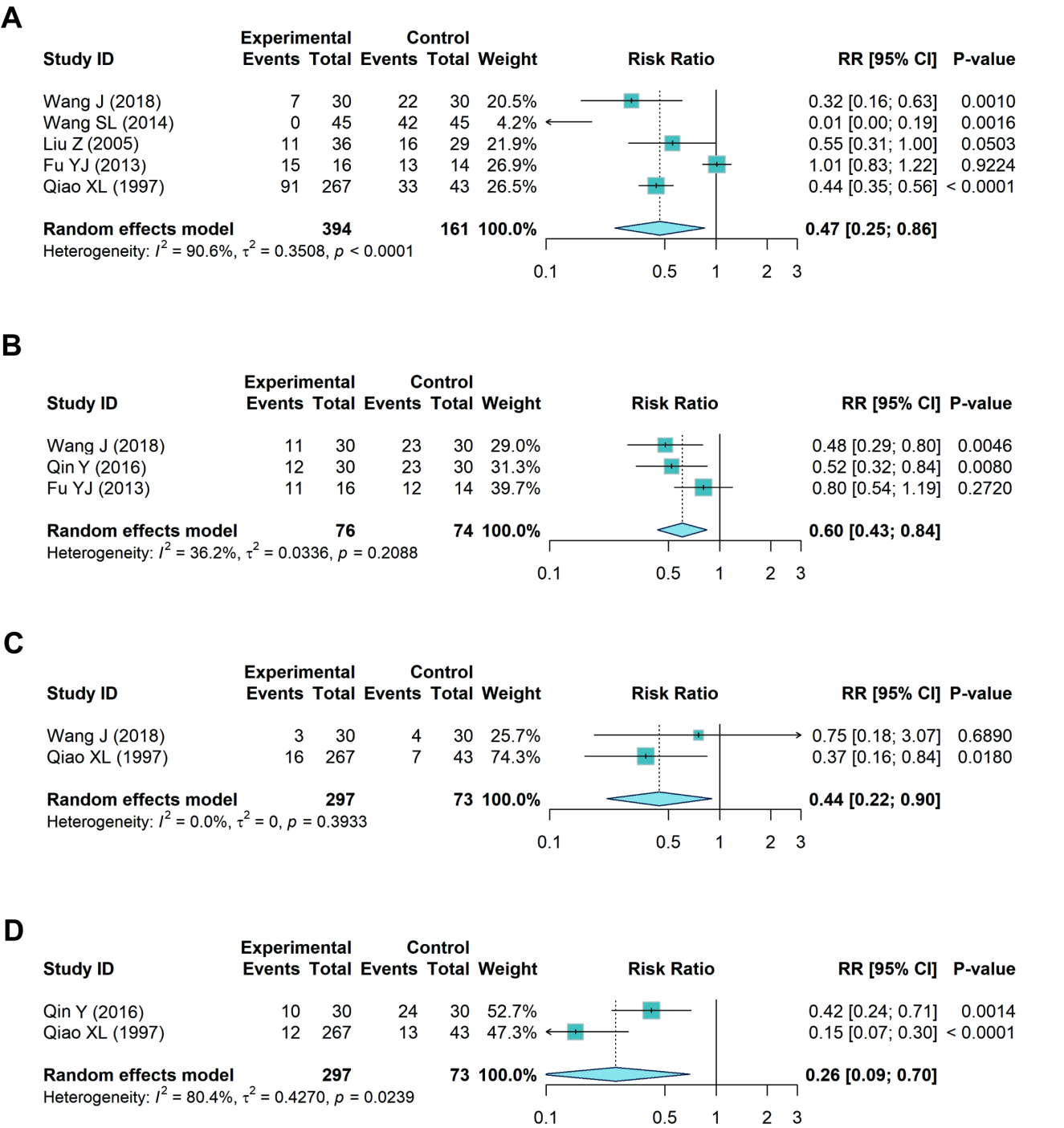


Figure 5 Forest plots of chemotherapy-related adverse events: (A) leukopenia rate; (B) gastrointestinal reaction rate; (C) hepatic dysfunction rate; (D) alopecia rate

Notes: CI: confidence interval; P: probability; RR: risk ratio.

Three studies^{8,20,28} reported gastrointestinal reactions. AG-containing TCM formulations plus CMT were associated with a lower incidence of gastrointestinal reactions than CMT alone (RR = 0.60, 95% CI: 0.43, 0.84), with low heterogeneity ($I^2 = 36.2\%$, $P = 0.209$; Figure 5B).

Two studies^{8,27} reported chemotherapy-related hepatic dysfunction. As shown in Figure 5C, AG-containing TCM formulations were associated with a lower incidence of hepatic dysfunction compared with the CMT group (RR = 0.44, 95% CI: 0.22, 0.90, $I^2 = 0\%$; Figure 5C).

Two studies^{20,27} reported alopecia. AG-containing TCM formulations plus

CMT were associated with a lower incidence of alopecia than CMT alone (RR = 0.26, 95% CI: 0.09, 0.70). Although the heterogeneity between the two studies was high ($I^2 = 80.4\%$, $P = 0.024$), both studies showed effects in the same direction.

Two studies^{25,26} reported CD3⁺ T-cell, CD4⁺ T-cell, CD4⁺/CD8⁺ ratio, and NK cell outcomes. Compared with CMT alone, AG-containing TCM formulations were associated with higher CD3⁺ T-cell values (MD = 11.59%, 95% CI: 0.60, 22.59). No statistically significant between-group differences were observed for CD4⁺ T-cell values (MD = 13.29%, 95% CI: -1.14, 27.73) or NK-

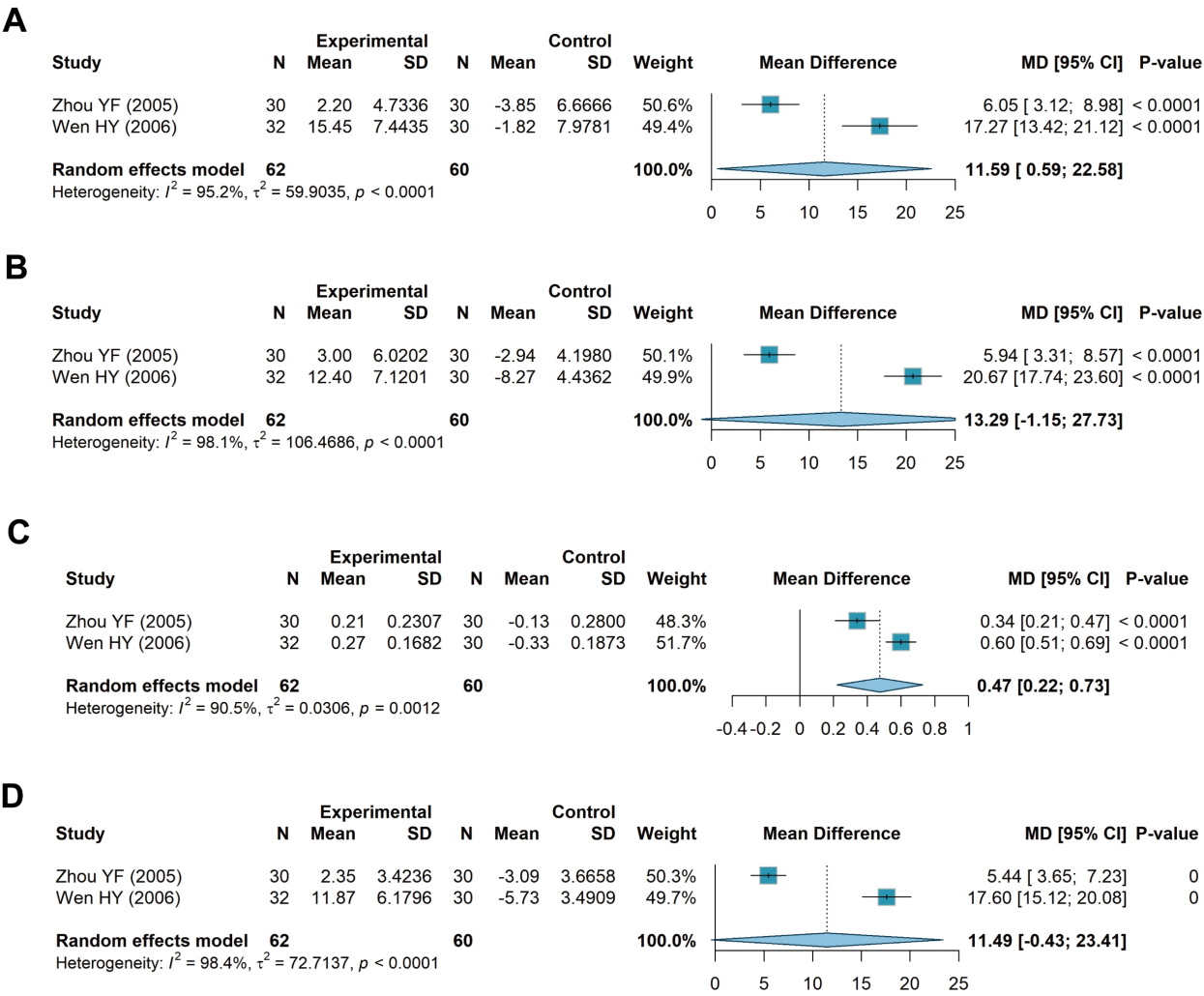


Figure 6 Forest plot of changes in immune function indicators: (A) CD3⁺ cell level; (B) CD4⁺ cell level; (C) CD4⁺/CD8⁺ ratio; (D) NK cell level

Notes: CD: cluster of differentiation; CI: confidence interval; MD: mean difference; P: probability; SD: standard deviation; NK: natural killer.

cell values (MD = 11.49%, 95% CI: -0.43, 23.41). Although the direction of the effect was consistent across both studies, heterogeneity was substantial across all four immune outcomes ($I^2 = 90.6\%$, $I^2 = 98.2\%$).

3.6. Subgroup analyses by cancer type

Among patients with lung cancer^{25,28}, AG-containing TCM formulations, administered alone or with CMT, were associated with higher DCR (RR = 1.29, 95% CI: 1.06, 1.57) and KPS improvement rates (RR = 2.60, 95% CI: 1.46, 4.61), both with low heterogeneity. ORR did not differ significantly between the groups (RR = 1.33, 95% CI: 0.78, 2.27) (Figure 7A–C).

Among patients with esophageal cancer^{8,19,23}, AG-containing TCM administered alone or with CMT was associated with higher KPS improvement rates (RR = 2.65, 95% CI: 1.02, 6.90), with low overall heterogeneity ($I^2 = 18.5\%$, $P = 0.293$). DCR showed a trend toward improvement but did not reach statistical significance (RR = 1.22, 95% CI: 0.81, 1.84) (Figure 7D–E).

3.7. Intervention-related adverse events

Among the included studies, one reported no intervention-related adverse events⁵, eight reported only chemotherapy-related toxicities without providing causal attribution^{8,19,20,22,25,26,27,28}, and six did not report adverse events specifically attributable to the study intervention.

3.8. Sensitivity analyses

Leave-one-out analyses did not reverse the direction of the pooled estimates (Appendix 3), although the magnitude of some estimates varied after excluding individual studies. In particular, exclusion of study²⁷ markedly attenuated the pooled estimate toward the null, indicating sensitivity to the influence of this individual study.

Funnel plot asymmetry was not formally assessed because no outcome was represented by at least 10 studies. Given the small number of studies in each synthesis, visual and regression-based tests for small-study effects would have limited ability to distinguish true asymmetry from chance. Publication bias therefore remains possible, particularly because the evidence base consisted primarily of small, single-center trials, most reports were published in Chinese (12/15), and prospective registration or publicly accessible protocols were uncommon.

3.9. GRADE evidence evaluation

The certainty of evidence for each outcome is summarized in Table 2. For combination therapy, certainty was rated as low for ORR, DCR, KPS improvement, and reductions in leukopenia, hepatic dysfunction, and alopecia, and as very low for reduction in gastrointestinal reactions and changes in CD3⁺ T-cell values, CD4⁺/CD8⁺ ratio, CD4⁺ T-cell values, and NK-cell values. For AG-containing TCM formulations administered without CMT, certainty

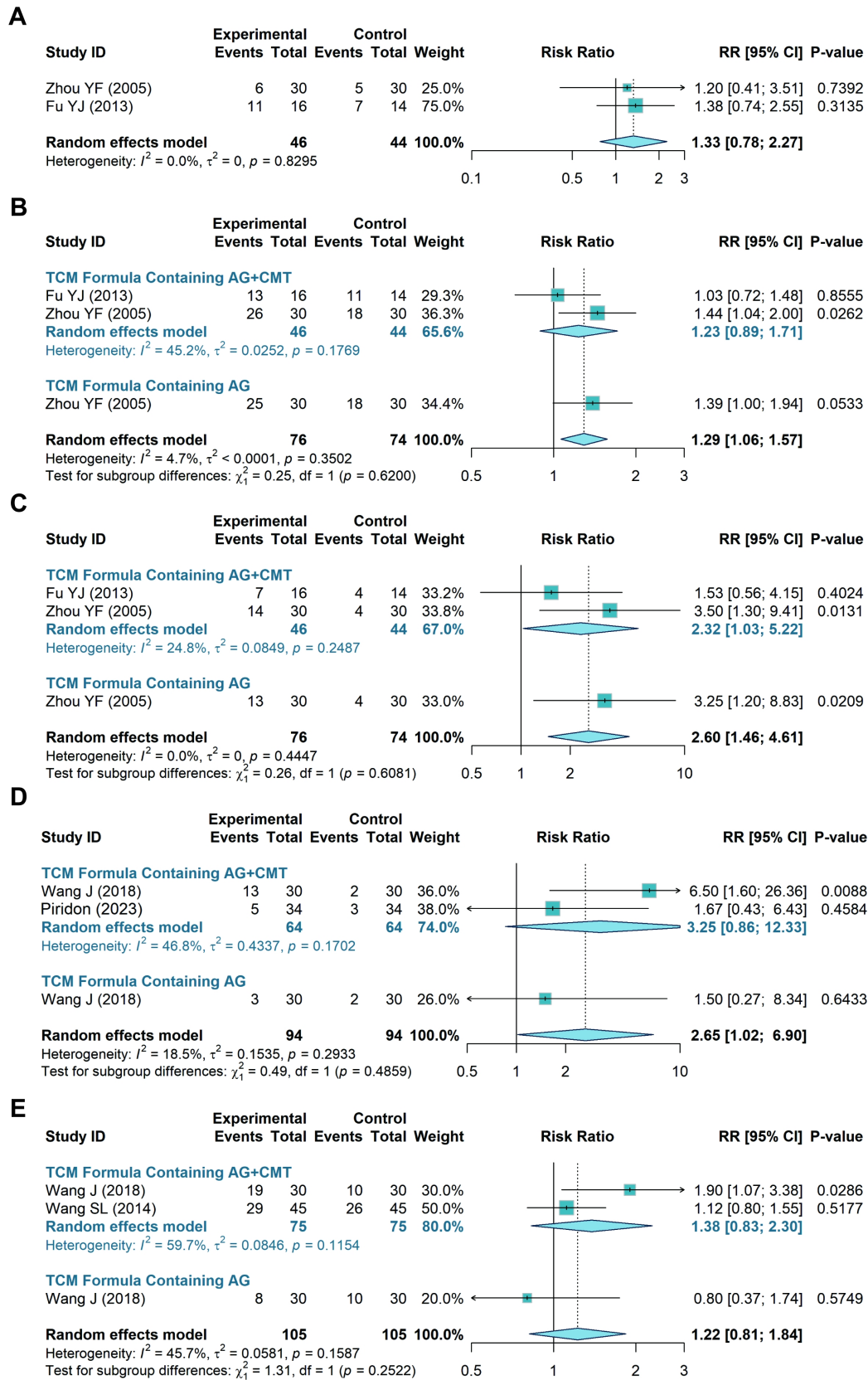


Figure 7 Forest plot of subgroup meta-analysis results by cancer type: (A) ORR of lung cancer; (B) DCR of lung cancer; (C) KPS improvement rate of lung cancer; (D) KPS improvement rate of esophageal cancer; (E) DCR of esophageal cancer

Notes: AG: American ginseng; CI: confidence interval; CMT: conventional medical treatment; DCR: disease control rate; KPS: Karnofsky Performance Status; ORR: objective response rate; P: probability; RR: risk ratio; TCM: traditional Chinese medicine.

Table 2 GRADE summary of findings

Outcome	Participants (studies)	Certainty assessment					Results			
		Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Certainty	Intervention	Control group	RR/MD (95% CI)
Intervention type: AG combination therapy vs. conventional treatment										
ORR (%)	300 (5 RCTs)	Serious ^a	Not serious	Serious ^b	Not serious	Not applicable	Low ^{a,b}	60/151 (39.7%)	44/149 (29.5%)	1.39 (1.04, 1.85)
DCR (%)	300 (5 RCTs)	Serious ^a	Not serious	Serious ^b	Not serious	Not applicable	Low ^{a,b}	116/151 (76.8%)	88/149 (59.1%)	1.26 (1.10, 1.44)
KPS improvement rate (%)	218 (4 RCTs)	Serious ^a	Not serious	Serious ^b	Not serious	Not applicable	Low ^{a,b}	39/110 (35.5%)	13/108 (12.0%)	2.61 (1.42, 4.78)
KPS score change	210 (3 RCTs)	Serious ^a	Not serious	Serious ^b	Not serious	Not applicable	Low ^{a,b}	105	105	14.85 (12.66, 17.04)
Leukopenia (%)	555 (5 RCTs)	Serious ^a	Not serious	Serious ^b	Not serious	Not applicable	Low ^{a,b}	124/394 (31.5%)	126/161 (78.3%)	0.47 (0.25, 0.86)
Hepatic dysfunction (%)	370 (2 RCTs)	Serious ^a	Not serious	Serious ^b	Not serious	Not applicable	Low ^{a,b}	19/297 (6.4%)	11/73 (15.1%)	0.44 (0.22, 0.90)
Gastrointestinal reactions (%)	150 (3 RCTs)	Serious ^a	Not serious	Very serious ^c	Not serious	Not applicable	Very low ^{a,c}	34/76 (44.7%)	58/74 (78.4%)	0.60 (0.43, 0.84)
Alopecia (%)	370 (2 RCTs)	Serious ^a	Not serious	Serious ^b	Not serious	Not applicable	Low ^{a,b}	22/297 (7.4%)	37/73 (50.7%)	0.26 (0.09, 0.70)
CD3 ⁺ (%)	122 (2 RCTs)	Serious ^a	Not serious	Serious ^b	Serious ^d	Not applicable	Very low ^{a,b,d}	62	60	11.59 (0.6, 22.59)
CD4 ⁺ (%)	122 (2 RCTs)	Serious ^a	Not serious	Serious ^b	Very serious ^c	Not applicable	Very low ^{a,b,c}	62	60	13.29 (−1.14, 27.73)
CD4 ⁺ /CD8 ⁺	122 (2 RCTs)	Serious ^a	Not serious	Serious ^b	Very serious ^c	Not applicable	Very low ^{a,b,c}	62	60	0.47 (0.22, 0.73)
NK (%)	122 (2 RCTs)	Serious ^a	Not serious	Serious ^b	Serious ^d	Not applicable	Very low ^{a,b,d}	62	60	11.49 (−0.43, 23.41)
Intervention type: AG monotherapy vs. conventional treatment										
DCR (%)	182 (3 RCTs)	Serious ^a	Not serious	Serious ^b	Serious ^d	Not applicable	Very low ^{a,b,d}	65/92 (70.7%)	54/90 (60.0%)	1.17 (1.03, 1.33)
KPS improvement rate (%)	120 (2 RCTs)	Serious ^a	Not serious	Serious ^b	Not serious	Not applicable	Low ^{a,b}	16/60 (26.7%)	6/60 (10.0%)	2.67 (1.13, 6.34)

Notes: AG: American ginseng; CI: confidence interval; CMT: conventional medical treatment; DCR: disease control rate; GRADE: Grading of Recommendations Assessment, Development and Evaluation; KPS: Karnofsky Performance Status; MD: mean difference; NK: natural killer; OIS: optimal information size; ORR: objective response rate; RD: risk difference; RR: risk ratio; TCM: traditional Chinese medicine. a. Serious risk of bias in allocation concealment and blinding across included studies. b. The intervention involved a multi-herb preparation. c. The intervention involved a multi-herb preparation, and the included studies provided unclear descriptions of the gastrointestinal reactions. d. The total sample size did not satisfy the optimal information size. e. The confidence interval was excessively wide and crossed the threshold for clinical decision-making.

was low for KPS improvement and very low for DCR.

4. Discussion

4.1. Main findings

This review synthesized 15 RCTs involving 1415 participants and evaluated AG-based therapies across several cancer settings. Quantitative evidence was derived from TCM formulations or proprietary medicines in which AG was the principal component rather than from single-ingredient AG preparations. Across the pooled analyses, estimates generally favored AG-containing interventions for tumor response, disease control, and KPS-based functional outcomes. Several chemotherapy-related toxicities were also less frequent in the intervention groups than in the control groups. However, given the low or very low certainty of evidence and substantial clinical heterogeneity among the formulations, these findings should be regarded as exploratory rather than confirmatory evidence of clinical benefit.

The tumor-response findings differed across endpoints. ORR favored AG-containing TCM formulations when added to CMT, whereas DCR favored these formulations both as adjunctive therapy and when administered with-

out concomitant CMT. Because DCR includes stable disease in addition to complete and partial responses, it may capture a different aspect of short-term tumor response than ORR. This distinction was also apparent in the lung cancer subgroup, in which the pooled estimate favored AG-containing interventions for DCR, whereas no statistically significant between-group difference in ORR was observed. Therefore, the available data support, at most, the hypothesis that AG-containing therapy may contribute to short-term disease stabilization in selected settings; they do not establish an independent cytotoxic effect of AG.

The KPS findings provide a complementary perspective of patient function. Both the proportion of patients meeting the trial-defined KPS improvement threshold and the absolute change in KPS score favored AG-containing interventions. The KPS reflects day-to-day functional capacity and the ability to perform self-care, which may deteriorate during anticancer therapy because of fatigue, appetite loss, weakness, and other treatment-related symptoms. However, evidence specifically addressing cancer-related fatigue is heterogeneous. Two RCTs^{5,17} reported a modest beneficial effect of AG on cancer-related fatigue, particularly during active anticancer treatment, whereas a trial in survivors of head and neck cancer did not demonstrate a significant reduction in fatigue.²⁹ Although all three studies^{5,17,29} were included in the present review, heterogeneity in outcome measures precluded quantitative

synthesis. Therefore, no firm conclusions could be drawn regarding this specific outcome.

The pooled analyses of chemotherapy-related adverse events favored AG-containing TCM formulations plus CMT for leukopenia, gastrointestinal reactions, hepatic dysfunction, and alopecia. These toxicities are clinically relevant because they may interfere with scheduled anticancer treatment through dose modification or treatment delay, even when they are not direct measures of tumor response. Pharmacological studies have proposed anti-inflammatory, antioxidant, and neuroregulatory actions of AG,^{4,30,31} providing possible mechanistic explanations; however, these findings do not establish that the pooled clinical effects were attributable to AG itself.

The analyses of immune outcomes yielded higher CD3⁺ T-cell values and CD4⁺/CD8⁺ ratios with AG-containing TCM formulations plus CMT, whereas no statistically significant between-group differences were observed for CD4⁺ T-cell or NK-cell values. Because these estimates were based on very small samples and showed substantial heterogeneity, the results should be considered exploratory rather than confirmatory. Although the findings may be compatible with previously reported immunomodulatory effects of AG,^{32,33} they do not establish an immunomodulatory effect of AG itself.

The reduction in chemotherapy-related events should be distinguished from the safety of AG-based interventions themselves. Reports of adverse events attributable to the study interventions were sparse, and information on serious events, treatment discontinuations, and investigators' causality was generally unavailable. Therefore, the included literature does not permit reliable conclusions regarding the safety of AG or AG-containing products.²⁹

Cancer-specific subgroup analyses were based on few trials and should also be considered exploratory. The lung and esophageal cancer studies differed in disease stage, conventional treatment, and the composition of the AG-containing intervention, and the subgroup datasets were too small to determine whether treatment effects truly differed by tumor type. Therefore, these analyses are useful for hypothesis generation but do not support cancer-specific treatment recommendations.

4.2. Strengths and limitations

This review has several limitations. First, the interventions varied substantially. AG was administered as tablets, capsules, proprietary medicines, and multi-herb prescriptions, with variation in preparation, constituent content, dose, and treatment course. Because most named formulations were evaluated in only one trial, further formulation-specific subgrouping would have resulted in sparse comparisons and unstable estimates. Second, reporting of trial methods was frequently incomplete. Details of sequence generation, allocation concealment, blinding, outcome-assessor masking, and prespecified protocols were often absent, which contributed to RoB 2 judgments of some concerns or high risk of bias. Third, several outcomes were based on only a few small, predominantly single-center, trials. Fourth, restricting eligibility to Chinese- and English-language reports may have introduced language bias. Fifth, the review excluded grey literature, conference abstracts, and unpublished datasets. Combined with the small number of studies in each meta-analysis, this limitation precluded reliable formal assessment of publication bias. Finally, the analyses were based on study-level summary data; therefore, potential differences in treatment effects across patient characteristics, such as age, disease stage, or chemotherapy regimen, could not be examined in detail.

Collectively, these limitations reduce confidence in the magnitude and stability of the pooled estimates. Similar concerns regarding small samples, heterogeneous herbal interventions, and limited standardization were identified in earlier reviews of ginseng-based therapies in supportive oncology.^{34–36} Thus, although several pooled estimates favored AG-containing interventions, the current evidence is insufficient to support strong clinical recommendations.

5. Conclusion

Several pooled estimates favored TCM formulations containing AG for selected tumor-response, functional, and chemotherapy-related outcomes. However, the certainty of evidence was low or very low, and methodological

limitations, small sample sizes, and heterogeneity among herbal formulations limit the clinical interpretability of these findings. Therefore, the available evidence is insufficient to establish the efficacy or safety of AG-based therapies, and the pooled findings should be regarded as exploratory. Further rigorously designed trials using standardized and well-characterized interventions are required.

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Author Contribution Statement

Yuan Liu: Conceptualization, methodology, investigation, data curation, formal analysis, visualization, and writing – original draft. **Ting-xiu Liu:** Methodology, data curation, validation, and writing – review & editing. **Yu Du:** Writing – review & editing. **Kai Liu:** Methodology and writing – review & editing. **Yi-ke Song:** Methodology, data curation, and validation. **Zi-yi Li:** Investigation, data curation, and validation. **Shi-yun Shi:** Investigation, data curation, and validation. **Zhao-lan Liu:** Supervision, conceptualization, project administration, funding acquisition, and writing – review & editing.

Use of AI statement

None.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have influenced the work reported in this study.

Electronic Supplementary Material

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