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A systematic review and meta-analysis on the efficacy and safety of combining traditional Chinese medicine with radiotherapy for breast cancer

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► ***Review article***

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ABSTRACT

Background: Variability in treatment sensitivity and radiation-induced toxicity can adversely affect clinical outcomes. Objective: To evaluate the effectiveness and safety of integrating traditional Chinese medicine with radiotherapy in the treatment. ***Materials and Methods:*** To identify eligible studies, a systematic search strategy was applied to five major biomedical databases. Radiotherapy mainly involved conventional external beam techniques, including three-dimensional conformal radiotherapy (3D-CRT), intensity-modulated radiotherapy (IMRT), and EBRT. TCM interventions consisted of injectable preparations and oral herbal formulas administered during or around radiotherapy. ***Results:*** 9 studies involving 655 patients were included. Combination therapy significantly improved objective response rate (RR = 1.44, P < 0.001) and reduced adverse outcomes (RR = 0.34, P < 0.001). $CD4^+$T cells increased significantly (MD = 9.55, P < 0.001), whereas $CD8^+$T-cell changes were nonsignificant (MD = −3.89, P = 0.280). The regimen also lowered gastrointestinal toxicity (RR = 0.52, P = 0.008) and myelosuppression (RR = 0.53, P < 0.001). The findings were validated through sensitivity analyses, demonstrating their robustness. ***Conclusion:*** TCM combined with radiotherapy may enhance efficacy and reduce toxicity in breast cancer, warranting further large-scale trials.

INTRODUCTION

Breast cancer constitutes the greatest oncologic burden in the female population worldwide. Since 2020, its incidence has surpassed that of lung cancer, making it one of the most prevalent cancers globally [1]. The data reported that in 2020, breast cancer constituted 24.5% of all new cancer diagnoses in women. Over 680,000 deaths were recorded, posing a significant burden on public health and socioeconomic systems [2]. Breast cancer exhibits significant heterogeneity and is mainly categorized into molecular subtypes: Luminal A, Luminal B, HER2 -positive, and triple-negative breast cancer (TNBC) [3]. These subtypes differ significantly in terms of biological behavior, progression rate, treatment response, and prognosis. Breast cancer typically manifests as a painless mass, alterations in breast structure, or axillary lymph node enlargement, though some cases may involve rapid progression, recurrence, or metastasis [4]. Given the increasing breast cancer rates and an aging global population, it is crucial to optimize treatment strategies to minimize recurrence and treatment-related toxicity [5, 6].

Individualized combination regimens are formulated based on breast cancer stage and subtype [7-10]. Radiotherapy is a crucial modality for local and regional control of breast cancer. Advanced radiotherapy methods, including three-dimensional conformal radiotherapy (3D-CRT), intensity-modulated radiotherapy (IMRT), and stereotactic body radiotherapy (SBRT), achieve superior dose distribution accuracy and decrease unintended irradiation to organs at risk such as the heart and lungs [11-14]. Nonetheless, radiotherapy may still lead to adverse effects such as skin reactions, fatigue, lymphedema, radiation pneumonitis, cardiac damage, and compromised immune function, which can affect patient adherence and quality of life [15, 16]. Therefore, identifying adjunctive measures that enhance radiotherapy efficacy and mitigate its toxicity has become a key clinical focus and forms the scientific rationale for this study.

Traditional Chinese medicine (TCM) offers benefits such as boosting immune function and reducing the side effects of radiotherapy. Mechanistically, regulation of inflammatory responses and reshaping of the tumor microenvironment may underlie its supportive role in anticancer therapy, with additional benefits in alleviating fatigue [17–19]. Clinical evidence on combining radiotherapy with TCM in breast cancer is currently fragmented. Most studies are single-center, involve small sample sizes, and vary in methodological quality, lacking systematic quantitative evaluation and evidence synthesis. Although radiotherapy combined with TCM has been

increasingly applied in clinical practice, there remains no comprehensive meta-analysis specifically evaluating its efficacy, safety, and immunomodulatory effects in breast cancer patients. A quantitative synthesis was conducted to integrate evidence on clinical benefit, adverse events, and immunological markers - such as $CD4^+$ and $CD8^+$ *T-cell* subsets - in patients receiving radiotherapy as an adjunct to traditional Chinese medicine. By integrating both therapeutic and immunological endpoints across different radiotherapy techniques and TCM formulations, the pooled findings contribute a more rigorous and data-driven perspective on this integrative therapeutic framework. The synthesized evidence provides a scientific basis for guiding treatment selection and advancing integrative oncology strategies.

MATERIALS AND METHODS

Study design

The review protocol complies with PRISMA reporting requirements and is registered on INPLASY platform (Registration number INPLASY2025110053) [20-22].

Eligibility criteria

Population: Studies enrolling patients with clinically or pathologically confirmed breast cancer were included. Both early-stage and advanced breast cancer populations were eligible, without restrictions on age, molecular subtype, cancer stage, or ethnicity. Intervention: Eligible studies evaluated radiotherapy combined with TCM. Radiotherapy was required to be delivered using external beam techniques, such as 3D-CRT, IMRT, or other standard fractionated radiotherapy approaches. Studies were required to report radiotherapy regimens, including fractionation schedules and total delivered dose. TCM interventions included herbal decoctions, proprietary Chinese medicines, injectable TCM preparations, oral granules, or other standardized TCM therapies. Studies were required to clearly describe the type, route of administration, and duration of TCM treatment. TCM could be administered concurrently with radiotherapy or initiated before or after radiotherapy as an adjuvant therapy, provided that radiotherapy remained the primary oncologic treatment. Comparator: The control group received radiotherapy alone or radiotherapy combined with conventional supportive care, without any form of TCM. Only full-text, peer-reviewed articles were included, without language or publication year restrictions. To minimize bias, publications that did not present primary research data were excluded.

Literature screening

The databases PubMed (http://www.ncbi.nlm.nih.gov/pubmed/), Web of Science (https://www.webofscience.com), Cochrane Library (https://www.cochranepubliclibrary.ca/), Embase (https://www.embase.com/), and China National Knowledge Infrastructure (CNKI, https://www.sinomed.ac.cn/) were used as data sources. Articles published from database inception to November 1, 2025, were included. A combination of standardized thesaurus terms and text-word queries was applied, with search formulations modified to meet the structural conventions of individual databases. Core search terms included: "breast cancer," "breast tumor," "radiotherapy," "radiation therapy," and "combined radiotherapy," without restrictions on language or publication status. Additionally, references of included studies were manually screened to avoid omissions.

Duplicates were eliminated and references managed using EndNote X9 (Clarivate Analytics, Philadelphia, PA, USA). Screening and information retrieval were undertaken by two researchers working independently. Divergent decisions were clarified through consultation with a third reviewer. Key study attributes, including publication information and participant numbers, were recorded in a standardized form.

The updated Cochrane risk-of-bias tool (version 2) was applied to judge internal validity across randomized trials [22]. Assessment domains encompassed allocation methodology, intervention fidelity, data completeness, outcome ascertainment, and the possibility of selective result disclosure. Two authors conducted independent assessments, with a third author resolving any disagreements. Quantitative tests for publication bias, such as Egger's or Begg's tests, were not conducted for outcomes with fewer than ten studies due to insufficient statistical power in small samples.

Study outcomes

The **primary outcomes** of this study include clinical efficacy indicators: objective response rate (ORR), quality of life improvement, and treatment-related adverse events (AEs). **Secondary outcomes** include changes in immune function (e.g., CD3, CD4, CD8, NK cell levels), recurrence rate, and changes in tumor marker levels.

Data transformation

For studies reporting continuous variables only in terms of median and interquartile range (Q1, Q3), we used statistical methods proposed by Wan *et al.* [23] and Luo *et al.* [24] to convert these into mean and standard deviation, ensuring data comparability. Given a sample size n, median m, and interquartile range (Q1, Q3), the conversion formulas are: $\bar{x} = (Q1 + m + Q3) / 3$ for the mean and standard deviation (SD) = (Q3 - Q1) / 1.35 for the standard deviation.

Statistical analysis

Quantitative outcomes were aggregated as mean

differences with associated dispersion measures, and binary endpoints were combined as relative risk estimates with 95% confidence bounds. Inter-study inconsistency was examined using the I^2 index. Summary effects were generated under both common- and random-effect modeling frameworks. The influence of single studies on pooled estimates was explored using iterative exclusion techniques. Analyses were conducted in the R environment (v4.3.2) employing dedicated meta-analytic toolkits [25, 26].

RESULTS

Study selection and data retrieval

Figure 1 outlines the process of database retrieval and study screening. A total of 633 citations were retrieved through electronic and supplementary searches. After duplicate removal and initial screening, 77 full-text reports underwent detailed evaluation. Nine eligible studies were ultimately retained for meta-analytic pooling, encompassing 655 breast cancer cases. These studies were conducted between 2010 and 2025, with detailed study attributes summarized in table 1. Of the patients, 328 underwent a combination of radiotherapy and traditional Chinese medicine, whereas 327 received only radiotherapy. Conventional external beam radiation, mainly in the form of three-dimensional conformal or intensity-modulated delivery, was utilized with similar fractionation patterns across trials. Traditional Chinese medicine was prescribed for periods spanning one to five months, most often in parallel with radiation therapy.

Bias analysis

The overall appraisal of internal validity is depicted in figure 2. One study showed substantial concerns regarding bias, four were deemed methodologically sound, and four presented indeterminate risk levels.

Table 1. Key methodological and clinical profiles of the included studies.

No.	Author (Year)	Cancer type	Radiotherapy type	Intervention (n)	Control (n)	Age (years, I vs C)	Radiotherapy regimen	TCM intervention (duration; route)	Concurrent with RT
1	Hu *et al.* (2010) [27]	aBC	3D-CRT	30	30	10.5 ± 45.0vs 45.0 ± 10.5	2Gy/fraction, once daily, 5×/week, total 40 Gy (28 days)	Kang'ai Injection (1 month; injection)	Yes
2	Zhai *et al.* (2025) [28]	aBC	3D-CRT	42	42	6.83 ± 55.50vs 55.56 ± 6.60	2Gy/fraction, 5×/week (30 days)	Kang'ai Injection (1 month; injection)	Yes
3	Qiao *et al.* (2016) [29]	eBC	IMRT	39	39	6.31 ± 55.73vs 56.09 ± 6.46	2Gy/fraction, 5×/week (30 days)	Liu Jun Zi Decoction (1.5 months; oral)	Yes
4	Shen *et al.* (2022) [30]	eBC	IMRT	32	32	2.4 ± 55.5vs 57.0 ± 2.2	2Gy/fraction, 5×/week (25 days)	Ping Gan Xiao Jia Decoction (3 months; oral)	Yes
5	Sima *et al.* (2016) [31]	eBC	3D-CRT	64	64	7.05 ± 49.22vs 48.25 ± 6.55	2Gy/fraction, 5×/week (25 days)	Compound Kushen Injection (5 months; injection)	Yes
6	Zhou *et al.* (2014) [32]	eBC	3D-CRT	22	21	4.69 ± 48.21vs 47.96 ± 4.51	2Gy/fraction, 5×/week (25 days)	Xihuang Capsule (1.5 months; oral)	No (started 1 week before RT)
7	Liu *et al.* (2018) [33]	eBC	3D-CRT	47	47	5.7 ± 47.5vs 46.2 ± 5.8	2Gy/fraction, 5×/week (30 days)	Xiao Ai Shun Qi Decoction (1 month; oral)	Yes
8	Tang *et al.* (2019) [34]	aBC	EBRT	31	31	3.18 ± 46.18vs 46.12 ± 3.14	2Gy/fraction, 5×/week (20 days)	Kang'ai Injection (1 month; injection)	Yes
9	Dong *et al.* (2023) [35]	eBC	IMRT	21	21	10.5 ± 45.0vs 45.0 ± 10.5	2Gy/fraction, 5×/week (25 days)	Zhenqi Liu Jun Yi Ai Decoction (1 month; oral)	Yes

Note: aBC = advanced breast cancer; eBC = early breast cancer; 3D-CRT = three-dimensional conformal radiotherapy; IMRT = intensity-modulated radiotherapy; EBRT = external beam radiotherapy; RT = radiotherapy; TCM = traditional Chinese medicine; I = intervention group; C = control group.

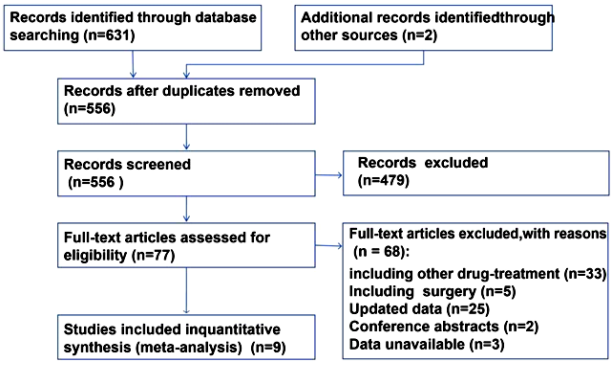


Figure 1. Diagram of study selection and exclusion process.

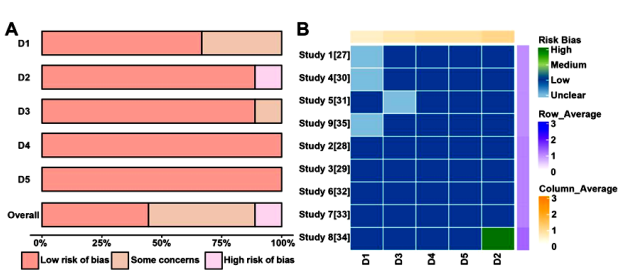


Figure 2. Risk of bias assessment of the included studies using the Cochrane Risk of Bias 2 (RoB 2) tool.

(A) Distribution of bias assessments across five predefined methodological dimensions and the overall appraisal outcome. (B) Domain-specific judgments for each included trial, displayed in heatmap format, where color gradients correspond to increasing levels of methodological concern.

Effectiveness analysis

A total of five studies reported on quality-of-life scores. The fixed-effects model revealed a significantly reduced risk of no improvement in the combination therapy group versus the radiotherapy-only group (RR = 0.34, 95% CI 0.24–0.50, Z = 5.47, P < 0.001) (figure 3A). Four studies evaluated the objective response rate (ORR), showing that the combination therapy group outperformed the radiotherapy group (RR = 1.44, 95% CI: 1.24–1.66, Z = 4.82, P < 0.001) (figure 3B). In terms of immunological indicators, $CD4^+$ T cell levels were significantly increased in the combination therapy group (MD = 9.55, 95% CI: 3.99–15.11, Z = 3.37, P < 0.001), although heterogeneity was high (I^2 = 97%) (figure 3C).Conversely, the difference in $CD8^+$ T cell levels was not statistically significant (MD = −3.89, 95% CI: −10.99–3.22, Z = 1.07, P = 0.280), with extremely high heterogeneity across studies (I^2 = 98%) (figure 3D).

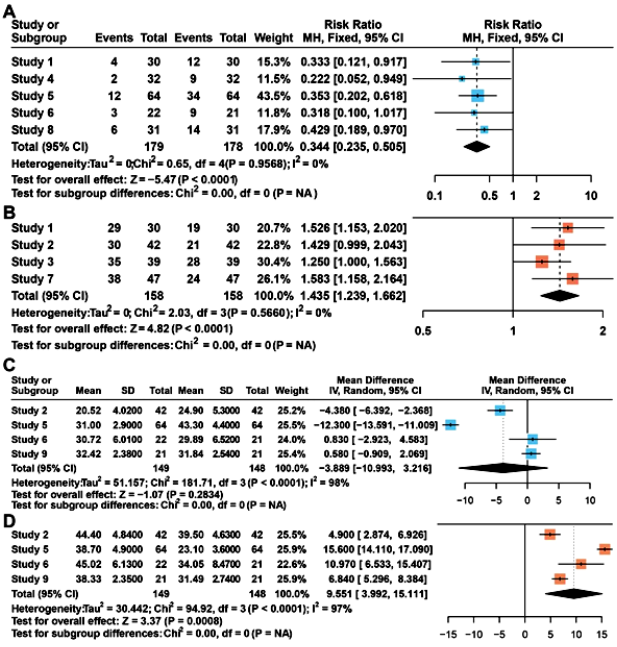


Figure 3. Forest plots of efficacy outcomes comparing combination therapy versus radiotherapy alone, including **(A)** risk of no improvement in quality of life, **(B)** objective response rate (ORR), **(C)** $CD4^+$ T-cell levels, and **(D)** $CD8^+$ T-cell levels. Relative risks with 95% confidence bounds were calculated for dichotomous outcomes using the Mantel-Haenszel fixed-effect model, whereas continuous immune indices were aggregated as mean differences under a random-effects assumption. In graphical displays, study-specific estimates are illustrated by squares proportional to their statistical weight, and pooled effects are shown as diamonds. Statistical inconsistency across studies was evaluated using the I^2 index.

Sensitivity analysis of effectiveness results

The leave-one-out sensitivity analysis demonstrated that the pooled effects for each outcome were generally stable after excluding individual studies. The RR for quality of life varied between 0.326 and 0.360, remaining significant (P<0.001). The RR for ORR ranged from 1.382 to 1.516, consistently significant (P<0.001). The mean difference in CD8 ranged from −1.10 to −5.44, indicating no significant difference, while the mean difference in CD4 varied between 6.90 and 11.15, remaining statistically significant. Overall, apart from the CD8 indicator being affected by high heterogeneity, the robustness of the other indicators was well maintained.

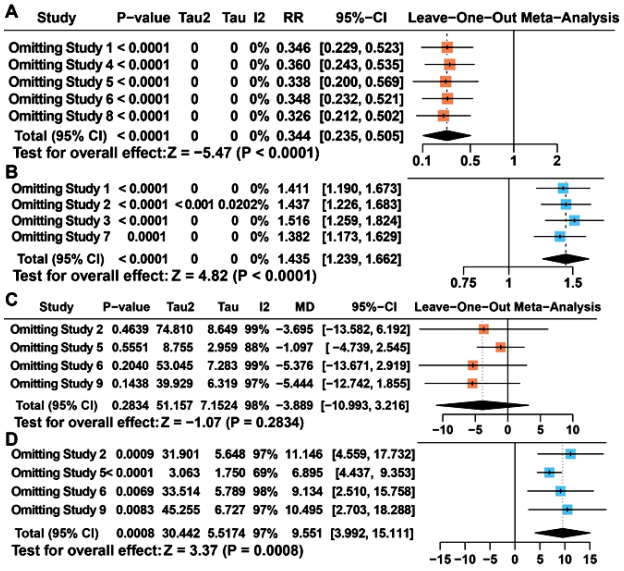


Figure 4. Leave-one-out sensitivity analyses for efficacy and immune-related outcomes. **(A)** Risk ratio for lack of improvement in quality of life, **(B)** Risk ratio for objective response rate, **(C)** Mean difference in $CD8^+$ T-cell levels, **(D)** Mean difference in $CD4^+$ T-cell levels. Robustness of the summary findings was explored through iterative re-analysis, with each study temporarily removed from the dataset. Re-estimated effect measures following iterative study removal are displayed as square symbols, with line extensions indicating the corresponding confidence bounds. The overall synthesized estimate appears as a diamond-shaped marker. The consistency of effect estimates across omissions indicates the robustness of the meta-analytic results.

Safety analysis

A fixed-effects model analysis of three studies indicated a significantly lower incidence of gastrointestinal adverse events in the combination therapy group compared to the control group (RR = 0.52, 95% CI 0.33–0.84, Z = 2.67, P = 0.008) (Figure 5). Similarly, for bone marrow suppression, after including three studies, combination therapy also significantly reduced the risk (RR = 0.53, 95% CI: 0.38 –0.72, Z = 3.99, P < 0.001). Both indicators showed low heterogeneity across studies, indicating stable results.

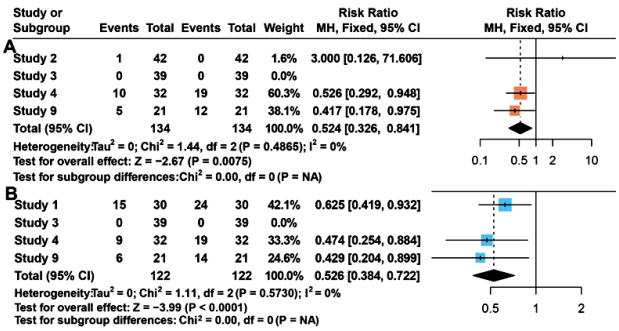


Figure 5. Comparative safety evaluation of radiotherapy integrated with traditional Chinese medicine versus radiotherapy alone among individuals with breast cancer. **(A)** Gastrointestinal adverse reactions. **(B)** Hematologic suppression events. Forest plot symbols denote weighted study estimates and their associated confidence dispersion, while diamond markers represent the aggregated effect. Dispersion across studies was examined using the I^2 statistic.

Sensitivity analysis of safety data

Sequential recalculation of the meta-analysis, excluding studies one at a time, yielded comparable risk estimates for gastrointestinal adverse events, with RR values spanning 0.484 to 0.590. Although the confidence intervals crossed the null line when Study 4 or Study 9 was excluded, the overall effect direction remained consistent (original RR = 0.524, 95% CI: 0.326–0.841) (figure 6). The sensitivity analysis for bone marrow suppression was even more robust, with RR values consistently ranging from 0.455 to 0.558 across all scenarios, all maintaining statistical significance and zero heterogeneity (original RR = 0.526, 95% CI: 0.384–0.722). Overall, the results for both types of adverse events demonstrated good robustness.

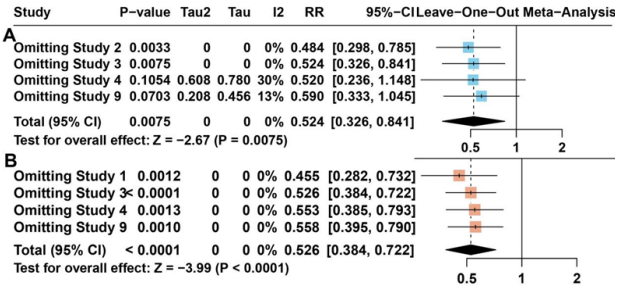


Figure 6. Conduct a leave-one-out sensitivity analysis focusing on gastrointestinal adverse events and myelosuppression.

DISCUSSION

Through pooled evidence synthesis, the combined therapeutic impact and safety characteristics of radiotherapy delivered with adjunct traditional Chinese medicine were systematically analyzed in breast cancer. The included studies predominantly employed conventional external beam radiotherapy, mainly 3D-CRT and IMRT, providing a relatively consistent radiotherapy framework across the analyzed trials. The TCM interventions were clearly defined and clinically representative, including injectable preparations such as Kang'ai Injection and Compound Kushen Injection, as well as oral herbal formulas (e.g., Liu Jun Zi Decoction, Ping Gan Xiao Jia Decoction, and Xihuang Capsule), most of which were administered concurrently with radiotherapy. Across these radiotherapy settings, the addition of TCM was associated with improved treatment efficacy, enhancement of immune-related parameters, particularly $CD4^+$ *T-cell* levels, and a reduced incidence of treatment-related adverse events, such as gastrointestinal toxicity and myelosuppression. Importantly, sensitivity analyses demonstrated that these beneficial effects were consistent across different radiotherapy techniques and TCM formulations, supporting the robustness and credibility of the observed clinical benefits.

Due to its multi-target, low-toxicity, and holistic regulatory characteristics, TCM has attracted increasing attention in the context of comprehensive cancer therapy in recent years [36,37]. Previous studies have shown that TCM can enhance the cytotoxic effects of radiotherapy, overcome radioresistance, and improve patients' clinical symptoms and quality of life [19,38]. Notably, commonly used clinical formulations -including injectable agents such as Kang'ai Injection and Compound Kushen Injection, as well as oral herbal prescriptions- have been reported to exert synergistic effects when administered alongside external beam radiotherapy by modulating oxidative stress, inflammatory responses, and tumor radiosensitivity [38-40].

For instance, research by Cai *et al.* demonstrated that combining TCM with chemoradiotherapy could improve therapeutic outcomes, reduce severe adverse reactions, and enhance immune function [41]. Similarly, Zhang *et al.* confirmed that TCM can augment chemotherapy efficacy and reduce toxicity in postoperative breast cancer patients [42]. Furthermore, Zhao *et al.* suggested that TCM may increase radiosensitivity in breast cancer by modulating multiple signaling pathways [38], a finding that is consistent with recent radiation-focused studies reporting that herbal medicines may influence DNA damage responses and immune regulation during radiotherapy [39,43].The safety analysis in the present study further supports and strengthens these findings by systematically comparing key adverse events such as gastrointestinal toxicity and myelosuppression, thereby providing a more comprehensive evidence base for the overall safety of combination therapy, in line with recent reports highlighting the radioprotective potential of TCM on normal tissues without compromising antitumor efficacy [40].

From an immunological perspective, this study found that radiotherapy combined with TCM significantly increased $CD4^+$ *T-cell* levels, suggesting a potential mechanism through which improved immune function may contribute to better clinical

outcomes. Prior research has also shown that TCM can synergize with radiotherapy by enhancing tumor immune recognition, inhibiting tumor cell proliferation, and promoting apoptosis [44–46]. Pan *et al.* proposed that TCM could regulate the $CD4^+/CD8^+$ ratio and improve the immune microenvironment, thus enhancing anti-tumor effects [47]. Other studies have suggested that TCM may modulate endoplasmic reticulum stress responses, thereby delaying tumor progression and increasing radiosensitivity [48]. These mechanisms are largely consistent with the findings of this study.

In summary, combining radiotherapy with TCM not only improves treatment efficacy but also reduces common adverse reactions such as gastrointestinal toxicity and myelosuppression, thereby enhancing patients' treatment tolerance. The improvement in immune markers-particularly $CD4^+$-also suggests potential value in restoring immune homeostasis. For breast cancer patients requiring long-term treatment, this combined approach, which balances efficacy with low toxicity, holds promise for improving treatment adherence and long-term quality of life. With increasing preclinical evidence indicating TCM's ability to influence the immune microenvironment, repair tissue damage, and regulate radiosensitivity, this systematic review further strengthens the case for integrating TCM into clinical guidelines and treatment pathways.

However, this study has certain limitations. The reliance on Chinese-language sources raises the possibility of selective dissemination patterns, especially if locally published studies disproportionately report favorable outcomes. Furthermore, as all trials were conducted within Chinese cohorts, the transferability of the results to other ethnic or geographic populations remains uncertain. The trials exhibited significant variability in TCM formula types, dosages, treatment durations, and methods for assessing immune markers. This heterogeneity, especially regarding $CD8^+$ T cell-related outcomes, reduces the reliability of those specific conclusions. Additionally, some studies did not report details such as blinding, stratified analysis, or randomization, potentially compromising evidence quality and introducing confounding factors. Hence, the conclusions of this review should be applied cautiously.

Future studies should prioritize multicenter, large -sample, high-quality randomized controlled trials to better understand the role, target populations, and optimal strategies for integrating TCM with radiotherapy in various breast cancer subtypes. More in-depth molecular-level studies are also needed to explore the active components of TCM, their mechanisms of action, and how they enhance radiosensitivity. Integrating immune cell monitoring, multi-omics analysis, and toxicity prediction models may accelerate the advancement of combined breast cancer therapies toward greater precision and individualization.

CONCLUSION

Evidence synthesized across eligible trials supports a beneficial role of adjunct traditional Chinese medicine in enhancing therapeutic outcomes and immune regulation during radiotherapy, with concurrent mitigation of treatment-related toxicities in breast cancer. The observed benefits, including increased $CD4^+$ *T-cell* levels and reduced gastrointestinal toxicity and myelosuppression, were supported by robust sensitivity analyses. Overall, this integrative approach offers a favorable balance between effectiveness and safety.

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Ethics approval: This systematic review and meta-analysis utilizes data from existing literature.It does not involve any patient privacy or prospective intervention, and therefore does not require additional ethics approval or informed consent.

Consent for publication: We utilize data sourced from publicly accessible literature, ensuring no inclusion of personally identifiable information. No new datasets were generated for this work; all data were derived from previously disseminated sources. Supplementary clarification may be obtained by contacting the corresponding author.

Competing interests: The authors affirm that this work was carried out without any competing interests that could be perceived as influencing the results.

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Authors' contributions: The study concept was developed by Y.Y., who also oversaw methodological planning, performed data consolidation and analysis, and led preparation of the manuscript. L.Z. participated in literature retrieval, data extraction, preliminary analysis, and assisted in manuscript preparation and formatting. W.G., the corresponding author, oversaw research supervision, ensured quality control, and conducted the final review and approval of the manuscript.

AI usage: This research was developed and executed independently of any artificial intelligence systems.

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