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REVIEW

METHODOLOGICAL QUALITY AND RISK OF BIAS ASSESSMENT IN RANDOMIZED CONTROLLED TRIALS OF ACUPUNCTURE FOR CANCER-RELATED PAIN MANAGEMENT

Thi Thuy Hien DOAN[1], Thi Bay NGUYEN[2,3], Ngoc Chi Lan NGUYEN[1], Minh Hoang LE[1]✉

[1] Faculty of Traditional Medicine, Can Tho University of Medicine and Pharmacy, Can Tho city, Vietnam
[2] Faculty of Traditional Medicine, University of Health Sciences, Vietnam National University Ho Chi Minh City, Ho Chi Minh City, Vietnam
[3] Faculty of Traditional Medicine, University of Medicine and Pharmacy at Ho Chi Minh City, Ho Chi Minh City, Vietnam

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Abstract

Introduction. Acupuncture has emerged as a promising adjunctive therapy for managing cancer pain. Over the past three decades, the number of randomized controlled trials (RCTs) has significantly increased. However, the methodological designs and quality of reporting have greatly influenced the outcomes and reliability of these studies.

The objectives of this study were to assess the methodological quality and risk of bias in recent acupuncture RCTs for cancer pain, to identify prevalent design limitations and provide evidence-based recommendations.

Materials and methods. We conducted a systematic review of RCTs from 7 databases (PubMed, Cochrane Library, Embase, Web of Science, CNKI, Wanfang, CQVIP) up to July 2024. Data on study characteristics were extracted. Methodological quality was assessed using the Cochrane Risk of Bias 2.0 (RoB 2.0) 2 tool.

Résumé

Évaluation de la qualité méthodologique et du risque de biais dans les essais contrôlés randomisés d'acupuncture pour la gestion de la douleur liée au cancer

Introduction. L'acupuncture est apparue comme une thérapie adjuvante prometteuse pour la prise en charge de la douleur cancéreuse. Au cours des trente dernières années, le nombre d'essais contrôlés randomisés (ECR) a considérablement augmenté. Cependant, la méthodologie et la qualité du compte rendu ont fortement influencé les résultats et la fiabilité de ces études.

Les objectifs de cette étude étaient d'évaluer la qualité méthodologique et le risque de biais des ECR récents sur l'acupuncture dans le traitement de la douleur cancéreuse, d'identifier les principales limites méthodologiques et de formuler des recommandations fondées sur des données probantes.

✉ Address for correspondence: Minh Hoang LE
Faculty of Traditional Medicine, Can Tho University of Medicine and Pharmacy, Can Tho, Vietnam
Address: 179 Nguyen Van Cu, Can Tho 900000, Vietnam
Email: lmhoang@ctump.edu.vn

Results. The analysis of 122 RCTs (10,685 patients) revealed that 83.6% had a high risk of bias, 13.1% some concerns, and 3.3% low risk. The primary flaw was outcome measurement (73% high risk) due to inadequate blinding. Only 23% fully described randomization procedures. Additionally, 26.2% utilized per-protocol analysis instead of the intention-to-treat principle, further increasing potential bias.
Conclusions. While the number of RCTs evaluating acupuncture for cancer pain management has surged in recent years, the quality of reports remains limited. Significant weaknesses persist, particularly regarding randomization processes, blinding designs, selection between Intent-to-Treat and Per-Protocol analysis and the objectivity of outcome assessment. To enhance clinical reliability, future studies must strictly adhere to the CONSORT and STRICTA guidelines.

Keywords: acupuncture, cancer pain, randomized controlled clinical trials.

List of abbreviations:
ASCO: American Society of Clinical Oncology
BPI: brief pain inventory
NRS: numeric rating scale
RCT: Randomized controlled trials
RoB: risk of bias
VAS: visual analogue scale
WHO: World Health Organization
GRADE: Grades of Recommendation, Assessment, Development

Matériel et méthodes. Nous avons réalisé une revue systématique des ECR issus de sept bases de données (PubMed, Cochrane Library, Embase, Web of Science, CNKI, Wanfang et CQVIP) jusqu'en juillet 2024. Les données relatives aux caractéristiques des études ont été extraites. La qualité méthodologique a été évaluée à l'aide de l'outil Cochrane Risk of Bias 2.0 (RoB 2.0).
Résultats. L'analyse de 122 ECR (10685 patients) a révélé que 83,6% présentaient un risque élevé de biais, 13,1% des biais modérés et 3,3% un faible risque. Le principal défaut résidait dans la mesure des résultats (risque élevé dans 73% des cas) en raison d'une mise en aveugle insuffisante. Seuls 23% des ECR décrivaient intégralement les procédures de randomisation. De plus, 26,2% ont utilisé une analyse per protocole au lieu de l'analyse en intention de traiter, ce qui accroît encore le risque de biais.
Conclusions. Bien que le nombre d'ECR évaluant l'acupuncture dans la prise en charge de la douleur cancéreuse ait fortement augmenté ces dernières années, la qualité des rapports demeure limitée. Des faiblesses importantes persistent, notamment concernant les processus de randomisation, les protocoles de mise en aveugle, le choix entre l'analyse en intention de traiter et l'analyse per protocole, ainsi que l'objectivité de l'évaluation des résultats. Afin d'améliorer la fiabilité clinique, les études futures doivent impérativement respecter les recommandations CONSORT et STRICTA.

Mots-clés: acupuncture, douleur cancéreuse, essais cliniques contrôlés randomisés.

Introduction

Cancer-related pain is a common issue among patients, both during and after treatment, affecting 44.5% of the oncological population, with over 30% experiencing moderate to severe pain[1]. The World Health Organization (WHO) three-step analgesic ladder is the gold standard for managing this pain, with opioids playing a central role[2]. However, clinical evidence shows that only some of patients achieve complete pain relief through pharmacological intervention alone, often facing adverse side effects[1,3].

Acupuncture is a traditional medical practice that has been used for more than a thousand years in several Asian countries to treat a wide range of diseases and symptoms, particularly pain and neurological disorders[4–7]. In recent decades, increasing scientific evidence has demonstrated its effectiveness, particularly in pain management. Numerous studies indicate that acupuncture is a promising approach for the treatment of chronic pain conditions[8]. Among these, cancer-related pain is one of the most common types of chronic pain for which acupuncture is frequently applied[9]. Systematic reviews have further confirmed that acupuncture is a safe and effective adjunctive therapy for pain control in oncological palliative care[10,11]. Consequently, the American Society of Clinical Oncology (ASCO) has issued moderate-strength recommendations supporting the use of acupuncture for managing joint pain or aromatase inhibitor–induced pain in patients with breast cancer[12].

The "Grades of Recommendation, Assessment, Development, and Evaluation" (GRADE) system provides a framework for evaluating the quality of evidence and the strength of clinical recommendations. According to the GRADE system, current recommendations for acupuncture have not yet achieved high-strength status because of a lack of high-quality evidence[13]. Numerous studies suggest that the Risk of Bias (RoB) is the primary obstacle preventing randomized controlled trials (RCTs) of acupuncture from being classified as highly reliable. High RoB weakens efficacy claims and hinders the integration of acupuncture into standard treatment guidelines[12,14–16].

While several systematic reviews have appraised clinical efficacy[15,16], there remains a paucity of in-depth analyses of the risk of bias and reporting quality of

RCTs specifically in this field. Therefore, our study was conducted to systematically assess the risk of bias using the Cochrane Risk of Bias 2.0 (RoB 2.0) tool for acupuncture RCTs in cancer pain management.

The main objective of the study was to identify common methodological flaws in current research designs and propose measures to enhance the scientific value and quality of future studies.

Material and methods

Study design

Systematic review of randomized controlled trials focusing on methodological quality and risk of bias assessment using the Cochrane RoB 2.0 tool.

Inclusion and exclusion criteria

Studies eligible for inclusion were RCTs determining the efficacy of acupuncture in cancer-related pain management. The intervention group received acupuncture alone or combined with other therapies, while the control group received distinct non-acupuncture interventions. There was at least one reported outcome evaluating the effectiveness of cancer-related pain relief. We excluded conference abstracts.

Search strategy

PubMed, Cochrane Library, Embase, Web of Science, China National Knowledge Infrastructure (CNKI), Chinese WanFang Database and China Science and Technology Journal Database (VIP) were searched from their inception to July 2024. We used a comprehensive search strategy combining text words and Medical Subject Headings (MeSH) terms related to acupuncture and systematic reviews. The search strategies across databases are shown in Table 1.

Table 1. Search strategies across databases

Database	No.	Search string
PubMed	#1	("cancer pain"[MeSH Terms] OR "cancer-related pain"[Title/Abstract] OR "tumor pain"[Title/Abstract] OR "oncology pain"[Title/Abstract])
	#2	("Acupuncture"[MeSH Terms] OR "Acupuncture"[Title/Abstract] OR "Acupuncture Therapy"[MeSH Terms] OR "Acupuncture Therapy"[Title/Abstract] OR "Manual acupuncture"[Title/Abstract] OR "Body Acupuncture"[Title/Abstract] OR "Warm acupuncture"[Title/Abstract] OR "Electroacupuncture"[MeSH Terms] OR "Electrical acupuncture"[Title/Abstract] OR "Auriculotherapy"[MeSH Terms] OR "Auriculotherapy"[Title/Abstract] OR "Ear acupuncture"[Title/Abstract] OR "Auricular acupuncture"[Title/Abstract] OR "Thread embedding acupuncture"[Title/Abstract] OR "Moxibustion"[Title/Abstract] OR "Acupuncture Points"[Title/Abstract] OR "Needle"[Title/Abstract])
	#3	("Randomized controlled trial"[Publication Type] OR "Randomized controlled trial"[Title/Abstract] OR "RCT"[Title/Abstract] OR "controlled clinical trial"[Title/Abstract])
	#4	#1 AND #2 AND #3
Cochrane Library	#1	MeSH descriptor: [Cancer Pain] explode all trees
	#2	(Acupuncture) OR (Acupuncture Therapy) OR (Manual acupuncture) OR (Body Acupuncture) OR (Warm acupuncture) OR (Electroacupuncture) OR (Electrical acupuncture) OR (Auriculotherapy) OR (Ear acupuncture) OR (Auricular acupuncture) OR (Thread embedding acupuncture) OR (moxibustion) OR (Acupuncture Points) OR (Needle)
	#3	MeSH descriptor: (Randomized Controlled Trial) explode all trees
	#4	MeSH descriptor: (Clinical Trial) explode all trees
	#5	((randomized controlled trial*) or (controlled clinical trial*) or (random*) or (trial*) or (group*)):ti,ab,kw
	#6	(placebo):ti,ab,kw
	#7	#3 OR #4 OR #5 OR #6
	#8	#1 AND #2 AND #7
Embase	#1	'cancer pain'/exp
	#2	'acupuncture'/exp OR 'acupuncture therapy'/exp OR 'acupuncture points'/exp OR 'electroacupuncture'/exp OR 'manual acupuncture'/exp OR 'auriculotherapy'/exp OR 'acupuncture, ear'/exp OR 'warm acupuncture'/exp OR 'moxibustion'/exp OR 'thread embedding acupuncture'/exp
	#3	[controlled clinical trial]/lim OR [randomized controlled trial]/lim
	#4	[humans]/lim
	#5	[english]/lim
	#6	#1 AND #2 AND #3 AND #4 AND #5

(Continuare în pagina următoare)

Table 1. Search strategies across databases (*Continuare*)

Database	No.	Search string
Web of Science	#1	TS=(Cancer Pain) OR TS=(Cancer Associated Pain) OR TS=(Neoplasm Related Pain) OR TS=(Oncological Pain) OR TS=(Tumor Related Pain) OR TS=(Tumor Associated Pain) OR TS=(Oncology Pain) OR TS=(Cancer Related Pain) OR TS=(Neoplasm Associated Pain)
	#2	TS=(Acupuncture) OR TS=(Acupuncture Therapy) OR TS=(Acupuncture Points) OR TS=(Manual acupuncture) OR TS=(Body acupuncture) OR TS=(Electroacupuncture) OR TS=(Electrical acupuncture) OR TS=(Auriculotherapy) OR TS=(Ear acupuncture) OR TS=(Auricular acupuncture) OR TS=(Warm acupuncture) OR TS=(Thread embedding acupuncture) OR TS=(moxibustion) OR TS=(Needle)
	#3	TI=(Randomized controlled trial) OR TI=(Controlled clinical trial)
	#4	#1 AND #2 AND #3
CNKI	#1	(TKA='癌痛' OR TKA='癌性疼痛' OR TKA='癌症' OR TKA='恶性肿瘤') AND (TKA='随机') AND (TKA='分为') AND (TKA='組') AND (TKA='針灸' OR TKA='穴位' OR TKA='电针' OR TKA='耳针' OR TKA='温针' OR TKA='艾灸' OR TKA='埋针')
Wanfang	#1	(全部:(Cancer pain) OR 全部:(癌痛) OR 全部:(癌性疼痛)) AND (全部:(acupuncture) OR 全部:(針灸) OR 全部:(电针) OR 全部:(穴位) OR 全部:(耳针) OR 全部:(温针) OR 全部:(艾灸) OR 全部:(埋针)) AND (全部:(random) OR 全部:(group))
CQVIP	#1	((U=Cancer pain) OR (U=Neoplasm related Pain) OR (U=Oncology Pain)) AND ((U=Acupuncture) OR (U=Acupuncture Points) OR (U=Manual acupuncture) OR (U=Body acupuncture) OR (U=Electroacupuncture) OR (U=Electrical acupuncture) OR (U=Auriculotherapy) OR (U=Ear acupuncture) OR (U=Auricular acupuncture) OR (U=Warm acupuncture) OR (U=Thread embedding acupuncture) OR (U=moxibustion) OR (U=Needle)) AND (U=random) AND (U=group)

Note: CNKI = China National Knowledge Infrastructure; CQVIP = Chongqing VIP Chinese Science and Technology Periodical Database.

Study selection

We rigorously conducted the study selection process in three independent stages, following the PRISMA 2020 guidelines. First, duplicate records were automatically removed using EndNote software, followed by manual verification. Subsequently, titles and abstracts were screened independently by two investigators to exclude ineligible articles. Finally, the full texts of potentially relevant documents were retrieved and thoroughly assessed against the established criteria. Any disagreements during this process were resolved through discussion or by consulting a third investigator to reach a consensus. Reasons for excluding studies at the full-text screening stage were recorded and reported in detail in the flow diagram.

Data extraction and standardization

Data were independently extracted by two investigators into a standardized Microsoft Excel template. Any discrepancies during the extraction process were resolved through discussion or by consulting a third expert. The following minimum data sets were collected:

- General information: author names, year of publication, country, and sample size.
- Methodological characteristics: randomization procedures, allocation concealment methods, blinding protocols (participants, personnel, and outcome assessors), and instances of dropouts or loss to follow-up.
- Reporting characteristics: statistical analysis methods (Intention-to-Treat – ITT or Per-Protocol – PP), the utilization of Traditional Chinese Medicine syndrome differentiation, and types of outcome measures (subjective scales such as VAS, NRS or objective markers).
- Intervention details: types of acupuncture (manual acupuncture, electroacupuncture, auricular acupuncture, etc) and control group characteristics (sham acupuncture, usual care, or analgesics).

To ensure evaluative consistency, methodological terminology was standardized according to the Cochrane Glossary and the CONSORT extensions for acupuncture (STRICTA).

Quality assessment

The methodological quality of the included studies was evaluated using the Cochrane Risk of Bias tool version 2 (RoB 2.0) – the current gold standard and most rigorous instrument for randomized controlled trials. Assessment was performed independently by two investigators based on five core bias domains:

- Bias arising from the randomization process: evaluation of the random sequence generation methods and the integrity of allocation concealment.
- Bias due to deviations from intended interventions: assessment of blinding of participants and personnel, as well as the impact of non-adherence to the assigned intervention.

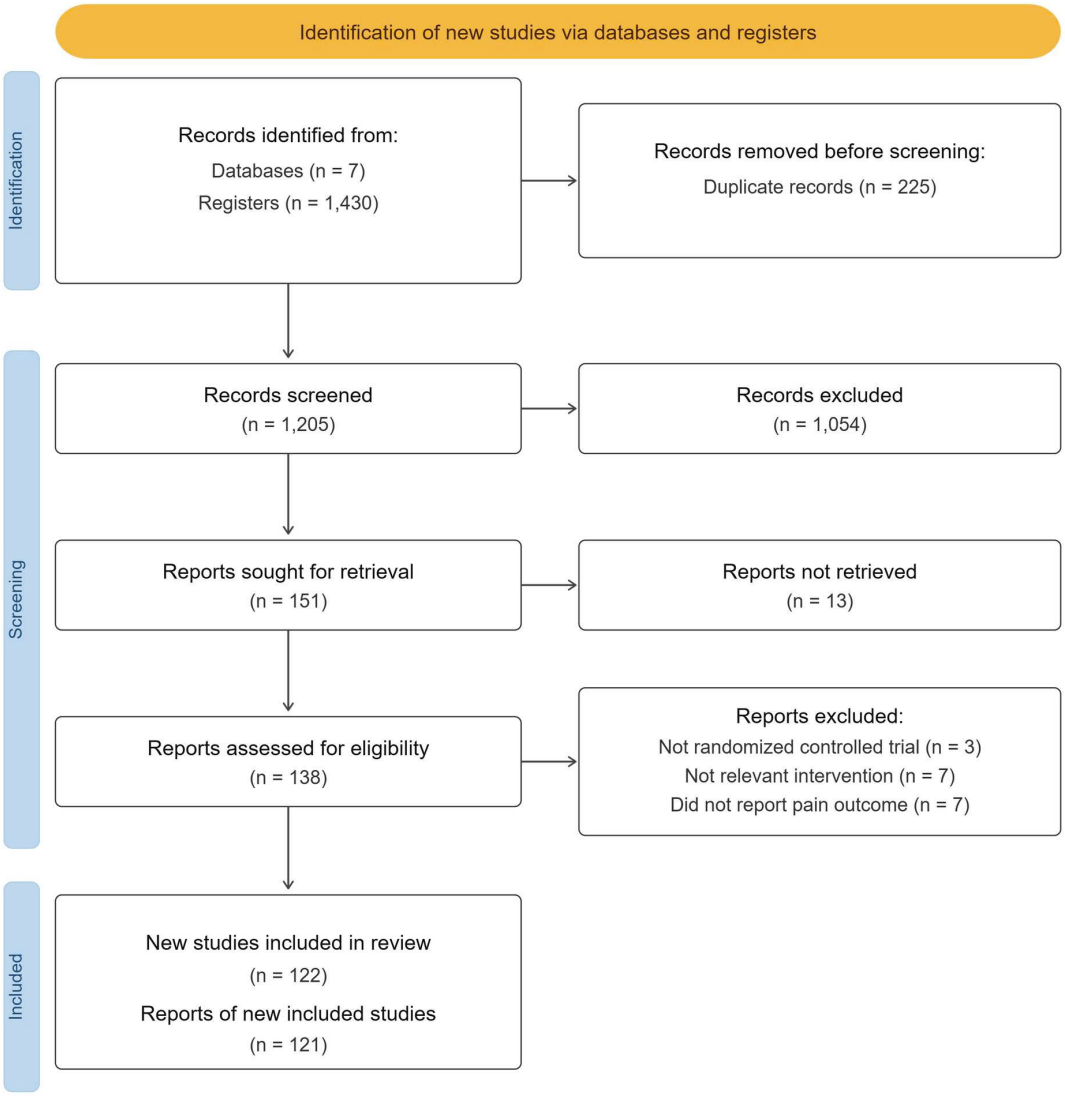


Figure 1. PRISMA flow diagram for the selection of articles.

– Bias due to missing outcome data: analysis of attrition rates and the appropriateness of methods used to handle missing data.
– Bias in measurement of the outcome: evaluation of the objectivity of measurement methods and the blinding of outcome assessors.
– Bias in selection of the reported result: comparison between the pre-registered study protocol and the actual published results.

Based on the RoB 2.0 algorithm, each domain was categorized into one of three levels: "Low risk", "Some concerns" or "High risk". The overall risk of bias for a study was determined as "High risk" if at least one domain reached this level, or "Some concerns" if multiple domains were identified as such. Any discrepancies in the assessment between the two investigators were resolved through discussion or by consulting a third expert to ensure the objectivity and consistency of the data.

Data analysis

Microsoft Excel 365 was employed to calculate the proportions of RCTs categorized as having "high risk", "some concerns" and "low risk" of bias.

Results

The initial search yielded 1430 records. After removing duplicates (n=225) and screening titles and abstracts (n=1054 excluded), 151 articles underwent full-text review. Eleven articles were inaccessible. Of the 138 re-viewed, 17 were excluded for various reasons (non-RCT, inappropriate intervention/outcome). Ultimately, 121 publications reporting 122 RCTs were included in the synthesis (PRISMA Flow Diagram, Figure 1).

Risk of bias assessment

Figures 2 and 3 summarize the risk of bias profile for the 122 RCTs. Of the 122 RCTs, 102 (83.6%) were

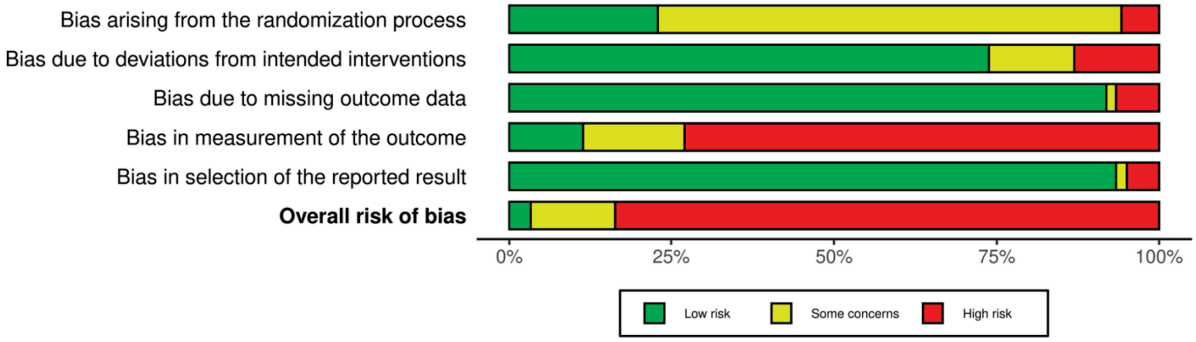


Figure 2. Risk of bias summary

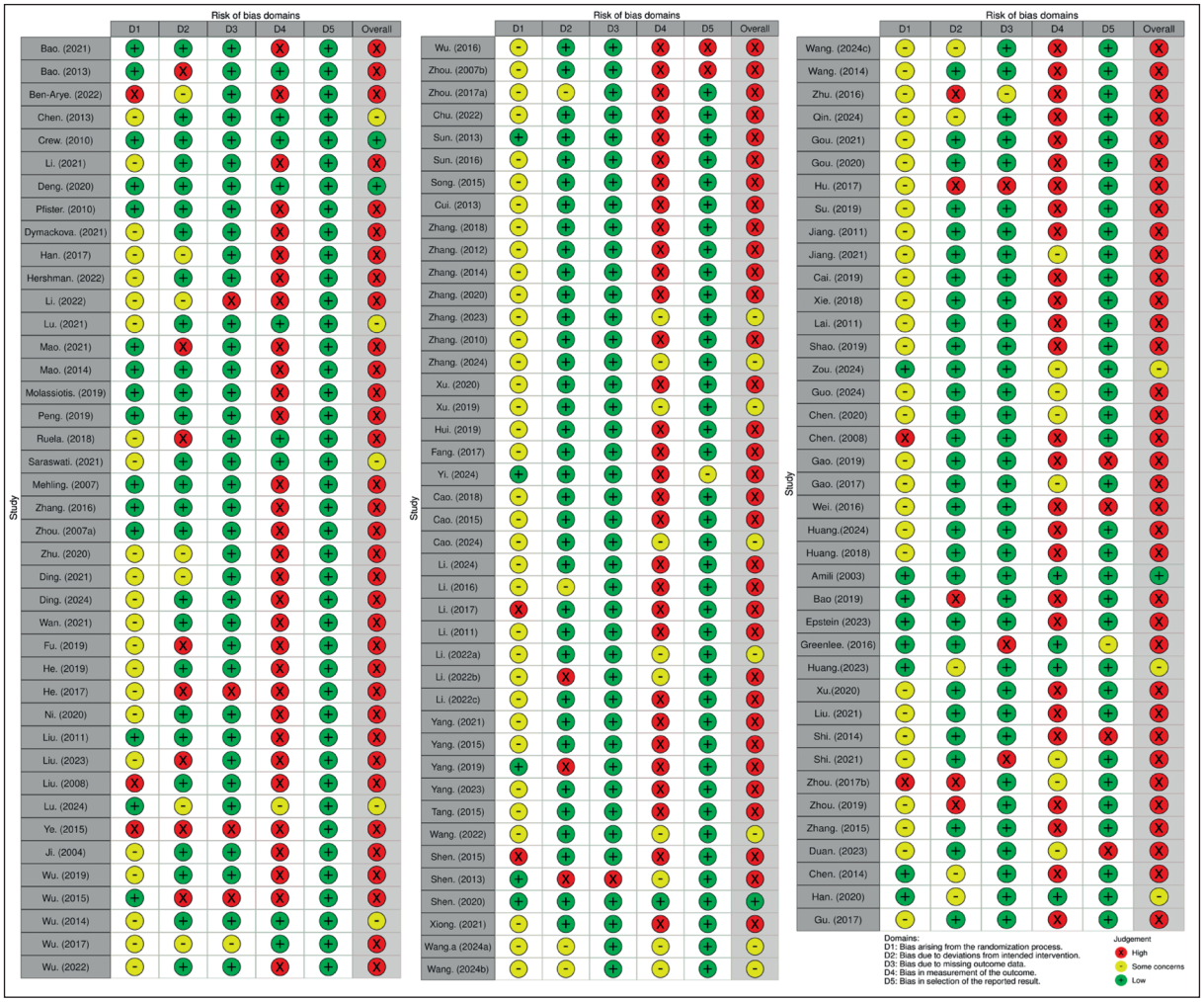


Figure 3. Risk of bias assessment

rated as high risk of bias overall, 16 (13.1%) had some concerns, and 4 (3.3%) achieved a low-risk rating.

Regarding individual domains, domain 4 (measurement of the outcome) was the primary driver of the high overall risk, with 73% (89/122) of the trials rated as high risk. Domain 1 (randomization process) also showed significant concerns, as 71.3% (87/122) of the studies provided insufficient details regarding allocation concealment. Conversely, domain 3 (missing outcome data) and domain 5 (selection of the reported result) demonstrated the highest compliance with methodological standards, with low-risk proportions of 91.8% and 93.4%, respectively. Detailed proportions for all five domains are summarized in Table 2.

Table 2. Summary of risk of bias assessment for included studies according to the Cochrane RoB 2.0 tool (N=122)

Domain	Low risk n (%)	Some concerns n (%)	High risk n (%)
D1: Randomization process	28 (23.0%)	87 (71.3%)	7 (5.7%)
D2: Deviations from intended interventions	90 (73.8%)	16 (13.1%)	16 (13.1%)
D3: Missing outcome data	112 (91.8%)	2 (1.6%)	8 (6.6%)
D4: Measurement of the outcome	14 (11.5%)	19 (15.6%)	89 (73.0%)
D5: Selection of the reported result	114 (93.4%)	2 (2.0%)	6 (4.9%)
Overall Risk of Bias	4 (3.3%)	16 (13.1%)	102 (83.6%)

Study design and reporting characteristics

Descriptive statistics regarding the methodology and reporting quality of the 122 included RCTs revealed the following characteristics:

Blinding Methods: A total of 13 studies (10.6%) implemented participant blinding using sham acupuncture. Only 11.5% (14/122) of the studies reported blinding of outcome assessors or utilized objective laboratory markers for cross – verification.

Randomization Bias Statistics: Among the studies that did not achieve a "low risk" rating in domain 1 (D1), 87 trials (71.3%) failed to provide information regarding the concealment of the random allocation sequence.

Data Analysis Methods: Intention-to-Treat (ITT) analysis was reported in 90 studies (73.77%), while the remaining 32 studies (26.23%) employed Per-Protocol (PP) analysis.

Measurement Tools: Most studies relied on self-reported scales (such as VAS, NRS, or quality-of-life questionnaires). The combination of subjective scales and objective laboratory tests was observed in only 12.3% (15/122) of the total studies.

Outcome Reporting: Signs of selective reporting from multiple outcome measurements were identified in 3.28% of the studies (4/122). Furthermore, 4.1% (5/122) performed statistically significant subgroup analyses despite finding no overall differences or such analyses not being part of the original protocol. Only one study conducted a subgroup analysis without indications of selective reporting.

Discussion

This study conducted a systematic analysis of 122 RCTs, a relatively large sample size reflecting the surge of evidence regarding acupuncture in cancer pain management. Notably, the rapid increase in publications between 2020 and 2024 suggests acupuncture is becoming a vital adjunctive therapy in palliative care. However, the extreme geographical concentration (over 85% of studies conducted in China) limits the generalizability of these findings. While this confirms China's leadership in Traditional Chinese Medicine (TCM), it poses challenges regarding population diversity and the generalizability of results to Western healthcare systems. Encouraging further research from Western countries – where modern medical systems are increasingly integrating complementary therapies – will enrich the global evidence base.

The findings are consistent with previous research by Long et al.[17], which indicated a predominance of unclear and high risk of bias in acupuncture RCTs. Previous authors also emphasized the critical role of random allocation and blinding in determining study quality. Furthermore, this analysis raises concerns regarding the selection of analytical methods and the scales used for outcome assessment.

Regarding methodological quality, more than 70% of the RCTs had an unclear or high risk of bias in the randomization process. Most studies merely mentioned the term "randomization" without detailed technical descriptions, such as the use of computer generators or random number tables. More critically, the lack of information on allocation concealment – a key factor in preventing selection bias – was the most prevalent flaw. According to Cochrane guidelines, without measures such as central randomization or opaque, sealed envelopes, the objectivity of group assignment remains unverified, even if the random sequence is perfectly generated[18]. However, using computer random number generators carries certain risks, while methods such as open allocation lists or non-opaque envelopes lack adequate concealment and were rated as high risk. Minimization is acceptable only when controlled by an independent unit; otherwise, it carries inherent risk. In this study, Cochrane guidelines were strictly followed. Studies failing to mention concealment methods, such as central randomization (controlled by an independent external unit) or sequentially numbered, opaque, sealed envelopes, were rated as having "some concerns". Conversely, studies with inappropriate random allocation, no mention of concealment, or statistically significant differences in baseline characteristics were categorized as "high risk".

Regarding blinding, acupuncture is a complex intervention involving multiple procedures and distinct

sensations. Developing a sham acupuncture control group that is indistinguishable from the verum group is highly challenging. Sham acupuncture may not fully simulate the necessary needle sensations required to maintain participant blinding, particularly for those with prior experience or knowledge of acupuncture[19]. Similarly, blinding the practitioner is infeasible, as the therapist must know the exact point locations and techniques, leading to potential performance bias. In the selected RCTs, sham methods included Streitberger needles for manual and electroacupuncture, and non-acupuncture points or non-penetrating patches for auricular acupuncture. This analysis revealed a very low blinding rate, consistent with reports by Lee et al.[20] and Liu et al.[19]. This deficiency, combined with the exclusive use of subjective scales (VAS, NRS, BPI), directly contributed to the high bias in the measurement of the outcome domain (D4 – 73%). When patients are aware of receiving real acupuncture, the expectancy effect may inflate the perceived efficacy.

Regarding data analysis, although most studies applied the Intention – to – Treat (ITT) principle, approximately one-quarter used Per – Protocol analysis. From a statistical perspective, using PP in trials with high dropout rates (particularly among late – stage cancer patients) often leads to biased efficacy estimates by breaking the initial random balance. Conversely, while ITT preserves randomness, it may underestimate the intervention effect if compliance is poor. This necessitates that future research adopt more advanced statistical methods, such as inverse probability weighting, to adjust for prognostic factors[18].

This is the first study to analyze the quality of RCTs in cancer-related pain management, a critical area in modern palliative care. The evaluation of 122 RCTs provides a comprehensive and updated overview of the research landscape. By utilizing the RoB 2.0 tool – Cochrane's most rigorous assessment instrument – this study dissected risks of bias at a detailed domain level. A comprehensive search strategy was employed, with two investigators independently screening and extracting data. This study transcends clinical outcomes to focus deeply on reporting quality and research design.

Despite providing a systematic assessment, several limitations should be considered. First, the reliance on reporting quality: RoB 2.0 assessment depends entirely on information published in the articles. Consequently, some studies might have been rigorously executed but were rated as "high risk" or "some concerns" due to inadequate descriptions. The gap between execution quality and reporting quality is an inherent barrier in systematic reviews. Second, the inclusion criteria were not strictly limited to studies using acupuncture as a combined therapy. Accepting trials where acupuncture was integrated with various other methods may confound the assessment of acupuncture-specific methodological quality. Third, the evidence source shows significant geographical concentration, with over 85% of RCTs conducted in China, which may limit the generalizability of findings to Western patient populations and healthcare systems.

Several strategies are proposed to improve the methodological rigor of future research. Primarily, authors must comply with international reporting standards. Investigators must rigorously implement the CONSORT guidelines and the STRICTA checklist[21]. Comprehensive descriptions of randomization, allocation concealment, and intervention protocols are critical for minimizing bias and guaranteeing reproducibility. Additionally, optimizing blinding and control group designs is crucial. The application of validated sham devices should be prioritized to maximize participant blinding[22–24]. When practitioner blinding is unfeasible, masking independent outcome assessors and data analysts remains mandatory to preserve objectivity[23]. To address measurement bias inherent in subjective pain scales, future trials must incorporate objective biological markers, such as serum levels of β-endorphin, serotonin, or substance P[25,26]. This approach solidifies the evidence concerning underlying physiological mechanisms. Specifically, study protocols demand formal registration. All clinical trials must be pre-registered before participant enrollment. Publicly accessible protocols deter selective outcome reporting and establish data transparency[27]. Finally, multi-center collaboration is necessary to diversify study populations. Study designs must focus on isolating the effects of acupuncture monotherapy from combination therapies to evaluate its intrinsic efficacy within palliative care protocols.

Conclusions

Despite a substantial increase in the volume of RCTs exploring acupuncture for cancer pain management, deficiencies in random sequence generation, outcome measurement, blinding protocols, and analytical approaches continue to undermine the scientific rigor of these reports. To enhance the value of future research, investigators must strictly adhere to CONSORT and STRICTA international reporting standards. Priority should be given to blinding of outcome assessment as a minimum requirement, the utilization of objective outcome measures, and the selection of optimal statistical models. Enhancing transparency and methodological standardization is a prerequisite for the sustainable and persuasive integration of acupuncture into global oncological palliative care systems.

Author Contributions:

Conceptualization, H.T.H.D and M.H.L; methodology, H.T.H.D and T.B.N; investigation, N.C.L.N and T.B.N; data curation, H.T.H.D and M.H.L; writing–original draft preparation, T.B,N. and N.C.L.N; writing–review and editing, H.T.H.D and M.H.L.; supervision, M.H.L. All the authors have read and agreed with the final version of the article.

Compliance with Ethics Requirements:

"The authors declare no conflict of interest regarding this article"

"This systematic review analyzed previously published data and did not involve direct recruitment of human participants. Ethics committee approval and informed consent were therefore not required "

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