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LETTER

Does Thunder-Fire Moxibustion Really Augment Therapeutic Efficacy in Knee Osteoarthritis? Methodological Critique of A Recent Pairwise Meta-Analysis [Letter]

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Dear editor

We appreciate Wei et al's meta-analysis[1] assessing Thunder-Fire Moxibustion (TFM) combined with other Traditional Chinese Medicine (TCM) modalities for knee osteoarthritis (KOA). However, we would like to raise some points for further discussion, as we believe that addressing these could enhance future studies and improve the robustness of the evidence in this field.

First, the title's phrasing "Osteoarthritis Knee" is non-standard. "Knee Osteoarthritis" or "Osteoarthritis of the Knee" are clinically accepted terms.

Second, while the study aimed to evaluate TFM combined with other TCM therapies for KOA through parallel-group RCTs, five included trials used controls that deviate from optimal methodological standards, such as waitlist controls, perfectly matched placebos, or guideline-recommended standard care (eg, land or aquatic exercise, topical/oral NSAIDs, intra-articular corticosteroid injections, or surgical treatment).[2] We acknowledge that excluding non-standard comparators is ideal, but may not always be feasible due to ethical or practical considerations. Thus, should the authors opt to include these trials with non-standard controls to enhance review comprehensiveness, a network meta-analysis approach, as discussed later, would be preferable, as it can effectively address inherent heterogeneity and better estimate comparative efficacy among multiple interventions.

Third, the exclusive reliance on clinical efficacy rate as the sole outcome measure is problematic due to substantial heterogeneity in calculation methods across studies and incomplete reporting of derivation procedures in some trials (Table 1). These methodological limitations fundamentally compromise the validity of pooled estimates. More standardized outcome measures, such as the Visual Analog Scale, Numeric Rating Scale, Western Ontario and McMaster Universities Arthritis Index, and Knee Injury and Osteoarthritis Outcome Score, would have better captured clinical efficacy and contributed to mitigating heterogeneity.

Fourth, in Wei et al's meta-analysis, heterogeneous TCM modalities (eg, various topical and oral herbal medicines, and different acupuncture or acupressure methods) were combined into broad subgroups, with minimal justification provided for this aggregation. This approach, coupled with the mixing of conventional and traditional medicine controls,

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Table 1 Evaluation of Methodological Limitations in the Seven RCTs Included by Wei et al

Incorporated RCTs	Protocol/Sample Size/Dosage		Grading Criteria of Clinical Efficacy Rate (CER)	Whether Blinding was Implemented	Whether Safety Outcomes were Reported	Justification for Unreasonableness
	Interventions	Controls				
Deng et al 2020[a]	TFM + EA/n = 35/one session per day for 28 days	Diclofenac Sodium Dual-Release Enteric-Coated Capsules (75mg/d) + Oral FuGui GuTong Capsule (a CPM, 0.33g*18/d)/n = 33/one session per day for 28 days	• ***Healed***: complete resolution of symptoms, GQSSTCM Reduction Rate ≥ 95% • ***Significant Efficacious***: significant improvement in symptoms, 70% ≤ GQSSTCM Reduction Rate < 95% • ***Efficacious***: moderate improvement in symptoms, 30% ≤ GQSSTCM Reduction Rate < 70% • ***Inefficacious***: no significant improvement in symptoms, GQSSTCM Reduction Rate < 30% GQSSTCM Reduction Rate (%) = [(pre-GQSS-TCM global score - post-GQSSTCM global score)/pre-GQSSTCM global score] × 100%	Not Clear	Not Reported	FuGui GuTong Capsule's therapeutic efficacy for KOA remains unproven, excluding it as a positive control
Hu et al 2019[b]	TFM + topical administration Shuangbai San/n = 33/one session per day for 4 weeks	TFM/n = 34/one session per day for 4 weeks	• ***Healed***: CER ≥ 95% • ***Significant Efficacious***:70% ≤ CER < 95% • ***Efficacious***: 30% ≤ CER < 70% • ***Inefficacious***: CER < 30% CER (%) = [(pre-WOMAC global score - post-WOMAC global score)/pre-WOMAC global score] × 100%	Not Clear	Not Reported	TFM's therapeutic efficacy for KOA remains unproven, excluding it as a positive control
Lin et al 2022[c]	TFM + Oral Duhuo Jisheng Decoction/n = 60/Not Reported	Celecoxib (0.2g/d) + Glucosamine Sulfate Capsule (0.628g*3/d)/n = 60/one session per day for 21 days	• ***Clinical Resolution***: Complete resolution of clinical symptoms, CSKO Reduction Rate ≥ 90% • ***Significant Efficacious***: significant improvement in clinical symptoms, 60% ≤ CSKO Reduction Rate < 89% • ***Efficacious***: moderate improvement in clinical symptoms, 30% ≤ CSKO Reduction Rate < 59% • ***Inefficacious***: no improvement or worsening of clinical symptoms, CSKO Reduction Rate < 30% CSKO Reduction Rate (%) = [(pre-CSKO global score – post-CSKO global score)/pre-CSKO global score] × 100%	Not Clear	Reported	(1) The therapeutic dose of TFM is unclear (2) Efficacy attribution (TFM, Duhuo Jisheng Decoction, or combination) remains uncertain

Miao et al 2014[d]	TFM + Acupressure/n = 75/one session per day for 4 weeks	Chinese Herbal Bath Therapy/n = 75/one session per day for 4 weeks	Not Reported	Not Clear	Not Reported	(1) Chinese Herbal Bath Therapy's therapeutic efficacy for KOA remains unproven, excluding it as a positive control (2) The Grading Criteria of CER is unclear
Wu 2021[e]	TFM + Oral JuanBi Decoction/n = 33/one session per day for 8 weeks	Glucosamine Sulfate Capsule (0.2g/d)/n = 34/one session per day for 8 weeks	• ***Healed***: absence of joint pain and swelling, normal joint mobility, JOA Increase Rate ≥ 95% • ***Significant Efficacious***: minimal joint pain/swelling, good functional recovery, 70% ≤ JOA Increase Rate < 95% • ***Efficacious***: moderate improvement in symptoms, 30% ≤ JOA Increase Rate < 70% • ***Inefficacious***: no significant improvement in pain, swelling, or mobility, slight mobility limitation, JOA Increase Rate < 30% JOA Increase Rate (%) = [(pre-GQSS-TCM global score - post-GQSSTCM global score)/pre-GQSSTCM global score] × 100%	Not Clear	Reported	Efficacy attribution (TFM, JuanBi Decoction, or combination) remains uncertain
Zhang et al 2016[f]	TFM + EA/n = 40/one session per day for 20 days	EA/n = 40/one session per day for 20 days	• ***Healed***: complete resolution of symptoms with no knee discomfort, GQSSTCM Reduction Rate ≥ 95% • ***Significant Efficacious***: significant improvement in symptoms with unrestricted knee movement, 70% ≤ GQSSTCM Reduction Rate < 95% • ***Efficacious***: moderate improvement in symptoms, mild limitation in knee joint mobility, 30% ≤ GQSSTCM Reduction Rate < 70% • ***Inefficacious***: no significant improvement in symptoms, GQSSTCM Reduction Rate < 30% GQSSTCM Reduction Rate (%) = [(pre-GQSS-TCM global score - post-GQSSTCM global score)/pre-GQSSTCM global score] × 100%	Not Clear	Reported	EA's therapeutic efficacy for KOA remains unproven, excluding it as a positive control

(*Continued*)

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Table 1 (Continued).

Incorporated RCTs	Protocol/Sample Size/Dosage		Grading Criteria of Clinical Efficacy Rate (CER)	Whether Blinding was Implemented	Whether Safety Outcomes were Reported	Justification for Unreasonableness
	Interventions	Controls				
Zhu et al 2023[g]	TFM + Beryllium Needling/n = 50/ one sessions/ one session every 3 days for 7 sessions	TFM + MA/n = 50/one session every 3 days for 7 sessions	• ***Clinical Resolution***: complete resolution of joint swelling, normal knee joint mobility, GQSSTCM Reduction Rate ≥ 95% • ***Significant Efficacious***: complete pain relief, normal knee joint mobility, 70% ≤ GQSSTCM Reduction Rate < 95% • ***Efficacious***: significant improvement in pain/ swelling, mild limitation in knee joint mobility, 30% ≤ GQSSTCM Reduction Rate < 70% • ***Inefficacious***: no symptomatic improvement, persistent knee joint mobility limitation, GQSSTCM Reduction Rate < 30% GQSSTCM Reduction Rate (%) = Not Reported	Not Clear	Not Reported	(1) TFM/MA's therapeutic efficacy for KOA remains unproven, excluding it as a positive control (2) Both the control and intervention groups received the same TFM protocols. Thus, the results could only compare the efficacy of MA and Beryllium Needling, which was inconsistent with the study's objectives (3) The calculation formula for the GQSSTCM reduction rate is unclear

Notes: Reference List for Table 1. [a]Deng KF, Zhu Y, Zhu SW et al. Thunder-Fire Moxibustion combined with electroacupuncture for knee osteoarthritis with Cold-Dampness Obstruction pattern: A randomized controlled trial. *Acupuncture Research*, 2020; 45(6): 484–489. [b]Hu Q, Zeng Z, Hu GY et al. Efficacy of Thunder-Fire Moxibustion combined with external application of *Shuangbai* San for mild-to-moderate knee osteoarthritis. *Chinese Acupuncture & Moxibustion*, 2019; 39(8):804–808. [c]Lin FX, Li ZM, Lai ZJ. Efficacy of Duhuo Jisheng Decoction combined with Thunder-Fire Moxibustion in treating knee osteoarthritis with Cold-Dampness Obstruction pattern and its effects on joint function and serum levels of MMP-3 and Osteopontin. *Journal of Clinical and Experimental Medicine*, 2022; 21(4): 395–399. [d]Miao YM, E HY, Zhang HK et al. Clinical nursing study on Thunder-Fire Moxibustion combined with acupressure for knee osteoarthritis. *Anhui Medical and Pharmaceutical Journal*, 2014; 18(6), 1177–1179. [e]Wu WY. A clinical study of JuanBi Decoction combined with Thunder-Fire Moxibustion in the treatment of knee osteoarthritis with Cold-Dampness Obstruction pattern. *Master Thesis*, Guangxi University of Chinese Medicine: 2021. [f]Zhang HJ, Xu HD, Liu TT et al. Clinical study of the electroacupuncture combined with Thunder-Fire Moxibustion in treatment of degenerative knee osteoarthritis with Cold-Dampness Obstruction pattern. *Chinese Acupuncture & Moxibustion*, 2016; 36(12):1266–1270. [g]Zhu QY, Cheng L, Xiong W et al. Effect analysis of Beryllium Needling combined with Thunder-Fire Moxibustion on patients with knee osteoarthritis. *Acta Med Sinica*, 2023; 36(1): 97–101.

Abbreviations: CER, Clinical Efficacy Rate; CPM, Chinese Patent Medicine; CSKO, Chinese Scale for Knee Osteoarthritis; EA, Electro-acupuncture; GQSSTCM, Graded Quantitative Scoring Scale for TCM Syndrome; JOA, JOA Scoring System for Knee Osteoarthritis; MA, Manual Acupuncture; RCT, Randomized Controlled Trial; TCM, Traditional Chinese Medicine; TFM, Thunder-Fire Moxibustion; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

poses challenges to clinical comparability and undermines the interpretability of effect estimates. We recommend clearer subgrouping with sufficient justification or the adoption of a network meta-analysis approach to establish efficacy hierarchies when addressing such clinical diversity. Notably, even though the intervention and control groups included multiple therapies, Wei et al's analysis reported minimal heterogeneity (I^2 = 0%).

Fifth, methodological concerns exist in RoB assessment using RoB 2.0 Tool:[3] (1) Three RCTs failing to report safety outcomes were incorrectly rated as low RoB for "Selective Outcome Reporting"; and (2) Four trials without reported outcome assessor blinding were judged as having low risk for "Measurement of Outcomes", when "Some Concerns" would have been more appropriate.

Sixth, the application of the GRADE framework[4] could be further refined. Given the substantial heterogeneity across included RCT designs, the "Indirectness" domain might warrant downgrading, contrary to the authors' assertion that "no downgrade was needed". Moreover, the absence of standard controls and inadequate blinding in the included trials warrant downgrading in the "Limitations" domain. Even under the authors' own criteria, "Incidence of Adverse Reactions" outcome presents multiple concerns across domains and should have been rated as "Very Low" certainty rather than "Low".

Seventh, based on the inclusion criteria outlined by Wei et al, we identified at least five eligible RCTs—without applying a formal search strategy—that were not included in their analysis (Table 2). This suggests that a substantial number of relevant studies may have been overlooked. Such omissions significantly affect the validity and outcomes of their meta-analysis.

Lastly, we encourage future systematic reviews to register their protocols in advance. Protocol registration enhances transparency, reduces research duplication, and minimizes selective reporting, thereby improving the overall credibility of the review process.[5]

Table 2 Eligible RCTs Meeting Wei et al's Inclusion Criteria but Omitted from Their Meta-Analysis

Incorporated RCTs	Protocol/Sample Size/Dosage		Outcome Tools
	Interventions	Controls	
He 2019[a]	TFM + EA/n = 40/5 sessions per week for 20 Sessions	Diclofenac Sodium Dual-Release Enteric-Coated Capsules (75mg/d) + Oral FuGui GuTong Capsule (a CPM, 0.33g*12/d)/n = 40/one session per day for one month	(1) LKSS (2) VAS (3) CER
Lian et al 2019[b]	TFM + MA/n = 40/one session per day for one month	Intra-articular Hyaluronate Sodium Injection (2mL)/n = 40/one session per week for one month	(1) Knee Function Scale (2) VAS (3) CER
Xu et al 2014[c]	TFM + MA/n = 49/one session per day for 4 weeks	MA/n = 49/one session per day for 4 weeks	(1) Knee Function Scale (2) IV Rating Scale (3) CER
Zhang 2020[d]	TFM + MA/n = 39/6 sessions per week for 3 weeks	MA/n = 39/6 sessions per week for 3 weeks	(1) WOMAC (2) VAS (3) CER (4) Serum IL-1
Zhong et al 2020[e]	MA/n = 25/one session per day for 21 days	MA/n = 25/one session per day for 21 days	(1) LKSS (2) VAS (3) CER

Notes: Reference List for Table 2. [a]He YL. Clinical study on Thunder-Fire Moxibustion combined with midnight-noon opposing electroacupuncture for knee osteoarthritis with cold-dampness pattern. *Master Thesis*, Guangxi University of Chinese Medicine; 2019. [b]Lian QQ, Chen JH, Zeng Y. Clinical observation on 40 cases of knee osteoarthritis treated with thunder-fire moxibustion combined with acupuncture. *Chinese Journal of Ethnomedicine and Ethnopharmacy*, 2019, 28(9): 100–102. [c]Xu YY, Hu BC. Therapeutic observation on degenerative knee osteoarthritis treated with triple needling combined with Thunder-Fire Moxibustion. *World Journal of Acupuncture-Moxibustion*, 2014; 24(3): 30–34. [d]Zhang XX. Clinical observation on 39 cases of knee osteoarthritis treated with acupuncture combined with Zhao's Thunder-Fire Moxibustion. *Hunan Journal of Traditional Chinese Medicine*, 2020, 36(5): 82–83. [e]Zhong QF, Kong WL. Therapeutic efficacy of Thunder-Fire Moxibustion combined with contralateral acupuncture therapy for knee osteoarthritis. *Clinical Journal of Chinese Medicine*, 2020, 12(23): 96–98.

Abbreviations: CER, Clinical Efficacy Rate; CPM, Chinese Patent Medicine; EA, Electro-acupuncture; LKSS, Lysholm Knee Scoring Scale; MA, Manual Acupuncture; RCT, Randomized Controlled Trial; TFM, Thunder-Fire Moxibustion; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index; VAS, Visual Analog Scale.

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In conclusion, while Wei et al's study offers preliminary evidence for TMF combined with other TCM therapies in KOA, its methodological limitations necessitate resolution for more robust and clinically translatable findings. Future studies should: (1) adopting stricter inclusion criteria to ensure high-quality evidence synthesis, ideally using network meta-analysis to compare intervention effects, and (2) unbiasedly evaluating the efficacy and safety of TMF as a monotherapy and as an adjunct to standard care separately. We hope these constructive suggestions foster further academic dialogue and methodological refinement within this field.

Abbreviations

GRADE, Grades of Recommendation, Assessment, Development, and Evaluation; KOA, Knee Osteoarthritis; NSAID(s), Non-Steroidal Anti-Inflammatory Drug(s); RCT(s), Randomized Controlled Trials; RoB, Risk of Bias; RoB 2.0 Tool, Revised Cochrane Risk-of-Bias Tool for Randomized Trials; TCM, Traditional Chinese Medicine; TFM, Thunder-Fire Moxibustion.

Data Sharing Statement

Data sharing is not applicable to this article as no datasets were generated or analyzed during the current study.

Author Contributions

Fei-Yi Zhao: Conceptualization, Investigation, Formal analysis, Writing - original draft. Qiang-Qiang Fu: Methodology, Formal analysis, Writing - review & editing. Yuen-Shan Ho: Conceptualization, Methodology, Formal analysis, Writing - review & editing. All authors gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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