Journal of Pain Research

Dovepress
Taylor & Francis Group

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LETTER

# Comments on "Preoperative Transcutaneous Electrical Acupoint Stimulation Alleviates Postoperative Pain and Improves Sleep Quality in Breast Cancer Patients with Preoperative Sleep Disturbance: A Partially Randomized Controlled Trial" [Letter]

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## Dear editor

We read with interest the partially randomized controlled trial by Ma et al[1] investigating whether preoperative transcutaneous electrical acupoint stimulation (TEAS) alleviates postoperative pain and improves sleep quality in breast cancer patients with preoperative sleep disturbance. The authors should be commended for addressing a clinically important and understudied population. However, we wish to raise several methodological concerns that may affect the robustness of the reported findings.

First, the partially randomized design creates a fundamental threat to validity. Patients with PSQI < 6 were non-randomly assigned to the control group (Group C), whereas only patients with PSQI ≥ 6 were randomized to Group S or Group T. Consequently, comparisons between Group C and Groups S/T are observational rather than randomized contrasts, yet the manuscript repeatedly presents these as if they were equivalent to randomized comparisons. This is not merely a design preference-it introduces systematic confounding because Group C differs inherently from Groups S/T in baseline sleep quality, anxiety, and potentially other unmeasured characteristics. The authors acknowledge this limitation in the Discussion but then proceed to state that "TEAS effectively normalized postoperative pain perception" by comparing Group T with Group C. Such a claim cannot be supported from a non-randomized comparison. As emphasized in contemporary methodological guidance, randomized allocation is the foundation for causal inference in clinical trials, and deviations from this principle substantially weaken the evidentiary value of between-group comparisons.[2] We suggest that all conclusions regarding TEAS efficacy should be restricted to the randomized comparison between Group S and Group T, and that comparisons involving Group C be explicitly labeled as exploratory or hypothesis-generating.

Second, the sample size calculation was based solely on the Athens Insomnia Scale (AIS), yet the Numerical Rating Scale (NRS) for pain was designated as a co-primary outcome of equal importance. The authors acknowledge that "formal power calculation for NRS was not performed". This is a serious issue because it means the study was not powered to detect the very outcome for which the most definitive conclusions are drawn. The statistically significant NRS differences may therefore reflect overoptimistic effect estimates or chance findings rather than true effects. Moreover, with only 16–17 patients per randomized group, the study is substantially underpowered for detecting clinically meaningful differences in many secondary outcomes. The problem of underpowered trials due to overly

https://doi.org/10.2147/JPR.S640983
Received: 16 July 2026
Accepted: 21 July 2026
Published: 22 July 2026

optimistic effect estimates is well recognized in the methodological literature, and such studies are prone to both false-negative results for their primary outcomes and inflated effect sizes for secondary findings.[3] We recommend that the authors report post-hoc power for the NRS comparisons and explicitly acknowledge that the study was not designed to provide confirmatory evidence for pain outcomes.

Third, the linear regression analyses combining Group C and Group S (non-TEAS patients) to examine associations between preoperative PSQI and postoperative outcomes raise concerns about ecological fallacy and model misspecification. Groups C and S differ fundamentally in their PSQI distributions (4.46±0.76 vs 9.63±2.68), with almost no overlap. Pooling them creates an artificial continuum where none exists, potentially inflating correlation coefficients and giving a misleading impression of a linear dose–response relationship across the entire patient population. Additionally, the regression models adjusted only for the PSQI score without including key confounders such as age, BMI, or surgical type, and the adjusted $R^2$ values (0.166–0.394) indicate that PSQI explains only a modest proportion of variance, limiting its predictive utility. A recent review on handling time-varying and group-based confounding emphasizes that pooling inherently distinct subgroups without appropriate interaction testing can produce spurious associations and should be avoided when the grouping variable is a known effect modifier.[4] We suggest that the authors stratify these analyses by group or include an interaction term to test whether the association between PSQI and outcomes differs by sleep status category.

Fourth, the study's interpretation of the relationship between preoperative PSQI and postoperative outcomes via linear regression may be further compromised by the absence of adjustment for multiplicity. Given that the regression analyses examined multiple postoperative time points (AIS on days 1 and 2; NRS at 24, 48, and 72 hours) without correction for multiple testing, the reported p-values are likely inflated, increasing the risk of false-positive findings. This concern is particularly relevant given the modest sample size and the exploratory nature of these analyses.[5] We recommend that the authors apply appropriate multiplicity adjustments, such as Bonferroni correction or false discovery rate control, or explicitly designate these analyses as hypothesis-generating.

Fifth, the generalizability of the findings is limited by the single-center design and the lack of objective sleep measures. The study relied exclusively on subjective self-report instruments (PSQI and AIS) without polysomnography or actigraphy to corroborate sleep quality. Previous research has demonstrated that subjective and objective sleep measures may diverge substantially, particularly in perioperative settings, and that this discrepancy can influence the interpretation of intervention effects on sleep-related outcomes.[6] Future multicenter studies incorporating both subjective and objective sleep assessments would strengthen the evidence base for TEAS in this population.

In summary, while the clinical question is timely and the intervention promising, the partially randomized design, inadequate power for co-primary pain outcomes, problematic pooling of non-randomized groups, absence of multiplicity adjustment, and reliance on subjective sleep measures warrant careful reconsideration. Addressing these issues would substantially strengthen the validity of the conclusions and better guide clinical practice.

## Disclosure

The authors report no conflicts of interest in this communication.

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