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ORIGINAL RESEARCH

Auricular Plaster Therapy for Preoperative Anxiety in Major Surgery: A Prospective Matched-Cohort Study of Total Knee Arthroplasty and Pancreaticoduodenectomy Patients

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Objective: To investigate the association of auricular plaster therapy (AP) with preoperative anxiety in patients undergoing total knee arthroplasty (TKA) and pancreaticoduodenectomy (Whipple).

Methods: A prospective matched-cohort observational study was conducted at Peking Union Medical College Hospital from March 2024 to May 2025. The primary outcome was Perioperative Anxiety Scale-7 (PAS-7) scores at different preoperative timepoints. Secondary outcomes included modified Pittsburgh Sleep Quality Index (M-PSQI), satisfaction visual analog scale (VAS-satisfaction), intraoperative blood loss, postoperative VAS-pain scores, Self-Rating Anxiety Scale (SAS) scores, and incidence of delirium.

Results: A total of 168 patients completed the study, and 98 patients (49 matched pairs) were included in the final analysis. The results revealed that auricular plaster (AP) therapy was significantly associated with reduced preoperative anxiety scores. Specifically, the AP exposed group demonstrated substantially lower median PAS-7 scores at both 12±2 hours before surgery (T2) and 2 hours before surgery (T3), with median differences of −4.00 points and −5.00 points, respectively (both $p < 0.001$). Generalized Estimating Equations further confirmed a significant group × time interaction effect (Wald $\chi^2 = 44.73$, $p < 0.001$), indicating a favorable association between AP therapy and attenuated anxiety progression. Similarly, AP therapy was significantly associated with improved perioperative sleep quality. The AP exposed group showed superior M-PSQI scores at T2 and at 72±2 hours postoperatively (T4), with a median difference of −4.00 points at T2 and a mean difference of −3.27 points at T4 (both $p < 0.001$). This was supported by a significant cumulative trend (Wald $\chi^2 = 30.44$, $p < 0.001$). Furthermore, the AP exposed group was associated with more favorable postoperative outcomes, including significantly lower VAS pain scores (mean difference: −1.00, $p < 0.001$) and SAS scores (mean difference: −4.02, $p = 0.012$). Multivariable regression identified treatment allocation as a key predictor of PAS-7 scores, with the model demonstrating moderate goodness-of-fit (adjusted $R^2 = 0.50$). No significant associations were observed between AP therapy and intraoperative blood loss, postoperative length of stay, or incidence of delirium. The AP exposed group exhibited a lower incidence of adverse events (10.2% vs 16.4%), with only three cases of mild local reactions reported, suggesting an acceptable safety profile.

Conclusion: In this observational study, AP was associated with reduced preoperative anxiety and improved sleep quality and may contribute to optimized postoperative recovery through its cumulative effects. Larger randomized controlled trials are needed to establish causality.

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Introduction

Preoperative anxiety (PA) is a common psychological stress response among surgical patients during the perioperative period. A multicenter study conducted in China reported a prevalence of 15.8% (95% CI: 14.8–16.9%),[1] whereas the global prevalence is significantly higher at 48% (95% CI: 39–47%).[2] It typically presents as multifaceted concerns regarding disease prognosis, anesthesia, surgical risks, pain, and perceived loss of control.[3,4] Clinical evidence links PA to increased anesthetic and analgesic requirements, hemodynamic instability, prolonged recovery, heightened postoperative pain, extended hospital stays, and reduced patient satisfaction.[5–8] In high-risk populations, severe PA may further elevate the risks of delirium and postoperative mortality, contributing to additional healthcare burdens.[9–11] Total knee arthroplasty (TKA) and pancreaticoduodenectomy (Whipple) are both classified as major surgeries (Grade IV in the Chinese surgical classification) and are associated with significant technical complexity, procedural risk, and resource utilization.[12] Patients undergoing these interventions often experience considerable PA, which may in turn worsen clinical outcomes. Current management of PA primarily involves pharmacologic sedatives and preoperative education. However, the safety and efficacy profile of sedatives remains uncertain,[13] underscoring the importance of developing non-pharmacological alternatives.

Auricular plaster therapy (AP), a non-invasive modality derived from auricular acupuncture, involves the application of stimulants such as Vaccaria seeds, magnetic beads, or medicated patches to specific auricular points. Periodic manual stimulation of these points is thought to modulate physiological functions.[14] Unlike needle-based acupuncture, AP is needle-free, enhancing its safety and feasibility in clinical settings. It also allows for more precise and sustained acupoint stimulation compared to acupressure, while enabling self-administration—features that may improve patient accessibility and adherence. These advantages support its applicability across various clinical scenarios.[15–17] Although TKA and Whipple procedure belong to different surgical specialties (orthopedics and general surgery, respectively), both are major operations that can induce significant perioperative psychological stress.[18,19] Including these two cohorts allows a preliminary assessment of the potential generalizability of AP across different surgical contexts. While previous studies have suggested a potential benefit of AP in reducing PA,[20–22] most of the available evidence comes from retrospective studies with methodological limitations, highlighting the need for more rigorous prospective evaluations. To fill this gap examine the association between AP and PA, we conducted a prospective observational cohort study employing a matched-comparison design in patients undergoing TKA or Whipple.

Materials and Methods

Study Design

This prospective observational cohort study with matched comparison was conducted in accordance with the Declaration of Helsinki among participants from the Departments of Orthopedics and General Surgery. It received ethical approval from the Institutional Review Board of Peking Union Medical College Hospital in March 2024 and July 2024 (approval nos. I-24PJ0652/I-24PJ1454) and was prospectively registered at ClinicalTrials.gov (registration nos. NCT06273488/NCT06580197). This study is reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement,[23] and the reporting of the AP intervention adheres to the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA).[24]

Study Setting

This study was conducted between March 2024 and May 2025 in the Departments of Orthopedics and General Surgery at Peking Union Medical College Hospital and enrolled patients scheduled for TKA or Whipple procedure. Exposure factors were ascertained via clinical visits, electronic medical records, and telephone follow-up, with the final follow-up of all participants completed in June 2025.

Participants

The inclusion and exclusion criteria were defined separately for each surgical specialty-orthopedics and general surgery-as follows.

Orthopedics Inclusion criteria: (1) Aged 40–80 years, either sex. (2) Scheduled to undergo primary total knee arthroplasty (TKA) for knee osteoarthritis after standard preoperative evaluation. (3) American Society of Anesthesiologists (ASA) physical status class I or II. (4) Participant able to comprehend the study objectives (independently or, in cases of limited literacy or comprehension due to linguistic or educational barriers, with the assistance of a legal guardian/representative), exhibits adequate protocol adherence, and signs the Informed Consent Form (ICF) (or, upon the participant's explicit request and for the reasons stated above, has the ICF signed by their legal guardian/representative). Orthopedics Exclusion criteria: (1) Emergency surgery without preoperative assessment. (2) TKA contraindications, documented psychiatric disorders, alcohol abuse, substance-use disorder, or history of vestibular dysfunction, Parkinson's disease, multiple sclerosis, or muscular dystrophy. (3) Bilateral auricular lesions (eg, breakage, erythema, bleeding, infection) precluding auricular plaster therapy. (4) Cognitive impairment preventing comprehension of study requirements or adequate cooperation. (5) Any other condition deemed by the investigator to render the patient unsuitable for participation.

General Surgery Inclusion criteria: (1) Aged 40–80 years, either sex. (2) Scheduled to undergo pancreaticoduodenectomy (Whipple procedure) for malignant neoplasms of the pancreatic head, periampullary region, or distal bile duct after standard preoperative evaluation. (3) American Society of Anesthesiologists (ASA) physical status class I or II. (4) Participant able to comprehend the study objectives (independently or, in cases of limited literacy or comprehension due to linguistic or educational barriers, with the assistance of a legal guardian/representative), exhibits adequate protocol adherence, and signs the ICF (or, upon the participant's explicit request and for the reasons stated above, has the ICF signed by their legal guardian/representative). General Surgery Exclusion criteria: (1) Emergency surgery without preoperative assessment. (2) Contraindications to pancreaticoduodenectomy, documented psychiatric disorders, alcohol abuse, substance-use disorder, or history of vestibular dysfunction, Parkinson's disease, multiple sclerosis, or muscular dystrophy. (3) Bilateral auricular lesions (eg, breakage, erythema, bleeding, infection) precluding auricular plaster therapy. (4) Cognitive impairment preventing adequate understanding of study requirements or cooperation. (5) Any other condition that, in the opinion of the investigator, renders the patient unsuitable for participation.

Cohort Determination and Auricular Plaster Therapy Protocol

Upon admission, researchers approached eligible patients, provided detailed explanations of the study protocol, and obtained written informed consent from all participants or their legal guardians. All auricular plaster therapy was administered strictly on a voluntary basis and only after securing clinical approval. Based on the naturally formed exposure status to auricular plaster therapy within the actual clinical setting, participants from the orthopedic and general surgery departments were categorized into two groups: (1) the exposed group: patients scheduled for surgery who actually received auricular plaster therapy; and (2) the non-exposed group: patients scheduled for surgery who did not receive auricular plaster therapy. All auricular plaster interventions in this study were provided free of charge, with costs funded by the Chinese Academy of Medical Sciences Innovation Fund for Medical Sciences and the Peking Union Medical College Hospital Scientific Research Endowment.

All participants received routine preoperative education; the exposed group additionally underwent standardized auricular plaster therapy (AP) commencing four days before surgery (first visit) according to the operative schedule. The selected auricular acupoints were Shenmen (TF4), Sympathetic (AH6a), Brainstem (AT3, 4i), Occiput (AT3), Heart (CO15), Liver (CO12), Kidney (CO10), Sanjiao (CO17), and Subcortex (AT4). Procedures strictly adhered to the Chinese national standards "Nomenclature and Location of Auricular Points" (GB/T 13734–2008) and "Standardized Manipulations of Acupuncture and Moxibustion-Part 3: Auricular Acupuncture" (GB/T 21709.3–2021). Bilateral auricular plastering was performed using Vaccaria-seed adhesive patches (Beijing Zhongyan Taihe Medical Device Co., Ltd.) and maintained for 4 consecutive days, with all patches removed at a uniform time on the day before surgery. During the intervention period, nurses instructed participants to perform self-pressing three times daily for one minute each session (additional pressing was permitted when surgery-related worry arose) and monitored patch adherence; any loosened patches were promptly re-secured by clinical staff to ensure protocol compliance. Figure 1 illustrates the anatomical locations of the auricular acupoints.

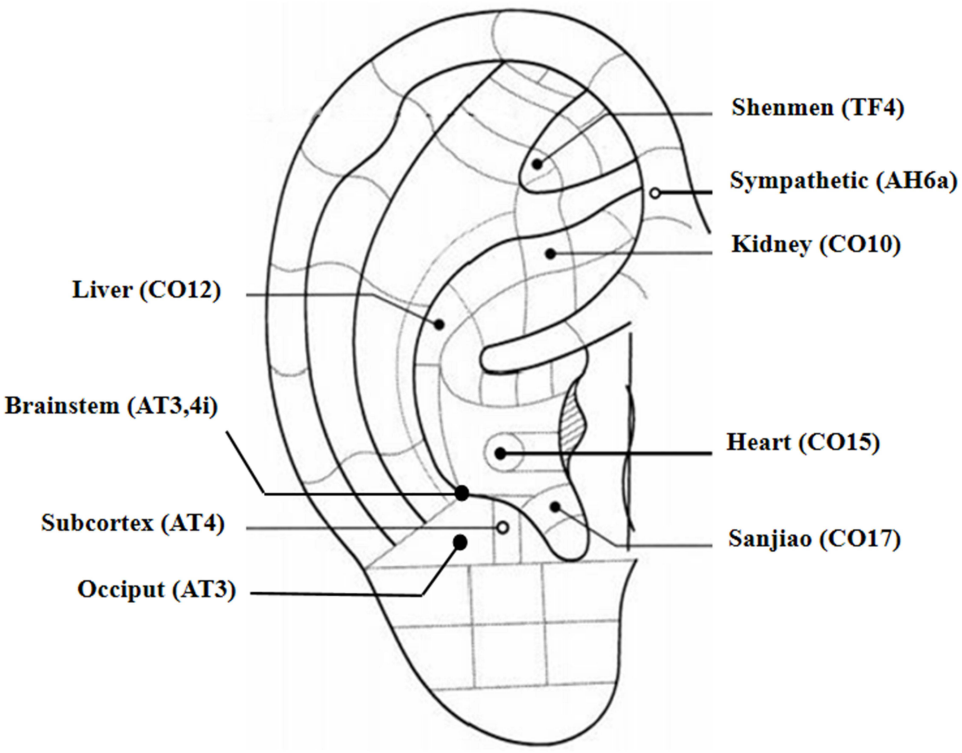

Figure 1 Primary auricular acupoint locations for Plaster Patches.
Notes: The acupoint is located on the inner wall of the auricle; The acupoint is located on the surface of the auricle.

Outcome Measures

Before conducting the outcome measurements, all participants had been informed of the "Participant Instructions for Self-Report Scale Assessment". (Supplementary Material- Box S1).

Primary outcome: Preoperative anxiety was assessed with the Perioperative Anxiety Scale-7 (PAS-7), which recent evidence indicates outperforms the Amsterdam Preoperative Anxiety and Information Scale (APAIS) in Chinese surgical populations (ROC: 0.808 vs 0.674)[25] PAS-7 scores were collected at three prespecified time points: 24±2h after the start of AP or first visit (T1), 12±2h before surgery (T2), and 2 h before surgery (T3). The PAS-7 scores at these consecutive time points served as the primary outcome measure to evaluate the efficacy of AP. The content of the PAS-7 scale can be found in Supplementary Material-Table S1.

Secondary outcomes were as follows: (1) Sleep quality was assessed using the modified Pittsburgh Sleep Quality Index (M-PSQI), a structured instrument adapted for profiling sleep quality in the inpatient surgical context. Assessments were conducted at T1, T2, and T4 (72±2 hours postoperatively). The adaptation process and its consideration of the instrument's multidimensional structure are detailed in the Supplementary Material- Tables S2 and S3. (2) Patient satisfaction with pre-operative preparation assessed with the visual analogue scale (VAS-Satisfaction) at T3, (Supplementary Material- Box S2 and Figure S1); (3) Intra-operative blood loss (mL); (4) Incidence of AP-related adverse events, including auricular skin lesions, infection, pain, or dizziness; (5) Pain intensity and anxiety measured at T4 using the visual analogue scale for pain (VAS-Pain) and the Self-Rating Anxiety Scale (SAS), (Supplementary Material- Box S3, Figure S2 and Table S4); (6) Post-operative length of stay (days); (7) Delirium within T4, determined with the Confusion Assessment Method (CAM), (Supplementary Material- Box S4); (8) Anxiety- or depression-related adverse events (eg, falls, self-harm, non-adherence) occurring within one month after surgery. Figure 2 illustrates the temporal design for outcome measures assessment.

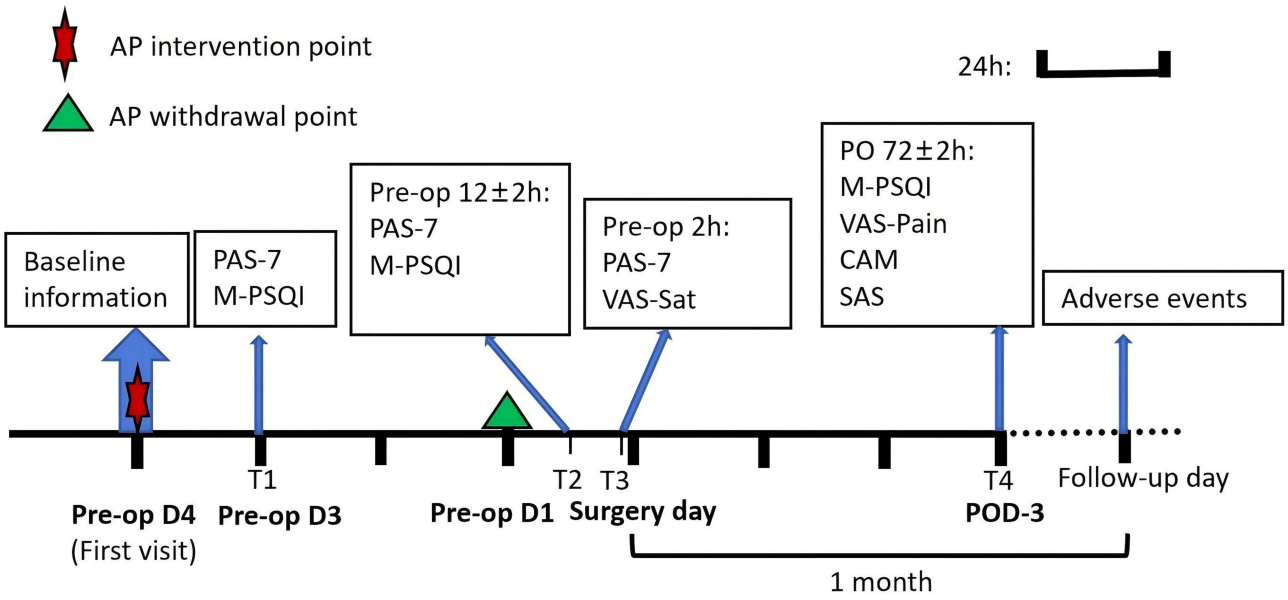

Figure 2 Temporal Design for Outcome Measures Assessment.

Potential Biases

To minimize potential bias, the study employed a rigorous design in which both outcome assessors were blinded to group allocation. Patient screening and enrolment were conducted by six surgical teams (three orthopedic and three general surgery teams), each with more than 15 years of experience in the relevant fields. All participants or their legal guardians provided written ICF before surgery and pledged to maintain the confidentiality of their group assignment. An independent, blinded assessment team-comprising experienced perioperative professionals not involved in treatment decisions-was responsible for collecting and measuring all clinical data using standardized instruments and uniform procedures to ensure objectivity. However, due to the nature of the auricular intervention, complete blinding of patients and practitioners was not feasible. This limitation and its potential impact on subjective patient-reported outcomes are explicitly addressed in the Discussion section.

Integrity of blinding was monitored by a blinded assessor who conducted monthly unmasking evaluations; assessors' accuracy in guessing group allocation was required not to exceed the 50% chance level. All study data were managed under hierarchical access controls, and statistical analyses were performed by an independent data team. Any unblinding had to be pre-approved by the principal investigator and was fully documented.

Sample Size Calculation

The sample size estimation was based on a preliminary analysis of 20 pilot cases (14 TKA, 6 Whipple) who received preoperative auricular plaster therapy (AP) between January and May 2024. These patients were propensity score-matched 1:1 with 20 concurrent control patients by surgical type, age, sex, education, occupation, residence, and prior surgical history. The AP group showed a mean PAS-7 score of 8.9 (±5.1), compared to 11.9 (±3.6) in the non-AP group. Using these parameters ($\alpha = 0.05$, power = 0.90, allocation ratio 1:1), a minimum of 92 participants per group was required.

To ensure sufficient statistical power after accounting for potential matching failure, loss to follow-up, and attrition—common in observational matched-cohort designs—we planned to enroll at least 184 participants (92 per group) in the initial cohort.

Statistical Analysis

Throughout the trial, research staff documented the reasons for missing data at every stage to classify the missing-data mechanism. Appropriate remedial actions were then implemented as follows: listwise deletion for data assumed missing

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completely at random (MCAR) with <5% missingness; regression imputation for data missing at random (MAR) with <5% missingness; multiple imputation for variables with 5–30% missingness; and exclusion of variables with >30% missingness.

All analyses were conducted in SPSS 27.0. First, we ensured balanced case numbers between exposed and non-exposed participants within each surgical specialty. Propensity-score matching (PSM) was subsequently performed using 1:1 nearest-neighbour matching with a caliper width of 0.02 to control confounding; each participant was matched only once and pairs were fixed after matching. Post-matching, continuous primary outcomes were analysed with multivariable linear regression. Normality was assessed with the Kolmogorov–Smirnov test: normally distributed data were compared using independent-sample t-tests, non-normally distributed data with the Mann–Whitney *U*-test, categorical variables with χ^2 tests, and repeated-measure outcomes with generalised estimating equations (GEE). A two-sided p-value <0.05 was considered statistically significant.

Additionally, To assess the consistency of AP effects across surgical disciplines, prespecified subgroup analyses were performed for the primary outcome (PAS-7 scores) by surgery type (TKA vs Whipple), with interaction terms tested in the regression models. To assess the robustness of our primary findings regarding the association between AP and perioperative outcomes, we performed a sensitivity analysis focused on the propensity score matching procedure. We tested the stability of our results by repeating the matching and primary analysis using alternative caliper widths of 0.01 and 0.05 (in addition to the primary caliper of 0.02). This approach evaluates whether our conclusions were sensitive to the specific stringency of the matching criteria.

Results

Baseline Characteristics

During the recruitment period, 227 patients (orthopedics n = 139; general surgery n = 88) scheduled for total knee arthroplasty, pancreaticoduodenectomy (Whipple procedure), distal pancreatectomy, or subtotal gastrectomy were screened. Of these, 212 individuals (orthopedics n = 136; general surgery n = 88) met the eligibility criteria, and all participants or their legal guardians provided written ICF; 12 were subsequently excluded after further application of the exclusion criteria, resulting in 200 participants enrolled (orthopedics n = 130; general surgery n = 70). Twenty-four participants were lost to follow-up or withdrew during the study, leaving 168 completers (orthopedics n = 111; general surgery n = 57). Propensity-score matching (PSM) was performed within each surgical cohort, yielding 49 well-matched pairs (general surgery 15 pairs; orthopedics 34 pairs; total n = 98) (Figure 3). Baseline comparison of the matched cohorts revealed no significant differences in age, sex, or body-mass index (BMI) (Table 1), confirming satisfactory balance.

Multivariate Analysis

Multivariable regression analysis incorporating age, sex, and other relevant covariates identified the principal determinants of PAS-7 scores at T2. The results showed that treatment allocation (exposed vs non-exposed) and surgical method (TKA vs Whipple) were significant predictors of PAS-7 at T2 ($P < 0.05$), a relationship that is illustrated graphically in Figure 4. The model demonstrated moderate goodness of fit (adjusted $R^2 = 0.50$), indicating that it partially explains the variance in PAS-7 scores (Table 2).

Comparison of Primary and Secondary Outcomes

In terms of PAS-7 scores, no significant between-group difference was observed at T1 (median both 4.00, P = 0.874); however, at T2 and immediately pre-operatively (T3), the exposed group exhibited markedly lower scores than the non-exposed group (T2: 7.00 vs 11.00, median difference –4.00, 95% CI [–5.00, –3.00], P < 0.001; T3: 8.00 vs 13.00, median difference –5.00, 95% CI [–6.00, –3.00], P < 0.001). Similarly, M-PSQI scores did not differ at T1 (9.00 vs 10.00, P = 0.113), whereas the exposed group showed significantly better sleep quality at both T2 (8.00 vs 13.00, median difference –4.00, 95% CI [–5.00, –3.00], P < 0.001) and T4 (11.51 ± 2.15 vs 14.78 ± 2.50, mean difference –3.27, 95% CI [–4.20, –2.33], P < 0.001). At T4, post-operative VAS-pain and SAS scores were more favorable in the exposed group (VAS-pain: 5.03 ± 1.05 vs 5.98 ± 1.20, mean difference –1.00, 95% CI [–1.50, –0.50], P < 0.001; SAS: 53.16 ± 6.56 vs 57.18 ± 8.79, mean difference –4.02, 95% CI [–7.13, –0.91], P = 0.012). No inter-group differences were

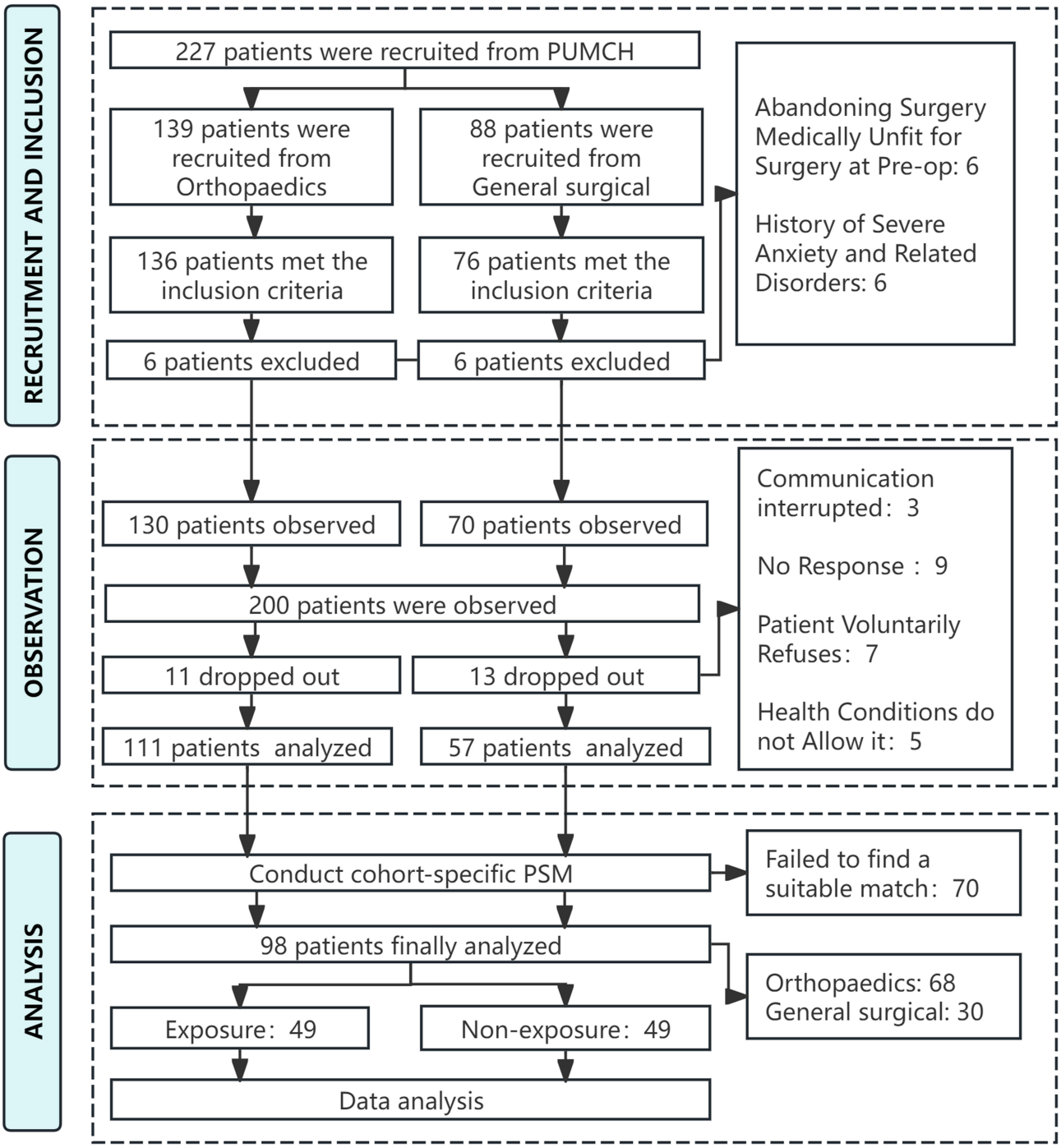

Figure 3 Flowchart of Data Screening Process.

detected for pre-operative VAS-satisfaction, intra-operative blood loss, or post-operative length of stay (all $P > 0.05$), and no participant in either group was adjudicated to have post-operative delirium between surgery and T4. Auricular-plaster-related adverse events in the exposed group consisted of mild local itching in one patient and mild local pain in two patients; all three individuals reported the symptoms but neither withdrew nor were lost to follow-up. The overall incidence of adverse events during follow-up was lower in the exposed group (10.2% vs 16.4%), although this difference did not reach statistical significance ($P = 0.347$) (Table 3). Psychometric evaluation of the M-PSQI at T2 revealed a Cronbach's alpha of 0.460. Item analysis indicated a distinct "Daytime Dysfunction" component; its removal yielded a higher alpha of 0.550 for the core sleep items. Details are in Supplementary Material- Table S5.

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Table 1 Demographics and Baseline Characteristics

Characteristic	Exposed	None-Exposed	X^2/Z	P
	N=49	N=49		
Age	66.00 (73.00–62.00)	65.00 (72.50–62.00)	0.02	0.986
Gender				
Female	35 (71.4%)	31 (63.3%)	0.742	0.389
Male	14 (28.6%)	18 (36.7%)		
BMI				
18.5–23.9	12 (24.5%)	12 (24.5%)	−0.292	0.770
24.0–27.9	28 (57.1%)	26 (53.1%)		
28.0+	9 (18.4%)	11 (22.4%)		
Marital Status				
Married	46 (93.90%)	43 (87.8%)	1.560	0.715
Divorced	1 (2.0%)	1 (2.0%)		
Widowed	2 (4.1%)	5 (10.2%)		
Geography				
North	48 (98.0%)	49 (19.0%)	1.00	0.500
Northwest	1 (2.0%)	0 (0.0%)		
Education				
BPE	6 (12.2%)	5 (10.2%)	−0.741	0.459
PE	15 (30.6%)	11 (22.4%)		
SE	24 (49.0%)	30 (61.2%)		
TE	4 (8.2%)	3 (6.1%)		
Surgical financial stress				
None	1 (2.0%)	2 (4.1%)	1.471	0.141
Mild	33 (67.3%)	38 (77.6%)		
Moderate	15 (30.6%)	9 (18.4%)		
Past surgical history				
Yes	13 (26.5%)	12 (24.5%)	0.054	0.817
No	36 (73.5%)	37 (75.5%)		
Surgical method				
Whipple	15 (30.6%)	15 (30.6%)		
TKA	34 (69.4%)	34 (69.4%)		
Surgical group				
A	3 (6.1%)	2 (4.10%)	7.525	0.103
B	8 (16.3%)	9 (18.40%)		
C	4 (8.16%)	4 (8.20%)		
E	10 (20.4%)	21 (42.90%)		
F	24 (49.0%)	13 (26.50%)		
G	0 (0.0%)	0 (0.00%)		
SAS	55.00 (59.00–49.00)	53.00 (58.50–46.00)	0.68	0.499

Notes: Data was presented as median (IQR), or n (%); p values were derived from Mann–Whitney *U*-tests for skewed data, and Chi-square tests (or Fisher's exact test) for categorical data.
Abbreviations: BMI, body mass index; BPE, Below Primary Education; PE, Primary Education; SE, Secondary Education; TE, Tertiary Education; TKA, Total Knee Arthroplasty; Whipple, Pancreaticoduodenectomy; SAS, Self-Rating Anxiety Scale.

Generalized Estimating Equations (GEE) Analysis

To comprehensively evaluate the association between ear patch (AP) therapy and the dynamic changes in preoperative anxiety and sleep quality, we used the generalized estimating equation (GEE) method. The detailed parameter estimates are provided in Table 4. Analysis of anxiety scores revealed significant main effects of time (Wald $\chi^2 = 452.28$, $P < 0.001$) and group × time interaction (Wald $\chi^2 = 44.73$, $P < 0.001$). As shown in the upper part of Table 4, PAS-7 scores in the non-exposed group increased significantly as surgery approached. The exposed group, however, showed

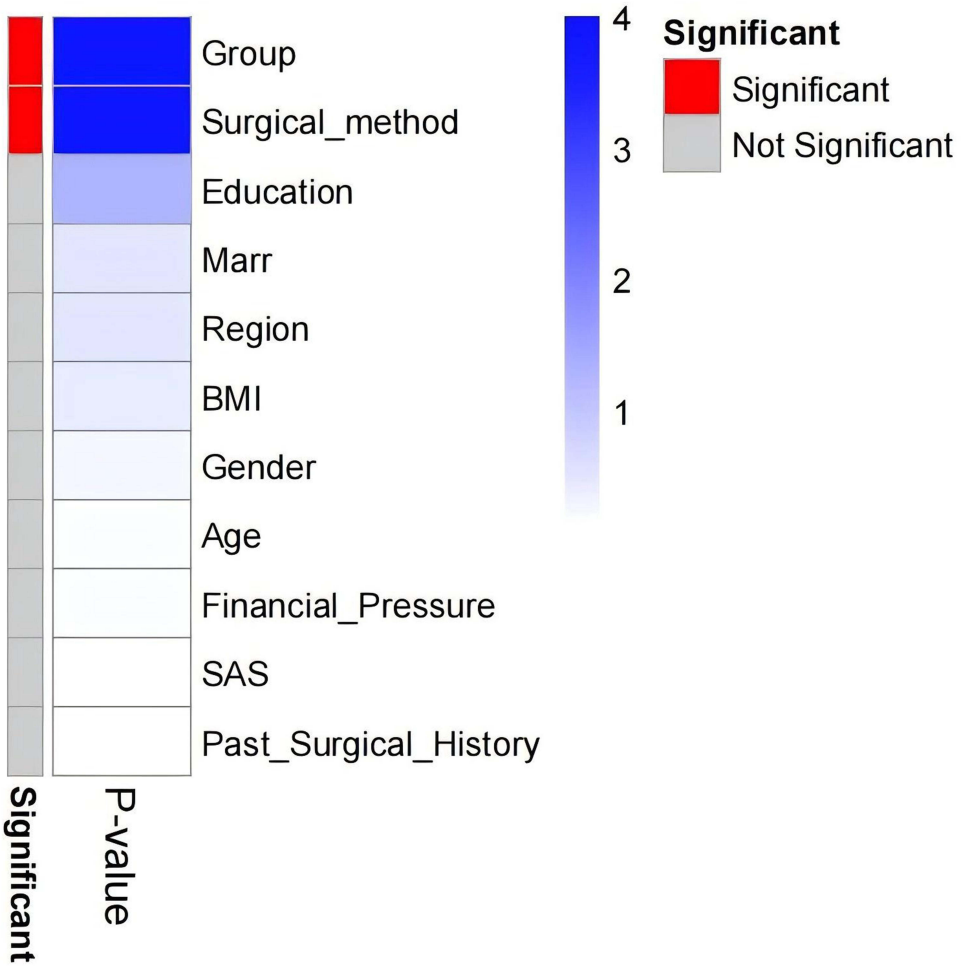

Figure 4 Significant predictor of PAS-7(T2).

a significantly attenuated increase in anxiety, with between-group differences of −3.57 points at T2 and −4.49 points at T3 compared to the non-exposed group, indicating that the exposed group maintained relatively stable anxiety levels throughout the preoperative period (Figure 5A).

Similarly, analysis of sleep quality showed significant main effects of time (Wald $\chi^2 = 288.70$, P <0.001) and a group × time interaction (Wald $\chi^2 = 30.44$, P <0.001). As detailed in the lower part of Table 4, M-PSQI scores (where higher scores indicate poorer sleep quality) worsened significantly over the perioperative period in the non-exposed group. The deterioration in sleep quality was significantly less pronounced in the exposed group, with between-group differences of −3.33 points at T2 and −2.43 points at T4, demonstrating that AP exposure was associated with improved perioperative sleep quality and may exerts a sustained, cumulative influence on post-operative sleep outcomes. (Figure 5B).

Table 2 Regression Analysis Results for Predictors of PAS-7(T2)

Predictors	B	SE	t	95% CI	P	Adjusted R^2
(constant)	24.71	9.50	2.60	(5.83, 43.59)	0.01	0.50
Group	−4.43	0.59	−7.55	(−5.59, −3.26)	<0.001	
Surgical method	4.71	0.90	5.21	(2.91, 6.50)	<0.001	

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Table 3 Comparison of Outcomes Between Exposed and Non-Exposed Groups

Indicator	Exposed	None-Exposed	Effect Size (95% CI)	P
PAS-7				
T1	4.00 (5.00–3.00)	4.00 (5.00–3.00)	0.00 [0.00, 1.00]	0.874
T2	7.00 (10.00–5.00)	11.00 (14.00–9.00)	−4.00 [−5.00, −3.00]	<0.001
T3	8.00 (11.00–7.00)	13.00 (16.00–13.00)	−5.00 [−6.00, −3.00]	<0.001
M-PSQI				
T1	9.00 (11.00–7.00)	10.00 (12.00–8.00)	−1.00 [−2.00, 0.00]	0.113
T2	8.00 (10.00–7.00)	13.00 (14.00–11.00)	−4.00[−5.00, −3.00]	<0.001
T4	11.51 ± 2.15	14.78 ± 2.50	−3.27 [−4.20, −2.33]	<0.001
VAS-Satisfaction	8.50 (9.10–7.50)	8.00 (9.00–7.00)	0.20 [−0.10, 0.70]	0.292
Blood Loss				
<50mL	41(83.7%)	40(81.6%)		0.940
50-200mL	4(8.2%)	4(8.2%)		
>200mL	5(10.2%)	4(8.2%)		
VAS-Pain	5.03 ± 1.05	5.98 ± 1.20	−1.0[−1.5, −0.5]	<0.001
SAS	53.16 ± 6.56	57.18 ± 8.79	−4.02[−7.13, −0.91]	0.012
CAM				
Positive	0(0.0%)	0(0.0%)		
Negative	49(100.0%)	49(100.0%)		
Postoperative Days				
<7days	21(42.9%)	14(42.9%)		0.260
7-14days	23(46.9%)	31(46.9%)		
14-30days	5(10.2%)	4(10.2%)		
>30days	0(0.0%)	0(0.0%)		
Accident				
Non-Adherence	3(6.1%)	4(8.2%)		
Self-destructive behavior	2(4.1%)	2(4.1%)		
Fall incident	0(0.0%)	2(4.1%)		0.347
Total	5(10.2%)	8(16.4%)		

Notes: Data was presented as median (IQR), mean ± standard deviation, or n (%); Effect sizes are presented as Hodges-Lehmann median difference for data reported as median (IQR), and Cohen's d for data reported as mean ± SD; p values were derived from Mann–Whitney *U*-tests for skewed data, independent samples t-tests for normally distributed data, and Chi-square tests (or Fisher's exact test) for categorical data.

Abbreviations: PAS-7, Pain Assessment Scale; M-PSQI, Modified Pittsburgh Sleep Quality Index; VAS, Visual Analog Scale; SAS, Self-rating Anxiety Scale; CAM, Confusion assessment method.

Subgroup and Sensitivity Analyses

A prespecified subgroup analysis was conducted to evaluate the consistency of auricular plaster therapy (AP) effects across the two surgical populations. As summarized in Table 4, the analysis revealed that while no significant between-group differences were observed at T1, AP demonstrated statistically significant associations with reduced PAS-7 scores in both the TKA and Whipple subgroups at T2 and T3 (all P <0.001). The results across all timepoints were consistent with the overall dataset. Furthermore, no significant subgroup-by-treatment interaction was found (χ^2 = 0.0001, P for interaction = 0.993), indicating that the magnitude of the association between AP and anxiety improvement was comparable between the two surgical types.

Given the absence of missing data for the primary outcome measures in the matched cohort, no sensitivity analysis was conducted for this aspect. However, sensitivity analyses using different propensity score matching parameters confirmed the robustness of the main study findings. The association between auricular acupressure therapy and improved clinical outcomes remained substantially consistent when the propensity score matching parameters were altered. When a stricter caliper value of 0.01 was applied, the reduction in PAS-7 scores in the exposure group at T2 and T3 time points remained statistically significant (P < 0.001). Similarly, comparable results were obtained using a more lenient caliper value of 0.05 (P < 0.001). Neither strategy showed significant differences at the T1 time point (Table 5). These effect sizes were highly consistent with the results of the primary analysis using a caliper value of 0.02.

Table 4 Consistent Association Between Auricular Plaster Therapy and PAS-7 Score Reduction Across Surgical Subgroups

Subgroup	Timepoint	Exposed Group	Non-Exposed Group	Effect Size (95% CI)	P
TKA (n=68)	T1	4.00 (4.00–5.00)	4.00 (5.00–3.00)	0.0 [−1.0, 0.0]	0.457
	T2	8.00 (6.00–12.00)	13.50 (15.00–11.00)	−4.0 [−2.0, −6.0]	<0.001
	T3	10.24 ± 3.70	14.97 ± 2.78	−4.74 [−6.32, −3.15]	<0.001
Whipple (n=30)	T1	4.00 (4.00–3.00)	4.00 (5.00–3.00)	1.0 [0.0, 1.0]	0.174
	T2	5.00 (6.00–5.00)	9.00 (9.00–8.00)	−4.0 [−3.0, −6.0]	<0.001
	T3	6.00 (8.00–5.00)	11.00 (11.00–10.00)	−6.0 [−4.0, −7.0]	<0.001

Notes: Data are presented as mean ± standard deviation/ Median (IQR). The consistent results across different caliper widths (0.02, 0.05) demonstrate the robustness of the primary findings.

Discussion

This prospective, observational cohort study with matched comparison in orthopedics and general surgery screened 227 patients and ultimately evaluated 98 matched pairs to examine the association between auricular plaster therapy (AP) on pre-operative anxiety. The findings demonstrate that AP was associated with significant improvements in both pre-operative anxiety and sleep quality, a result consistent with earlier meta-analyses and clinical reports on auricular interventions. It must be acknowledged, however, that prior trials were hampered by very low evidence quality.[26] It should be noted that most previous studies were limited by retrospective designs and methodological constraints. In contrast, the present investigation provides a methodologically robust, prospective dataset that adopted a standardized design, reported the intervention in accordance with STRICTA guidelines, balanced baseline characteristics with propensity-score matching, and evaluated associations through multivariable modelling and trend analyses. This study thus contributes higher-quality observational evidence for the potential role of AP in managing pre-operative anxiety.

Total knee arthroplasty (TKA) and pancreaticoduodenectomy (Whipple) are complex, resource-intensive procedures commonly performed in orthopedic and general surgery departments; the substantial psychological and financial burden they impose frequently precipitates more severe pre-operative anxiety. Although pre-operative anxiety is recognized as an independent risk factor that adversely affects peri-operative outcomes and long-term prognosis,[27] its systematic assessment and management regrettably remain absent from routine care pathways for these operations.[28] In recent years, non-pharmacological interventions-primarily cognitive-behavioural strategies and pre-operative education-have been investigated,[29–31] yet their efficacy has been modest[32] and the interventions are difficult to integrate synergistically.

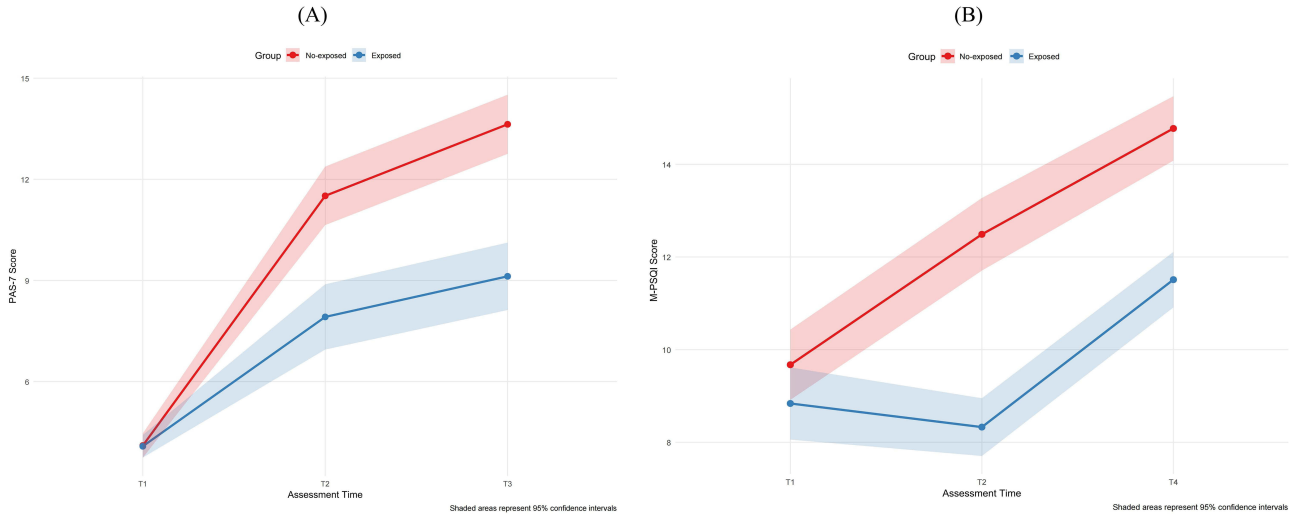

Figure 5 Trajectories of preoperative Anxiety and Sleep Quality Changes Across Study Time Points.
Notes: (**A**) Trajectory of PAS-7. (**B**) Trajectory of M-PSQI; Higher scores indicate high preoperative anxiety or poorer sleep quality.

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Table 5 Sensitivity Analysis of PAS-7 Using Different Propensity Score Matching Calipers

Analysis Model	Timepoint	Exposed Group	Non-Exposed Group	Effect Size (95% CI)	P
(Caliper Width =0.01, 45 pairs)	T1	4.00 (5.00–3.00)	4.00 (5.00–3.00)	0.0 [0.0, 1.0]	0.818
	T2	6.00 (9.00–5.00)	12.00 (14.00–9.00)	4.0 [3.0, 6.0]	<0.001
	T3	8.00 (10.00–6.00)	13.00 (17.00–12.00)	6.0 [4.0, 7.0]	<0.001
(Caliper Width =0.05, 54 pairs)	T1	4.00 (5.00–3.00)	4.00 (5.00–3.00)	0.0 [0.0, −1.0]	0.854
	T2	6.50 (9.25–5.00)	11.00 (14.00–8.75)	4.0 [3.0, 5.0]	<0.001
	T3	8.00 (10.25–6.75)	13.00 (16.00–11.00)	5.0 [4.0, 6.0]	<0.001

Notes: Data are presented as Median (IQR). The consistent results across different caliper widths (0.02, 0.05) demonstrate the robustness of the primary findings.

This study suggests that AP therapy demonstrates significant associations with anxiety alleviation and sleep quality improvement. Although no statistically significant between-group differences in PAS-7 and M-PSQI scores were detected two hours post-intervention (T1) (Table 3), This therapy was significantly associated with reduced anxiety levels at the immediate preoperative time point (T3), and it closely related to improved sleep quality in the postoperative phase (T4) (Table 3), and may exerts a sustained, cumulative influence on post-operative sleep outcomes. (Table 6 and Figure 5B). These findings collectively support the potential clinical value of AP therapy. Therefore, AP therapy not only provides a safe and non-invasive alternative for preoperative anxiety management, but also demonstrates synergistic potential for developing multimodal intervention protocols with non-pharmacological approaches such as music therapy and virtual reality technology, thereby establishing a practical pathway toward enhancing comprehensive efficacy in preoperative anxiety management.

The precise mechanisms by which AP therapy alleviates pre-operative anxiety remain to be fully elucidated; however, emerging evidence has begun to delineate its potential pathways. The acupoints selected in this study-Shenmen (TF4), Sympathetic (AH6a), Brainstem, Occiput (AT3), Heart (CO15), Liver (CO12), Kidney (CO10), Sanjiao (CO17), and Subcortex (AT4)-are situated within the overlapping territories of the auricular branches of the vagus (ABVN), trigeminal, and cervical plexus nerves.[33] AP may therefore modulate activity in key stress-responsive brain regions through the synergistic action of the ABVN and other cranial nerves. Functional magnetic resonance imaging studies have identified functional connectivity of the putamen, globus pallidus, thalamus, angular gyrus, and inferior occipital gyrus as critical biomarkers predicting the therapeutic efficacy of transcutaneous auricular vagus nerve stimulation (taVNS).[34,35] These cerebral areas participate in the regulation of anxiety, sleep, and mood via multiple neurotransmitters-including serotonin, dopamine, norepinephrine, GABA, and glutamate-that represent pharmacological targets of anxiolytic medications[36–38] Notably, It is noteworthy that this study observed that the exposure effect of auricular acupressure showed a time-accumulated association, which is consistent with the hypothesis that acupoint stimulation can induce neural plasticity.[39] We postulate that sustained AP may drive adaptive remodeling of relevant neural circuits, thereby persistently altering the functional activity and signaling patterns of key brain regions and ultimately producing enduring clinical benefits; this proposition, however, requires further clinical and mechanistic validation.

Limitations of the Study

Given the prospective observational design of this study, which aimed to evaluate the associations between AP therapy and preoperative anxiety along with multiple perioperative outcomes, several limitations should be acknowledged when interpreting the findings. First, as a single-center prospective cohort study conducted in a renowned tertiary academic hospital, our findings may be influenced by the specific medical infrastructure, surgical expertise, and patient demographics. The standardized protocols and high patient adherence, while strengthening internal validity, may limit the generalizability of our findings to primary-care settings or regions with different resources. Furthermore, the exclusion of patients with documented psychiatric histories, a decision made to control for confounding, may lead to an underestimation of the intervention's effect in this high-risk population, which often experiences heightened preoperative anxiety. Second, the observational nature of this study introduces potential biases. The decision to receive AP was based on patient preference, introducing possible selection bias. Although propensity-score matching was used to balance

Table 6 Results of GEE Analysis for Time, Group, and Time-by-Group Interaction Effects

Outcome	Parameter	B (Coefficient)	Std. Error	95% Wald CI	Wald x^2	P
PAS-7	Intercept	4.10	0.18	(3.74, 4.46)	501.94	<0.001
	Group (Exposed vs Non-exposed)	−0.02	0.25	(−0.51, 0.47)	0.01	0.935
	Time (T2 vs T1)	7.41	0.45	(6.53, 8.28)	274.61	<0.001
	Time (T3 vs T1)	9.53	0.45	(8.65, 10.41)	452.28	<0.001
	Group × Time (T2)	−3.57	0.66	(−4.87, −2.27)	29.04	<0.001
	Group × Time (T3)	−4.49	0.67	(−5.81, −3.17)	44.73	<0.001
M-PSQI	Intercept	9.67	0.39	(8.92, 10.42)	629.74	<0.001
	Group (AP vs Control)	−0.84	0.55	(−1.92, 0.25)	2.29	0.130
	Time (T2 vs T1)	2.82	0.31	(2.21, 3.43)	81.61	<0.001
	Time (T4 vs T1)	5.10	0.30	(4.51, 5.69)	288.70	<0.001
	Group × Time (T2)	−3.33	0.41	(−4.13, −2.53)	66.49	<0.001
	Group × Time (T4)	−2.43	0.44	(−3.29, −1.57)	30.44	<0.001

Notes: Reference categories: Non-exposed group for Group, T1 for Time. Both models used an unstructured working correlation matrix. Significant interaction effects (highlighted in bold) represent the beneficial effects of AP exposure - negative coefficients indicate reduced anxiety increases and attenuated sleep quality deterioration in the Exposed group compared to the Non-exposed group.
Abbreviations: GEE, Generalized Estimating Equations; CI, Confidence Interval; PAS-7, Perioperative Anxiety Scale-7; PSQI, Pittsburgh Sleep Quality Index.

known covariates, residual confounding from unmeasured factors cannot be entirely excluded. Third, the nature of auricular plaster therapy prevents blinding of patients and practitioners, potentially introducing bias in assessing subjective outcomes. More importantly, the required physical contact inherently generates placebo effects through therapeutic attention and tactile stimulation. While these nonspecific effects may enhance subjective symptom relief, they complicate the distinction between specific treatment effects and placebo responses. Fourth, this study lacked objective biomarker data (eg, heart rate variability, salivary cortisol) or neuroimaging to elucidate the biological mechanisms underlying the observed clinical benefits. While our discussion posits plausible pathways involving the auricular vagus nerve and neuroplasticity, based on extant literature, these hypotheses require direct validation in future trials designed with integrated mechanistic evaluations. Finally, while multiple comparisons were performed for a comprehensive outcome analysis, this increases the risk of Type I error; these findings should thus be interpreted as generating hypotheses. The four-day intervention period and 30-day follow-up, though informative for acute perioperative effects, preclude assessment of longer-term efficacy and sustainability.

Looking forward, the success of multi-modal prognostic models in fields like neuro-oncology provides a compelling roadmap.[40] Future research on AP therapy could similarly integrate physiological biomarkers with clinical outcomes to elucidate mechanisms and personalize treatment strategies. Future directions should include rigorously designed multicenter RCTs that specifically incorporate sham AP or other control groups to disentangle the specific effects of AP from the potent contextual and placebo effects inherent to this intervention. Such studies, employing diverse patient populations, longer follow-up, and biomarker endpoints, are crucial to confirm efficacy, establish causality, and unravel the underlying mechanisms.

Conclusion

In summary, this prospective observational study suggests that auricular plaster therapy (AP) was associated with reduced preoperative anxiety and improved sleep quality in patients undergoing major surgery, with potential benefits extending to short-term postoperative outcomes. These preliminary findings indicate that AP could be considered as a potential non-pharmacological adjunct in perioperative care. This methodologically standardized investigation provides a foundation for future research, though larger, multicenter randomized controlled trials are needed to verify these observed associations and further evaluate the intervention's efficacy.

Data Sharing Statement

The individual deidentified participant data underlying the results reported in this article will not be publicly shared due to restrictions imposed by the ethical review board/privacy laws. However, the data can be made available to qualified researchers upon reasonable request. Proposals for data access should be directed to the corresponding author. All requests will be reviewed and must be approved by the Ethics Committee of Peking Union Medical College Hospital, Chinese Academy of Medical Sciences.

Ethical Statement

This study was conducted in accordance with the principles of the Declaration of Helsinki. This study received ethical approval from the Institutional Review Board of Peking Union Medical College Hospital, with approvals granted in March 2024 (No. I-24PJ0652) and July 2024 (No. I-24PJ1454).

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Disclosure

The authors report no conflicts of interest with respect to the research, authorship, and/or publication of this article.

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