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Efficacy and Safety of Buccal Acupuncture as an Adjunct to Epidural Labor Analgesia: A Prospective Randomized Controlled Trial

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Abstract: This study, designed as a prospective randomized controlled trial, was undertaken to rigorously evaluate the clinical efficacy and safety profile of buccal acupuncture therapy when employed as an adjunct to epidural analgesia for labor pain management. Conducted at Wanzhou Maternal and Child Health Hospital between September 2023 and September 2024, the trial enrolled 100 full-term parturients undergoing spontaneous vaginal delivery. Participants were randomly assigned, utilizing a random number table, to either a control group or an observation group, each comprising 50 individuals. While both groups received standardized epidural analgesia initiated at 2 cm cervical dilation, the observation group additionally benefited from buccal acupuncture therapy. The study meticulously tracked key indicators—visual analog scale (VAS) scores, mean arterial pressure (MAP), heart rate (HR), labor duration, and maternal-neonatal outcomes—at critical cervical dilation stages: 1 cm (T0), 3 cm (T1), 10 cm (T2), and during delivery (T3). The findings revealed that at T1, T2, and T3, the observation group exhibited statistically significant reductions in VAS scores, MAP, and HR when compared to the control group ($P < 0.05$). Conversely, no significant intergroup differences were observed at T0 ($P > 0.05$). Labor duration, postpartum hemorrhage, and neonatal Apgar scores showed no statistical differences between groups ($P > 0.05$). The incidence of nausea and vomiting was similar between groups ($P > 0.05$). In conclusion, buccal acupuncture therapy appears to significantly augment the analgesic effectiveness of epidural labor analgesia without demonstrably prolonging labor, increasing adverse maternal-neonatal sequelae, or elevating the risk of nausea and vomiting, thereby underscoring its potential as a safe and effective complementary strategy for both mother and infant well-being.

1. Introduction

Childbirth-associated pain, a severe nociceptive experience, challenges maternal physiological homeostasis and psychological well-being [1,2]. It triggers autonomic responses (tachycardia, hypertension, hyperventilation) that increase cardiovascular strain [3] and risk postpartum complications. The psychological burden manifests as anxiety, helplessness, and fear, often causing enduring sequelae [4]. Amid declining birth rates, effective labor analgesia is now critical in obstetrics-anesthesiology [5], with significant implications for maternal satisfaction and perinatal outcomes [6].

Epidural analgesia is a common intervention [7] that blocks nerve pain signals, reducing labor pain. However, incomplete relief, poor breakthrough pain control [8-9], and intrapartum fever [10-13] limit its adoption. Potential complications like hypotension, respiratory depression, and rare nerve injury require mothers to carefully weigh risks and benefits.

Traditional Chinese Medicine (TCM) acupuncture—with its safety, efficacy, and cost-effectiveness—attracts increasing scientific attention. Rooted in TCM principles, acupuncture restores Qi flow through meridians, alleviating pain [14] and normalizing physiology [15]. With millennia of clinical application [16,17], it shows promise for labor analgesia in modern studies [18,19]. Buccal acupuncture, a specialized microsystem, stimulates facial acupoints to regulate energy and blood circulation, potentially reducing childbirth discomfort [20]. This approach expands therapeutic options [21] and bridges traditional and modern medicine. Combining epidural and buccal acupuncture represents a promising multimodal strategy requiring clinical validation to enhance maternal outcomes.

2. Materials and Methods

2.1 General Information

This prospective study at Wanzhou Maternal and Child Health Hospital (Chongqing, Sep 2023–Sep 2024) enrolled 100 term primiparas undergoing vaginal delivery. Inclusion: ASA II, aged 18–35 years, singleton cephalic pregnancy (37–41 weeks), uncomplicated gestation, consenting to epidural-acupuncture. Exclusion: psychiatric/neurological disorders, coagulation dysfunction, neuraxial contraindications, facial pathologies, trigeminal neuralgia, or dystonia.

2.2 Sample Size Calculation

Sample size was determined using PASS software based on preliminary data. With α=0.05 and 90% power, calculations required 38 per group. Adjusting for 20% attrition, 46 participants per group (total N=100) were enrolled.

2.3 Ethical Approval

This study received Ethics Committee approval from Wanzhou Maternal and Child Health Hospital. All participants provided written informed consent following full disclosure of study protocols, risks, and benefits, ensuring compliance with ethical standards for vulnerable populations.

2.4 Inclusion Process

The study compared epidural analgesia with buccal acupuncture (48 cases) to epidural analgesia alone (47 cases), after excluding 5 total cases due to social-factor cesarean sections. It aimed to evaluate the additional effect of buccal acupuncture on labor pain relief.

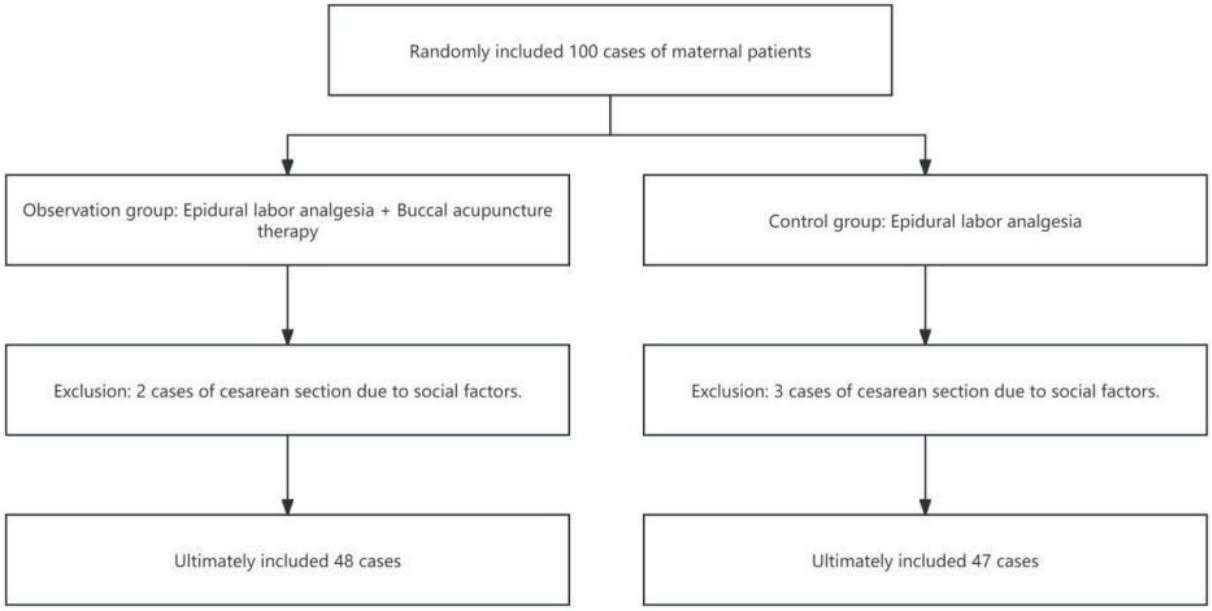

Figure 1 Inclusion Process

2.5 Baseline Characteristics

Table 1 Comparison of basic data ($\bar{x} \pm s$)

Basic data	Observation group (n=48)	Control group (n=47)	P-value	Cohen's d value
Age (years)	26.792±4.385	26.553±4.159	0.786	0.056
Gestational age (weeks)	38.604±0.921	38.696±1.034	0.649	0.094
BMI(kg/m²)	23.223±3.186	24.353±3.176	0.087*	0.355
Parity (Primiparous/Multiparous)	21/27	14/33	0.158	/

Note: BMI refers to Body Mass Index. The data are shown as means ± standard deviations or as counts. The P-value was obtained using the independent samples t-test for continuous variables and the Chi-square test for categorical variables.

Table 1 shows comparable baseline data (age, gestational age, BMI, obstetric history) between observation and control groups post-randomization, with all parameters showing P>0.05. This confirms intergroup homogeneity, minimizing confounding bias in outcome interpretation.

2.6 Anesthesia Implementation

At admission, parturients received routine preparation (IV access, oxygen, monitoring). Epidural

analgesia commenced at cervical dilation ≥2 cm: L2-3 interspace identified via loss-of-resistance, catheter inserted 3-4 cm cephalad. After negative test dose (lidocaine-epinephrine) confirmation, PCEA with 0.1% ropivacaine was initiated: 10 mL loading dose, 5 mL bolus on-demand, 10 mL/h basal rate, 30-min lockout. Protocol maintained until 1h postpartum.

Licensed TCM (Traditional Chinese Medicine) acupuncturists performed buccal acupuncture in the observation group, following holographic mapping principles. Bilateral CA-5 (cervical), CA-6 (dorsal), CA-7 (lumbar), and CA-8 (sacral) acupoints were selected. Sterile single-use needles (0.16×13 mm) were inserted 5-10 mm after skin disinfection. Needle placement success was confirmed via patient-reported deqi (soreness/numbness) and pain relief. Needles were retained for 40 min with continuous monitoring; adjustments were made based on clinical response. Patients were instructed to minimize oral movements (talking/chewing) during insertion/retention to prevent complications. Post-treatment, needles were counted and removed under direct midwife supervision. Insertion sites were compressed with sterile cotton to prevent bleeding/hematoma.

2.7 Observation Indicators

This study evaluated labor pain and maternal/neonatal outcomes using VAS scores (0-10), analgesic use, PCA requests, MAP/HR, labor duration, 1/5-min Apgar scores, postpartum hemorrhage, and nausea/vomiting. Pain was assessed at cervical dilation stages (T0=1cm, T1=3cm, T2=10cm, T3=delivery). Labor duration spans three stages: cervical dilation, fetal expulsion, and placental delivery. Metrics collectively assess pain impacts and health outcomes for mothers/newborns.

2.8 Statistical Methods

Data analysis used SPSS 26.0. Normality assessed via Shapiro-Wilk test. Normally distributed data (equal variances) used independent t-tests (mean±SD); Welch's t-test for unequal variances. Non-normal data employed Mann-Whitney U (median±IQR). Categorical data analyzed with Fisher's exact test (n (%)). Significance defined as two-sided $P<0.05$; Cohen's d measured effect sizes.

3. Results

3.1 Visual Analog Scale (VAS) Scores Across Labor Stages

Table 2 compares labor VAS pain scores between groups. At baseline (T0), no difference existed ($P=1.000$). By T1, the observation group had significant pain reduction ($P<0.001$, $d=1.042$). Differences persisted at T2 ($P<0.001$, $d=1.163$) and T3 ($P<0.001$, $d=1.103$), indicating buccal acupuncture with epidural analgesia improves labor pain management.

Table 2 Comparison of Visual Analog Scale, Mean Arterial Pressure, and Heart Rate ($\bar{x} \pm s$)

Observation indicators	Observation group (n=48)	Control group (n=47)	P-value	Cohen's d value
Visual Analog Scale				

VAS (points)				
T0	6 ±0.684	6 ±0.692	1.000	0
T1	3.146 ±0.743	3.872 ±0.647	0.000***	1.042
T2	4.5 ±0.715	5.511 ±0.505	0.000***	1.163
T3	5.312 ±0.689	6.064 ±0.673	0.000***	1.103
Mean Arterial Pressure MAP (mmHg)				
T0	92.679 ±5.831	94.377 ±5.574	0.150	0.298
T1	83.9 ±4.933	89.783 ±5.191	0.000***	1.162
T2	90.0 ±4.049	93.679 ±5.01	0.000***	0.809
T3	89.471 ±3.529	93.67 ±3.671	0.000***	1.167
Heart rate HR (bpm)				
T0	84 ±6.981	85 ±7.209	0.890	0.047
T1	78 ±5.556	85 ±6.749	0.001***	0.779
T2	86.5 ±4.762	91.213 ±5.073	0.000***	0.958
T3	88.333 ±4.483	92.532 ±5.179	0.000***	0.868

3.2 Hemodynamic Parameters (MAP and HR) Across Labor Stages

3.2.1 Mean Arterial Pressure (MAP)

Analysis of mean arterial pressure (MAP) during labor revealed significant intergroup differences (Table 2). Baseline MAP was similar at T0. At T1 (3 cm dilation), the buccal acupuncture group had significantly lower MAP versus controls ($P<0.001$, $d=1.162$). Differences persisted at T2 ($P<0.001$, $d=0.809$) and T3 ($P<0.001$, $d=1.167$). Buccal acupuncture stabilized labor-induced blood pressure fluctuations from sympathetic activation, improving maternal hemodynamic stability and analgesic safety.

3.2.2 Heart Rate (HR)

HR analysis showed significant intergroup differences during labor stages (Table 2). At baseline (T0), both groups had comparable HR. By T1, the observation group showed significantly lower HR than controls ($p=0.001$, Cohen's $d=0.779$). This difference intensified at T2 ($p<0.001$, $d=0.958$) and T3 ($p<0.001$, $d=0.868$), indicating buccal acupuncture effectively stabilizes maternal HR during epidural analgesia, potentially reducing sympathetic-induced fluctuations. These hemodynamic findings suggest buccal acupuncture-assisted epidural labor analgesia enhances maternal physiological stability and analgesic safety/efficacy.

3.3 Analgesic Drug Consumption and PCA Bolus Requests

Table 3 compares analgesic consumption and PCA bolus requests between groups. The observation group had lower analgesic use (80.584±7.695 vs 87.816±23.689 mL; P=0.051, d=0.412) and significantly fewer PCA requests (median 0 vs 0; P=0.019, d=0.501), indicating buccal acupuncture may reduce breakthrough pain needs.

Table 3 Comparison of analgesic drug usage and PCA additional times ($\bar{x} \pm s$)

Observation indicators	Observation group (n=48)	Control group (n=47)	P-value	Cohen's d value
Analgesic drug usage volume (ml)	80.584±7.695	87.816±23.689	0.051*	0.412
Number of additional times for PCA	0±0.526	0±0.825	0.019**	0.501

3.4 Labor Duration

Welch's T-test analysis of Table 4 revealed no significant differences in labor stage durations (first, second, third) or total duration between groups. Effect sizes (0.26-0.356) suggested minimal clinical impact, indicating limited efficacy of buccal acupuncture with epidural analgesia in shortening labor.

Table 4 Comparison of maternal and infant outcomes, adverse reactions ($\bar{x} \pm s$)

Observation indicators	Observation group (n=48)	Control group (n=47)	P-value	Cohen's d value
Duration of labor (min)				
First stage of labor	426.786±34.944	458.663±122.251	0.091*	0.356
Second stage of labor	42.45±9.325	45.658±14.812	0.211	0.26
Third stage of labor	8.965±1.852	9.811±3.305	0.139	0.309
Total production process	478.222±45.294	514.132±137.572	0.094*	0.352
Nausea and vomiting.				
No	44(91.67%)	43(91.48%)	1.000	
Yes	4(8.33%)	4(8.52%)	1.000	
Newborn Apgar Score				
1 minute (points)	9.354±0.758	9.277±0.926	0.656	0.092
5 minutes (points)	9.917±0.279	9.872±0.337	0.487	0.143
Postpartum blood loss (ml)	393.542±43.442	405.106±49.602	0.229	0.248

3.5 Comparison of Maternal-Neonatal Outcomes and Adverse Reactions

3.5.1 Neonatal Outcomes

Table 4 shows no significant differences in neonates' Apgar scores between groups at 1- and 5-minute intervals, with P-values >0.05 (P=0.487 at 5-min) and Cohen's d=0.143. Buccal acupuncture-assisted epidural analgesia demonstrates neonatal safety, consistent with non-pharmacological labor pain relief studies. Findings support its clinical reliability for positive neonatal outcomes.

3.5.2 Postpartum Hemorrhage

Researchers compared postpartum hemorrhage between two groups using t-tests, showing no significant difference (p=0.229) with Cohen's d=0.248, indicating minimal clinical impact of combining buccal acupuncture with epidural analgesia on blood loss. Results confirm buccal acupuncture doesn't increase hemorrhage risk, supporting its maternal safety and clinical acceptability.

3.5.3 Nausea and Vomiting

Table 4 compares nausea/vomiting incidence between observation and control groups during labor analgesia. No significant differences were found (P=1.000), indicating buccal acupuncture with epidural analgesia does not increase maternal adverse event risks. While opioid-induced nausea/vomiting wasn't studied, findings suggest exploring buccal acupuncture's potential to reduce these effects in opioid-containing epidural analgesia. Further research could optimize safety and comfort in labor analgesia regimens given opioids' association with such reactions.

4. Discussion

Modern obstetric care increasingly adopts labor analgesia as essential for maternal-infant safety and childbirth experience. While epidural analgesia remains effective, limitations like breakthrough pain, maternal fever, hypotension, and nausea/vomiting persist.

A clinical trial demonstrated that combining buccal acupuncture with epidural analgesia synergistically improved labor pain control, evidenced by reduced VAS scores and PCA usage while maintaining maternal hemodynamic stability. This integrated approach expands analgesic options and suggests potential for optimized pain management strategies.

4.1 Enhancement of Labor Analgesia Efficacy by Buccal Acupuncture Therapy

The observation group showed significantly lower labor VAS scores vs controls (P<0.05), indicating buccal acupuncture's efficacy. It stimulates facial acupoints to activate HPA axis, increasing β-EP and CCK-8 secretion for pain reduction[22].

Buccal acupuncture regulates central-peripheral neurotransmitters and targets pain-related brain regions (limbic system, frontal cortex), reducing pain while adjusting DA and 5-HT levels to enhance analgesia and emotional state[23].

The therapy balances autonomic nervous functions, reducing stress and preventing anxiety/depression. PCA observations show reduced analgesic needs, decreased drug

dependence[24], and lower risks of adverse reactions/addiction.

Economically, buccal acupuncture lowers medical costs by reducing analgesic use, easing financial burdens and improving healthcare efficiency, supporting wider application in labor analgesia.

4.2 The Impact of Buccal Acupuncture Therapy on Hemodynamics

The study observed the observation group's MAP and HR at T1-T3, showing significant improvements versus controls ($p<0.05$), indicating vital sign benefits. Buccal acupuncture stabilizes parturients' hemodynamics[25], likely via regulating autonomic nervous system balance between SNS and PNS, reducing labor stress. The therapy aids heart rate/blood pressure regulation and enhances cardiovascular health in laboring women[26], demonstrating its obstetric utility.

This treatment improves postpartum women's microcirculation and organ blood supply, enhancing oxygen/nutrient delivery for maternal-fetal health while reducing fetal hypoxia risk. It regulates stress responses to adjust NE and 5-HT levels[27], stabilizing heart rate/blood pressure to lower cardiovascular risks. These mechanisms promote stable maternal physiology, ensuring mother-infant health and safety.

4.3 The Impact of Buccal Acupuncture Therapy on Labor Duration and Maternal-Neonatal Safety

The study showed no significant differences in labor duration between buccal acupuncture and control groups, indicating minimal impact on labor progression. However, it effectively reduced labor pain safely, potentially through neuro-humoral regulation activating specific acupoints to modulate pain perception[28].

This research confirmed buccal acupuncture's maternal-neonatal safety. Apgar scores showed no newborn harm, postpartum hemorrhage volumes revealed comparable risks, and adverse effect rates (nausea/vomiting) demonstrated good tolerance, supporting its clinical safety in maternal care.

4.4 Limitations and Shortcomings

The study's small sample size limits findings' reliability/applicability. Buccal acupuncture's mechanisms and physiological processes remain unclear, requiring further efficacy research. Short follow-up periods impede long-term effectiveness/safety assessment. Future multi-center trials with larger samples and extended observation are needed to validate results and examine mechanisms, sustained effects, and safety profiles.

5. Conclusion

This study shows that combining buccal acupuncture with epidural analgesia improves labor pain management without compromising delivery progression or maternal-neonatal safety. This integrative approach enhances pain relief, maintains maternal hemodynamic stability, and reduces adverse effects linked to traditional analgesic methods. The synergy between ancient Chinese therapy and modern anesthesia advances multimodal labor analgesia and underscores cross-cultural medical collaboration's potential. Future research should expand mechanistic studies and observation periods to fully assess buccal acupuncture's long-term efficacy, safety, and

physiological mechanisms in obstetric pain management.

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