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Application of Auricular Acupoint Seed Embedding Combined with a Bundled Pain Management Program for Postoperative Pain in Patients with Common Bile Duct Stones

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Abstract: This study aimed to investigate the effect of auricular acupressure with Vaccaria seeds combined with a bundled pain management program on postoperative pain relief in patients undergoing surgery for common bile duct stones. A total of 70 patients with common bile duct stones who met the inclusion and exclusion criteria and underwent surgery at a tertiary Grade A hospital in Ganzhou, China, from July to December 2024 were enrolled using convenience sampling. Participants were allocated by a random-number table to an intervention group and a control group, with 35 patients in each group. The control group received a bundled postoperative pain management program. The intervention group received auricular acupressure with Vaccaria seeds before and after surgery in addition to the same bundled pain management program. Post-intervention pain scores, analgesic consumption, early postoperative sleep quality, and patient satisfaction with analgesic treatment were compared between the two groups. After the intervention, the pain scores on postoperative days 1 and 2 were 4.94 ± 1.33 and 2.94 ± 0.77 in the intervention group, respectively, compared with 6.09 ± 1.56 and 3.83 ± 1.27 in the control group. The postoperative analgesic consumption was 1.26 ± 0.85 doses in the intervention group and 2.20 ± 0.96 doses in the control group. The early postoperative sleep quality scores were 6.29 ± 2.08 and 9.71 ± 3.35 in the intervention and control groups, respectively. Patient satisfaction with analgesic treatment was 94.3% in the intervention group and 71.4% in the control group. All between-group differences were statistically significant ($P < 0.05$). Compared with bundled pain management alone, the integrated traditional Chinese and Western medicine approach of auricular acupressure with Vaccaria seeds combined with bundled pain management can further alleviate postoperative pain, reduce postoperative analgesic use, improve early postoperative sleep quality, and enhance patient satisfaction with analgesic treatment.

1. Introduction

Common bile duct stones (CBDS) refer to primary or secondary stones within the common bile duct, accounting for approximately 9%-21% of all cholelithiasis cases and representing one of the most common benign biliary tract disorders in China [1]. CBDS readily obstruct the bile ducts, leading to acute cholangitis, pancreatitis, and other conditions characterized by severe abdominal pain, fever, jaundice, and even life-threatening complications such as septic shock. Therefore, treatment should adhere to the principles of "removing obstruction, completely removing stones, and ensuring unimpeded drainage." This involves not only promptly relieving bile duct obstruction to prevent acute inflammatory shock but also maintaining adequate postoperative bile drainage to avoid stone retention and recurrence [2]. Surgery is an effective treatment for CBDS, with laparoscopic common bile duct exploration and stone removal (LCBDE) being a routine, safe, and efficient procedure. This technique not only effectively removes stones and resolves obstruction but also ensures continuous postoperative bile drainage through the placement of a T-tube. However, CBDS patients often experience postoperative pain due to factors such as biliary tract inflammation, surgical trauma, or T-tube traction [3-5]. Studies indicate that pain adversely affects patients' physiological, psychological, and social well-being, triggering physiological stress, inflammatory responses, and exercise avoidance, thereby impairing postoperative recovery [6,7]. Currently, based on evidence-based medicine, existing pain management measures have been systematically reviewed, integrated, and consolidated into evidence-based protocols, which effectively manage and alleviate perioperative pain in patients and promote recovery [8,9]. However, these evidence-based pain management protocols rely heavily on pharmacological interventions and lack the incorporation of Traditional Chinese Medicine (TCM). Studies indicate that an integrated approach combining Western and TCM therapies can significantly alleviate postoperative pain while reducing the use and side effects of conventional analgesics [10]. Auricular seed embedding, a TCM acupoint therapy characterized by its simplicity, cost-effectiveness, safety, and non-invasiveness, has demonstrated notable efficacy in mitigating postoperative pain according to multiple studies [11]. This study therefore investigates the feasibility of combining auricular seed embedding with evidence-based pain management protocols to reduce pain levels in patients following common bile duct stone surgery, aiming to provide novel strategies for postoperative pain management in such patients.

2. Subjects and Methods

2.1 Study Subjects

Using convenience sampling, 70 patients with common bile duct stones who visited the Hepatobiliary and Pancreatic Surgery Department of a tertiary Grade A hospital in Ganzhou City from July to December 2024 were selected as study subjects. They were randomly divided into a control group and an experimental group using a random number table, with 35 cases in each group. Inclusion criteria: (1) Undergoing LCBDE with T-tube placement; (2) Age greater than 18 years and less than 75 years; (3) Possessing basic communication skills. Exclusion criteria: (1) Those who underwent laparotomy or primary closure of the common bile duct; (2) Those who developed severe complications or severe infections on the first postoperative day; (3) Pregnant or breastfeeding women; (4) Those with concurrent malignant tumors or functional impairments of vital organs such as the heart, liver, or kidneys; (5) Individuals with mental disorders or a history of psychological illnesses. This study was funded by the Ganzhou Municipal Science and Technology Program (GZ2023ZSF149). The study received approval from the hospital's ethics committee (LLSC-2023 No.397). All participants voluntarily enrolled and signed informed consent forms.

Based on the sample size estimation method for randomized controlled clinical trials [12], the primary outcome measure was the NRS score at 48 hours postoperatively. Literature review of similar designs [13] revealed that the mean pain score in the control group ($\mu 1$) was 5.78 points, while the mean pain score in the auricular acupoint seed implant group ($\mu 2$) was 4.43 points, with a standard deviation (σ) of 1.34. The type I error probability was set at = 0.05, and the power (1-β) was 80%. The following formula was employed:

$$n1 = n2 = \frac{2(Z_{\alpha/2}+Z_{\beta})^2 \times \sigma^2}{(\mu 1-\mu 2)^2} \quad (1)$$

The calculations determined that each group required a sample size of 16 cases; considering a 10% dropout rate, at least 18 cases were needed per group. This study enrolled 35 cases in each group, meeting the required sample size. Since the intervention of embedding beans in the middle ear acupoints is clinically challenging to implement with a blind method, this study did not employ a blind design. In principle, the control group and the experimental group were not housed in the same ward to minimize potential confounding effects on the results.

2.2 Research Methods

2.2.1 Members of the Research Team

The research team consisted of seven members: one principal investigator (senior nurse), responsible for study design, project application, literature review, and paper drafting; one associate chief physician of Traditional Chinese Medicine (TCM) (Ph.D. in TCM), tasked with staff training and guidance on treatment implementation; three nurses from the Hepatobiliary and Pancreatic Surgery Department (senior nurses), who participated in training and assessment of the auricular acupoint seed implantation technique and, upon successful completion, proceeded to perform the procedure and collect data; one head nurse (associate chief nurse), overseeing quality control and project guidance during implementation; and one doctoral candidate (attending physician), responsible for statistical analysis of the data.

2.2.2 Personnel Training

Prior to the commencement of the study, the project leader provided a detailed introduction to the research objectives, methods, procedures, and precautions. The Deputy Chief Physician of Traditional Chinese Medicine conducted comprehensive training on the theoretical foundations and operational techniques of auricular acupoint seed implantation for all team members. The training included multimedia lectures, video demonstrations, hands-on practice with molds, live demonstration sessions, and scenario simulations, spanning a duration of one week. Upon completion, the Head Nurse and the Deputy Chief Physician of Traditional Chinese Medicine administered theoretical and practical examinations to all participants. Those who failed the examinations underwent additional training and re-examination until all members met the required standards.

2.2.3 Intervention Method for the Control Group

Implement bundled pain management measures, which include the following specific components: 1. Preoperative assessment and education: (1) Use the Numerical Rating Scale (NRS) to evaluate the patient's baseline preoperative pain level and develop an individualized plan. (2) Identify high-risk populations and initiate early pain intervention. (3) Provide patient education and psychological support, explaining postoperative pain mechanisms and analgesic methods,

dispelling the misconception of "enduring pain," and emphasizing the importance of early analgesia in preventing chronic pain. 2. Postoperative multimodal analgesia: (1) Dynamic pain assessment and recording: Monitor pain intensity daily using the NRS, document pain characteristics (e.g., incisional pain, visceral pain), and its impact on activities. (2) Non-pharmacological analgesia: Employ physical analgesia methods such as cold compresses (to reduce inflammation) or hot compresses (to alleviate muscle spasms), combined with comfortable positioning (e.g., semi-Fowler's position to minimize incision tension). Psychological interventions such as music therapy, meditation, or guided imagery can also be used to reduce pain sensitivity. (3) Pharmacological analgesia: Initiate pharmacological analgesia for patients with a pain score ≥4 who respond poorly to non-pharmacological measures. The protocol adopts a stepwise medication approach, prioritizing nonsteroidal anti-inflammatory drugs (NSAIDs) or weak opioids; strong opioids may be considered for severe pain, while combination therapy with opioids and NSAIDs can be used for persistent pain episodes to minimize single-drug dosage and side effects. (4) For patients with high-risk factors for postoperative pain, guide them toward the use of wireless electronic analgesic pumps or mechanical analgesic pumps. 3. Prevention of analgesic complications: (1) Monitor adverse effects of analgesic medications and adjust the regimen promptly. (2) For patients using analgesic pumps, enhance monitoring to identify adverse reactions.

2.2.4 Intervention Method for the Experimental Group

Building upon cluster-based pain management, ear acupoint seed embedding was implemented to alleviate postoperative pain. The specific seed embedding procedure is as follows: On the morning of the surgery and for the first three postoperative days, seed embedding and pressure application were performed on patients in accordance with the "Standard Technical Operating Procedures for Traditional Chinese Medicine Nursing" issued by the China Association of Chinese Medicine [14]. The procedure was conducted by trained nursing staff from the research team. The detailed steps are as follows: (1) Selection of acupoints: Shenmen (GV4), subcortical regions, liver, pancreas, gallbladder, and other relevant acupoints. (2) Procedure: The patient was placed in a lateral decubitus position. The auricular surface was disinfected with 75% alcohol until dry. An ear acupoint probe was used to identify the tender points of the selected acupoints, with positive response points being pinpointed. Wangliuxing seed patches were picked up with forceps and applied firmly against the acupoints. The index and thumb were used to rotate and press the patches anteriorly and posteriorly to enhance stimulation, gradually increasing the pressure until the patient could tolerate it. Each acupoint was pressed for 3-5 minutes until sensations of soreness, distension, pain, or numbness were observed. (3) To maintain efficacy, patients and caregivers were instructed to repeat the pressure application every 2 hours, performing 3-5 sessions daily. If pain recurred, the procedure was continued. Should the Wangliuxing seed patches detach during application, nursing staff repositioned and reapplied them.

2.2.5 Quality Control

(1) The research team shall be established and managed by the principal investigator of the project. Team members include one Associate Chief Physician of Traditional Chinese Medicine (with a Ph.D. in Traditional Chinese Medicine), responsible for guiding and supervising the implementation of relevant techniques. (2) A standardized management system, along with detailed and feasible work plans and procedures, shall be established. (3) The head nurse of the department shall participate in the research team, overseeing personnel allocation and transfers, and establishing a WeChat group for team members to facilitate resource sharing and collaborative communication. (4) Strict adherence to enrollment criteria shall be ensured to maintain consistency among enrolled

cases. (5) All practitioners performing auricular acupoint seed implantation must undergo training and assessment to ensure standardized and consistent intervention practices. Quality control over the entire implantation process shall be conducted by the head nurse and the Traditional Chinese Medicine physician. (6) Unified instructions and explanatory language shall be used during data collection to ensure accuracy and consistency of records. All data must be verified by two individuals before being recorded, organized, and statistically analyzed.

2.3 Evaluation Indicators

2.3.1 Pain Rating

This study employed the Numerical Rating Scale (NRS) for pain assessment, where a score of 0 indicates no pain or symptoms at all, and a score of 10 represents the most severe pain imaginable-higher scores correspond to more intense pain. During the assessment, patients were required to select numbers independently; healthcare providers provided only explanations without interfering with the selection process, and any suggestive questioning was prohibited.

2.3.2 Dosage of Analgesic Drugs

Record the postoperative dosage of analgesic medications for both patient groups, including any additional analgesics administered temporarily after surgery.

2.3.3 Sleep Quality

The postoperative sleep quality of patients was assessed using the Pittsburgh Sleep Quality Index (PSQI) on the fourth postoperative day, primarily evaluating early postoperative sleep quality. The PSQI is a widely used clinical scale for sleep quality assessment, comprising 19 self-rated items and 5 other-rated items. It comprehensively evaluates sleep quality across seven dimensions: subjective sleep quality, sleep onset time, sleep duration, sleep efficiency, sleep disorders, hypnotic medication use, and daytime functioning. Each dimension is scored from 0 to 3, with a total score ranging from 0 to 21. Higher scores indicate poorer sleep quality. The Cronbach's α coefficient for this scale is 0.832 [15].

2.3.4 Effect Evaluation

The analgesic efficacy was assessed based on the NRS scores before and after treatment, categorized into four grades as detailed in Table 1. The total number of effective cases = number of completely relieved cases + number of partially relieved cases; the response rate = (number of completely relieved cases + number of partially relieved cases) / total number of cases × 100%.

Table 1: Grading of Efficacy Evaluation

grade	therapeutic index (%)	clinical manifestation
complete remission	>90%	The pain completely disappeared after treatment.
partial remission	>60%; ≤90%	The pain intensity has significantly decreased compared to before treatment, without affecting sleep, and daily activities remain largely normal.
Mild relief	>30%; ≤60%	The pain has alleviated compared to before treatment, but significant pain persists, markedly affecting sleep quality.
of no avail	≤30%	Compared with the condition prior to treatment, there is essentially no improvement; in some cases, the condition has even worsened.

Note: Clinical manifestations serve as the primary criterion, while the efficacy index serves as the secondary criterion. The efficacy index is calculated as: (Pre-treatment NRS score-Post-treatment NRS score) / Pre-treatment NRS score × 100%.

2.4 Statistical Methods

Statistical analysis was performed using SPSS 22.0 software. Categorical data were expressed as counts and percentages (%), with intergroup x comparisons conducted using the chi-square test. Normally distributed continuous variables were presented as mean ± standard deviation (mean ± SD), and intergroup comparisons were performed using the t-test. Non-normally distributed continuous variables were expressed as medians (25th percentile; 75th percentile), with intergroup comparisons performed using the rank-sum test. A P-value <0.05 was considered statistically significant.

3. Results

3.1 Comparison of General Characteristics between the Two Groups

In this study, the experimental group comprised 35 cases with a mean age of 60.29 years, including 20 males and 15 females, while the control group consisted of 35 cases with a mean age of 59.69years, including 17 males and 18 females. Comparison of baseline characteristics-including age, gender, admission blood pressure, pulse rate, height, weight, and BMI-between the two groups revealed no statistically significant differences (P > 0.05) (see Table 2).

Table 2: Comparison of general data in the two groups

Item	experimental group (n=35)	control group (n=35)	test statistic	P value
Age (years)	60.29±10.72	59.69±10.08	0.233[a]	0.816
Gender [Example (percentage,%)]			0.516[b]	0.473
man	20(57.1)	17(48.6)		
woman	15(42.9)	18(51.4)		
Inpatient blood pressure (mmHg)				
High pressure	129.03±23.81	129.89±17.31	0.172[a]	0.864
low pressure	77.37±12.33	80.97±13.14	1.182[a]	0.241
Pulse (beats)	78.83±10.15	76.31±10.98	0.995[a]	0.323
stature (cm)	159.09±7.72	160.37±9.26	0.631[a]	0.530
weight (kg)	55.41±9.13	57.46±9.13	0.939[a]	0.351
BMI	21.85±3.02	22.37±2.94	0.729[a]	0.468

a is the t-value, and b is the (χ^2).

3.2 Comparison of NRS scores before and after intervention between the two groups

Prior to intervention, the baseline NRS scores were 1.54 ± 0.89 in the experimental group and 1.46 ± 0.85 in the control group, with no statistically significant difference between the two groups (t = 0.413, P = 0.681). After intervention, the NRS scores on the first postoperative day were (4.94 ± 1.33) and (6.09 ± 1.56) in the experimental and control groups, respectively; on the second postoperative day, the scores were (2.94 ± 0.77) and (3.83 ± 1.27), respectively. During the first two postoperative days, the NRS scores in the experimental group were lower than those in the control group, with a statistically significant difference (P <0.05). On the third postoperative day, the NRS scores were 1.14 ± 0.81 in the experimental group and 1.54 ± 0.95 in the control group; although the experimental group scored lower, the difference was not statistically significant (t = 1.896, P =

0.062) (see Table 3).

3.3 Comparison of postoperative sleep quality scores and analgesic medication usage between the two groups

The postoperative sleep quality score in the experimental group was 6.29 ± 2.08, while that in the control group was 9.71. The experimental group exhibited superior early postoperative sleep quality compared to the control group, with a statistically significant difference (t = 5.146, P <0.001). The average postoperative use of analgesic drugs was 1.26 ± 0.85 units in the experimental group versus 2.20 ± 0.96 units in the control group, indicating higher consumption in the control group with a statistically significant difference (t = 4.335, P <0.001) (see Table 3).

Table 3: Comparison of NRS score, sleep quality and pain medication use in two groups of patients

group	Baseline preoperative NRS score	Postoperative NRS score			Sleep quality score	Dose of analgesic medication (units)
		first day	the next day	Dieb tert		
experimental group	1.54±0.89	4.94±1.33	2.94±0.77	1.14±0.81	6.29±2.08	1.26±0.85
control group	1.46±0.85	6.09±1.56	3.83±1.27	1.54±0.95	9.71±3.35	2.20±0.96
t price	0.413	3.301	3.531	1.896	5.146	4.335
P	0.681	0.002	0.001	0.062	<0.001	<0.001

3.4 Comparison of analgesic efficacy between the two intervention groups

After intervention, the experimental group achieved complete remission in 25 cases and partial remission in 8 cases, with a total effective count of 33 cases, yielding an analgesic efficacy rate of 94.3%. The control group achieved complete remission in 16 cases and partial remission in 9 cases, with a total effective count of 25 cases, yielding an analgesic efficacy rate of 71.4%. Compared between the two groups, the difference was statistically significant (χ^2 = 7.303, P = 0.046) (see Table 4).

Table 4: Comparison of Pain Relief Effects between Two Groups [Cases (Percentage,%)]

group	Total number of cases	whole laxation	part laxation	mild laxation	of no avail	relieve pain Efficiency Rate	χ^2	*P*
experimental group	35	25(71.4)	8(22.9)	2(5.7)	0(0)	94.3%	7.303	0.046
control group	35	16(45.7)	9(25.7)	7(20)	3(8.6)	71.4%		

4. Discussion

Studies indicate that postoperative pain incidence is relatively high and persists for an extended duration in patients undergoing common bile duct surgery, necessitating effective pain management [16,17]. Inadequate pain management increases the risk of complications, prolongs hospital stays, and may induce psychological anxiety and fear in patients, adversely affecting postoperative recovery [18-20]. Cluster-based pain management integrates a series of evidence-based pain management strategies to address postoperative pain, providing continuous, evidence-based, and

comprehensive interventions that are more effective than standalone analgesic measures [9]. However, current postoperative pain management remains heavily reliant on analgesic medications, thereby exacerbating complications such as gastrointestinal adverse reactions, respiratory depression, nausea, and vomiting, causing additional harm to patients [21,22].

Traditional Chinese Medicine (TCM) posits that the core pathogenesis of postoperative pain stems from "impaired circulation of qi and blood, meridian obstruction, and dysfunction of visceral organs." Surgical trauma damages local meridians, disrupting the flow of qi and blood, leading to blood stasis and subsequent pain. Meridian obstruction prevents qi and blood from nourishing the affected area, resulting in the pathogenic principle of "pain due to obstruction" [23]. Additionally, the liver governs free flow, while the gallbladder is connected to it; these two organs are interdependent. Postoperative liver and gallbladder dysfunction impair free-flowing functions, causing qi stagnation and exacerbating pain. Thus, TCM emphasizes "unblocking" as the primary approach for pain relief [24]. In TCM, the ear is regarded as the convergence point of the Zongmai (the Governor Vessel) (as described in the “Huangdi Neijing·Lingshu”). Auricular acupoints connect the twelve meridians to all visceral organs and limbs. Stimulating these acupoints activates meridian conduction, resolves qi and blood stasis, and restores circulation in "pain due to obstruction" areas, thereby alleviating pain [25]. Modern medical research also indicates that the auricle is richly innervated with nerve endings. Stimulating auricular acupoints activates the neuroendocrine-immune network, releasing endogenous analgesic substances such as β-endorphin, which inhibit pain transmission [26]. Furthermore, auricular stimulation dilates blood vessels, improves microcirculation, accelerates the clearance of metabolic waste products, and reduces tissue edema and inflammatory responses [27]. It also regulates the balance between sympathetic and parasympathetic nerves, alleviating spasmodic pain and relaxing visceral smooth muscles [28]. Therefore, continuous stimulation of specific auricular acupoints via seed implantation can effectively relieve postoperative pain in patients.

The ear acupoint bean embedding technique is simple, non-invasive, and represents a form of external treatment in Traditional Chinese Medicine (TCM). It serves as an adjunct or alternative therapy for various acute and chronic postoperative pains and is widely applied in clinical practice. Shen Xinfeng et al. [29] utilized this technique to alleviate pain and stress responses in patients undergoing routine colonoscopy, demonstrating that ear acupoint bean embedding effectively reduced stress responses, pain intensity, and duration, warranting clinical promotion. Zhao Zhengmin et al. [30] also found that ear acupoint bean embedding for postoperative pain in gynecological abdominal surgery patients significantly alleviated pain and improved psychological status and sleep quality. Building upon cluster-based pain management, this study administered ear acupoint bean embedding to the experimental group, selecting two acupoints (Shenmen and Piqixia) with sedative, analgesic, and hypnotic effects, as well as two disease-specific acupoints (Gan and Pankreas-Biliary). Multiple sessions of bean embedding were performed on the mornings of preoperative days and the first three postoperative days, yielding significant analgesic and sleep-promoting effects. Compared to the control group, the ear acupoint embedding group exhibited lower postoperative pain scores, reduced analgesic medication use, improved sleep quality, and superior analgesic efficacy, with all differences being statistically significant ($P<0.05$). These findings indicate that ear acupoint bean embedding combined with cluster-based pain management effectively alleviates postoperative pain in patients with common bile duct stones, improves early postoperative sleep quality, reduces analgesic medication consumption, and enhances analgesic efficacy.

5. Summary

This study preliminarily demonstrates that auricular bean implantation exhibits certain efficacy in alleviating postoperative pain following common bile duct stone surgery. When combined with a cluster-based pain management protocol for analgesia, it not only effectively reduces the use of analgesic medications but also enhances analgesic efficacy and improves sleep quality, offering a novel approach for postoperative pain management in biliary surgery. The ear acupoint bean implantation technique causes minimal trauma, offers sustained efficacy, and demonstrates safe, simple, and long-lasting analgesic effects, making it highly acceptable to patients and worthy of clinical widespread adoption. However, as this study was limited to single-center data with a small sample size and lacked blinding, potential biases may exist during the research process, necessitating cautious interpretation of the results. Future studies should prioritize multicenter, large-sample randomized controlled double-blind trials to minimize outcome bias.

Author Contribution Statement

Huanguling Huang: conceived and designed the experiments, drafted the article, performed statistical analysis, and interpreted the data.

Zhang Linmei: Data collection;

Huang Danping: Conduct research;

Li Yanhong: Conduct research;

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