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Comparison of the Effects of Body Acupressure and Ear Acupressure on Shoulder Pain in Iranian Patients Undergoing Laparoscopic Cholecystectomy: A Randomized Controlled Trial

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Abstract

Shoulder pain after laparoscopic cholecystectomy surgery is one of the important complications that can increase patients' discomfort and their length of stay at the hospital. This study aimed to compare the effects of body acupressure and ear acupressure on shoulder pain in patients undergoing laparoscopic cholecystectomy. Total of 101 patients participated in this randomized controlled clinical trial in 2022. They completed the demographic information form and the Spielberger State-Trait Anxiety Inventory. Then, they were assigned into ear acupressure, body acupressure, and control groups through block randomization. The control group did not receive any intervention. The amount of shoulder pain in patients was recorded in all three groups by using the VAS one (T1), four (T2), and eight (T3) hours after the intervention. The mean shoulder pain score in the ear acupressure group was lower than that in the body acupressure group and the control group in T1 (P<0.001). The median shoulder pain score in the body acupressure group was lower than that in the control group at T2 (P<0.001); the median pain score in the ear acupressure group was significantly lower than that in the other two groups at T2 (P<0.001). The median pain score in the control group was higher than that in the body acupressure and ear acupressure groups at T3 (P<0.001). We observed no statistically significant difference between the body acupressure and ear acupressure groups at T3 (P= 0.12). Statistical analysis showed no difference between the mean anxiety scores of patients in the control, body acupressure, and ear acupressure groups (Z=1.41, P=0.49). Body acupressure and ear acupressure were effective in reducing shoulder pain after laparoscopic cholecystectomy, but ear acupressure was more effective and it showed its analgesic effect faster than body acupressure.

Keywords: Acupressure; Ear acupressure; Laparoscopic cholecystectomy; Shoulder pain

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Introduction

Laparoscopic cholecystectomy due to less complications such as smaller surgical wounds, less breathing problems, a faster recovery period, and lower admission costs is known as standard treatment [1]. Shoulder pain after surgery is an unpleasant complication that is reported by about 50% of patients undergoing laparoscopic cholecystectomy [2]. The main cause of shoulder pain is direct damage to the diaphragm during surgery or stretching of the diaphragm by the remaining CO_2 in the abdominal cavity, which stimulates the phrenic nerve and ultimately leads to shoulder pain [3]. This pain increases patients' discomfort and anxiety prolongs the length of hospital stay and can increase the re-admission rate [4]. Opioids usually reduce shoulder pain in these patients. However, high doses of opioids cause many side effects such as respiratory depression, urinary retention, nausea, vomiting, itching, drowsiness or ileus [5]. Therefore, it is necessary to consider other options for the adequate management of shoulder pain after laparoscopic cholecystectomy. In addition to drug treatment, non-pharmacological approaches such as complementary and alternative medicine can be considered for reducing shoulder pain after laparoscopic cholecystectomy. Complementary and alternative medicine consists of non-pharmacological methods, including body acupressure and ear acupressure [6]. Acupressure has its roots in traditional Chinese medicine. It is the application of gentle pressure of the finger on the energy meridian points of the body, which stimulates the body's regulatory processes. Each point has specific psychological and physical effects that ultimately balance their functions [7,8]. Acupressure is a type of acupuncture that is performed using pressure on the same acupuncture points to achieve therapeutic effects [9]. Applying pressure on the acupoints stimulates soothing channels, relieves muscle spasms, and also helps to release endorphin, encephalin and serotonin, leading to pain relief [10]. Acupressure is a non-invasive method that is easy to use in many situations [11]. It is a cost-effective method that does not damage the skin and does not cause infection or bleeding. In many cases, acupressure effectively manages pain symptoms without significant complications [12]. Although some research has failed to show the effectiveness of body acupressure in reducing pain intensity after laparoscopic cholecystectomy [13], several studies suggest the effectiveness of body acupressure and acupuncture in reducing pain intensity and shoulder pain intensity in laparoscopic cholecystectomy [14,15,16]. Auriculotherapy, also known as auricular acupoint pressure or ear stimulation, diagnoses and treats diseases by stimulating specific acupoints in the outer ear [17]. Auricular acupuncture, electro-acupuncture stimulation, and ear acupressure are types of auriculotherapy. The first two approaches insert needles or apply intense electrical stimulation to auricular acupoints [18], but auricular acupressure is not invasive and applies pressure on the same points as auricular acupuncture [19]. The ear is where the meridians of the body connect and converge at the main point of Qi. Therefore, stimulation of the auricular points can activate Qi and lead to analgesia [20]. Furthermore, ear acupressure improves heart rate variability and thus reduces the activity of the sympathetic nervous system [21], which in turn reduces the secretion of epinephrine and cortisol, strengthens the relaxation response, and thus reduces pain, stress and anxiety levels [22]. Auricular point acupressure has been useful in reducing acute postoperative pain, dental pain, and musculoskeletal pain among older adults. It is also considered an adjunct analgesic among cancer patients [23,24]. Villegas et al. (2017) found that auriculotherapy was better than routine treatment for postoperative pain control after laparoscopic cholecystectomy surgery [25]. Abedini et al. (2020) also showed the effectiveness of auriculotherapy in the reduction of shoulder pain after cesarean section [26].

To the best of our knowledge, researchers have not compared the effects of body acupressure and ear acupressure on shoulder pain after laparoscopic cholecystectomy. As body acupressure and ear acupressure are different methods, patients or healthcare workers may have different preferences for the use of these two methods. Therefore, this study compared the effects of body acupressure and ear acupressure on shoulder pain in patients undergoing laparoscopic cholecystectomy so that patients or nurses can decide which method to choose.

Methods

This study adheres to the Consolidated Standards of Reporting Trials (CONSORT) statement and Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA).

Study design and sample

This study was a randomized controlled clinical trial. The study population included patients undergoing laparoscopic cholecystectomy referred to the surgery department of Imam Reza Hospital in Birjand, Iran in 2022-2023. According to a previous study [27] and the parameters of α=0.05, β=0.1, the sample size was calculated to be 31 patients for each group. Assuming an attrition rate of 15 percent, 36 participants were required for each group. The convenience sampling method was used in this study. The inclusion criteria were patients' consent to participate in the study who had a visual analogue scale (VAS) pain score higher than 3 in the first assessment (T0) with no lesions or

wounds in the selected acupoints, no history of chronic shoulder or neck pain, no cognitive disorders such as dementia, having no history of bleeding or blood clotting disorders, no pregnancy or breastfeeding, and no history of syncope or seizures. Unwillingness to continue the study at any time and the occurrence of complications such as postoperative bleeding were considered exclusion criteria. Using the block randomization method with a block size of 6 and with a 1:1:1 assignment ratio, 108 selected patients were allocated to three groups (control group, body acupressure group, and ear acupressure group).

Data collection and procedure

The first author visited patients two hours after laparoscopic cholecystectomy, explained the study purpose, checked the inclusion criteria, including a VAS score above 3 (T0), and received written consent from the patients of the study. The patients completed the demographic information form and the first part of the Spielberger State-Trait Anxiety Inventory (STAI) which evaluates state anxiety. Then, the selected patients were assigned to three study groups (control group, body acupressure group, and ear acupressure group) using the block randomization method. Notably, randomization was performed by a research assistant who was unaware of the goals of the study. The first author, who received a certificate from a traditional Chinese medicine specialist, applied body acupressure and ear acupressure. The control group received no acupressure intervention and only received routine care. Another research assistant who was unaware of group allocation evaluated the amount of shoulder pain in the patients using the VAS one (T1), four (T2) and eight (T3) hours after the intervention and collected The STAI that was completed by patients eight hours after the intervention.

Instruments

1) Demographic information form

Demographic information form included age, gender, marital status, education level, underlying disease, history of smoking, analgesic use, and past surgery experience.

2) VAS

The VAS is the most common tool used to assess pain intensity [28]. This scale asks patients to mark the intensity of pain they feel on a line drawn between two points that can be vertical or horizontal. The VAS is a continuum that is often 10 cm long, with two endpoints representing 0 (without pain) and 10 (the most pain) [29]. The patients mark the level of pain on this line, which starts from the "without pain" point. The overall score ranges from 0 to 10 cm. The Visual Analogue Scale can be easily used to determine pain. This scale is sensitive in determining the effects of treatment and its results can be analyzed with parametric statistical tests [30].

3) STAI

The 40-item self-report STAI examines patients' anxiety on a 4-point Likert scale (from 1 = not at all to 4 = very much). This tool has two parts: the first part measures state anxiety, i.e. how a person feels at that moment. The second part evaluates trait anxiety, that is, how a person feels in general. The first part of the instrument was applied in this study. This part consists of 20 items, with 10 items being scored in reverse. The minimum score is 20 and the maximum score is 80, respectively, with higher scores indicating higher patient anxiety [31]. In Iran, this tool has been used to measure the anxiety of patients who are candidates for laparoscopic cholecystectomy, and its reliability has been satisfactory [32]. In this study, Cronbach's alpha for the first part of STAI was 0.89, indicating acceptable reliability.

Intervention

To apply body acupressure, the researcher (MZP) first washed her hands with warm water. Then, while the position of the patient was supine, the acupoints including GB21, ST38 and TW15 [33,34] were located using the measurements of the patient's fingers. These acupoints were selected according to one of the authors (HRBT) who was a specialist in traditional Chinese medicine and had 13 years of work experience in traditional Chinese medicine. The researcher (MZP) applied body acupressure with her thumb pulp on the GB21, ST38, and TW15 acupoints for 3 minutes on the side where shoulder pain was reported by the patient. Between pressing each point, one minute of rest was considered for the patient, so the intervention time was 11 minutes. The amount of applied pressure was adjusted based on the patient's tolerance level [35]. In other words, the pressure was applied to the extent that the patient reported fullness and positive pain. Using the VAS, a research assistant collected information about the pain intensity of the patients one (T1), four (T2) and eight (T3) hours after the intervention.

To apply ear acupressure, the researcher (MZP) cleaned the ears of the patients with 70% alcohol. Then, while the position of patients was supine, the ear acupoints of the shoulder, shoulder joint and clavicle [36] were located on their ears on the side where shoulder pain was reported. These points were gently pressed with a pressure equal to 1 kg [37] for 3 minutes by a copper ear probe pen with a soft and round tip (SUPVOX Ear Acupuncture Pen; Dimensions: 5.12 × 0.31 × 0.31 inches). Between pressing each point, one

minute of rest was considered for the patient. Thus, in this group, the intervention lasted 11 minutes. Then, a research assistant evaluated the pain intensity of the patients one (T1), four (T2) and eight (T3) hours after the intervention.
The intensity of shoulder pain in the control group was evaluated at the same times as the patients in the intervention groups by a researcher's assistant.
The flow of the study is shown in figure 1.

Statistical Analysis

Data were analyzed using the SPSS software (v. 25). The descriptive statistics including mean, standard deviation, and frequency were used for data description. Statistical tests including the Chi-square, the Fisher's exact, the One-way ANOVA, the Kruskal-Wallis, and independent t-tests were used to compare the demographic and clinical characteristics between three groups i.e., age, gender, marital status, level of education, smoking status, history of chronic disease, anxiety, past surgery experience, and analgesic use. The Shapiro–Wilk test indicated that the distribution of the scores of shoulder pain intensity was not normal. Thus, the Friedman test followed by the Wilcoxon Signed-Rank test was applied to evaluate the changes in pain intensity score in each group across the four time points. Also, the Kruskal–Wallis test was used to compare the pain intensity score at each measurement time point between the three groups. For all analyses, a $P < 0.05$ was considered statistically significant.

Ethical consideration

This study proposal was approved by the ethics committee of Birjand University of Medical Science with the code of ethics no. IR.BUMS.REC.1400.444. This clinical trial was registered in the Iranian Registry of Clinical Trials (IRCT) with No. IRCT20220310054249N1. We received written consent from the participants, explained to them that they had full authority to participate in the study, and assured them that their information would remain confidential.

Results

We finally analyzed the data of 101 patients. Subjects were then assigned including a control group of 35 patients, a body acupressure group of 33 patients, and an ear acupressure group of 33 patients.
Statistical analysis showed no significant difference in the demographic characteristics between the three study groups (Table 1).
The mean anxiety scores of patients in the control, body acupressure, and ear acupressure groups were 46.51 ± 2.83, 45.75 ± 7.71, and 45.15 ± 3.63, respectively. The Kruskal-Wallis test showed no difference in the mean anxiety score between the three groups ($Z=1.41$, $P=0.49$).
As shown in table 2, Friedman's test showed significant changes in the shoulder pain intensity score between the three groups five times ($P < 0.001$).
The Friedman's test indicated significant differences in the median pain scores between all three groups at four times ($P < 0.001$). The Wilcoxon test revealed a significant reduction in the control group's median shoulder pain intensity over time from T0 to T2 ($P < 0.001$), but it had no significant difference at T2 and T3 ($P=0.06$). The pain intensity in the body acupressure group significantly decreased from T1 to T4 ($P<0.001$) but not in T0 and T1 ($P=0.99$). Finally, the Wilcoxon test showed a significant reduction in the ear acupressure group's shoulder pain from T0 to T4 ($P < 0.001$).
Statistical analysis showed a significant difference in shoulder pain intensity between the three study groups at T1, T2 and T3 but not at T0 (Table 2).
Pairwise comparison of these groups at T1 showed no significant difference in the median score of shoulder pain between the body acupressure group and the control group ($P=0.78$), but the median score of shoulder pain in the ear acupressure group was lower than that in the body acupressure and control groups at T1 ($P<0.001$). The median shoulder pain score in the body acupressure group was lower than that in the control group at T2 ($P<0.001$). In addition, the median pain score in the ear acupressure group was significantly lower than that in the other two groups at T2 ($P<0.001$). Although the median pain score in the control group was higher than that in the body acupressure and ear acupressure groups at T3 ($P<0.001$), we observed no statistically significant difference between the body acupressure and ear acupressure groups ($P= 0.12$) (Table 3).
The graph of changes in the intensity of shoulder pain over time in the 3 studied groups is shown in figure 2.

Discussions

This study aimed to compare the effects of body acupressure and ear acupressure on shoulder pain in a sample of Iranian patients undergoing laparoscopic cholecystectomy.
We observed a significant reduction in the control group's median shoulder pain intensity from T0 to T2 but found no significant difference in the pain intensity at T2 and T3. According to researchers, shoulder pain usually begins 2-6 hours after laparoscopic cholecystectomy [38]. In this study, the shoulder pain score for all participants was higher than 3, so participants might have received analgesics. The patients in this study received analgesics three hours after they entered the ward that is around T1; therefore, pain reduction in the control group was expected from T0 to T2.

This study indicated no difference in the shoulder pain intensity in the body acupressure group at T0 and T1. Nevertheless, pain decreased significantly from T1 to T3. The median VAS score in the body acupressure group was significantly lower than that in the control group at T2 and T3; therefore, body acupressure generally was effective in improving shoulder pain in patients. Researchers believe that acupressure reduces pain through two mechanisms: first, it prevents the pain stimulus from reaching the various gates leading to the spinal cord or brain, and second, acupressure stimulates the release of endorphins, thereby reducing pain [7].

Contradictory results are available regarding the effect of body acupressure on pain patients after laparoscopic cholecystectomy surgery. Kreindler et al. (2014), for instance, A total of 25 patients were evaluated and results showed that acupuncture in combination with conventional treatment could reduce shoulder pain and general postoperative pain in laparoscopic surgeries, including laparoscopic cholecystectomy [16]. Also, Soylu et al. (2021) 53 participants were evaluated and the results indicated the effect of body acupressure on reducing the acute pain of patients after laparoscopic cholecystectomy four and eight hours after surgery [15]. In contrast, in a study by Klinic et al. (2022) 188 patients were evaluated and reported no significant difference in pain in patients undergoing laparoscopic cholecystectomy 2, 6, and 24 hours after body acupressure compared to the control and placebo groups [39]. Klinic et al. only stimulated the PC6 acupoint using a wristband.

We found a significant reduction in the ear acupressure group's shoulder pain from T0 to T4; the median shoulder pain score in the ear acupressure group was lower than that in the control group at T1, T2, and T3. Villegas et al. (2017) 46 patients were evaluated and found that auriculotherapy was more effective

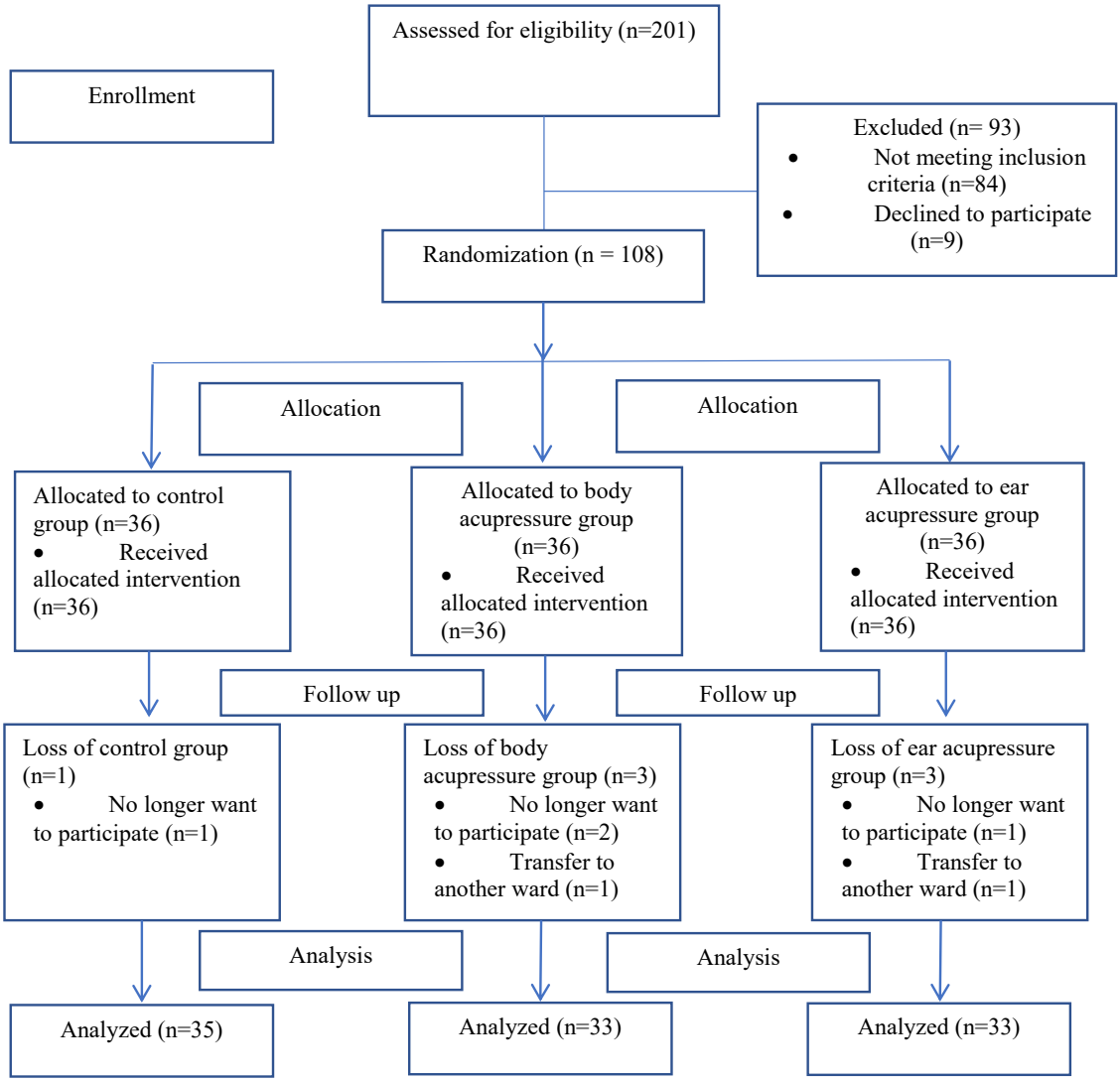

Figure 1. Flow of study

Table 1. Comparison of groups in terms of participants' demographic and clinical features

Characteristics	Control group (n=35) n (%)	Body acupressure group (n=33) n (%)	Ear acupressure group (n=33) n (%)	Test results
Age (Mean± SD)	48. 78 ± 12.06	45.78± 12.06	44.69± 12.26	F= 2.31, P= 0.37^
Gender				
Female	29 (82.9)	27 (81.8)	22 (66.7)	Z= 3.11, P=0.21*
Male	6 (17.2)	6 (18.2)	11(33.3)	
Marital status				
Married	4 (11.4)	29 (87.9)	5 (15.2)	
Single	31 (88.6)	4 (12.1)	25 (75.7)	Z= 4.83, P= 0.25**
Widowed	0 (0.0)	0 (0.0)	3 (9.1)	
Level of education				
Unschooled/ primary school	19 (54.3)	9 (27.3)	7 (21.2)	
Middle school	2 (5.7)	6 (18.2)	6 (18.2)	Z= 11.3, P=0.09**
High school	7 (20.0)	11 (33.3)	9 (27.3)	
University	7 (20.0)	7 (21.2)	11 (33.3)	
Current smoking				
Yes	6 (17.1)	4 (12.1)	3 (9.1)	Z= 0.99, P=0.66**
No	29 (82.9)	29 (87.9)	30 (90.9)	
Past surgery experience				
Yes	11 (31.4)	8 (24.2)	10 (30.3)	Z= 0.48, P=0.86*
No	24 (68.6)	25 (75.8)	23 (69.7)	
Having chronic disease				
Yes	17 (48.6)	8 (24.2)	9 (27.3)	Z= 5.39, P=0.08*
No	18 (51.4)	25 (75.8)	24 (72.7)	
Analgesic use	33 (94.28)	28 (84.8)	25 (75.8)	Z= 4.56, P= 0.11^^
Spielberger State-Trait Anxiety Inventory (STAI)	46.51 ± 2.83	45.75 ± 7.71	45.15 ± 3.63	Z=1.41, P=0.49^^

^: Analyzed using the One-way ANOVA test
*: Analyzed using the Chi-square test
**: Analyzed using Fisher's exact test
^^: Analyzed using the Kruskal–Wallis test

Table 2. Between and within-group comparisons respecting shoulder pain intensity

Time \ Group	Control group Median (IQR) Mean± SD	Body Acupressure group Median (IQR) Mean± SD	Ear acupressure group Median (IQR) Mean± SD	Test results*
T0	5.00 (4.00-5.00)	5.00 (4.00-5.00)	5.00 (4.00-5.00)	$\chi2$= 2.23, P= 0.32
T1	5.00 (4.00-5.00)	5.00 (5.00-5.00)	3.00 (2.00-3.00)	$\chi2$= 60.83, P < 0.001
T2	4.00 (3.00-4.00)	3.00 (2.00-3.00)	1.50 (1.00-2.00)	$\chi2$= 60.92, P < 0.001
T3	4.00 (3.00-5.00)	1.50 (1.00-2.00)	1.00 (1.00-2.00)	$\chi2$= 54.86, P < 0.001
Test results**	$\chi2$= 72.60, P < 0.001	$\chi2$= 97.33, P < 0.001	$\chi2$= 95.29, P < 0.001	---

*: Analyzed using the Kruskal–Wallis test;
**: Analyzed using the Friedman test

Table 3. Pairwise comparisons of the study groups

Time \ Groups	Control- Body acupressure Test result^	Control- Ear acupressure Test result^	Body acupressure- Ear acupressure Test result^
T0	Z= -1.42, P= 0.15	Z= -0.42, P= 0.67	Z= -1.06, P= 0.28
T1	Z= -0.27, P= 0.78	Z= -6.75, P< 0.001	Z= -6.69, P< 0.001
T2	Z= -3.94, P< 0.001	Z= -6.95, P< 0.001	Z= -5.48, P< 0.001
T3	Z= -5.75, P< 0.001	Z= -6.67, P< 0.001	Z= -1.52, P= 0.12

^: Analyzed using the Mann-Whitney test

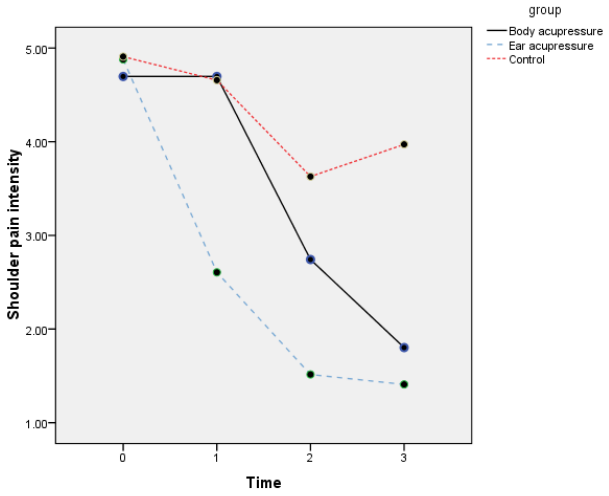

Figure 2. Trends of pain intensity in study groups over time

than conventional analgesics for postoperative pain control in patients who underwent laparoscopic cholecystectomy [25]. Auricular therapy in the treatment of shoulder pain after laparoscopy has rarely been investigated. In the study by Abedini et al. (2020), 90 candidates for a cesarean section were selected and the results showed that the use of auriculotherapy was effective in preventing and reducing shoulder pain after a cesarean section [26]. Generally speaking, auricular acupressure relieves pain and neuronal excitability by briefly stimulating the terminal part of the outer ear nerves and balancing the pathological hypersensitive reflex that connects the ear microsystem and the somatotopic brain [40]. The analgesic effects of auricular acupressure are induced by activating the descending pain inhibitory pathway of the brainstem, thereby inhibiting the ascending pain pathway and increasing the concentration of beta-endorphins [20]. Moreover, according to Xia et al. (2018), 29 participants were evaluated and results showed that ear acupressure could reduce postoperative pain by modulating the action of inflammatory cytokines and neuropeptides [41].

The study results confirmed no significant difference in shoulder pain between the two groups of body acupressure and ear acupressure at T3, but ear acupressure was more effective than body acupressure in reducing shoulder pain at T1 and T2. Unfortunately, we found no study that compared the effects of two interventions on shoulder pain. Only one study compared the effect of body acupressure and auricular acupressure on labor pain and the length of the active phase of labor and reported that both auricular acupressure and body acupressure were effective in reducing labor pain. In this study, ear acupressure was significantly more effective in shortening the active phase of labor than body acupressure [42].

No side effects were observed in the intervention groups including body acupressure and ear acupressure.

Ear acupressure is inexpensive, simple, effective, and without side effects, which can be applied in many settings [43]. Therefore, performing ear acupressure alongside other conventional treatments may reduce the use of opioids.

This study was conducted in only one laparoscopic cholecystectomy center, so we suggest conducting this study in several centers to increase the generalizability of the study results.

Conclusion

Body acupressure and ear acupressure were effective in reducing shoulder pain among patients undergoing laparoscopic cholecystectomy, but ear acupressure was more effective and it showed its analgesic effect faster than body acupressure. Therefore, ear acupressure can be used as a better option to reduce shoulder pain after laparoscopic cholecystectomy. The results of this study showed no significant difference in the mean anxiety score between the body acupressure, ear acupressure and control groups.

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None declared.

Conflict of Interests
Authors state no conflict of interest.

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