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Original Research

The Effects of Ear Acupressure on Back Pain after Coronary Angiography: A Randomized Controlled Trial

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Abstract

Back pain is a common complaint seen in patients after coronary angiography. This study investigated the efficacy of ear acupressure for reduction of back pain in patients after coronary angiography. In this trial, 120 patients recruited from a post-angiography ward were allocated to an ear acupressure or a control group. Pain assessment in intervention group was performed immediately after participants entered post- coronary angiography ward (T0), twenty minutes after entering the ward (T1), and two, four, and six hours after the intervention (T2–T4). Pain in control group was assessed at the times similar to intervention group. Data were analyzed using the SPSS software (v. 19) by Chi-square, Fisher's exact, independent t tests, Friedman test, Wilcoxon signed-rank, and Mann-Whitney U test.

Final data analysis was done on the data gathered from 58 participants in the control group and 59 in the ear acupressure group. The pain intensity at T1–T4 for patients in the control group was significantly higher than T0 ($P < 0.001$), while patients in the ear acupressure group reported that pain intensity at T2–T4 was significantly higher than T0 for them ($P < 0.001$). Only at T1 and T2, pain intensity in the ear acupressure group was significantly less compared to the control group ($P < 0.05$). Ear acupressure in this study was effective to some extent in reducing back pain after coronary angiography. Future studies can be designed to examine the effects of ear acupressure using different ear acupressure points on the back pain after coronary angiography.

Keywords: Ear acupressure; Back pain; Coronary angiography

Introduction

Cardiovascular disease is considered as primary cause of death across the world. The most common cardiovascular disease is coronary artery disease [1,2]. Coronary angiography (CAG) is the gold standard method for diagnosing coronary artery blockage or stenosis in coronary artery disease [3].

CAG is mostly performed through transfemoral puncture. During CAG through transfemoral puncture, a sheath is placed in the femoral artery and a catheter is inserted to access coronary arteries [4]. After CAG, patients are at risk for different complications, specially bleeding from the puncture site [5]. Therefore, after CAG, the transfemoral sheath is

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immediately removed, hemostasis is achieved through manual or mechanical pressure, dressing is applied, and patient is limited to complete bed rest in supine position with afflicted leg straight for 4–6 hours. Post-CAG complete bed rest in supine position can cause pain and discomfort [4-7]. Previous studies frequently reported the prevalence of post-CAG back pain with a high prevalence rate of 71.8% [8-10].

Different mechanisms have been suggested for post-CAG back pain. Some scholars believe that lengthy bed rest in a still position can increase tissue pressure in muscles, decrease muscular blood flow, and result in fatigue and pain [11,12]. Ineffective pain relief can stimulate sympathetic response, which in turn causes tachycardia, tachypnea, increased myocardial oxygen consumption, and increased cardiac workload. Increased cardiac workload in patients with cardiac problems who cannot keep a balance between oxygen supply and demand can pose significant risks [13-15]. There are different pharmacological and non-pharmacological methods for reducing post-CAG back pain. Pharmacological methods include analgesic agents such as opioids. Unfortunately, these methods are usually associated with adverse side effects, including respiratory depression which can result in brain hypoxia [16]. Therefore, non-pharmacological methods have received great attention in recent years. These methods include complementary and alternative medicine therapies such as auriculotherapy. Ear acupuncture and ear acupressure are common forms of auriculotherapy [17].

Auriculotherapy is a division of acupuncture, in which ears are considered as a microsystem of the body. In this method, the stimulation of certain points on the auricle is supposed to stimulate an organ in the body which is connected to those points. Auriculotherapy points are usually stimulated using vaccaria seeds, fingers, probes, needles, or other methods [18-19]. The results of previous studies regarding the effects of different forms of auriculotherapy such as ear acupressure are not consistent. Some studies reported the effectiveness of ear acupressure in reducing pain in patients with dementia, labor pain, and menstrual pain [20-22]; while Kwan WS, Li (2014) reported that ear acupressure was not effective in reducing acute postpartum perineal pain [23]. In this line, a meta-analysis comprising 13 studies concluded that further studies, particularly large scale of randomized controlled trials are needed to further confirm the efficacy of auriculotherapy including ear acupressure for relieving different types of pain [24].

Although some forms of auriculotherapy may have potential effects on post-CAG pain, the results of previous studies respecting their effects on pain are contradictory. Consequently, further studies are still needed to produce reliable evidence in this area. Furthermore, the authors did not retrieve studies examining the efficacy of ear acupressure for reduction of back pain after CAG.

The present study investigated the efficacy of ear acupressure for reduction of back pain in patients after CAG.

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 enrollment of study participants

The current study used an open labelled two-arm parallel randomized controlled trial. Data were collected in 2018–2019 among patients hospitalized in the post-angiography ward of Razi university hospital, Birjand, Iran.

A total of 120 patients who had undergone CAG in the angiography ward of Razi university hospital, Birjand, Iran were selected. Sampling was performed using the convenience sampling method. Inclusion criteria were an age of 30–60 years, undergoing CAG through the femoral artery, full consciousness, no symptom of back pain within the last week before angiography, no back pain in the first back pain assessment after CA (immediately after admission), no known bleeding disorder, no inflammation, infection, or injury in the auricles, no history of bone metabolic problems, osteoarthritis, or rheumatic diseases, no history of conditions impairing pain perception (e.g., some types of stroke), no history of herniated disk or surgery on spine or spinal cord, and no use of opioids, tranquilizers, and anesthetic agents during the four hours before and after CAG. Exclusion criteria were development of life-threatening conditions such as serious cardiac arrhythmia, post-CAG hemodynamic instability, and serious CAG-related complications such as active bleeding, as well as a high risk of vasovagal attack as determined by attending cardiologists.

Considering results of a previous study in which the pretest and the posttest mean scores of back pain were 1.62 ± 2.75 and 0.34 ± 1.16, respectively [25], sample size was calculated to be sixty per group. Sample size calculation parameters were a α of 0.05, a β of 0.20, as well as a potential attrition rate of 15%.

Participant randomization

Participants were randomly allocated to an ear acupressure or a control group using block randomization with a fixed block size of four and a 1:1 allocation ratio. Randomization was done by a researcher assistant using sequentially numbered

opaque envelopes. Each of these envelops contained a card that was marked with the group assignment (ear acupressure or control group). When a patient was determined to be eligible, the researcher assistant opened the next sealed envelope in the sequence and the patient was assigned to the study group indicated on the card.

Data collection

A demographic and clinical characteristics questionnaire and a visual analogue scale (VAS) were used for data collection. The items of the questionnaire were on age, gender, level of education, marital status, body mass index (BMI), and smoking status, and back pain history. The visual analogue scale was used to assess the primary outcome of the study, i.e. back pain intensity. VAS is one of the most commonly applied instruments for pain evaluation. VAS is horizontal 100-milimeter line with a "No pain" expression at the left end and a "Worst possible pain" at the right end. Respondents are asked to determine their pain intensity by putting a checkmark on the scale and then, the distance between the "No pain" point and the checkmark is measured in millimeters and considered as pain intensity score. This scale has acceptable sensitivity for pain assessment and has frequently been used for back pain assessment in previous studies [26-28]. For reliability assessment in the present study, fifteen patients with mild to moderate pain in the post-CAG ward twice responded the scale with a five minutes interval. Intraclass correlation coefficient was calculated to be 0.83, confirming the acceptable test-retest stability of the scale.

Intervention

In this study, the ear acupressure points were selected based on Traditional Chinese Medicine meridian theory. Study intervention was ear acupressure as a form of auriculotherapy for participants in the ear acupressure group which was implemented in the post-CAG ward by the second author who had already received necessary ear acupressure training from a traditional Chinese medicine specialist (the fourth author). With 12 years of experience in teaching and clinical traditional Chinese medicine including acupuncture, the fourth author selected the ear acupressure points using a list of points previously reported as being effective in back pain and according to his own clinical and teaching practice. For ear acupressure, ears were cleansed using 70% alcohol. Then, the Shen Men, kidney, and spinal column points [19, 29] were located on the right ear and each was gently pressed (with a pressure of one kilogram) using a copper ear probe pen with a round tip (SUPVOX Ear Acupuncture Pen; Dimensions: 5.12 × 0.31 × 0.31 inches). Immediately afterwards, ear acupressure was applied to the left ear with the same technique. A one-minute interval was considered between the pressing of each point and hence, the intervention lasted eight minutes for each ear and sixteen minutes for both ears. All patients in the ear acupressure group received the same intervention.

In the control group, patients received routine care; including complete bed rest in supine position with afflicted leg straight for 6 hours, keeping sandbag over catheter insertion site, and evaluating complications following CAG such as bleeding, hematoma or aneurysm formation.

Pain assessment in all groups was performed immediately after the participants entered post-CAG ward (T0), immediately after the intervention, i.e., twenty minutes after entering the ward (T1), and two, four, and six hours after the intervention (T2–T4).

It is notable that pain assessment was performed by a research assistant. Also, the data analyzer was blind to the allocation of groups to intervention and control.

Statistical Analysis

Data were analyzed using the SPSS software (v. 19). The descriptive statistics (e.g., mean, standard deviation, and frequency) were used for data description. Statistical tests including the Chi-square, the Fisher's exact, and independent t tests were used to compare the demographic characteristics between two groups i.e., age, body mass index (BMI), gender, marital status, level of education, back pain history, and smoking status. As the distribution of the scores of pain intensity was not normal, the Friedman test was used to assess the changes of pain intensity score in each group across the five time points. When the results of Friedman's test were significant, these results were followed by the Wilcoxon signed-rank. Also, the Mann-Whitney U test was applied to compare the pain intensity score at each measurement time point between the two groups. For all analysis, a $p < 0.05$ was considered as significant.

Ethical consideration

The Ethics Committee of Birjand University of Medical Sciences, Birjand, Iran, approved this study (Code: IR.BUMS.REC.1397.289). The trial proposal was also registered in the Iranian Registry of Clinical Trials (IRCT) (Identifier: IRCT20190203042606N1). All participants were ensured of voluntary participation in the study and confidential management of their data. The aim of the study was also explained for them and written informed consent was obtained from all of them.

Results

Basic demographical findings

Primarily, sixty participants were recruited to each group. During the study, one patient of the ear

acupressure group as well as two patients of the control group were excluded because of voluntary withdrawal or transfer to other hospital wards. Therefore, final data analysis was done on the data gathered from 58 participants in the control group and 59 in the ear acupressure group (Figure 1).

Age mean was 52.83 ± 6.72 in the control group and 53.31 ± 6.04 in the ear acupressure group. The mean of BMI in the control groups was 25.28 ± 5.1 and in the ear acupressure group was 24.55 ± 4.09. Most participants in both groups were married and did not report a history of back pain and smoking. Respecting patients' age, BMI, gender, level of education, marital status, back pain and smoking status, no significant differences were observed between the groups (P > 0.05; Table 1).

Table 1. Comparison of participants' demographic characteristics between the two groups

Characteristics \ Group		Control N (%)	Auriculotherapy N (%)	P value
Sex	Male	30 (51.7)	25 (42.3)	0.35*
	Female	28 (48.3)	34 (57.7)	
Marital status	Married	51 (87.9)	56 (94.9)	0.2*
	Single	7 (12.1)	3 (5.1)	
Level of education	Unschooled	20 (34.5)	25 (42.4)	0.47^
	Primary school	17 (29.3)	21 (35.5)	
	Guidance school	4 (6.9)	4 (6.8)	
	High school	12 (20.7)	6 (10.2)	
	University	5 (8.6)	3 (5.1)	
Back pain history	Yes	17 (29.3)	18 (30.5)	0.87*
	No	41 (70.7)	41 (69.5)	
Smoking status	Yes	11 (19)	14 (23.7)	0.53*
	No	47 (81)	45 (76.3)	

*: Analyzed using results of the Chi-square test; ^: Analyzed using the Fisher exact test

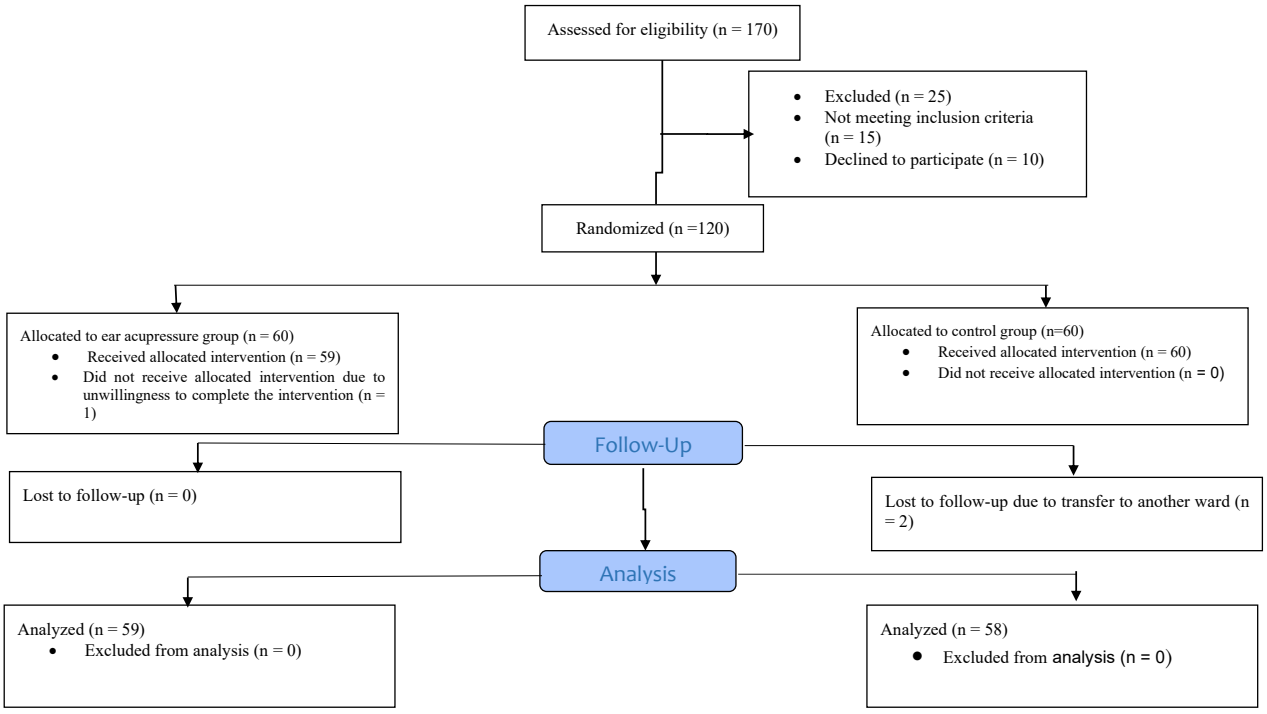

Figure 1. The Consort diagram of participant flow

Comparison of clinical findings

Regarding changes of the pain intensity score in two groups over the five time points, the Friedman test showed significant changes ($P < 0.001$; Table 2). The Wilcoxon signed-rank test for post hoc analysis revealed that the pain intensity at T1–T4 for patients in the control group was significantly higher than T0 ($P < 0.001$); while patients in the ear acupressure group reported that pain intensity at T2–T4 was significantly higher than T0 for them ($P < 0.001$). In fact, in ear acupressure group pain intensity at T1 did not significantly differ from T0 ($P > 0.99$).

Considering between-groups comparisons using Mann–Whitney U test, statistical analysis revealed that pain intensity in the ear acupressure was significantly less than the control group just at T1 and T2 ($P < 0.05$).

Finally, pain intensity in two groups decreased from T3 to T4, but none of these decreases were significant ($P > 0.05$; Table 2).

Trends of back pain intensity in control and ear acupressure group over time is displayed in figure 2.

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

Time \ Group	Control Median (IQR) Mean ± SD	Auriculotherapy Median (IQR) Mean ± SD	Test results^
Immediately after entering post-CAG ward (T0)	0.00 (0.00 – 0.00) 0.00 ± 0.00	0.00 (0.00 – 0.00) 0.00 ± 0.00	Z = 0.00 P > 0.99
Immediately after the intervention (i.e., twenty minutes after T0) (T1)	0.00 (0.00 – 0.00) 6.12 ± 16.23	0.00 (0.00 – 0.00) 0.00 ± 0.00	Z = -3.49 P < 0.001
Two hours after the intervention (T2)	0.00 (0.00 – 25.00) 15.62 ± 23.50	0.00 (0.00 – 18.00) 8.08 ± 11.62	Z = -1.45 P = 0.001
Four hours after the intervention (T3)	0.00 (0.00 – 32.75) 17.19 ± 25.29	0.00 (0.00 – 20.00) 9.31 ± 13.54	Z = -1.56 P = 0.11
Six hours after the intervention (T4)	0.00 (0.00 – 25.00) 15.84 ± 24.43	0.00 (0.00 – 20.00) 9.254±13.58	Z = -1.23 P = 0.21
Test results*	$\chi2 = 55.86$ P < 0.001	$\chi2 = 69.58$ P < 0.001	—

IQR: Interquartile range; SD: Standard deviation;
*: Analyzed using the Friedman test;
^: Analyzed using the Mann-Whitney U test

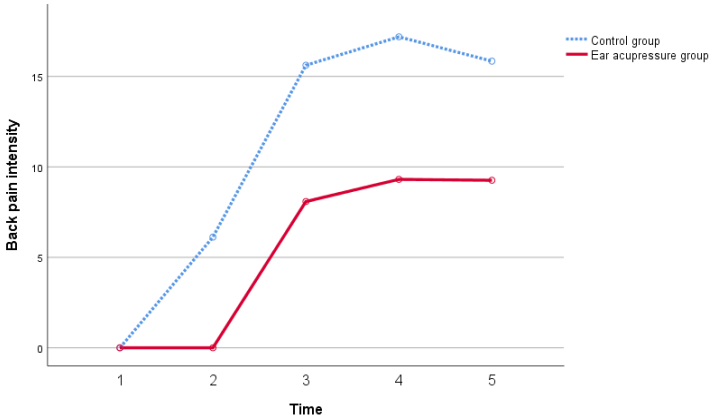

Figure 2. Trends of pain intensity in control and ear acupressure groups over time

Discussion

Back pain is a common complaint seen in in patients after CAG [8-10]. This study evaluated the efficacy of ear acupressure for reduction of back pain in patients after coronary angiography. In this study, statistical analysis indicated that intensity of back pain significantly increased over time in both groups. Similarly, a former study reported significant increase in back pain intensity during the first six hours after CAG both in the control and the intervention groups [30]. Bed rest in a still position for long time increases tissue pressure and decreases muscular blood flow, including lumbar muscles, and thence, causes pain, discomfort, and fatigue [11,12]. Therefore, increase in intensity of back pain over time is expected.

Our findings also showed that although not significant, six hours after CAG, pain intensity reduced in two groups. This finding may be due to the fact that six hours after CAG, patients expect to get out of bed. Expectations and concerns in a specific situation affect individuals' perceptions of that situation [27]. On the other hand, six hours after CAG, patients are usually allowed to change their position. This can obviously influence on the reduction of intensity of back pain.

Study findings also showed that intensity of back pain in the ear acupressure group patients was significantly less compared with those in the control group only at T1, i.e., immediately after the intervention and T2, i.e., two hours after the intervention.

Previous studies reported contradictory results in terms of the effects of different forms of auriculotherapy on pain. For example, some previous research reported that ear acupressure could significantly decrease pain in patients with dementia [20], pain associated with hip labor [21], and menstrual pain [22]. Asher et al (2010) in a meta-analysis, found that auriculotherapy including ear acupressure may be effective for the management of different types of pain, especially postoperative pain [18]. Contrarily, a systematic review and meta-analysis study showed that evidence regarding the effects of auricular acupuncture on immediate pain reduction was not conclusive [31]. These findings suggest that different characteristics of pain, including whether it is chronic or acute, can influence the effects of auriculotherapy.

Furthermore, a study interestingly showed that the effects of auricular acupuncture on acute postoperative pain were greater among patients with abdominal surgeries [32]. These findings imply that the effects of auriculotherapy may also depend on the pain location and underlying cause of pain. Other factors such as duration of auriculotherapy and type of auriculotherapy points can also contribute to the contradictory results of previous studies respecting the effects of auriculotherapy.

Considering findings of this study, large scale clinical trials are recommended in order to provide firmer evidence regarding the effects of auriculotherapy on intensity of back pain after CAG.

None of the study participants experienced serious adverse effects due to auriculotherapy, indicating that auriculotherapy is a safe and non-invasive intervention. Previous studies confirmed that in overall, auriculotherapy did not cause serious adverse effects [33].

This study faced some limitations. First, it was conducted in a single setting. Second, it was conducted on older adults aged 30–60 years. Third, it just assessed the short-term effects of auriculotherapy on post-CAG back pain. Therefore, findings should be generalized with caution. Further studies are needed to assess the long-term effects of these interventions on post-CAG pain.

Conclusion

Generally, ear acupressure as a form of auriculotherapy in this study was effective to some extent in reducing back pain after CAG. Future studies can be designed to examine the effects of ear acupressure using different auriculotherapy points or different duration of this method on the back pain after CAG.

Conflict of Interests

The authors declare that there is no conflict of interest.

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