

Comparing the effect of two methods of using ear protective device on pain intensity in patients undergoing coronary artery bypass grafting: A randomized clinical trial

Abstract

Background: Severe pain is the most prevalent complication after Coronary Artery Bypass Grafting (CABG). The aim of this study is to compare the impact of two methods using ear protective devices on pain intensity in patients undergoing CABG. **Materials and Methods:** The present randomized clinical trial was conducted between October 2019 and February 2020. The participants included 84 patients undergoing CABG, who were randomly divided into two intervention groups (A, B) and a control group. On the first night after the heart surgery, ear protective devices were used for the patients in group A during the evening and night sleep, while they were used in group B only during the night sleep. A demographic questionnaire and Visual Analog Scale (VAS) were the data collection tools used in this study. Data were analyzed using Chi-square test, paired *t*-test, and one-way Analysis of Variance (ANOVA) in Statistical Package for the Social Sciences (SPSS) software. **Results:** Before the intervention, the mean (SD) of pain intensity in the two intervention groups (A, B) and the control group was 6.46 (1.71), 6.32 (1.36), and 6.54 (1.45), respectively, and there was no significant difference between the groups ($F_{2,81} = 0.14$; $p = 0.86$). However, after the intervention, the mean (SD) of pain intensity in the two intervention groups (A, B) and the control group was 3.39 (1.87), 4.46 (1.55), and 6.39 (1.54), respectively, which showed a significant difference ($F_{2,81} = 23.37$; $p < 0.001$). **Conclusions:** The use of ear protective device is recommended as a non-invasive and accessible way of reducing pain intensity in patients after CABG.

Keywords: Coronary artery bypass, ear protective device, pain

Introduction

Severe pain is one of the most common complications after Coronary Artery Bypass Grafting (CABG), and 49% of patients reported experiencing pain at rest, 78% during coughing, and 62% during movement within the first four days after the surgery.^[1] Because of the high intensity of pain and subsequent high stress and serious hemodynamic complications, the management of pain after heart surgery has always been a major concern for physicians and nurses.^[2] To control postoperative pain, pharmacological and non-pharmacological treatments (such as acupuncture, massage, Transcutaneous Electrical Nerve Stimulation [TENS], and heat or cold packs) might be considered. Treatment interventions that are commonly used include opioids, paracetamol, Nonsteroidal Anti-Inflammatory Drugs (NSAIDs), and more recently anticonvulsants.^[1]

However, pain intensity is among the multifactorial problems in patients after CABG, which is affected by a number of uncontrollable factors such as age, gender, health status, and type of intervention.^[2] Moreover, results of a study in 2018 showed that environmental factors such as noise, light, and temperature are stressors for patients admitted to the Intensive Care Unit (ICU).^[3] Kryter,^[4] in his book "Effects of Noise in Man," proposed that noise stimulates the reticular nervous system, leading to arousal responses of the central nervous system which tends to pain perception in different organs of the body. The existence of excessive noise in the ICU, such as the alarms of ventilators and heart monitors, additional noise caused by worn out air-conditioning devices, loud ringtones, and cases of medical staff arguing over patient's beds, which are sometimes inevitable, may cause sensory

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overload, delirium, psychosis, biological rhythm disorders, and hemodynamic disorders in patients.^[5] In this regard, few studies have been performed to investigate the effect of sound reduction on pain intensity.

In an interventional study, ear protective device was used for the patient on the first night after the heart surgery and examined its effect on sleep quality, pain intensity, and length of stay in the ICU. The results showed that despite receiving an equal dose of analgesics, the intervention group reported lower pain severity ($p = 0.047$).^[6] In Iran, only two studies have evaluated the effect of noise reduction on pain intensity in infants. These studies have examined the effect of ear protective devices on heart rate and pain caused by venous sampling in premature infants. According to the results of these two studies, the use of ear protective devices can be effective in reducing pain in premature infants during blood sampling.^[7,8] Pain control and sensory overload prevention are the top priorities of nursing care. Furthermore, very few studies have been performed in this field. Therefore, we aimed to determine the effect of two methods of using ear protective device on the pain intensity of patients undergoing CABG.

Materials and Methods

This three-group randomized clinical trial was conducted from October 2019 to February 2020. This study was registered in the Iranian Registry of Clinical Trials with the registration code of IRCT20120215009014N291. It was conducted on 84 patients undergoing CABG and hospitalized in the open-heart ICU at an educational hospital affiliated to Isfahan University of Medical Sciences, Iran. The inclusion criteria consisted of age >65 years, lack of deafness, lack of history of presbycusis and use of hearing aids, lack of history of diabetes, lack of drug addiction, and permission for using ear protective devices based on the diagnosis and discretion of the treating physician. The exclusion criteria consisted of any symptom of ear allergy. Based on a similar study,^[6] the estimated sample size was 75 patients, at a 95% Confidence Interval (CI) and 80% test power. Given the probable 10% drop in the samples, the number was considered to be 84 patients.

The sealed envelope method was used for random allocation. Thus, 84 cards were placed in an envelope (for the research samples to have an equal chance 28 cards with number 1, 28 cards with number 2, and 28 cards with number 3), and then, the participants were asked to select a card from the envelope. The patients with numbers 1, 2, and 3 were assigned to the A intervention group, the B intervention group, and the control group, respectively. Given the fact that in the first 24 h after the operation, patients are generally placed on a ventilator and are under general anesthesia, the intervention was performed 24 h after the surgery [Figure 1]. To prevent sensory deprivation, the ear protective devices (XPand ear protective devices made of soft polyurethane foam made by the CanaSafe

Company of Canada, with 32 dB noise reduction) were not continuously kept in the patients' ears, but were used in the two intervention groups in two different ways and at different times. Before the study, the ward nurses were trained by the researcher to place the ear protective devices in the patient's ear. In this study, because patients in the control and intervention groups were in adjacent beds in the ICU and observed the placement of the ear protective device, and only a limited number of nurses participated in the intervention, blinding was not possible. The normality of continuous data was evaluated using Kolmogorov–Smirnov (K–S) test.

Data were collected using a demographic characteristic questionnaire including questions on age, gender, marital status, history of diabetes, duration of surgery and duration of heart disease, and pain intensity as a Visual Analog Scale (VAS) score. The VAS is a 10 cm horizontal ruler, with the number 0 on the left side (showing no pain) and the number 10 on the right side (showing the most severe pain). The patients put a “x” on the ruler to indicate the intensity of their pain. Then, to determine the intensity of pain, from zero to the point marked by the patient is measured using a ruler. Scores of 8–10, 4–7, and <3 indicate severe pain, moderate pain, and mild pain, respectively.^[9] This tool has been used in many studies for measuring pain and fatigue in different patients including those undergoing CABG. Additionally, the scientific reliability of the tool has been confirmed with Cronbach's alpha coefficient of 0.89–0.919 for pain and 0.86–0.92 for fatigue.^[10]

The ear protective devices were used in the A intervention group, first, during the afternoon sleep between 2 and 5 pm, and then, once again during the night sleep from 10 pm to 6 am. This method was used based on the physiological cycles of adult sleep, which includes one afternoon sleep cycle, usually lasting 90 min and four to six night sleep cycles lasting 90 min.^[11] The ear protective devices were used in the B intervention group only during the night sleep from 10 pm to 6 am. It should be noted that the ear protective devices were removed only when necessary (such as for temperature control through the ear). Patients in the control group only underwent their usual pain management care, which included intravenous morphine sulfate injection if needed. Moreover, if the ear protective device was moved or removed by itself, the researcher or his/her colleague could put it back in its place. However, if the patient was asleep, he or she would not wake up at all to fix it. If the patient removed the ear protective device, he or she was free to decide whether to put it back or not. Using the VAS tool, the patients' pain was assessed and recorded once before the intervention, once again after the intervention in the next shift, and 3 h after taking the analgesic. For all patients, after weaning from the ventilator, pro re nata (PRN) range opioid analgesics (morphine sulfate 3–5 mg) orders were used to relieve pain. The collected data were analyzed and

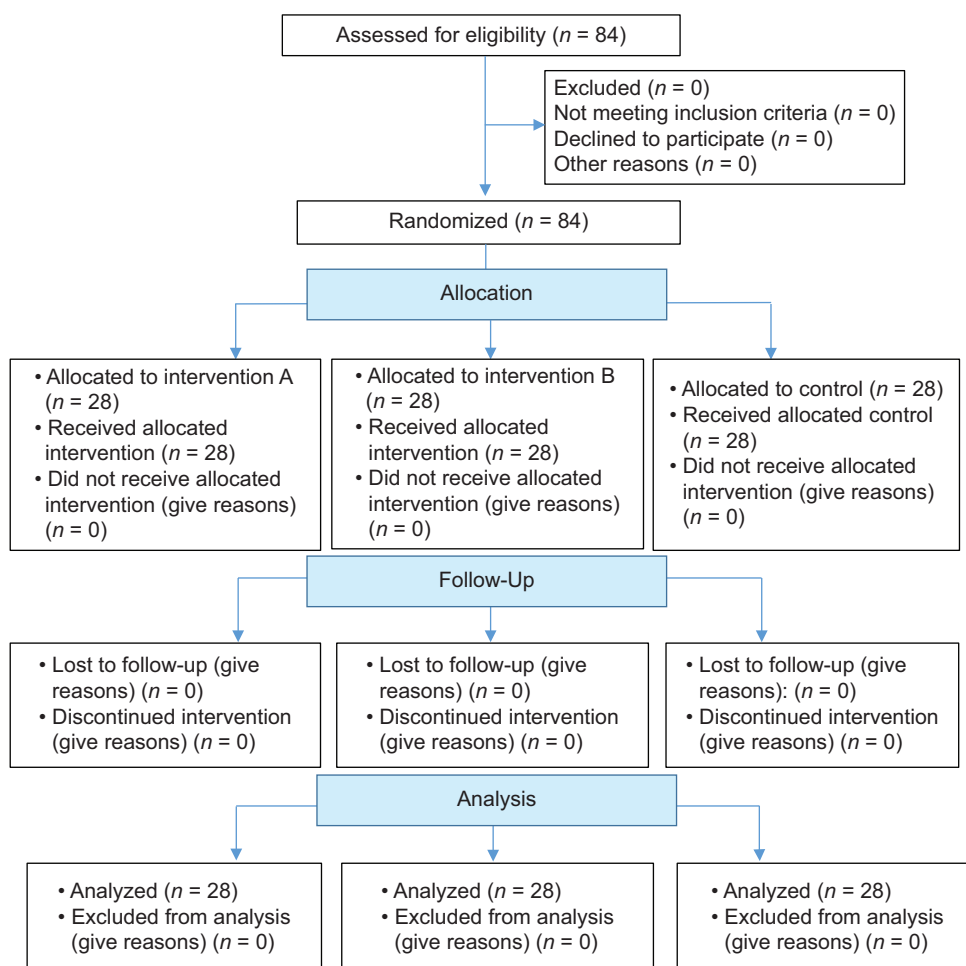


Figure 1: Consort flow diagram

compared using descriptive statistics including frequency, mean, percentage, and standard deviation and inferential statistics such as Chi-square, one-way Analysis of Variance (ANOVA), Fisher's Least Significant Difference (LSD), and paired sample *t*-test (pre-intervention and post-intervention). The data were analyzed using Statistical Package for the Social Sciences (SPSS) software (version 16.0; SPSS Inc., Chicago, IL, USA) at a significance level of <0.05 .

Ethical considerations

The Ethics Committee of Isfahan University of Medical Sciences approved this research (IR.MUI.RESEARCH.REC.1398.293). The participants were informed about the study's purpose and procedure. A written informed consent was obtained from each participant before beginning the study. Moreover, they were ensured that their information would remain confidential. They were also free to leave the study at any time.

Results

The present study was conducted on 84 patients (51.20% men). None of the participants were excluded during the study process. As shown in Table 1, all groups were

similar in terms of age, gender, duration of surgery, and duration of heart disease, and there was no statistically significant difference between them. The comparison of the mean score of pain intensity before and after the intervention in each group is shown in Table 2. The paired *t*-test showed that the mean score of pain intensity did not differ significantly in the control group before [6.54 (1.45)] and after [6.39 (1.54)] the intervention ($t_{27} = 1.16$; $p = 0.25$); however, in the two intervention groups, the mean score of pain intensity after the intervention was significantly lower than that before the intervention [Intervention A: 6.46 (1.71) to 3.39 (1.87); $t_{27} = 18.06$; $p < 0.001$] [Intervention B: 6.32 (1.36) to 4.46 (1.55); $t_{27} = 13.93$; $p < 0.001$]. Table 2 presents a comparison of the mean score of pain intensity between all three groups before and after the intervention. One-way ANOVA results showed that the mean score of pain intensity did not significantly differ between the three groups before the intervention [Intervention A: 6.46 (1.71); Intervention B: 6.32 (1.36); Control: 6.54 (1.45)] ($F_{2,81} = 0.14$; $p = 0.86$). Nevertheless, after the intervention a significant difference was observed between the three groups [Intervention A: 6.46 (1.71); Intervention

Table 1: Comparison of demographic variables in the study groups

Variable	Mean (SD)			One-way ANOVA		
	Intervention A (n=28)	Intervention B (n=28)	Control (n=28)	F	df	p
Age	52.79 (7.32)	52.50 (7.94)	50.75 (6.77)	0.63	2,81	0.54
Duration of surgery (h)	4.17 (0.97)	4.15 (0.86)	4.25 (0.96)	0.08	2,81	0.92
Duration of heart disease (year)	17.43 (2.89)	18.32 (10.06)	15.04 (10.43)	0.64	2,81	0.53
	n (%)			Chi-square statistic		
				χ^2	df	p
Gender						
Male	15 (53.6)	14 (50)	14 (50)	0.09	2	0.95
Female	13 (46.4)	14 (50)	14 (50)			

Table 2: Comparison of pain intensity between the study groups (before and after the intervention)

Time	Mean (SD)			One-way ANOVA			LSD* <i>post hoc</i>		
	Intervention A (n=28)	Intervention B (n=28)	Control (n=28)	F	df	p	A, B	0.020	
Before the intervention	6.46 (1.71)	6.32 (1.36)	6.54 (1.45)	0.14	2,81	0.86	A, C	<0.001	
After the intervention	3.39 (1.87)	4.46 (1.55)	6.39 (1.54)	23.37	2,81	<0.001	B, C	<0.001	
	t	df	p	t	df	p	t	df	p
Paired sample t-test	18.06	27	<0.001	13.93	27	<0.001	1.16	27	0.25

*Fisher's least significant difference

B: 6.32 (1.36); Control: 6.54 (1.45)] ($F_{2,81} = 23.37$; $p < 0.001$). The LSD *post-hoc* test indicated that after the intervention the mean score of pain intensity in group A was significantly lower than group B, and in group B was lower than the control group ($p < 0.05$) [Table 2].

Discussion

This study aimed to compare the effect of two methods of using ear protective devices on pain intensity in patients undergoing CABG. The results of the study indicated that the use of ear protective devices had a positive effect on reducing pain intensity in patients undergoing CABG. The results also indicated that the first method of using ear protective devices both during the afternoon and night sleep had a greater effect on reducing pain intensity in these patients. Few studies have been conducted around the world examining the effect of environmental interventions on the intensity of pain in adult patients, and most studies have focused on the impact of environmental interventions such as noise reduction and reduced contact on infant pain intensity. In recent years, only Menger *et al.*,^[6] in an interventional study, have examined the effect of using ear protective devices on sleep quality, pain intensity, and length of stay at the ICU on the first night after heart surgery. Their results showed that despite receiving an equal dose of analgesics, the pain intensity was lower in the intervention group ($p = 0.047$).^[6] The results of this study are in line with the results of our study.

Ayazi *et al.*^[7] in 2017 investigated the effect of ear protectors on the heart rate and pain caused by intravenous sampling in preterm infants. As the intervention results showed, the use of ear protectors was effective in reducing pain during venipuncture. The results of another study

by Baharlooei *et al.*^[8] also showed that the reduction of ambient noise by using ear protective devices in infants 30 min before to 30 min after blood sampling from the sole of the foot of the infant significantly reduced the intensity of pain in infants of the intervention group compared to those of the control group.

Pain control is one of the oldest needs of humans and is considered to be a high priority in nursing care. As a patient's right, pain control should be evaluated and managed by physicians and nurses.^[12] According to Nightingale, unnecessary noise pollution is the most brutal negative factor in providing patient care and can adversely affect the patient and others.^[13] Although pain management is one of the most important and most studied topics in the medical and healthcare professions, various studies still show that the issue of pain relief is not taken seriously by doctors and nurses.^[2,14,15]

In recent years, many changes have been made with regard to the use of light sedation the primary objective of which is, first, to relieve pain, and second, to help patients to be more conscious for early mobilization, getting out of bed, and having better communication with caregivers in ICUs. This approach is called early Comfort using Analgesia, minimal Sedatives, and maximal Humane care (eCASH).^[16] Therefore, for a better achievement of this goal and as drugs and other analgesics have minor to major side effects, the use of non-pharmaceutical techniques is recommended.^[17]

The results of this study showed that the use of ear protective devices as a non-invasive method can reduce the severity of pain in patients after CABG. Therefore, environmental interventions such as noise reduction can be

considered as a way of reducing the intensity of pain in patients after CABG.

One of the limitations of this study was the three-day stay of patients in the cardiothoracic surgery ICU after the surgery. This was a short time for performing the intervention. However, although the results in this situation were positive, the results would be more generalizable if the intervention was carried out over several consecutive days.

Conclusion

Based on the results of this study, the reduction of ambient noise by using ear protective devices can decrease the intensity of pain in patients after CABG. Pain management, now considered the fifth vital sign, is an important area of health care and nursing care. Therefore, in addition to pharmacological interventions to control pain, interventions such as reducing environmental sound can be considered as a non-invasive and applicable method in pain management of patients after CABG.

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Conflicts of interest

There are no conflicts of interest.

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