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Comparison of the Effect of Pressure Bracelet at P6 Point on Prevention of Nitroglycerin Infusion-Induced Headache in Patients Admitted to the Cardiac Intensive Care Unit

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ABSTRACT

Background: Nitroglycerin is a vital medication in cardiac intensive care units, but headache induced by it is a common and distressing complication that can lead to reduced patient cooperation and even treatment discontinuation. Acupressure at point P6 considered a non-pharmacological, safe, and cost-effective method. This study aimed to determine the effect of pressure band on point P6 on the prevention of nitroglycerin infusion-induced headache in patients hospitalized in the cardiac intensive care unit.

Methods: This study was a three-group parallel-randomized clinical trial conducted on 78 patients hospitalized in the cardiac intensive care unit of Farshchian Heart Hospital in Hamadan during 2024-2025. Patients were allocated using permuted block sampling method into three groups of 26 patients each: P6 pressure band group, sham group (band without pressure), and control group (routine care). Time of headache onset, headache severity (NRS scale), and vital signs including mean arterial pressure, heart rate, and oxygen saturation were measured at 0, 15, 30, 60, and 120 minutes after starting the infusion. Data analyzed using Kruskal-Wallis test, one-way ANOVA, Tukey's post hoc test, repeated measures ANOVA, and Friedman test.

Results: The mean time of headache onset in the pressure band group (101.92 minutes) was significantly longer than the sham group (73.27 minutes) and control group (54.96 minutes) ($P<0.001$). The mean headache severity in the pressure band group (0.62) was significantly lower than the sham group (2.15) and control group (3.69) ($P<0.001$). Mean arterial pressure at 15 and 30 minutes showed significant differences among the three groups ($P=0.026$ and $P=0.001$, respectively). Heart rate showed no significant difference among the groups. Oxygen saturation showed significant changes only in the pressure band group ($P=0.039$).

Conclusion: P6 point pressure band is an effective, safe, non-invasive, and cost-effective method for delaying the onset and reducing the severity of nitroglycerin infusion-induced headache in patients hospitalized in cardiac intensive care units. This method integrated into care protocols as an evidence-based nursing intervention.

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Introduction

Nitroglycerin is a vital and widely used medication in cardiac intensive care units for the treatment of patients with angina pectoris and heart failure. However, the use of this drug is often associated with the common and distressing side effect of headache, which occurs due to the dilation of cerebral blood vessels. This headache not only affects patients' quality of life and cooperation but also, in some cases, may lead to dose reduction or even discontinuation of treatment, thereby challenging the patient's primary therapeutic process. Conventional approaches used to control this headache, such as analgesic medications, may themselves cause additional side effects. Therefore, finding a non-pharmacological, safe, simple, and cost-effective method to prevent or reduce this complication has become an important clinical need in cardiac intensive care units.

In this context, complementary and noninvasive methods such as acupressure have attracted attention because of their simplicity and minimal risk. One promising approach in this field is the use of a pressure bracelet applied to the P6 point on the wrist. The P6 point well known in traditional medicine for reducing nausea, and there are reports suggesting its potential effects in reducing headaches and regulating vital signs. Despite the simplicity and low cost of this method, there is still insufficient research evidence to thoroughly evaluate its effect on preventing nitroglycerin-induced headache as well as its influence on basic vital signs such as blood pressure and heart rate in critically ill patients admitted to cardiac intensive care units. Therefore, the present study designed and conducted to determine the direct effect of this non-pharmacological method and to evaluate the potential role of this complementary intervention in improving patients' clinical experience and reducing treatment-related complications.

Significance of the Study: The necessity of conducting the present study entitled "The Effect of a Pressure Bracelet at the P6 Point on the Prevention of Nitroglycerin Infusion-Induced Headache in Patients Admitted to the Cardiac Intensive Care Unit" explained from several perspectives. Nitroglycerin is a standard and essential medication in cardiac care units for controlling angina pectoris and reducing cardiac preload; however, the common and debilitating side effect of headache poses a major challenge to optimal treatment. These headaches not only cause considerable discomfort and suffering for patients but may also lead to reduced patient cooperation, discontinuation of the medication by healthcare staff due to intolerance, and ultimately failure to achieve therapeutic goals. This situation highlights the urgent need for an effective and low-risk strategy to manage this common problem.

Current pharmacological approaches used to control these headaches may introduce additional side effects and increase the patient's medication burden during critical conditions. Therefore, focusing on non-pharmacological and low-risk approaches considered a clinical priority. In this regard, acupressure and stimulation of the P6 point—, which has a long history in managing symptoms such as nausea and headache—have proposed as promising options. Although the effectiveness of this point has well studied in conditions such as postoperative nausea, evidence regarding its use in preventing nitroglycerin-induced headache in the sensitive population of cardiac patients remains very limited. The use of a pressure bracelet as a noninvasive, cost-effective, and simple method has the potential applied as an independent or complementary nursing intervention alongside standard treatment. If proven effective, this method could improve patients' quality of life during hospitalization, increase treatment tolerance, and potentially reduce the length of hospital stay and healthcare costs by decreasing complications.

Therefore, conducting this study may fill an existing knowledge gap and provide a scientific basis for implementing a practical and safe strategy to enhance the quality of care for patients in cardiac intensive care units.

Research Background

Nadali et al. (2024) conducted a study entitled "The Effect of Acupressure at the Third Eye Point (EX-HN3) on Psychological Distress, Comfort, and Physiological Parameters in Patients Undergoing Coronary Angiography" in Tehran. This study designed as a randomized clinical trial involving patients undergoing coronary angiography. In this research, 70 patients randomly assigned to intervention and control groups. The intervention protocol included applying therapeutic pressure for 20 minutes at the Yintang point, while the control group received only standard medical care. Data collection tools included the Depression, Anxiety, and Stress Scale (DASS-21), the General Comfort Questionnaire (GCQ), and standard monitoring of vital signs, which completed before and after the intervention as well as after angiography. Data were analyzed using independent t-tests, chi-square tests, and repeated-measures analysis of variance in SPSS software, with a significance level set at 0.05.

The results showed that before the acupressure intervention, there were no statistically significant differences between the two groups. After the intervention, anxiety and stress scores, as well as patients' comfort levels, decreased significantly in the intervention group ($p<0.001$), while no significant change was observed in depression scores ($p=0.873$). In addition, significant reductions in blood pressure, respiratory rate, and heart rate

observed in the intervention group. The findings indicated that therapeutic pressure (acupressure) can reduce anxiety and stress in patients undergoing angiography and improve their comfort levels. Furthermore, this method leads to reductions in blood pressure, respiratory rate, and heart rate. Conducting further studies on different pressure points and on a larger scale with more detailed analysis is recommended (24).

Afshar et al. (2023) conducted a study titled "The Effect of P6 Acupressure on Nausea, Vomiting, and Comfort in Patients with Myocardial Infarction" in Hamadan. This study designed as a randomized, single-blind, placebo-controlled clinical trial. The aim of the study was to determine the effect of pressure therapy at the P6 point on reducing nausea and vomiting, improving comfort levels, and decreasing the need for antiemetic medications in patients with myocardial infarction. The study conducted on 90 patients with acute myocardial infarction who experienced persistent nausea despite receiving antiemetic medications. The patients divided into three groups: the acupressure group, the placebo group, and the control group. The acupressure group used a wristband with a pressure button, the placebo group received a similar wristband without a pressure button, and the control group received no wristband.

Data on nausea severity comfort level, frequency of nausea and vomiting, and retching collected before and after the intervention at different time points. In addition, the use of antiemetic medications during the 24 hours following the intervention evaluated. Patients in the acupressure group experienced a significant reduction in nausea severity, vomiting frequency, nausea episodes, and retching, as well as a significant increase in comfort levels at two, four, and six hours after the start of the intervention compared with the placebo and control groups ($P<0.05$). However, no significant difference observed between the placebo and control groups ($P>0.05$). During the 24 hours following the intervention, antiemetic medication use in the acupressure group was significantly lower than in the placebo and control groups ($P<0.05$). The results indicated that acupressure at the P6 point reduces nausea, vomiting, and retching while improving comfort levels in patients with myocardial infarction. This method therefore used as a useful complementary intervention in managing symptoms in these patients (25).

Methodology

Study Design: The present study conducted as a randomized, three-group parallel clinical trial including a control group.

Study Setting and Time: The study conducted in the Cardiac Intensive Care Unit of Farshchian Heart Hospital in Hamadan during the years 2024-2025.

Study Population and Sample: The study population consisted of all patients admitted to the cardiac intensive care unit of Farshchian Heart Hospital in Hamadan who were receiving nitroglycerin infusion. The study sample included eligible patients hospitalized in the cardiac intensive care unit who were receiving nitroglycerin infusion and met the inclusion criteria.

Materials Used

- ✓ Pressure bracelet (PSIBANDS).
- ✓ Pulse oximeter model (Proactive).
- ✓ Blood pressure monitor model (ALPK2).

Data Collection Tools and Validity/Reliability:

- ✓ **Demographic and Clinical Information Form:.**10 faculty members confirmed the content validity of this form.
- ✓ **Pressure Bracelet:** A PSIBANDS pressure bracelet used for each patient, with one bracelet allocated per patient to maintain hygiene.
- ✓ **Pulse Oximeter:** A Proactive pulse oximeter used to measure heart rate and oxygen saturation. Its reliability confirmed by the hospital's medical equipment engineering department.
- ✓ **Blood Pressure Monitor:** Blood pressure measured using an ALPK2 sphygmomanometer at time points of 0, 15, 30, 60, and 120 minutes after the intervention.

Sampling Method

In this study, permuted block randomization used to assign participants to three groups (A, B, and C). This method applied to maintain balance in the number of participants in each group during the data collection period and to prevent potential imbalance. Initially, block sizes considered as multiples of the number of groups (3, 6, or 12 participants per block) so that each block contained an equal number of participants in each group. To reduce predictability of assignments, block sizes were determined randomly and variably. For each block, one of the possible permutations of the three-group sequence randomly selected. In larger blocks (6 and 12 participants), permutations were generated as combinations of several three-participant sequences. The random allocation sequence generated by an independent researcher using statistical software and placed in sealed, numbered envelopes to ensure allocation concealment for evaluators. Thus, participants assigned according to the order of entry without any subjective influence. The study designed as single-blind, meaning that participants were unaware of the type of intervention they received, while evaluators were aware of the intervention type.

Sample Size and Calculation Method:
The sample size in this study was determined based on the study by Lee et al. (2008)**,** in which the effect size calculated as 0.95**.** Considering a type, I error probability of 5% and a statistical power of 90%**,** the minimum sample size for two groups estimated to be 50 participants. The calculations performed using G-Power software**.**

t tests – Means: Difference between two independent means (two groups)

Analysis:	A priori: Compute required sample size	
Input:	Tail(s)	= Two
	Effect size d	= 0.9519276
	α err prob	= 0.05
	Power (1−β err prob)	= 0.90
	Allocation ratio N2/N1	= 1
Output:	Noncentrality parameter δ	= 3.3655723
	Critical t	= 2.0106348
	Df	= 48
	Sample size group 1	= 25
	Sample size group 2	= 25
	Total sample size	= 50
	Actual power	= 0.9094773

Therefore, the minimum total sample size for the three groups considering a 10% attrition rate was determined to be 78 participants.

Characteristics of Research Units and Inclusion/Exclusion Criteria
Inclusion Criteria:

- ✓ Absence of an intravenous cannula (angiocatheter) in the wrist area (P6 region).
- ✓ Age between 18 and 75 years.
- ✓ Receiving nitroglycerin infusion for cardiac indications.
- ✓ Full consciousness (GCS=15).
- ✓ No skin disorders in the wrist area.
- ✓ No history of other diseases such as cancer, neurological disorders, or psychiatric conditions.
- ✓ No substance uses or addiction.
- ✓ Not pregnant.

Exclusion Criteria

- ✓ Patient's unwillingness to continue participation.
- ✓ Occurrence of acute cardiac or respiratory complications during the study.
- ✓ Sensitivity to materials used in the pressure bracelet or vaccaria seeds.
- ✓ Change in dosage or discontinuation of nitroglycerin infusion during the study.

Data Collection Procedure
After obtaining the ethics approval code and IRCT registration, the researcher introduced herself to Farshchian Heart Hospital and approached eligible patients. After identifying the individuals assigned to the study groups, the researcher personally explained the study procedure to the patients a few minutes prior to initiation of nitroglycerin infusion. After obtaining informed consent from the patient and their companion, eligible and willing participants assigned to one of the three groups according to the randomization method.
All procedures, potential side effects, expected outcomes, and the voluntary nature of participation thoroughly explained to the patients. It emphasized that their information would remain confidential and that they could withdraw from the study at any time for any reason. It is important to note that patients in all three groups were not restricted from receiving analgesic medications at any stage of the study.
Based on the above, patients assigned to the following groups:

- ✓ Group A (P6 Pressure Bracelet): Stimulation of the P6 point using a disposable pressure bracelet.
- ✓ Group B (Sham Pressure Bracelet): Use of a pressure bracelet without applying actual pressure on the wrist.
- ✓ Group C (Control): Receiving routine standard care without any intervention.

The research procedures carried out as follows
Intervention in Group A (P6 Pressure Bracelet)
In this group, the P6 point located three cun below the wrist crease between the flexor tendons was stimulated. The researcher received supervised training from the consultant, Dr. Biglar Khani, to locate the point and provided with a certification of competency.
After cleaning the patient's wrist with soap and water, identical disposable pressure bracelets applied on the arm with the intravenous cannula. The pressure adjusted so that the patient clearly felt pressure but did not experience discomfort or numbness. The bracelet applied from the beginning

of nitroglycerin infusion and remained in place for 120 minutes.

If the patient developed a headache, they were excluded from the headache-assessment process but continued to have their vital signs monitored at 0, 15, 30, 60, and 120 minutes.

Intervention in Group B (Sham Pressure Bracelet)

In this group, the P6 point identified in the same manner. After cleaning the wrist, identical disposable bracelets applied to the arm with the intravenous cannula, but the screw mechanism that creates pressure left unfastened**,** meaning no actual pressure applied.

The bracelet remained in place for 120 minutes from the start of nitroglycerin infusion. If a headache occurred, the patient removed from the pain-assessment portion but continued vital-sign monitoring at the specified time intervals.

Intervention in Group C (Control Group)

Patients in the control group received only routine standard care with no additional intervention. Their vital signs assessed and recorded at 0, 15, 30, 60, and 120 minutes after initiation of nitroglycerin infusion. This group served as a benchmark to compare the effectiveness of the interventions.

Study Outcomes

Primary Outcome

- ✓ Time to onset of headache (in minutes) from the beginning of nitroglycerin infusion until the patient reports headache.

Secondary Outcomes:

- ✓ Vital signs (mean arterial pressure, heart rate, oxygen saturation) at 0, 15, 30, 60, and 120 minutes after the start of the intervention.

Data Analysis

In this study, the collected data were analyzed using SPSS version 26**.**

- ✓ **Descriptive statistics**
  - o Mean and standard deviation for normally distributed quantitative data.
  - o Median and interquartile range for non-normal quantitative data.
  - o Frequency and percentage for qualitative data.
- ✓ **Inferential statistics**
  - o One-way ANOVA for comparing normally distributed quantitative variables across the three groups.
  - o Tukey post-hoc test for pairwise group comparisons.
  - o Repeated-measures ANOVA for within-group comparison of normally distributed data over time.
  - o Kruskal Wallis test for non-normally distributed quantitative variables across groups.
  - o Friedman test for within-group comparison of non-normal variables over time.
  - o Chi-square test or Fisher's exact test (as needed) for qualitative variables.

A significance level of 0.05 considered for all analyses.

Results

Descriptive statistics for quantitative and qualitative variables according to subgroup analysis objectives across the three groups are as follows:

(Your next content would continue here)

gender

intervention's			Frequency	Percent	Valid Percent	Cumulative Percent
CONTROL	Valid	female	12	46.2	46.2	46.2
		male	14	53.8	53.8	100.0
		Total	26	100.0	100.0	
SHAM	Valid	female	15	57.7	57.7	57.7
		male	11	42.3	42.3	100.0
		Total	26	100.0	100.0	
BRACELET	Valid	female	11	42.3	42.3	42.3
		male	15	57.7	57.7	100.0
		Total	26	100.0	100.0	

Marital

intervention's			Frequency	Percent	Valid Percent	Cumulative Percent
CONTROL	Valid	Single	1	3.8	3.8	3.8
		Married	23	88.5	88.5	92.3

		Widowed	2	7.7	7.7	100.0
		Total	26	100.0	100.0	
SHAM	Valid	Single	3	11.5	11.5	11.5
		Married	20	76.9	76.9	88.5
		Widowed	3	11.5	11.5	100.0
		Total	26	100.0	100.0	
BRACELET	Valid	Single	4	15.4	15.4	15.4
		Married	21	80.8	80.8	96.2
		Widowed	1	3.8	3.8	100.0
		Total	26	100.0	100.0	

Location

intervention's			Frequency	Percent	Valid Percent	Cumulative Percent
CONTROL	Valid	Hamedan	16	61.5	61.5	61.5
		Others city	7	26.9	26.9	88.5
		Etc.	3	11.5	11.5	100.0
		Total	26	100.0	100.0	
SHAM	Valid	Hamedan	16	61.5	61.5	61.5
		Others city	7	26.9	26.9	88.5
		Etc.	3	11.5	11.5	100.0
		Total	26	100.0	100.0	
BRACELET	Valid	Hamedan	18	69.2	69.2	69.2
		Others city	7	26.9	26.9	96.2
		Etc.	1	3.8	3.8	100.0
		Total	26	100.0	100.0	

Education

intervention's			Frequency	Percent	Valid Percent	Cumulative Percent
CONTROL	Valid	Illiterate	6	23.1	23.1	23.1
		Below Diploma	9	34.6	34.6	57.7
		Diploma	4	15.4	15.4	73.1
		Educational Level	7	26.9	26.9	100.0
		Total	26	100.0	100.0	
SHAM	Valid	Illiterate	2	7.7	7.7	7.7
		Below Diploma	5	19.2	19.2	26.9
		Diploma	8	30.8	30.8	57.7
		Educational Level	11	42.3	42.3	100.0
		Total	26	100.0	100.0	
BRACELET	Valid	Illiterate	4	15.4	15.4	15.4
		Below Diploma	10	38.5	38.5	53.8
		Diploma	5	19.2	19.2	73.1
		Educational Level	7	26.9	26.9	100.0
		Total	26	100.0	100.0	

Drugs

Intervention's	Frequency	Percent	Valid Percent	Cumulative Percent

CONTROL	Valid	NO.	26	100.0	100.0	100.0
SHAM	Valid	NO.	26	100.0	100.0	100.0
BRACELET	Valid	NO.	26	100.0	100.0	100.0

Comparison of Headache Onset Time among the Three Groups:

Normality Assessment:

Tests of Normality

	intervention.g	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
		Statistic	df	Sig.	Statistic	df	Sig.
time_headache_m	CONTROL	.374	26	.000	.652	26	.000
	SHAM	.296	26	.000	.700	26	.000
	BRACELET	.431	26	.000	.640	26	.000

a. Lilliefors Significance Correction

Not normal.

Kruskal–Wallis test for comparison:

Ranks

	intervention.g	N	Mean Rank
time_headache_m	CONTROL	26	25.42
	SHAM	26	40.08
	BRACELET	26	53.00
	Total	78	

Test Statistics[a,b]

	time_headache_m
Kruskal-Wallis H	21.600
df	2
Asymp. Sig.	.000

a. Kruskal Wallis Test

b. Grouping Variable: intervention.g

The headache onset time differs among the three groups.

Comparison of headache intensity (NRS score) among the three groups:

Tests of Normality

	intervention.g	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
		Statistic	df	Sig.	Statistic	df	Sig.
NRS	CONTROL	.268	26	.000	.787	26	.000
	SHAM	.286	26	.000	.782	26	.000
	BRACELET	.419	26	.000	.642	26	.000

a. Lilliefors Significance Correction

Test Statistics[a,b]

	NRS
Kruskal-Wallis H	20.386
df	2
Asymp. Sig.	.000

a. Kruskal Wallis Test

b. Grouping Variable: intervention.g

Comparison of vital signs (MAP, heart rate, and oxygen saturation) among the three groups at different time points:

Tests of Normality

	intervention.g	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
		Statistic	df	Sig.	Statistic	df	Sig.

T0_MAP	CONTROL	.159	26	.090	.971	26	.641
	SHAM	.171	26	.049	.934	26	.094
	BRACELET	.128	26	.200*	.947	26	.196
T15_MAP	CONTROL	.130	26	.200*	.973	26	.695
	SHAM	.117	26	.200*	.966	26	.527
	BRACELET	.179	26	.031	.946	26	.184
T30_MAP	CONTROL	.128	26	.200*	.952	26	.259
	SHAM	.175	26	.040	.949	26	.222
	BRACELET	.159	26	.089	.937	26	.112
T60_MAP	CONTROL	.108	26	.200*	.973	26	.707
	SHAM	.157	26	.098	.943	26	.156
	BRACELET	.122	26	.200*	.947	26	.198
T120_MAP	CONTROL	.144	26	.174	.979	26	.854
	SHAM	.209	26	.005	.900	26	.056
	BRACELET	.132	26	.200*	.973	26	.703
T0_SPO	CONTROL	.245	26	.000	.867	26	.003
	SHAM	.210	26	.005	.876	26	.005
	BRACELET	.193	26	.014	.915	26	.034
T15_SPO	CONTROL	.233	26	.001	.858	26	.002
	SHAM	.243	26	.000	.878	26	.005
	BRACELET	.237	26	.001	.856	26	.002
T30_SPO	CONTROL	.256	26	.000	.852	26	.002
	SHAM	.248	26	.000	.878	26	.005
	BRACELET	.306	26	.000	.833	26	.001
T60_SPO	CONTROL	.327	26	.000	.819	26	.000
	SHAM	.251	26	.000	.831	26	.001
	BRACELET	.272	26	.000	.784	26	.000
T120_SPO	CONTROL	.255	26	.000	.887	26	.008
	SHAM	.243	26	.000	.866	26	.003
	BRACELET	.304	26	.000	.844	26	.001
T0_HR	CONTROL	.122	26	.200*	.988	26	.987
	SHAM	.083	26	.200*	.977	26	.800
	BRACELET	.110	26	.200*	.973	26	.693
T15_HR	CONTROL	.104	26	.200*	.984	26	.950
	SHAM	.126	26	.200*	.976	26	.773
	BRACELET	.117	26	.200*	.971	26	.652
T30_HR	CONTROL	.092	26	.200*	.982	26	.915
	SHAM	.110	26	.200*	.975	26	.743
	BRACELET	.082	26	.200*	.973	26	.703
T60_HR	CONTROL	.145	26	.169	.969	26	.601
	SHAM	.085	26	.200*	.978	26	.821
	BRACELET	.110	26	.200*	.974	26	.721
T120_HR	CONTROL	.105	26	.200*	.982	26	.920
	SHAM	.085	26	.200*	.979	26	.851
	BRACELET	.131	26	.200*	.976	26	.776

*. This is a lower bound of the true significance.
a. Lilliefors Significance Correction

The green values are normally distributed. The yellow values are not normally distributed (SpO_2 at different time points in the groups is not normally distributed).

ANOVA test for comparison of MAP and HR:

ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
T0_MAP	Between Groups	15.487	2	7.744	.580	.562
	Within Groups	1001.346	75	13.351		

	Total	1016.833	77			
T15_MAP	Between Groups	100.795	2	50.397	3.843	.026
	Within Groups	983.577	75	13.114		
	Total	1084.372	77			
T30_MAP	Between Groups	182.333	2	91.167	8.194	.001
	Within Groups	834.500	75	11.127		
	Total	1016.833	77			
T60_MAP	Between Groups	57.333	2	28.667	2.556	.084
	Within Groups	841.038	75	11.214		
	Total	898.372	77			
T120_MAP	Between Groups	26.949	2	13.474	1.221	.301
	Within Groups	827.731	75	11.036		
	Total	854.679	77			
T0_HR	Between Groups	34.564	2	17.282	.324	.725
	Within Groups	4004.769	75	53.397		
	Total	4039.333	77			
T15_HR	Between Groups	217.923	2	108.962	1.947	.150
	Within Groups	4196.231	75	55.950		
	Total	4414.154	77			
T30_HR	Between Groups	327.000	2	163.500	2.855	.064
	Within Groups	4294.538	75	57.261		
	Total	4621.538	77			
T60_HR	Between Groups	265.949	2	132.974	2.553	.085
	Within Groups	3906.000	75	52.080		
	Total	4171.949	77			
T120_HR	Between Groups	73.000	2	36.500	.671	.514
	Within Groups	4082.538	75	54.434		
	Total	4155.538	77			

Oxygen Saturation (SpO_2)

In the control group**,** there was no statistically significant difference in SpO_2 across the five measurement stages. In other words, oxygen saturation in these patients did not change significantly over time**.**

Similarly, in the sham group**,** no significant difference in SpO_2 observed across the five measurement stages.

However, in the main intervention group (pressure bracelet)**,** a statistically significant difference in SpO_2 was observed across the five measurement stages.

Discussion

The present study conducted to determine the effect of a pressure bracelet applied at the P6 point on the prevention of nitroglycerin infusion-induced headache in patients admitted to the Cardiac Intensive Care Unit (CCU) of Farshchian Heart Hospital in Hamadan**.** This study was designed and implemented as a three-group randomized clinical trial (P6 pressure bracelet intervention group, sham group, and control group) with a total sample size of 78 patients (26 patients in each group)**.**

The findings of this study demonstrated a significant and positive effect of using a pressure bracelet at the P6 point on reducing nitroglycerin-induced headache and improving some physiological indicators in cardiac patients**.** In this section, the research findings discussed and interpreted in comparison with previous studies. Finally, the overall conclusion, practical recommendations, and limitations of the study are presented.

Demographic Findings

According to the descriptive findings, the gender distribution among the study groups relatively balanced. In the control group, 53.8% were male and 46.2% were female**;** in the sham group, 42.3% were male and 57.7% were female**;** and in the pressure bracelet group, 57.7% were male and 42.3% were female. This distribution is consistent with similar studies on acupressure in cardiac patients. For example, in the study conducted by Afshar et al. (2023) on patients with myocardial infarction in Hamadan, a similar gender distribution reported.

The mean age of patients was 63.35 years in the control group, 58.85 years in the sham group, and 60.69 years in the pressure bracelet group**.** This age range corresponds with the typical population of patients admitted to cardiac intensive care units, who are generally in their sixth and seventh decades of life**.** Previous studies, such as the research by Nadali et al. (2024) in Tehran, also reported a similar age range among patients undergoing coronary angiography.

Other demographic variables such as marital status, education level, occupation, income, and place of residence did not show substantial differences across the three groups, indicating that the groups were homogeneous with respect to these characteristics**.** This homogeneity achieved through permuted block randomization and random allocation of patients**,** which strengthens the validity of the study results.

Clinical Characteristics of Patients

Regarding the history of cardiovascular disease**,** 57.7% of patients in the control group**,** 57.7% in the sham group**,** and 69.2% in the pressure bracelet group reported a history of heart disease.

Additionally, 61.5% of patients in the control group**,** 53.8% in the sham group**,** and 73.1% in the pressure bracelet group reported a history of previous hospitalization**.**

These findings indicate that most participants had prior cardiac disease and hospitalization, which is consistent with the chronic nature of cardiovascular diseases and the need for specialized care in CCU settings.

Regarding the history of headache prior to hospitalization**,** 46.2% of the control group**,** 30.8% of the sham group**,** and 26.9% of the pressure bracelet group reported a previous history of headache. Although these differences were not statistically significant (due to random allocation), the presence of a headache history in some patients may be considered a potential confounding variable. In similar studies, such as the research by Moradi et al. (2022) in Isfahan, attention to patients' headache history has also emphasized as one of the inclusion and exclusion considerations**.**

Regarding the use of other medications**,** 80.8% of patients in both the control and pressure bracelet groups, and 73.1% of patients in the sham group, were receiving medications other than nitroglycerin. This high level of concomitant medication use is common and expected among CCU patients, as these patients are typically treated with multiple cardiovascular and non-cardiovascular drugs simultaneously**.**

Effect of the P6 Pressure Bracelet on the Time of Headache Onset

One of the most important findings of this study was the significant difference in the time of headache onset among the three study groups**.** The Kruskal–Wallis test yielded a value of 21.600 with a significance level of 0.001**,** indicating a statistically significant difference in headache onset time among the groups.

Specifically, the mean time to headache onset was:

- ✓ 54.96 minutes in the control group.
- ✓ 73.27 minutes in the sham group.
- ✓ 101.92 minutes in the P6 pressure bracelet group.

These findings indicate that the use of a pressure bracelet at the P6 point significantly delayed the onset of nitroglycerin-induced headache**.** In other words, patients who used the actual pressure bracelet experienced headache nearly twice as late as those in the control group**.**

This delay in headache onset is clinically important, as it allows patients to receive a more effective dose of nitroglycerin without experiencing the adverse effect of headache**.**

These findings are consistent with previous studies investigating the effectiveness of P6 acupressure in reducing various symptoms**.** In the study by Afshar et al. (2023) conducted in Hamadan, acupressure at the P6 point significantly reduced nausea severity, vomiting frequency, and increased comfort levels in patients with myocardial infarction.

Similarly, the study by Unlu and Kaya (2018) in Turkey demonstrated that applying pressure to the P6 point using a wristband was effective in preventing vomiting and improving patient comfort**.** In a systematic review by Lee et al. (2009)**,** stimulation of the P6 point significantly reduced postoperative nausea and vomiting**.** Although the present study focuses on nitroglycerin-induced headache rather than nausea**,** a similar mechanism involving the autonomic nervous system may explain this effect.

From a physiological perspective, this finding explained through several mechanisms. First, stimulation of the P6 point may modulate sympathetic and parasympathetic nervous system activity**,** thereby altering the vascular response to nitroglycerin. Nitroglycerin causes the release of nitric oxide (NO)**,** which leads to cerebral vasodilation and headache**.** Acupressure may reduce vascular responsiveness to nitric oxide or modulate pain pathways, thereby delaying headache onset **(**Brunton et al.,2018**).**

Second, stimulation of the P6 point may lead to the release of endorphins and other endogenous analgesic substances**,** increasing the pain threshold and consequently delaying the onset of headache.

Comparison of the Sham Group with the Control and Intervention Groups

One of the strengths of the present study was the inclusion of a sham (placebo) group alongside the control group. The findings showed that variables such as time to headache onset (73.27 minutes in the sham group versus 54.96 minutes in the control group, 101.92 minutes in the intervention group). And headache intensity (2.15 in the sham group versus 3.69 in the control group, 0.62 in the intervention group) the sham group performed better than the control group but weaker than the intervention group**.**

Although the numerical differences between the sham and control groups were not statistically significant (as indicated by Tukey's post-hoc test,

P>0.05 for most comparisons between the sham and control groups), the presence of these numerical differences suggests the possibility of a placebo effect**.**

The placebo effect is a well-recognized phenomenon in acupressure studies, and some investigations, such as the study by Afshar et al. (2023)**,** similarly reported no statistically significant differences between sham and control groups. The importance of including a sham group lies in its ability to distinguish the true effectiveness of the intervention from psychological and expectancy effects**.**

Given that the sham group in the present study did not differ significantly from the control group, it concluded that the observed effects in the intervention group were primarily attributable to the genuine physiological effects of P6 point stimulation**,** rather than being solely due to placebo effects.

Possible Mechanisms of Action of the P6 Pressure Bracelet

Based on the findings of the present study and previous research, several potential mechanisms may explain the effect of the P6 pressure bracelet in preventing nitroglycerin-induced headache:

Modulation of the Autonomic Nervous System: In traditional Chinese medicine, the P6 point recognized as having a regulatory effect on the autonomic nervous system. Stimulation of this point may modulate the balance between the sympathetic and parasympathetic nervous systems**,** thereby altering the vascular response to nitroglycerin. Nitroglycerin induces headache by releasing nitric oxide (NO)**,** which leads to cerebral vasodilation. Acupressure may reduce vascular responsiveness to NO, thereby decreasing the extent of vasodilation and subsequent headache **(**Brunton et al.,2018**).**

Release of Endogenous Analgesic Substances: Stimulation of acupressure points may lead to the release of endorphins and enkephalins within the central nervous system. These substances bind to opioid receptors, increase the pain threshold, and reduce pain perception **(**Micozzi,2018**).** This mechanism may explain the significant reduction in headache intensity observed in the intervention group.

Effects on Cerebral Blood Flow: Some studies suggest that acupressure may influence cerebral blood flow. Since nitroglycerin-induced headache primarily caused by increased cerebral blood flow, modulation of this flow may contribute to headache prevention.

Anti-Inflammatory Effects: There is evidence indicating that acupressure may exert anti-inflammatory effects by reducing levels of inflammatory cytokines. Vascular inflammation is one of the contributing factors in headache development, and its reduction may help prevent headache.

Sedative and Stress-Reducing Effects: Patients admitted to CCUs commonly experience high levels of stress and anxiety. The study by Nadali et al. (2024) demonstrated that acupressure can reduce patients' anxiety and stress levels. Reduced stress may, in turn, increase the pain threshold and decrease headache severity.

Clinical Significance of the Findings

The findings of this study have several important clinical implications:

First**,** nitroglycerin-induced headache is one of the most common adverse effects of this vital medication and may lead to dose reduction, treatment discontinuation, or prolonged hospitalization. The use of the P6 pressure bracelet as a non-pharmacological, safe, and low-cost method can substantially reduce this adverse effect. In the present study, the use of the pressure bracelet resulted in an approximately 83% reduction in headache intensity and an 85% increase in time to headache onset**.**

Second**,** the pressure bracelet method is simple and easily performed by either patients or nurses. Unlike acupuncture, which requires specialized skills and equipment, the pressure bracelet used with minimal training, making it readily implementable in various hospital settings.

Third**,** the side effects of this method are rare and minimal**.** In the present study, no significant adverse effects reported. In contrast, commonly used headache medications such as nonsteroidal anti-inflammatory drugs may cause adverse effects including gastrointestinal bleeding, renal dysfunction, and drug interactions **(**Twiner et al.,2022**).**

Fourth**,** the P6 pressure bracelet may have a synergistic effect with nitroglycerin in reducing blood pressure**.** In this study, greater reductions in blood pressure observed in the intervention group at 15 and 30 minutes after the initiation of infusion. However, excessive blood pressure reduction may be hazardous; therefore, careful blood pressure monitoring is recommended when using this method concurrently.

Fifth**,** the low cost of this method (approximately 1,450,000 Iranian Rials per bracelet**)** compared with the cost of analgesic medications and complications associated with nitroglycerin discontinuation makes it a cost-effective option**.** The total cost of purchasing 40 pressure bracelets for this study was approximately 62,000,000 Iranian Rials**,** which is negligible compared to treatment-related complication costs.

Study Limitations

Despite its strengths, the present study had several limitations that considered when interpreting the findings:

- ✓ **Single-blind design:** The study conducted as a single-blind trial, meaning that patients were unaware of group allocation, but evaluators were informed. This may have introduced measurement bias, particularly in assessing headache intensity. Although a double-blind design would have been ideal, it was difficult to implement due to the nature of the intervention (presence or absence of pressure).
- ✓ **Incomplete control of confounding variables:** Despite randomization, some confounders such as concurrent use of analgesics or sedatives and a history of migraine—may have influenced the results. Although patients who had used analgesics within 6 hours prior to the study excluded, the effects of long-term medication use not fully controlled.
- ✓ **Limited generalizability:** The study conducted in a single center (Farshchian Heart Hospital, Hamadan) and included patients with specific conditions (no intravenous catheter at the P6 site, full consciousness, and age range of 18–75 years). Therefore, generalization to other patient populations made with caution.
- ✓ **Relatively small sample size:** Although the sample size was determined based on statistical calculations, 78 patients (26 per group) may not provide sufficient power to detect subtle between-group differences. Future studies with larger sample sizes recommended.
- ✓ **Short follow-up duration:** Patients followed for only 120 minutes after the initiation of nitroglycerin infusion. It remains unclear whether the benefits of the pressure bracelet persist beyond this period.
- ✓ **Lack of biochemical and neurohormonal measurements:** Measuring levels of endorphins, cortisol, and other neurochemical mediators would have provided a deeper understanding of the underlying mechanisms. This study focused primarily on clinical outcomes, and these intermediary variables not assessed.

Conclusion

The present study designed, conducted to evaluate the effect of a P6 pressure bracelet on the prevention of nitroglycerin-induced headache in patients admitted to the cardiac intensive care unit**.** In summary, the findings demonstrated that:

- ✓ The use of a P6 pressure bracelet significantly delayed the onset of nitroglycerin-induced headache (from 54.96 minutes in the control group to 101.92 minutes in the intervention group, $P < 0.001$).
- ✓ Headache intensity was significantly lower in patients using the pressure bracelet compared with both the control and sham groups (mean NRS score: 0.62 vs. 3.69 in the control group, $P < 0.001$).
- ✓ The P6 pressure bracelet may exert a synergistic effect with nitroglycerin in reducing blood pressure**,** particularly at 15 and 30 minutes after infusion initiation.
- ✓ The intervention had no significant effect on heart rate, indicating no undesirable interference with cardiovascular compensatory mechanisms.
- ✓ A relative improvement in oxygen saturation observed in the intervention group, possibly reflecting improved tissue perfusion.
- ✓ The sham group did not differ significantly from the control group in the main outcomes, indicating that the observed effects were largely due to the true physiological impact of P6 stimulation rather than placebo effects**.**

Overall, the findings suggest that the P6 pressure bracelet is an effective, safe, non-invasive, simple, and low-cost method for preventing nitroglycerin-induced headache in CCU patients. This method implemented as an independent, evidence-based nursing intervention alongside standard pharmacological treatments.

Given the critical role of nitroglycerin in cardiac patient management and the common and distressing adverse effect of headache, introducing an effective non-pharmacological intervention may significantly enhance patient comfort, treatment adherence, and overall clinical outcomes. From a health economics perspective, reducing the need for analgesics, shortening hospital stays, and preventing treatment discontinuation may contribute to lowering healthcare costs.

Nevertheless, further studies with larger sample sizes, double-blind designs, longer follow-up periods, and multicenter settings recommended to confirm, expand upon these findings. Future research should also focus on elucidating the precise mechanisms of action, comparing this intervention with other non-pharmacological approaches, and evaluating its effectiveness in different patient subgroups. Ultimately, it hoped that the findings of this study represent a meaningful step toward improving the quality of nursing care and the clinical experience of cardiac patients**,** while encouraging further research in the valuable field of complementary and integrative therapies in critical care settings.

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Authors' Contributions

All authors contributed to data analysis, drafting, and revising of the paper and agreed to be responsible for all the aspects of this work.

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