Effect of Cryotherapy on Pain Intensity for Patients Undergoing Arterial Sheath Removal After Percutaneous Coronary Intervention: A Randomized Controlled Trial

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ABSTRACT
Introduction: Coronary artery disease is the main cause of mortality globally, making up approximately 33% of all deaths Patients with coronary artery disease experience pain and discomfort post-percutaneous coronary intervention after the femoral catheter is removed, which might raise the patient's duration of hospitalisation and the hospital's costs. Aims: The purpose of the study is to evaluate the effect of cryotherapy on the degree of pain that patients who have had their arterial sheath removed after percutaneous coronary intervention felt. Methods: A test-and-retest design in a randomised controlled trial was conducted from January 7, 2024, to February 19, 2024, at Babylon Centre/Imam Al-Sadiq Hospital. A probability (simple random) sampling method was used in a two-group design, with 50 patients in each group as a control and cryotherapy group, and evaluating pain levels utilizing the visual analogue scale. Descriptive and inferential statistics were used in data analysis frequency, percentage, mean, paired sample t-test, standard deviation, and ANOVA. Results: This stated the mean pain level was similar before cryotherapy. However, after cryotherapy, the level of pain in the cryotherapy group was significantly less than that of the control group (2.38± 5.1 vs. 23.34± 11.5), respectively. P = 0.000 (<0.05) demonstrating a statistically significant variation. Conclusions: According to the study, cryotherapy applied to the femoral sheath region assisted the percutaneous coronary intervention patients feel less pain when their femoral catheter was removed. In these situations, a local cold gel bag may be advised as a nursing intervention for pain management.

1. Introduction

Coronary artery disease is the leading cause of mortality globally, in 2021 heart disease causes 17.9 million deaths every year, making up approximately 33% of all deaths (WHO, 2021) (Hassan and Al-Fayyadh, 2023). It is projected that by 2030, that number will have risen to over 23.6 million, more than the deaths from cancer and chronic lung illnesses combined (Huang et al., 2019). Coronary artery disorders are The primary cause of illness and death in both industrialized and underdeveloped countries; Additionally, they are responsible for about 129 million disability-adjusted life years (Ralapanawa and Sivakanesan, 2021). Iraq is one of the highest 25 Middle Eastern countries, with CAD fatality rates adjusted for age of over 214 per 100,000 persons (Raheem, 2023).

Percutaneous coronary intervention (PCI) is the most utilised technique for treating the condition of coronary arteries to enhance myocardial perfusion (Khan and Ludman, 2022) (Mousa and Mansour, 2020). Originally developed as a non-surgical method in 1977, percutaneous coronary intervention, or PTCA, is also known as percutaneous transluminal coronary angioplasty, Andreas Gru¨ntzig carried out the first balloon coronary angioplasty in Zurich (Maktoof and Abd, 2018). This includes revascularization of the coronary artery using procedures like stent insertion and balloon angioplasty to increase the perfusion of the coronary arteries (Hussein and Mohammed, 2022), which is widely accepted as an effective way to treat coronary artery disease (Kurt and Kaşıkçı, 2019) (Khan and Ludman, 2022). That involves making a small incision in the skin and introducing a catheter into the lumen of the artery to open blocked or constricted coronary arteries (Wicaksono and Djamil, 2020).

When the catheter was being withdrawn, 99% of the patients experienced pain (Kurt and Kaşıkçı, 2019). Pain is a significant global health problem that has to be managed (Majeed et al., 2023). Many patients experience discomfort and pain when a catheter that was previously inserted in the femoral area is removed, and between 29% and 65% of patients experience local problems (Kurt and Kaşıkçı, 2019) (Sokhanvar et al., 2023). Pain increases the body's sympathetic nervous system, causing a rise in cortisol, anti-diuretic hormones, catecholamine, immune suppression, and hemodynamic alterations. Breathing issues might result from discomfort that is not managed and psychological problems such as stress and anxiety (Bachi and AL-Fayyadh, 2022), and increased heart rate, blood pressure, and oxygen demand, all of which have the potential to cause myocardial infarction, ischemia, and left ventricular dysfunction. The patient is more likely to move after the arterial sheath is removed because of severe pain, which raises the risk of vascular events (Vagharseyyedin et al., 2022).

Pain management strategies including pharmaceuticals, like lidocaine infiltration or morphine sulphate treatment, can be employed to treat pain following femoral catheter removal. However, it has also been mentioned that these procedures may have side effects like more bleeding, infections, transient nerve damage, and catheter punctures. Pain can be reduced with the use of non-pharmacological methods(Ali, Kadhim and Khachian, 2023).

Cryotherapy, often known as cold application (Ramadan et al., 2016), is one non-pharmacological approach to pain management. Applying ice is one of the simplest and oldest ways to manage pain. It lowers the speed at which pain signals are transferred via nerve fibres from the peripheral to the central nervous system, raising the threshold for pain (Bayındır, Çürük and Oguzhan, 2017). Cold application is an easy and inexpensive method to reduce painful sensations (Al-Jubouri et al., 2024), other benefits of cold application are low side effects rate, and convenience of application and commonly used because of the physiological effects of cold, which include vasoconstriction, slower tissue metabolism, and local anaesthesia (Kurt and Kaşıkçı, 2019). The nurses play a vital role in professional pain management teams, participating in pain assessment and management (Majeed, Hassan and Abid, 2020). Pain management involves using pharmaceutical and non-pharmacological methods (Abd-Alrazzaq and Aziz, 2021). Effective pain management is key to providing patients with high-quality care (Hasan and Hussein, 2020).

This study aimed to determine if applying cryotherapy could reduce pain following arterial sheath removal after PCI. This was due to the rising use of catheterization in the management of heart disease and its consequences. It was also carried out to comprehend the lack of knowledge about the effectiveness of this method of minimizing pain following the procedure. Also, locally in Iraq, there is no study examining cryotherapy's impact on sheath removal pain, so based on these gaps, the researcher chose to carry out this investigation to evaluate if applying a cold application affected the degree of pain and discomfort after the sheath was removed.

2. Methodology

Study design and sample size This study used an open-label (unblended) randomized control trial with a parallel design to assess the effects of cryotherapy on the level of pain for patients undergoing arterial sheath removal after percutaneous coronary intervention at the Babylon Centre for Catheterization and Cardiac Surgery at Imam Al-Sadiq Hospital. The data gathering from January 7, 2024, until February 19, 2024. Two groups were created out of those patients: The experimental group (50 participants) that applied cryotherapy and the control group (50 participants) that did not receive cryotherapy. The minimum sample size for every group should be 50 participants. This was computed with an accuracy of 5% and an 80% level of confidence based on SurveyMonkey online (SurveyMonkey, n.d.). A sample of 118 patients consented to participate in the present investigation.

Study setting and participants: The study’s participants were adult patients according to the criteria for inclusion and exclusion undergoing removal of the arterial sheath in the cardiac care unit following percutaneous coronary intervention conducted at Babylon Center for Catheterization and Cardiac Surgery/ Imam Al-Sadiq Hospital in Babylon Province/ Iraq. The gathering of data from January 7, 2024, until February 19, 2024.

Participant selection criteria The inclusion criteria included male and female Individuals who are at least eighteen years old and willing to partake in the research and patients who underwent a single catheter through the femoral artery. The participants had to read and write. They had not taken analgesics in the last four hours and were free from any hematoma or infection on the skin surrounding the sheath site. while exclusion criteria included patients suffering from severe visual impairment, a changed mental state, skin conditions linked to cold sensitivity (such as Raynaud's disease), sensory-motor deficiency, diabetes, neuropathy, and scar tissue from burns, wounds, or other injuries surrounding the sheath site.

Study Instrument The study instrument consisted of socio-demographic and clinical characteristics in the first part (age, gender, education level, marital status, occupation, body mass index, and marital status). Clinical characteristics included a history of painkiller use and the number of previous PCI procedures. The Visual Analogue Scale (VAS) in the second part was employed to assess the severity of pain by the participant's putting the mark on the line of VAS (0-100 mm) representing the patient's pain. This scale is reliable and valid (Doi, Ueda and Imamachi, 2022). The VAS classifies pain to be "no pain" (0 – 4 mm), "mild" (5 – 44 mm), "moderate" (45 – 74 mm), or "severe" (75 – 100 mm) on a scale of 1–100 mm. A license was obtained from the original researcher to use the questionnaire and its scale by Email permission. It was then presented to a panel of twelve (12) experts to evaluate the questionnaire instrument and scale to determine their suitability for the research project. The experts in the field possessed over five years of experience. A few of the questionnaire's sections were slightly altered under the experts' suggestions. The evaluation of 12 patients through the pilot study aimed to analyze the questionnaire's components, participants' responses, and the researcher's time required for the research, and identify potential mistakes or challenges. The determination of the internal consistency and the Cronbach alpha coefficient (r = 0.839) is used to calculate the questionnaire's reliability.

Sample and sampling A Probability-based random sampling technique grounded in science was used to assign participants (adult patients undergoing excision of the arterial sheath in a cardiac care unit following percutaneous coronary intervention) to guarantee that every patient has an equal opportunity to be allocated to any group. Offering the participants' cards in two various colours in a box. The participants used the random allocation mechanism to choose one card representing the research group. The blue card represents the intervention (cryotherapy) group, while the yellow card defines the control group. In this study, 118 participants were eligible to participate as a study sample. Three were eliminated due to twin femoral sheaths, while six others were eliminated because they refused to participate in the trial; five were excluded because they had peripheral catheterisation; and four were excluded because they had bleeding and hematoma. In the end, a total of 100 participants were divided as every group included 50 patients in the data analysis (Figure 1).

Study intervention Formal approval was required before gathering study data and then answering the questionnaire. Four hours following the PCI, they routinely removed the femoral catheters when the patient supine position. Immediately following the removal of its femoral sheath, the sheath site was covered with a tiny dressing, and patients in the sample were instructed to record their pain level post-sheath removal. In the cryotherapy group, a cold gel bag was covered with sterile gauze, and this cold bag was pressed against the sheath site for 20 minutes (Wicaksono and Djamil, 2020). When the cold gel bag was removed, the participants' pain level was recorded again. The cold bag used in this study is manufactured by Delhi Trading Company, Ludhiana, India, with an amount of 800 ml (9-inch) and a model name or number (VHC 126), brand Vadic. The control group followed the participant's completion of the questionnaire. Starting the sheath removal with standard procedures and determine the degree of pain as soon as the sheath is removed by asking participants to mark a point on the line VAS (0–100 mm) to indicate their pain status. Assess the level of pain intensity without extra intervention after 20 minutes by asking the patient to mark a point on the VAS scale (0–100 mm) line to indicate their level of pain and discomfort. Finally, all patients in the sample got standard care.

Ethical consideration Regarding the ethical consideration, on November 30, 2023, the study was approved by the research ethics committee of the University of Baghdad's College of Nursing. The researcher presented a comprehensive description of the study to the Statistics Centre in the Iraqi Ministry of Planning and then to the Training and Development Centre in the Babylon Health Directorate to obtain approval for the study procedure. On January 6, 2024, the Iranian Registry of Clinical Trials authorized and registered the clinical study protocol, which can be accessed through the website https://www.irct.ir. Additionally, after being registered with the Iranian Register of Clinical Trials (IRCT), the trial was provided with the number assigned to the registration as an IRCT ID (IRCT20231101059928N1), which assured Helsinki approval. Finally, written consent and participants' verbal agreement to take part in the study were obtained.

Data analysis Descriptive and inferential statistics were employed in the data analysis using the Statistical Package for Social Sciences (SPSS), which was applied for data analysis and the assessment of results. To compute demographic variables and pain intensity, use frequency (F), mean scores, percentage (%), standard deviation, ANOVA, and t-test for matched samples. P <0.05 was used as the significance threshold or p-value.

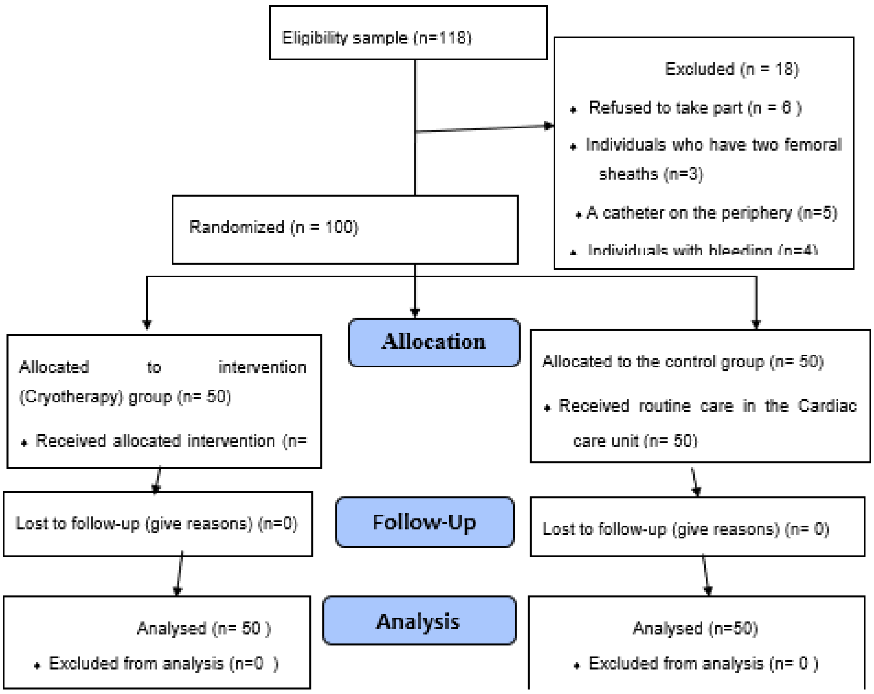

Figure 1: CONSORT Flow Diagram of the study

3. Results and discussion

Table 1. Shows how the study samples were distributed based on their demographic data.

Variables	Groups	Study		control	
		Freq.	**%**	**Freq.**	**%**
Age	Mean ± SD	62.92	9.61	57.48	9.81
Gender	Male	25	50	35	70
	Female	25	50	15	30
Variables	**Groups**	**Study**		**control**	
		Freq.	**%**	**Freq.**	**%**
Marital Status	Married	39	78	49	98
	Divorced	4	8	0	0
	Separated	1	2	1	2
	Widowed	6	12	0	0
Level of	Read and write	14	28	12	24

education	Primary	17	34	15	30
	Secondary	7	14	10	20
	Institution	7	14	8	16
	Bachelors	5	10	5	10
Occupation	Free work	8	16	10	20
	Unemployed	4	8	14	28
	Employed	17	34	13	26
	Retired	21	42	13	26
Weight	Mean ± SD	79.66	12.1	80.6	14
Height	Mean ± SD	164.42	6.3	166.08	7.8
BMI	Healthy weight (18.5 – 24.9)	8	16	10	20
	Overweight (25 – 29.9)	21	42	18	36
	Obese (30 and over)	21	42	22	44
History of painkiller use	Yes	25	50	23	46
	No	25	50	27	54
Number of previous PCI	0 time	27	54	29	58
	1 time	15	30	16	32
	2 times	3	6	3	6
	3 times	5	10	2	4

The results in Table 1 showed that the cryotherapy group's average age was 62.9 years old, and the control group was 57.4 years. Males and females made up an equal percentage of the experimental group, and the highest rate of the control group was 35 (70%) males. Furthermore, the biggest percentage of the control group 15 (30%) had an elementary school certificate, whereas only 14 (28%) of the experimental group could read and write. Moreover, 17 (34%) of the experimental group were employed, and 14 (28%) of the control group were unemployed. Regarding BMI, 21 (42%) of the cryotherapy group and 22 (44%) were obese in the control group. About the same percent of the study group and control group were taking painkiller drugs, accounting for approximately half of each group. In addition, 15 (30%) of the cryotherapy group and 16(32%) of the control group performed PCI for the first time.

Table 2. Distribution and difference of the pain of the sample before and after the procedure (study group)

No.	**Pain**		**Results**			**t-test**	**Significant level**
			F	**M**	**SD**		
1	Pain score before the procedure	No pain (0 – 4 mm)	2	44.94	20.3	14.94	.000
		Mild pain (5 – 44 mm)	25				
		Moderate pain (45 – 74 mm)	19				
		Severe pain (75 – 100 mm)	4				
2	Pain score after the procedure	No pain (0 – 4 mm)	43	2.38	5.1		
		Mild pain (5 – 44 mm)	7				
		Moderate pain (45 – 74 mm)	0				
		Severe pain (75 – 100 mm)	0				

Table 2 presented the difference between the study groups according to pain responses, in which the pretest and posttest differed significantly from one another after manipulation of intervention at p = .000.

Table 3. Distribution and difference of the pain of the sample before and after the procedure (control group).

No.	Pain		Results			t-test	Significant level
			Freq	M	SD		
1	Pain score before the procedure	No pain (0 to 4 mm)	0	47.4	17.8	11.32	.000
		Mild (5 to 44 mm)	25				
		Moderate (45 to 74 mm)	21				
		Severe (75 to 100 mm)	4				
2	Pain score after the procedure	No pain (0 to 4 mm)	1	23.34	11.5		
		Mild (5 to 44 mm)	45				
		Moderate (45 to 74 mm)	4				
		Severe (75 – 100 mm)	0				

SD: Standard deviation, M: Mean, Freq. = frequency, t-test: paired sample t-test, Significant p-value < 0.05, pain score: No pain = 0 – 4 mm; Mild = 5 – 44 mm; Moderate = 45 – 74 mm; Severe = 75 – 100 mm

Table 3 presented the difference between the control group according to pain responses, in which there the pretest and posttest showed a statistically significant difference at p = .000 by increasing numbers of patients suffering from mild pain according to pain score as presented from 25 patients at the pretest level with mild pain to 45 patients with mild pain at post-test duration without manipulation

. Table 4. Difference of the pain of the sample after the procedure (study and control groups)

No.	Pain		Results			t-test	Significant level
			Freq	M	SD		
1	Pain after the procedure	Study group	50	2.38	5.1	12.41	.000
		Control group	50	23.34	11.5		

SD: Standard deviation, M: Mean, Freq. = frequency, t-test: paired sample t-test, Significant p-value < 0.05,

Table 4. compares the variations in pain responses between the research and control groups. Observe that after manipulating at p < 0.05, there was a significant difference between the pretest and posttest.

Discussion

The current study aimed to assess how cryotherapy affected patients' pain levels undergoing the removal of their arterial sheaths post-percutaneous coronary intervention. The sample distribution based on demographic characteristics was displayed by the data analysis in Table 1. Tables 2 present the study's findings regarding pain intensity for the cryotherapy group before and after the intervention. That showed the difference between the study group according to pain responses when the difference between the pre and post-tests was statistically significant after manipulation of the intervention (t-test = 14.94 and p =.000). Table 3. presents the difference between the control group according to pain responses between the pre and post-tests (t-test =11.32 and p =.000) showed an increased number of patients suffering from mild pain according to pain score, as presented from 25 patients at the pretest level with mild pain to 45 patients with mild pain at post-test duration without manipulation. It is evident that, before the cold intervention, the mean pain score for the study and control groups was almost identical (44.94±20.3 vs. 47.4±17.8), respectively. The pre-test and post-test mean and standard deviation varied considerably. By comparison, the cryotherapy group's mean pain score is much less than the control group following the intervention of the cold intervention. (2.38±5.1 vs. 23.34±11.5). The results of the current investigation showed there are significant differences in the participants' pain assessments following percutaneous coronary intervention between the cryotherapy and control groups during sheath removal after intervention (p =.000) at (<0.05) as shown in Table 4. So the use of cryotherapy is effective in decreasing sheath removal pain among percutaneous coronary interventions in contrast to the control group and the passage of time also plays an important role in fading pain. This result is consistent with research done by Bayındır et al. (2017) in Turkey to assess the efficacy of using ice packs in the femoral region of patients during PCI for pain relief. showed that discomfort experienced by PCI participants post-sheath removal was decreased by cold application (Bayındır, Çürük and Oguzhan, 2017). This finding was similar to the study in Indonesia that conducted true experimental research To investigate how cold compression with ice gel affects the level of discomfort in individuals who have had PCI for a femoral sheath, which funded the use of ice gel as an effective method to reduce femoral sheath pain (Wicaksono and Djamil, 2020).

This study was supported by the study conducted in Turkey, where 200 patients participated in experimental research to assess the impact of cold on pain severity following the extraction of the sheath during cardiac catheterization. There were 200 patients total; 100 belonged to the experimental group and the other 100 to the control group. The study's findings demonstrated that following the intervention, the experimental group had statistically significantly less discomfort at the catheter entrance site than the control group ($P < 0.01$) (Kurt and Kaşıkçı, 2019). Also, the current study agrees with another study, a Randomized Clinical Trial conducted by Valikhani et al. in 2020 in Iran. The objective of the study was to evaluate the efficiency of an ice bag and a sandbag in lowering sheath removal pain after percutaneous coronary intervention. They found that the group that received sandbags with ice bags had a mean pain intensity score of 1.1±1.0 after three hours following sheath removal, which was significantly less than the group that received sandbags (2.4±0.9) and had a p-value of less than 0.001 (Valikhani et al., 2023).

According to the researcher, the use of cryotherapy, a non-pharmaceutical intervention technique for pain reduction, may influence nerve impulse transmission and help relieve pain. The application of cold therapy relieves pain without the need for pharmaceutical intervention. This therapeutic approach, which is the oldest and most basic, increases pain sensitivity to pain and decreases the speed at which pain signals are transferred from the periphery to the central nervous system of the brain (Ibrahim and Deif, 2021). Applying ice is an effective way to decrease pain, and this method produces less pain and nerve conduction right away (Mohammadi et al., 2018). More research should be done to enhance patient comfort and with ease, low-cost, non-invasive techniques. The fact that the intervention is safe, readily available, and efficient is one of the study's advantages of the current study. The current study has some limitations which are as follows: limited sample size restricts the generalization of the study outcomes to the whole country, furthermore, The perception of the pain that people experience varies from one individual to another regarding the subjectivity of the pain scale, which can affect how accurately the data are evaluated and may expose the study to bias.

4. Conclusion and future scope

The study's findings showed that applying cryotherapy to the femoral sheath area assisted patients with percutaneous coronary intervention to feel fewer feelings of pain when their femoral catheter was removed. In these situations, using a local cold gel bag may be advised as a nursing application for pain management. Encouraging the use of cryotherapy in national hospitals and training nurses to use non-pharmacological treatments effectively for patient benefits and improved nursing care.

Conflicts Of Interest: None

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