

Research Paper

The Effect of Sandbag and Ice Bag on the Pain After Percutaneous Coronary Intervention: A Randomized Clinical Trial



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ABSTRACT

Background and Purpose: One of the significant complications of angioplasty is the pain at the catheterization site. These complications will increase the hospitalization duration and hospital costs. The objective of this study is to investigate the combined impact of using sand and ice bags on mitigating pain following percutaneous coronary intervention (PCI).

Materials and Methods: In this clinical trial research, we recruited 60 patient candidates for femoral PCI who were referred to Imam Reza Hospital of Mashhad City, Iran, in 2017. The patients were assigned to the control and intervention groups by simple randomization. The statistical analyst was blind to the study. The arterial sheath was removed 4 hours after coronary intervention. Then, a sandbag was placed on the site in control group subjects for up to 4 hours. The ice and sand bags were placed on the site for 15 minutes in the intervention group. Using a numerical pain measurement tool, the pain intensity was recorded at the beginning of the patient's admission and 3, 6, and 12 hours after the sheath removal. The obtained data were analyzed by descriptive statistics (mean & SD) and inferential statistics (The Chi-Square, Fisher exact, Mann-Whitney, Friedman, and t-tests).

Results: The mean score of pain intensity in the sandbag combined with the ice bag group (1.1 ± 1.0) was significantly lower than the sandbag group (2.4 ± 0.9) at the 3 hours after the sheath removal ($P < 0.001$). The mean pain intensity scores at the 6 hours after the sheath removal were 0.7 ± 0.7 in the sandbag combined with the ice bag group and 1.0 ± 0.8 ($P = 0.407$) in the sandbag group. Also, 12 hours later, the pain difference between groups was not significant (0.2 ± 0.4 in the sandbag combined with the ice bag group and 0.4 ± 0.6 in the sandbag group ($P = 0.482$)).

Conclusion: Although both interventions reduced the patient's pain, the group with the combination of ice bag and sandbag tolerated less pain 3 hours after removing the sheath. Thus, this method can be applied as an available, effective, and cost-effective technique in angiography units of hospitals for reducing local pain.

Keywords: Percutaneous coronary intervention, Ice, Sand, Pain

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1. Introduction

Percutaneous coronary intervention (PCI) is used to treat and diagnose chronic coronary artery disease [1]. The femoral arterial site is commonly used for PCI [2]. Currently, almost 600 000 PCI cases are conducted in the United States, and about 95% of them are performed through femoral arteries [3]. Coronary heart diseases impose a significant economic burden of \$4715 to \$ 4908 billion upon Iran's economic system [4]. Nonetheless, many patients experience discomfort and pain during femoral artery interventions when the catheters previously inserted into the femoral site are removed [5]. Despite good care, access-site (A-S) complications, like hematoma, bleeding, pseudoaneurysm, artery spasm, or thrombosis, can occur along with pain and possibly need urgent intervention [6].

Local vascular complications and vasovagal responses can be developed when the pain caused by catheter removal is not controlled effectively; hence, reducing the pain in patients undergoing this procedure is necessary [5]. Pharmacological treatment is one way to control pain after PCI [7]. Non-pharmacological methods are other ways of pain control after PCI. These methods are patient-specific and aimed at establishing empathic communication with healthcare staff [8, 9]. Non-pharmacological approaches for pain control provided positive effects, like decreased anxiety and psychological support. Patients reported satisfaction with these non-pharmacological methods [5]. Using the sandbag is currently the conventional non-pharmacological method to control PCI's local complications and pain. In this procedure, patients have to rest entirely on the bed (for 6-24 hours, depending on the treatment protocol), have absolute immobility of foot, and use of sandbag weighing 2.5 to 4 kg for about 6 hours after sheath removal [10]. Total resting of the patients immediately after angiography causes intolerance, discomfort, and hemodynamic instability. Patients' non-cooperation in compliance with absolute resting on the bed after the procedure has been reported as a significant factor in femoral complications [10]. Other pain reduction methods are using ice and cold. Ice therapy has been employed since the old days as a non-invasive technique to control bleeding and reduce pain. One of the physiological effects of ice therapy is the reduction of nerve conduction, vascular contraction, and lowering of histamine release, thus reducing inflammation, muscle spasm, and pain [11]. The use of ice and cold therapy after orthopedic and maxillofacial surgeries has been associated with reduced pain

and inflammation in some cases [12]. As angioplasty is used increasingly in the treatment of heart disease and complications and due to the lack of information about the more effective methods to reduce pain after this procedure, this research was conducted to compare the effect of sandbag alone with sandbag plus ice bag in reducing the pain after PCI.

2. Materials and Methods

This study was designed according to CONSORT guidelines for randomized clinical trials [13] in the Angiography Ward of Imam Reza Hospital, Mashhad City, Iran, in 2018.

The sample size was determined based on a pilot study involving 10 individuals in each group. The estimation was based on the formula for comparing the means of the two populations in terms of pain variable while taking into account the type I ($\alpha=0.05$) and type II error ($\beta=0.20$). The highest estimated sample size was associated with the mean scores of pain (27 in each group). At least 30 subjects were included in each group to ensure adequate statistical power.

Sixty patients who were candidates for angiography and referred to Imam Reza Hospital were randomly assigned to the intervention and control groups after obtaining the approval of the Ethics Committee from the Mashhad University of Medical Sciences and obtaining the written consent of patients. The researchers selected the subjects based on the inclusion and exclusion criteria using a convenient sampling method in coordination with hospital authorities. The inclusion criteria were age over 18 years, a body mass index between 18 and 30 kg/m², no history of addiction, only one catheter puncture for insertion, and alertness. The exclusion criteria comprised the use of sedatives, dysphoria, sudden changes in blood pressure, and undergoing cardiopulmonary resuscitation. They randomly assigned the patients into the sandbag group (control) and the sandbag combined with the ice bag group (intervention). We used simple randomization based on a lottery.

In the control group (sandbag), the patients were transferred to the unit in the supine position and placed on the bed without moving their legs. The pain intensity was checked and recorded at the beginning of the study. Then, the arterial sheath was removed 4 hours after completing the procedure. After initial coagulation, a transparent dressing was placed on-site with hand pressure, and the patient was placed in position again for up to 4 hours, and a sandbag with a fixed weight of

3 kg was placed on the angiography site. Then, the bag was removed, and the patient rested for 3 hours in the direction of his or her healthy foot.

In the intervention group (sandbag and ice bag), the arterial sheath was removed 4 hours after completing the procedure. After initial coagulation, a transparent dressing was placed on the site, and an ice bag with a cloth cover (weighed less than 100 g) and a sandbag weighing 3 kg were placed on it for 15 minutes. After 15 minutes, the ice bag was removed gently, and the sandbag was placed alone on the site for 45 minutes. This cycle was repeated 4 times (a total of 4 hours). Then, the sandbag was removed, and the patient rested for three hours without moving toward his or her healthy foot. The pain was checked and recorded in both groups at the beginning of sheath removal (before) and 3, 6, and 12 hours after the intervention.

The data collection tool included two sections. The first section consisted of a demographic questionnaire obtained through interviews with patients and their medical records, including age, gender, marital status, education, history of angiography, weight, and height of patients, and drugs used. The second section included a numerical rating scale (NRS) for measuring the pain of the patients [14]. The validity of the subjects' selection checklist, the demographic and clinical characteristics of the subjects, and the physiological characteristics recording questionnaire were determined using content validity. Accordingly, it was developed by studying the latest books and articles on research under the guidance of supervisors and advisors. Then, it was given to 7 experts and faculty members of The Department of Nursing and Midwifery of Mashhad University of Medical Sciences to be evaluated. After considering the required suggestions and reforms, the final tool was developed.

The numeric rating scale is an 11-point scale ranging from 0 through 10, where 0 represents "No pain" and 10 represents "Worst imaginable pain". Participants are asked to choose the number that best describes their pain intensity [14]. The NRS has demonstrated validity and sensitivity to change [15, 16], with good construct validity reported in experimental settings and individuals with rheumatic disease [16]. In the current study, the reliability of the NRS was confirmed by test-retest, yielding a coefficient of 0.86.

The obtained data were analyzed by descriptive (mean±SD) and inferential statistics using SPSS software, version 11.5 (SPSS, Inc. Chicago, IL, USA). The

Kolmogorov-Smirnov test was used to check the normality of the data. To compare two groups in terms of the homogeneity of contextual, intervening, and dependent variables, in the case of quantitative variables with normal distribution, independent t-test and in the case of quantitative variables with non-normal distribution, the Mann-Whitney test and in nominal and rank qualitative variables Fisher exact test, Chi-square, and exact Chi-square tests were used. The researchers employed the Mann-Whitney and Friedman test to compare the mean changes of the pain immediately, 3, 6, and 12 hours after sheath removal compared to the baseline between groups. The significance level was considered less than 0.05.

3. Results

In this study, 30 patients in both groups completed the study (Figure 1). The statistical analyses revealed that both groups were comparable in all underlying and confounding variables, with no significant differences observed (Table 1).

The Kolmogorov-Smirnov statistical test result showed that the pain variable was only normal at the beginning of sheath removal (before the intervention). The results of the Mann-Whitney test showed that at the beginning of sheath removal, the difference between the two groups was not significant in terms of pain ($P=0.124$). However, the mean pain severity in the sandbag combined with the ice bag group was significantly lower than that of the other group at 3 hours after the sheath removal ($P<0.001$). However, the difference between the two groups was not significant at the 6 ($P=0.407$) and 12 hours ($P=0.482$) after sheath removal.

The Friedman test results showed a significant difference regarding the pain intensity in different stages of measurement in both groups ($P<0.001$). The post hoc test showed these differences were significant in the ice bag group between the beginning of sheath removal and 3, 6, and 12 hours after the intervention ($P<0.001$), between the 3 hours and 12 hours ($P<0.001$), and between 6 and 12 hours ($P<0.001$). In contrast, the difference between the 3 and 6 hours was not significant ($P=0.084$). However, a significant difference was found in the mean pain in the sandbag combined with the ice bag group at the beginning of sheath removal and 3, 6, and 12 hours after the intervention ($P<0.001$) (Table 2).

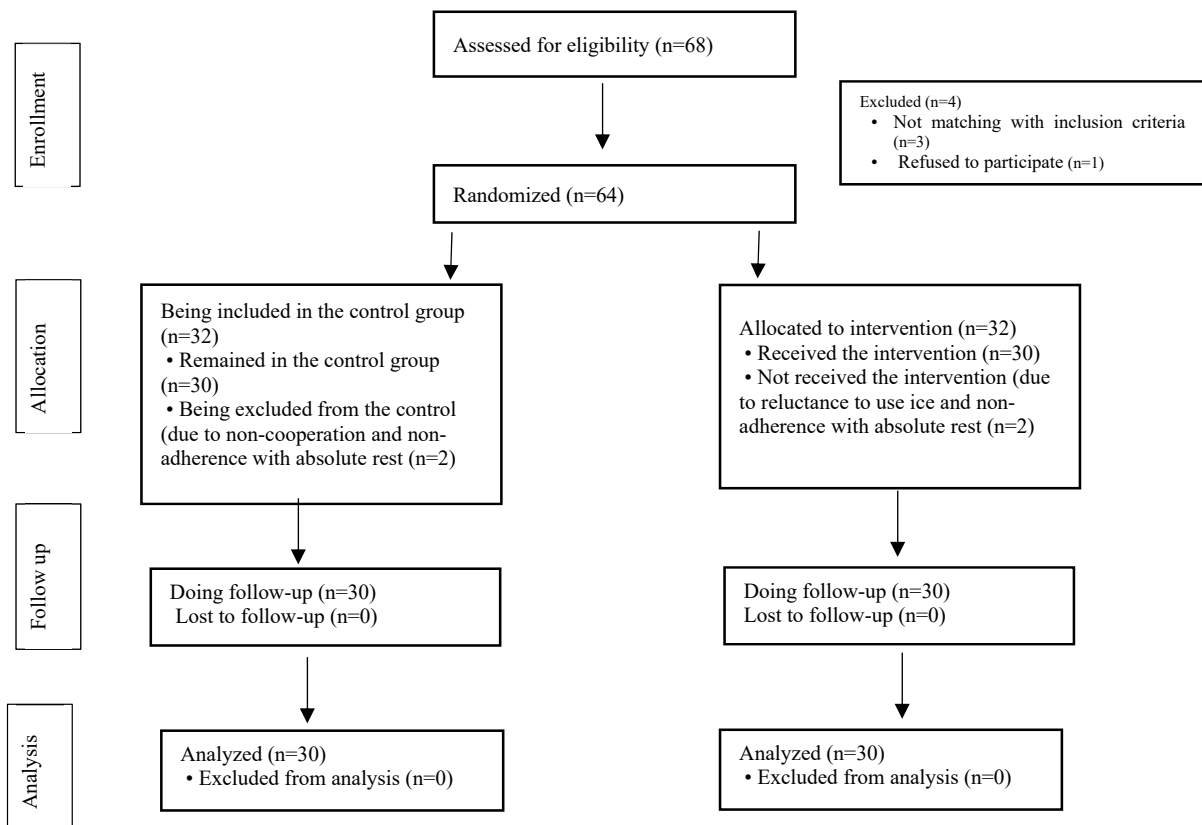


Figure 1. Flowchart of the study

4. Discussion

This research compared the effect of sandbag alone and ice bag plus sandbag in reducing patients' pain after angiography. Results showed that the simultaneous sand-ice bag use reduced post-PCI pain better than the sandbag alone: sandbag as an agent for creating external pressure, and ice bag as an agent for lowering neurotransmission conduction to minimize pain after coronary angioplasty. Another study reported that ice bag use at the femoral site effectively decreased pain caused by femoral catheter removal in cases receiving the percutaneous coronary intervention [5]. A study showed that ice application before arterial puncture was well tolerated and reduced procedure-related pain [17]. Therefore, the cold application can be used as an essential non-pharmacological nursing initiative for pain management.

Non-pharmacological methods, like cold application, should be regarded to reduce analgesic use by the patient [5]. Pain relief using the cold application is done by many mechanisms, such as inhibition of nociceptors, altered nerve conduction velocity, reduced muscle spasms, and decreased metabolic enzyme activity [18].

A clinical trial compared sandbag and air cushion methods on post-angioplasty complications in Mazandaran Province, Iran, in 80 patients. In this study, the low back and groin pain were significantly higher in the sandbag group than in the air cushion group ($P=0.001$). In the air cushion group, 10% of patients needed opioids, and 30% required opioids [19]. In the mentioned study, pain in the groin area was reported with the presence of a sandbag. Therefore, the researcher of this study tried to maintain sandbags on the site (due to their necessity in preventing vascular complications). Another applied method is the combination with ice to reduce the patient's pain rate in the groin caused by catheter insertion and the presence of a sandbag [19]. Another study was conducted on 51 patients undergoing heart surgery at Imam Reza Hospital in Mashhad City with at least two chest tubes. Patients were divided into three groups: ice bag, placebo, and control. The bags were inserted around the tube for 20 minutes before removing the chest tube. In this study, cold therapy was used once for each patient [20] but 4 times for each patient in the current study. In addition, the visual analog scale was used as a pain measurement tool in the mentioned study, while the numerical pain measurement scale was used in the current research.

Table 1. Demographics information of both groups

Variable	Mean±SD/No. (%)		Test Results			
	Sandbag	Sandbag Combined With Ice Bag				
Age (y)	56.8±9.8	54.9±8.7	t=0.8	df=58	P=0.400	
Sex	Female	12(40.0)	11(36.7)	$\chi^2=0.07$	df=1	P=0.791
	Male	18(60.0)	19(63.3)			
Education	None	10(33.3)	6(20.0)	$\chi^2=3.2$	df=4	P=0.574
	Elementary	5(16.7)	5(16.7)			
	Third-grade middle school	9(30.0)	7(23.3)			
	Diploma	5(16.7)	10(33.3)			
Employment status	Academic	1(3.3)	2(6.7)	$\chi^2=4.5$	df=2	P=0.125
	Employed	9(30.0)	17(56.7)			
	Unemployed	19(63.3)	11(36.7)			
	Retired	2(6.7)	2(6.7)			
Disease history,	None	2(6.7)	2(6.7)	$\chi^2=3.8$	df=5	P=0.631
	Diabetes	3(10.0)	3(10.0)			
	Hypertension	8(26.7)	7(23.3)			
	Hyperlipidemia	8(26.7)	4(13.3)			
Smoking	Other	0	2(6.7)	$\chi^2=0.4$	df=1	P=0.365
	multi	9(30.0)	12(40.0)			
	Yes	4(13.3)	6(20.0)			
	No	26(86.7)	24(80.0)			

Table 2. Severity of pain in patients undergoing percutaneous coronary Intervention in different Stages in the sandbag group and sandbag combined with ice bag group

Stages	Mean±SD		Intergroup Comparison Result
	Sandbag	Sandbag Combined With Ice Bag	
Beginning of sheath removal (before the intervention)	3.0±1.2	2.5±1.4	Z=-1.5, P=0.124
Three hours after the sheath removal	2.4±0.9	1.1±1.0	Z=-4.6, P=0.000
Six hours after the sheath removal	1.0±0.8	0.7±0.7	Z=-0.829, P=0.407
Twelve hours after sheath removal	0.4±0.6	0.2±0.4	Z=-0.703, P=0.482
Intragroup comparison result	$\chi^2=63.110$ P<0.001	$\chi^2=46.703$ P<0.001	-

This study was consistent with our investigation and showed a positive effect of ice and sandbags in reducing patients' pain. An important limitation of this study was the difference in pain threshold and patient's perception of maximum pain according to the different experiences of each individual and the impossibility of eliminating its effect.

5. Conclusion

Although both interventions reduced the patient's pain, the group with the combination of ice and sandbag tolerated less pain 3 and 6 hours after removing the sheath. Thus, this method can be applied as an available, effective, and cost-effective technique in angiography units of hospitals for reducing local pain.

Ethical Considerations

Compliance with ethical guidelines

We obtained the license of the Ethics Committee from the [Mashhad University of Medical Sciences](#) (Ethics No.: IR.MUMS.REC.1396.312) and obtained patients' written consent.

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Authors contributions

Conceptualization and Supervision: Seyad Mousa Mahdizadeh and Maryam Valikhani; Methodology: Seyed Reza Mazlum; Investigation, Writing-original draft, and Writing-review & editing: All authors; Data collection: Maryam Valikhani and Javad Dehghani; Data analysis: Seyed Reza Mazlum and Seyad Mousa Mahdizadeh; Funding acquisition and Resources: Maryam Valikhani and Seyad Mousa Mahdizadeh.

Conflict of interest

The authors declared no conflict of interest.

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