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Original Article

The Effect of Simultaneous Sand-Ice Bag Application on Hemorrhage and Hematoma after Percutaneous Coronary Intervention: A Randomized Clinical Trial

Maryam Valikhani[1], Seyed Mousa Mahdizadeh[1*], Ali Eshraghi[2], Seyed Reza Mazlum[1], Javad Dehghani[3]

[1]Department of medical-surgical nursing, Nursing and Midwifery Care Research Center, Mashhad University of Medical Sciences, Mashhad, Iran
[2]Department of Cardiology, Imam Reza Hospital, Mashhad University of Medical Sciences, Mashhad, Iran
[3]Department of Nursing, School of Nursing and Midwifery, Neyshabour University of Medical Sciences, Neyshabour, Iran

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Corresponding Author:
Seyed Mousa Mahdizadeh,
Email: Mahdizadehm@mums.ac.ir

Abstract
Introduction: Angioplasty is widely used as a selective treatment for acute coronary syndromes. The complications of this procedure often lead to an increase in the length of the patients' stay and hospital costs. Therefore, this study aimed to determine the effect of using sand and ice bags on hematoma and hemorrhage after percutaneous coronary intervention (PCI).
Methods: In this randomized clinical trial, study was completed with participation of 60 patients with femoral angioplasty candidate, referring to Imam Reza hospital in Mashhad, were randomly divided into control and intervention groups. In the control group, a sand bag was placed on the location for up to 4 hours. In the intervention group, the ice bag and the sand bag were used simultaneously for 15 minutes, and then for 45 minutes, with the pressure of the sand bag only. This cycle was repeated four times. Hemorrhage (volume and weight) and hematoma (area and lump) were checked four times. The data were analyzed using SPSS software version 22.
Results: The rate of hemorrhage after intervention was significantly reduced in the intervention group compared to the control group. Although the incidence of hematoma in the intervention group decreased from control to 20% to 6.7%, but the statistical test was not significant.
Conclusion: According to the results of the present study, the simultaneous sand-ice bag application can reduce post-PCI' hemorrhage (and hematoma rate, though insignificantly) through compression and vasoconstriction.

Introduction

Known as ischemic heart disease, the coronary artery disease (CAD) is the most prevalent kind of cardiovascular diseases (CVDs).[1] The World Health Organization (WHO) reported almost 17.5 million people to have died from CVDs worldwide in 2012.[2] Heart diseases are the main cause of mortality in Iran. According to a statement issued by the Ministry of Health 46% of death is ceased by coronary diseases.[3] It is predicted that mortality rate from CVDs might reach 25 million in 2020, and ascend to more than 23.6 million in 2030.[4]

Several invasive and noninvasive methods have been proposed in order to determine the severity and extent of CAD involvement. The typical CAD assessment method is angiography which is considered as the gold standard for the diagnosis of CAD and has recently become the most common diagnostic intervention used for heart patients.[5] Percutaneous coronary intervention (PCI) refers to all CAD-restorative interventions performed through catheterization under fluoroscopic guidance such as balloon angioplasty, stenting and Atherectomy.[6] Currently, an annual approximation of 3 million PCI angioplasty cases is accomplished in the United States, about 95% of which is performed via femoral arteries.[4] These interventions, however, are not risk-free, rather they are often associated with general and vascular complications.[7] The general PCI complications include cardiac tamponed, dysrhythmia, pneumothorax, hypovolemia, cardiac arrest and arterial embolism while the vascular complications of PCI procedure involve hematoma, microvascular aneurysm, hemorrhage, edema, painful catheter insertion site, embolism, arterial occlusion, arterial spasm, arteriovenous fistula and retroperitoneal hematoma, all of which increase the risk of mortality, morbidity, treatment costs and prolonged hospitalization.[8] PCI complications are more likely to occur in the femoral arteries.[7]

In order to prevent the aforesaid PCI complications, it is necessary to follow special nursing care such as

restraining patient's movement in supine position, avoiding hip flexion, setting the head angle at <30 degrees and receiving a 4-to-6-hour local pressure over femoral catheter insertion site, using a sandbag after the removal of arterial sheath. Despite preventive interventions, post-PCI vascular complications may still occur. Recent studies have reported post-PCI hemorrhage and hematoma as the most significant cause of mortality, following PCI procedure.[9]

Nowadays, a variety of vascular closure devices (VCDs) have been designed for their ease of use and safety in reducing time to hemostasis, faster sheath removal and earlier patient ambulation and recovery.[10] Nevertheless, VCDs are not risk-free yet, and fail to be used efficiently.[11] Some VCDs are vascular closure clips, FemoStop, C-shaped clamp and collagen injection to block the arterial hole.[12] The unaffordable costs of VCDs may significantly affect hospital costs; hence, they are less likely to be widely used especially in developing countries.[11] The use of ice and cooling is another way to achieve hemostasis and prevent hematoma. Contracting the infected arterial site, cold therapy reduces the amount of blood flow to the area and ceases such complications as hemorrhage and hematoma.[13] Ice therapy has long been used as a noninvasive method of bleeding control. The physiological effects of ice therapy include arterial contraction that ultimately results in decreased peripheral blood circulation, histamine release, inflammation, muscular spasm and nerve conduction velocity in succession.[14] Decelerating the blood flow by increasing the viscosity of bloodstream to the invasively-administered bleeding site, ice bag can also facilitate the achievement of better hemostasis and fewer vascular complications such as hematoma. Ice therapy has, in some cases, reduced pain and inflammation after orthopedic and maxillofacial surgeries.[13]

In most countries, hand-held pressure is currently being used as a more affordable way to achieve hemostasis over the arterial puncture site and sandbag is used to maintain hemostasis once the catheter sheath is removed.[15] In this procedure, patients have to follow complete rest-cure for 6 to 24 hours, depending on the treatment protocol of the medical center, maintain absolute leg immobility and use a sandbag (2.5-4 kg) for 6 hours after sheath removal. Subsequent to this condition is low back pain,[16] as the most common complaint of patients after angiography, which results from movement restraints during the bed rest and the weight of sandbag.[9] Moreover, researchers argue that common techniques in long-term immobilization

do more harm than good to both patients and nurses after angiography. Notwithstanding their shortcomings and failure in use,[16] a variety of VCDs have been designed for their ease of use and safety in reducing time to hemostasis, faster sheath removal and earlier patient ambulation. Since VCD complications are a major contributor to patients' morbidity, there is a pressing need for devising newer techniques.[9]

In view of increasing need for angioplasty in the treatment of CVDs and the associated complications, coupled with the lack of simple and efficient post-PCI hemostasis processes in Iran, on the one hand, and considering the fact that ice therapy has not yet been used to prevent either post-PCI hemorrhage and hematoma or general hemorrhage and hematoma originating from such a large artery as femoral artery, on the other hand, it seems necessary to study the efficacy of this method on CAD patients. To this end, the present study compared sandbag application alone and in combination with ice bag so as to investigate the effect of simultaneous sand-ice bag application on the extent of post-PCI hemorrhage and hematoma in CAD patients.

Materials and Methods

This randomized clinical trial was approved under the code IR.MUMS.REC.1396.312 by the committee of ethics in Mashhad University of Medical Sciences and clinical trial code IRCT2018031503910N1. The participants were selected through convenience sampling method, which lasted from November 22, 2017 to February 19, 2018 in Imam Reza hospital in Mashhad. The inclusion criteria were being over 18 years of age range, International Normalized Ratio (INR) <1.8, body mass index (BMI) = 18-30, no addiction, do not puncture more than once to insert the catheter, being alert, do not take Integrin (eptifibatide) during the procedure. The exclusion criteria included taking anticoagulant or thrombolytic or sedatives medicine, dysphoria, sudden changes in blood pressure and doing CPR. The subjects were randomly assigned into the control and intervention groups. Since a similar study was not found, the sample size was determined by conducting a pilot study on ten individuals in each group. The sample size was estimated, considering the error of the first (0.05 alpha) and second type (0.20 beta) and the formula for comparing the mean of the two populations in the variables of hemorrhage and hematoma. This variable was considered as the highest estimated sample size was related to the amount of hemorrhage (27 in each group). To be sure, at least 30 subjects were considered for each group.

The forms and tools used in the current study consisted of a sampling checklist, demographic and clinical profiles of the participants, patients' physiological report sheets, chequered rulers, digital scales, and an estimation formula of hematoma volume and informed consent forms.

Sampling Checklist: The checklist was a 17-item sampling inventory used to select the research participants, with the inclusion and exclusion criteria outlined, which was developed based on the current research objectives, latest resources and related articles under the consultation of an advisor and a supervisor.

Demographic and Clinical Profile

This 17-item form was used to assess the effect of

background and confounding variables in this study.

Physiological Report Sheet

It was a researcher-made form comprising 6 items, namely hemorrhage, hematoma, blood pressure, heart rhythm and heart rate, for recording patients' physiological information and dependent variables.

Chequered Ruler

It was used to measure the amount of bleeding. To this end, a nylon layer was placed on blood-stained gauges, bleeding angles were plotted on the nylon by a marker, and the nylon was placed on the ruler to measure the bleeding volume.

Digital Scale

The amount of bleeding was determined by weighing the blood-stained gauges using a digital scale (with 0.1 gram sensitivity) and subtracting it from the weight of dry gauges.

Estimation Formula of Hematoma Volume

This formula is equal to 1.2 πab (1.2*3.14*a*b) where *'a'* is the maximum hematoma diameter and *'b'* is the minimum diameter in millimeters. The area of hematoma was calculated by measuring hematoma diameters both and placing the values in the formula. This formula was used in the study of King et al.[8]

The consent form used in the present study was developed in accordance informed consent forms.

The construct of sampling checklist, demographic and clinical profiles of the participants, and the patients' physiological report sheets were measured based on content validity. Accordingly, these tools were developed on the basis of current research objectives, latest resources and related articles under the consultation of an advisor and a supervisor. They were then evaluated by 7 experts and professors from the school of nursing and midwifery in Mashhad University of Medical Sciences, and the final version was prepared, modified and amended. Chequered ruler was a measurement tool designed by Rezaei-Adaryani et al., whose validity was confirmed by 12 professors from Tehran, Mashhad and Tarbiat Modarres universities (P=0.91).[17] The reliability of the chequered ruler and digital scale was calculated using test-retest and Pearson Correlation, indicating a coefficient of 0.98 for the chequered ruler, 1.0 for the digital scale. The validity and reliability of hematoma estimation formula (1.2πab), used in King's et al., study, have also been verified.[18]

First, an informed consent was obtained from the patients participating in the study. The demographic data, (including age, sex, education level, occupation, family income, underlying diseases, medications, smoking, coagulation tests, BMI, and duration of surgery) blood coagulation tests, body mass index, and duration of surgery were completed from the patients as well as their medical records in both intervention and control groups.

The control patients (treated with sandbag) were transferred to the ward in supine position with their legs straightened on the bed. Their bleeding volume was checked and recorded upon arrival to the ward. Next, the arterial sheath was removed about 4 hours after the procedure fulfilment. A transparent dressing was applied to the affected area once blood coagulated by a hand-held pressure. The patients lay on the bed in supine position for another 4 hours again with a 3-kg sandbag placed on the angiography area. Afterwards, the sandbag was removed and the patients rested motionlessly on the healthy leg side for 3 hours.

For the intervention group (treated with sand and ice bag), the arterial sheath was removed about 4 hours after the procedure fulfilment. Once blood coagulated by a hand-held pressure, a transparent dressing was applied to the affected area, on which a cloth ice bag (<100 g) topped with a sandbag (3 kg) were simultaneously placed for 15 minutes. The duration of ice use and removal was adjusted according to the ice treatment protocol.[19]

As the due time was over, the ice bag was gently drawn (from underneath the sandbag), with the sandbag left alone on the area for 45 minutes. This procedure cycled for 4 consecutive times (4 hours in total). Finally, the sandbag was removed and the patients rested motionlessly on the healthy leg side for 3 hours.

The hemorrhage and hematoma volume of both control and intervention groups were checked and recorded upon arrival to the ward (stage1) and rechecked 3 hours after sheath removal (stage2), 6 hours after sheath removal (stage3) and 12 hours after sheath removal (stage4). Figure 1 shows flowchart of the study.

Results

According to the results of the statistical tests, the two groups were homogeneous in terms of all the underlying and confounding variables and there were no significant differences. The mean (SD) age of the control participants was 56.8)9.8) and intervention has equaled 54.9)8.7(. About 60% of the control group and 63.3% of the intervention group were male. The mean (SD) body mass index in the control group was 26.3 (3.4) kg/m^2, and 26.5)3.1(kg/m^2 in the intervention group. About 86.7% in the control group and 80.0% in the intervention group had no history of smoking. In both intervention and control groups, 10% of the patients had diabetes. The prevalence of hypertension was 23.3% in the intervention group and 26.7% in the control group, with prevalence of hyperlipidemia being 13.3% in the intervention group and 26.7% in the control group. Thirty percent of the patients in the control group and 40% of the patients in the intervention group had diabetes, hypertension and hyperlipidemia, simultaneously.

The INR of patients in the intervention group was 1.1 and in the control group was 0.9.

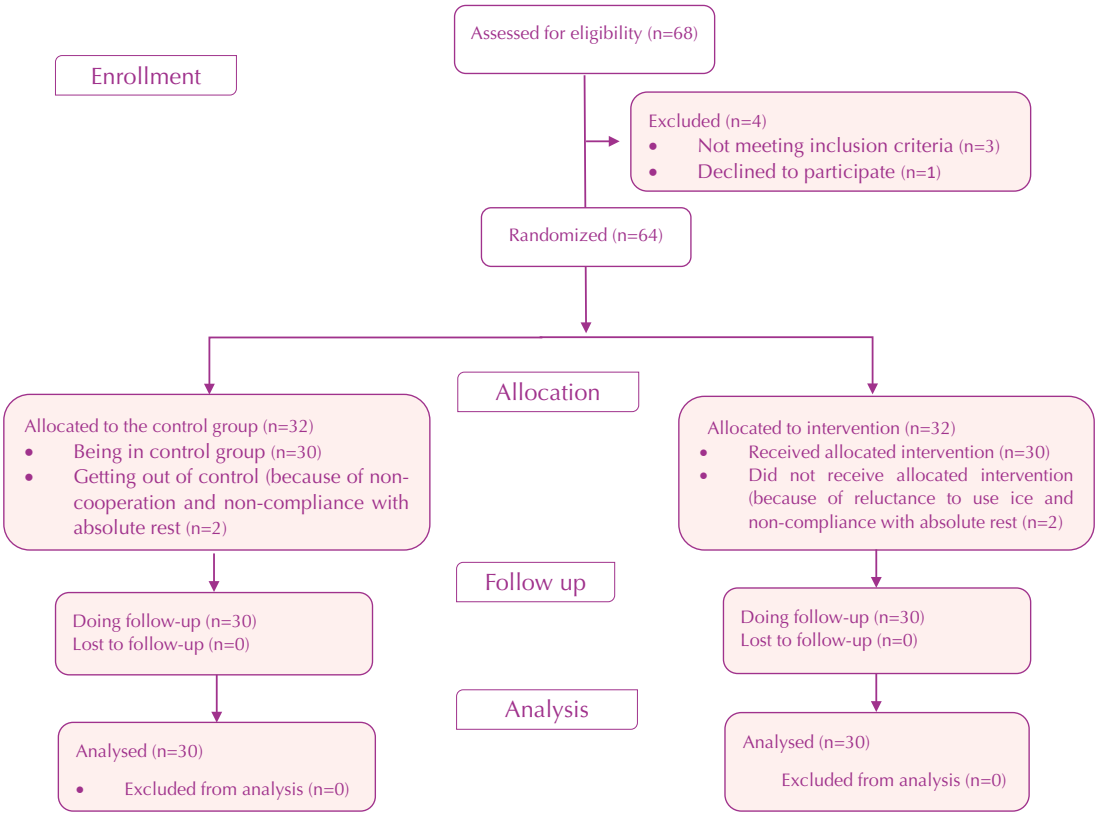

Figure 1. Flowchart of the study.

Mean (SD) blood platelet count was 271 770 (75 483.5)/μL in the control group and 256330 (82273)/μL in the intervention group. As the statistical results indicated, all the intended background (age, sex, education etc.) and confounding variables (BMI, disease history, smoking status etc.) were homogeneous in both groups. In this study, all patients had arterial sheath No. 6 in the femoral artery and took heparin as an anti-coagulant during angioplasty.

The results of intergroup comparison showed that there was not any significant difference between the mean values of hemorrhage weight (in terms of grams) in the intervention and control groups during the pre-interventional stage i.e. from PCI execution to sheath removal (P=0.42). However, the mean value of hemorrhage weight significantly descended in the intervention group in the 2nd stage (from sheath removal to 3 hours later), 3rd stage (within 3 to 6 hours after sheath removal) and 4th stage (within 6-12 hours after sheath removal) of intervention, indicating probability coefficients 0.002, 0.03 and 0.001 respectively, compared with the control group (Table 1).

In the measurement of hemorrhage per blood loss volume, the results did not represent any significant differences between the intervention and control patients in their mean hemorrhage (in terms of cc, cubic centimeter) during the pre-interventional stage i.e. from PCI execution to sheath removal (P=0.84). Likewise, the mean of 3rd-stage intervention (within 3 to 6 hours after sheath removal) was not significantly different between the two groups (P=0.051). In contrast, the 2nd stage (from sheath removal to 3 hours later) and 4th interventional stage (within 6-12 hours after sheath removal) exhibited a significantly lower mean hemorrhage values for the intervention group by probability coefficients 0.02 and 0.001 respectively, than the control group (Table 2).

Table 1. The mean and standard deviation of hemorrhage (in grams) of patients undergoing PCI in different stages

Variable	Intervention group	Control group	Statistical indicators	
	Mean (SD)	Mean (SD)		
Hemorrhage stage1 (g)	5.8 (2.0)	4.8 (1.6)	P=0.42[a]	Z=-0.80
Hemorrhage stage2 (g)	1.8 (0.7)	2.7 (1.3)	P=0.002[b,*]	t=3.2
Hemorrhage stage3 (g)	1.0 (0.5)	1.7 (0.7)	P=0.03[a,*]	Z=-2.1
Hemorrhage stage4 (g)	1.3 (0.7)	2.3 (0.8)	P=0.001[a,*]	Z=-3.2
P value[c] (χ^2)	0.004 (13.08)	0.08 (6.70)		

[a]Mann-Whitney U, [b]Independent t-test, [c]Friedman test, [*]Statistically significant.

The hematoma area was calculated by measuring the small and large hematoma diameter and placing the values in the formula. This formula is equal to1.2 πab (1.2* 3.14* a*b*) where *'a'* is the maximum hematoma diameter and *'b'* is the minimum diameter in millimeters.

There was not any significant difference in the size and dimensions of post-PCI hematoma between the intervention and control group. The results of comparison demonstrated that the area of hematoma was not significantly different between the two groups in the 1st pre-interventional stage (upon sheath removal; $P=0.98$), 2nd stage (3 hours. after sheath removal; $P=0.98$), 3rd stage (6 hours. after sheath removal; $P=0.31$) and 4th stage (12 hours. after sheath removal; $P=0.76$), as presented in Table 3.

The presence or absence of protrusion caused by hematoma was determined by touching the area around the sheath. According to the results, there was no significant difference in the size of post-PCI hematoma lump between intervention and control groups. Based on Chi-square, the frequency of hematoma projection was not significantly different between the two groups in the 1st pre-interventional stage (upon sheath removal; $P=1.00$), 2nd stage (3 hours after sheath removal; $P=1.00$), 3rd stage (6 hours after sheath removal; $P=0.23$) and 4th stage (12 hours after sheath removal; $P=0.13$).

Frequency distribution of patients according to hematoma incidence (12 hours after sheath excision) was 20% in control group and 6.7% in intervention group, as presented in Table 4.

Discussion

The results of the current study revealed that the simultaneous sand-ice bag application can reduce post-PCI hemorrhage (and hematoma rate, though insignificant) through compression and vasoconstriction. Many studies have been conducted on the incidence of vascular complications of percutaneous coronary angioplasty, including the comparison of techniques such as mechanical pressure, hand pressure, sandbag and other techniques.

Despite numerous studies that have been done to reduce the incidence of puncture vascular complications, we did not manage to find a study-within the limits of our sources and research tools- to have used a combination of the two methods as a more effective way in reducing vascular complications. Therefore, the present study combined the two methods of using sandbag as an external pressure generator and ice bag as a vasoconstrictor to reduce hemorrhage and hematoma after PCI. In a clinical trial, Yasrebirad et al., studied the effect of elastic bandage and sandbag application on 100 patients with post-angiography vascular complications. They found that such vascular access (femoral) complications as hemorrhage, pain etc. were significantly more prevalent amongst elastic-bandage patients (intervention group) than the sandbag patients ($P<0.001$).[20]

According to Yasrebirad et al., findings, prolonged sandbag application on catheterization site is necessary to prevent hemorrhage and hematoma while compression bandage cannot act as an alternative. In the current study, the risk of post-PCI hemorrhage and hematoma decreased by the simultaneous application of sandbag and ice bag on the affected area. In other words, Yasrebirad et al., study was not consistent with the present study in that the risk of vascular complications increased via intervention in the former.[20] Mutlu and Yılmaz investigated the effect of anti-inflammatory and anti-hematopoietic properties of ice on the treatment of soft issue hematoma on 99 patients at three time intervals, ranging from 10 to 20-30 minutes. They found no significant differences in hematoma reduction among the three groups, time wise. On the contrary, the longer the ice bag application, the higher the risk of icebag's local complications ($P<0.05$).[19] besides, they showed that a 10-to-20-minute local cold compression would not only maximize its positive effects but also minimize its complications. Similarly, the current study followed a 15-minute local ice bag application on the affected area, reaching in-parallel positive effects,

Table 2. The mean and standard deviation of hemorrhage (in CC) of patients undergoing PCI in different stages

Variable	Intervention group	Control group	*P* value[b] (Z)
	Mean (SD)	Mean (SD)	
Hemorrhage stage1	4.7 (1.4)	4.1 (1.3)	0.84 (0.20)
Hemorrhage stage 2	1.6 (0.5)	2.2 (0.1)	0.02* (2.3)
Hemorrhage stage 3	0.7 (0.4)	1.5 (0.4)	0.051 (1.9)
Hemorrhage stage 4	1.1 (0.8)	1.9 (0.8)	0.001* (3.3)
P value[a]	0.01 (10.80)	0.06 (7.10)	

*Statistically significant, [a]Friedman test, [b]Mann-Whitney U test.

Table 3. Average and standard deviation of area of hematoma (in cm^2) of patients undergoing PCI in different stages

Area of hematoma (cm^2)	Intervention group	Control group	*P* value[b] (Z)
	Mean (SD)	Mean (SD)	
Stage 1	3.4 (0.6)	2.0 (0.2)	0.981 (0.0)
Stage 2	3.4 (0.6)	2.1 (0.2)	0.981 (0.0)
Stage 3	4.4 (1.3)	6.2 (2.2)	0.312 (1.0)
Stage 4	4.4 (1.6)	6.4 (1.3)	0.767 (0.2)
P value[a]	0.007 (12)	0.16 (5)	

[a]Friedman test, [b]Mann-Whitney U test.

Table 4. Hematoma percentage in patients undergoing PCI in two groups (12 hours after PCI)

Hematoma	Intervention group	Control group	*P* value[a] (χ^2)
	No. (%)	No. (%)	
Happened	2 (6.7)	6 (20.0)	
Did not happen	28 (93.3)	24 (80.0)	0.25 (2.3)
Total	30 (100.0)	30 (100.0)	

[a]Fisher exact test.

as in Mutlu and Yılmaz study, without observing complications.[19] Mutlu and Yılmaz and current study were in line in terms of the effectiveness of icebag application in the treatment of hematoma patients.

King et al., conducted a randomized controlled trial called "The use of compression versus vasoconstriction in the treatment of femoral hematoma occurring after percutaneous coronary intervention" on 50 patients, so as to identify an optimal method for reducing the risk of hematoma. One group was treated with a 2-kg sandbag while the other used a 365-g ice bag to achieve hemostasis at the femoral region after arterial sheath removal site. The sandbag group was the control while the icebag group was the intervention group. Hematoma occurred in both groups in 30-minute intervals for 3 hours. The results indicated a significant difference in the rate of hematoma reduction between the two groups i.e. hematoma significantly decreased in the ice bag group (intervention) compared with the sandbag group ($P<0.05$).[18] This study was also consistent with our study of hematoma reduction.

Ice therapy was considered as a therapeutic solution for the treatment of hematoma in Mutlu and Yılmaz and King's et al., studies, both of which reported a significant reduction in the rate of hematoma after ice bag application. Conversely, the current study applied ice therapy as a preventive solution for hematoma incidence (according to the principle of priority of prevention to treatment). Although there was no significant difference in the rate of hematoma between the two groups, its reduction rate from 20% to 6.7% seems to be clinically significant, which is in line with the aforementioned two studies. However, further research is required with a larger sample size to verify the results of these studies. In some studies in this area, the amount of bleeding is determined only by the weight of the dressing or the time required for coagulation. In the current study, considering the importance of hemorrhage in these patients, it was attempted to measure the lost blood in the best way, so the volume and weight of the lost blood were analyzed.

In the current study, a significant decrease was observed in the rate of hemorrhage and a reduction in the incidence of hematoma in the patients, suggesting that complications can be reduced by using ice bags in these patients. The ice bag is one of the inexpensive, affordable and safe medical devices that is easy to use.

This study was associated with limitations such as the reluctance of a small percentage of patients to use ice and the lack of absolute bed rest in the early hours. These limitations were restrained in a way that did not cause problems in the research.

Conclusion

According to the results of this study, the simultaneous sand-ice bag application can reduce post-PCI hemorrhage (and hematoma rate, though insignificant) through compression and vasocontraction. In the clinical domain, using this care approach in patients with similar complaints and complications, including patients undergoing angiography, can reduce hemorrhage and hematoma and provide a new and positive approach to health.

In the field of clinical management, the use of the proposed method, which is low cost and available, can reduce the number of hospitalization days, reduce treatment costs, make up for a lack of financial and human resources, as well as increase patient satisfaction by reducing complications after angioplasty. The method mentioned above could help institutions achieve their goals and standards of care. Given the evidence-based effectiveness and no complications for patients, this approach, if approved by experts, can be incorporated into the educational materials in this field.

Given the positive impact of co-administration of sandbag and ice bag on PCI patients, this might prove to be an affordable, effective and low-cost method to be used in angiographic units of hospitals to create faster and more effective homeostasis and also reduce the incidence of hematoma.

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Ethical Issues

This trial study has been approved by the ethics committee of Mashhad University of Medical Sciences (code of ethics: IR.MUMS.REC.1396.312)

Conflict of Interest

The authors declare no conflict of interest in this study.

Authors' Contributions

SMM and MV collaborated in stages of designing study and writing manuscripts. SRM assisted in data analysis. JD participated in data collection. Also AE contributed to scientific counselling in the study.

Research Highlights

What is the current knowledge?

In most countries, hand-held pressure has currently been used as a more affordable way to achieve hemostasis over the arterial puncture site and sandbag is used to maintain hemostasis once the catheter sheath is removed.

What is new here?

The current study showed the simultaneous sand-ice bag application can reduce post-PCI hemorrhage (and hematoma rate, though statistically insignificant) through compression and vasoconstriction.

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