The effect of the application of cold on hematoma, ecchymosis, and pain at the catheter site in patients undergoing percutaneous coronary intervention

Yeter Kurt a, *, Mağfiret Kaşıkçı b

a Fundamentals and Management of Nursing Department, Faculty of Health Sciences, Karadeniz Technical University, Trabzon, Turkey
b Nursing Faculty, Atatürk University, Erzurum, Turkey

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Abstract

Objective: This study was conducted to determine the effect of the application of cold on hematoma, ecchymosis, and pain in patients undergoing percutaneous coronary intervention.

Methods: It is a quasi-experimental study with a control group. A total of 200 patients (100 in the control group and 100 in the experimental group) were included in the research. In the experimental group, a cold pack was applied to the bottom of the sandbag for the first 15 min after withdrawing the femoral arterial catheter. Both groups were assessed and followed up at the first 15th minute and 4th, 48th and 72nd h.

Results: After the femoral arterial catheter was withdrawn, ecchymosis and hematoma were smaller and pain was less in the experimental group at the catheter entry site compared to the control group, and the difference was statistically significant (P < 0.01).

Conclusion: It was determined that the application of cold reduced the formation of hematomas, ecchymoses and pain in patients after the withdrawal of the femoral arterial catheter.

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What is known?

• Hematomas, ecchymoses and pain were common complications at the catheter entry site of patients after PCI.
• These complications cause patients to undergo additional diagnostic procedures, the length of hospital stay to prolong, and hospital costs to increase.

What is new?

• The application of cold reduces hematoma, ecchymosis and pain developed after the withdrawal of the femoral arterial catheter.
• The application of cold provides nonpharmacological, effective, cost-effective and practical care that nurses can easily apply for preventing of possible vascular complications after PCI.

1. Introduction

Percutaneous coronary intervention (PCI) is a procedure that involves revascularization of coronary artery procedures, such as balloon angioplasty and stent placement, which are widely accepted in the treatment of coronary artery disease [1,2]. Complications after PCI are more frequent compared to other diagnostic cardiac catheterizations. The fact that revascularization of PCI has become more complex over time has increased the severity and frequency of complications [3,4]. In recent years, the radial and brachial arteries have started to be used in PCI. Femoral artery is still the most preferred access site artery because it is larger and wider [5–7]. The use of the femoral artery in PCI has increased the incidence of vascular complications, which are among the extracardiac complications [8,9]. Life-threatening vascular complications are seen in 2%–6% of patients undergoing invasive intervention via the femoral artery [10–12]. The most common vascular complications following PCI performed via the femoral artery are hematoma (15.5%), bleeding (1.5%), arteriovenous fistula (1.0%), and pseudoaneurysm (0.7%) [13]. In addition, leakage and ecchymosis are complications that are common but do not require serious treatment after the withdrawal of the catheter from the femoral artery.

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However, hematoma is a major complication that can manifest with pain and swelling [14–17]. In the emergence of vascular complications after PCI, the use of complex techniques in PCI, insufficient hemostasis after PCI [10,18–20], use of antiplatelet or anticoagulant drugs during or after the procedure, application of a long catheter to the femoral artery, long duration of catheter stay, and quality of nursing care provided [21,22] play a role. These vascular complications, leading to an increase in morbidity and mortality, cause patients to undergo additional diagnostic and treatment procedures, thereby prolonging their hospital stay and increasing hospital costs [2,23–25]. Because of these complications, care should be taken after PCI. Therefore, managing most of post-PCI femoral arterial catheter complications is one of the main responsibilities of nurses in acute and critical care settings [13,26]. In this context, nurses endeavor to minimize the risk of complications after cardiac catheterization and check for complications of PCI at the entry site [27]. However, they should first avoid bleeding and hematoma formation with care after PCI [2]. Despite medical and nursing practices, vascular complications are frequently seen [28]. Nevertheless, there are very few studies on nursing interventions that can be applied to prevent vascular complications, can contribute to the literature, and are valid and accepted [13–15,26]. When these studies were examined, it was found that the use of various vascular closure devices for compression after catheter withdrawal had a decreasing effect on bleeding [29–31]. Also, the different bed rest positions given to patients after stopping bleeding following catheter withdrawal did not affect bleeding [32]. In addition, the bed rest time after catheter withdrawal and the ambulation time after rest were not found to be effective in bleeding and hematoma [33,34]. It has been reported that the use of a cold pack is more effective in reducing hematomas after bleeding [39]. One strategy to prevent or reduce complications such as bleeding, hematoma, ecchymosis, and pain is the application of cold [36,37]. The application of cold is widely used because of its physiological effects such as vasoconstriction, slowing of tissue metabolism, increase in blood viscosity, and local anesthesia [37,38]. The application of cold reduces the blood flow and capillary permeability by causing vasoconstriction of arterioles, thereby reducing bleeding. In addition, it reduces blood flow velocity and increases viscosity and coagulation. Increased blood coagulation and decreased capillary permeability and metabolic requirements facilitate the control of hemorrhage and reduce ecchymosis and hematoma formation [36,37,39]. In this sense, it is thought that the application of cold may be useful in reducing bleeding, ecchymosis, hemorrhage, and pain commonly seen after PCI. No study has reported on the application of cold to prevent or reduce complications at the catheter site or the femoral artery after PCI. It has been determined that there is a need for interventional studies to determine the effectiveness after PCI, shorten the treatment duration, and prevent possible complications.

This study was designed to determine the effect of the application of cold on hematoma, ecchymosis, and pain after the withdrawal of the femoral arterial catheter in patients undergoing PCI.

2. Methods

2.1. Study design

It was an experimental study with a control group.

2.2. Population and sample

This study was conducted between August 2011 and January 2012 at the Coronary Intensive Care Unit of the Thoracic and Cardiovascular Surgery Training and Research Hospital of the University of Health Sciences. The hospital performs more than 6000 angiograms per year.

The sample of the study consisted of patients who were admitted to the Coronary Intensive Care Unit because of the diagnosis of myocardial infarction; the patients underwent PCI and agreed to participate in the study. The level of power was set at 0.94 with an α level of 0.05, at the 95% confidence interval and the sample size was calculated about 100 people in each control and intervention group, met the appropriate sample size. As a result of the power analysis, the 200 patients were determined as 100 patients for the experimental group and 100 patients for the control group. In the coronary intensive care unit, the first 100 patients meeting the inclusion criteria were included in the control group and the last 100 patients were included in the experimental group.

2.3. Inclusion and exclusion criteria

The inclusion criteria were as follows: aged 18 years and older; having an open consciousness; having a femoral arterial intervention, having a single catheter on their femoral region; having platelet count within normal range; and agreeing to participate in the study. The exclusion criteria were oozing hemorrhage, hematoma, and ecchymosis of the femoral artery region prior to catheter withdrawal; patients treated without a cold pack; use of thrombolytic drugs and glycoprotein 2b/3a; and presence of coagulation disorder and plegia.

2.4. Data collection instruments

Data collection tools included a patient identification form to record the sociodemographic characteristics, a patient follow-up form to record the hematoma and ecchymosis measurements (cm), the OPSITE FLEXIGRID (Smith & Nephew, Hull, UK) measurement device to determine the ecchymotic area (mm²), and the Numeric Pain Rating Scale (NPRS) to measure the patients’ pain.

- **Patient identification form**: The form was prepared by the researchers on the basis of the literature [13,14,23,30,40–43]. Age, gender, height, weight, day of hospitalization, time of starting coronary angiography, diagnosis, previous angiography, medications used, and some blood values were included in the form.
- **Patient follow-up form**: The form was developed by the researchers based on the literature [13,14,23,30,40–43]. Numbness and pain were determined by the subjective expression of the patients at first. For the presence of numbness and pain “present” and for the absence of numbness and pain “absent” responses were recorded. The state of occurrence of hemorrhage was defined as the presence of outward bleeding and evaluated as “present” or “absent” from the catheter insertion in the femoral artery region after catheter withdrawal. The state of occurrence of color change in the femoral artery region was evaluated as “present” or “absent” by observation after catheter withdrawal. The presence of color change was defined as ecchymosis. The form included the dimensions of ecchymotic area (mm²), hematoma size measurements (cm), pain scores, and pre- and post-PCI vital signs during the withdrawal of the femoral arterial catheter at the 15th minute and 4th hour and on the 2nd and 3rd days.
- **OPSITE FLEXIGRID measurement device**: This device was used to measure ecchymosis after the withdrawal of the femoral arterial catheter. It is a millimetric sliceable, plastic film that is made of polyethylene and can calculate surface area in square millimeters.
- **Numeric Pain Rating Scale**: It was used to determine the intensity of pain in the femoral artery region after the withdrawal of the
femoral arterial catheter. The validity of NPRS was established by Ferreria-Valente et al. [44]. In NPRS, the pain is scored between 0 and 10: “0” signifies no pain; “5” signifies moderate pain; and “10” signifies worst pain [45,46].

- **Hematoma measurement method**: Hematoma measurement in the femoral artery region after the withdrawal of the femoral arterial catheter was calculated in centimeter via palpation.

**The application of cold tool selection.** A pilot study was performed to determine the tools in the application of cold to the femoral arterial catheter entry site before starting the study. Ten patients who gave written consent were included in the pilot study. After the femoral arterial catheter was withdrawn and hemostasis was achieved by compression, a frozen 100-ml physiological saline solution package (measuring 11.3 cm x 13.3 cm, 117 g) was applied to five patients and a gel-shaped pack was applied to five patients. The application of cold was continued for 15 min for both groups. Hematoma, ecchymosis, and pain were more common in patients who used cold gel-shaped pack. It was decided to use the frozen 100-ml physiological saline solution package (cold pack) for this study.

**Application process.** The patients were recruited first to the control group and then to the experimental group. The post-PCI femoral arterial catheters were routinely withdrawn by the physician, with manual pressure applied 6 hours after the procedure. After hemostasis was achieved, the researcher evaluated the patients’ femoral artery region in terms of hemorrhage, ecchymosis, and hematoma. The routine protocol of a sandbag (5 kg) placed in the femoral artery region was performed in the control group. Immediately after the catheter was withdrawn and hemostasis was achieved in the experimental group, a cold pack covered with sterile gauze was placed under the sandbag for a duration of 15 min. The cold pack was removed from the region after 15 min later. The femoral artery region of the patients in the experimental and control groups was assessed immediately at the 15th min. Numbness, hemorrhage, color change, hematoma, ecchymosis, pain, and vital signs were recorded in Patient follow-up form. The routine application of the sandbag was continued in both groups. It was completed at the 4th hour, and the femoral artery region of both groups was assessed again for numbness, hemorrhage, color change, hematoma, ecchymosis, and pain, and the patients’ vital signs were recorded. Shortly after the catheter was withdrawn and bleeding was stopped by compression, the femoral artery region of both groups continued to be observed at the 48th and 72nd hour. Data were recorded on the patient follow-up form. The duration and type of hemorrhage were also recorded on the patient follow-up form. Ecchymosis was measured using OPSITE FLEXIGRID, and the area was calculated and recorded. The presence of hematoma was manually palpated and the measurement was recorded (cm) on the form. For pain assessment, the intensity of pain was rated using NPRS.

2.5. **Ethical considerations**

This study had the approval (numbered 2.1/24) of the University’s Institute of Health Sciences’ Ethics Committee. Written permission from the management of the hospital was obtained. In addition, the patients were informed about the aims and procedures of the study before data collection, and their questions were answered before written consent was obtained.

2.6. **Data analysis**

Characteristics of the patients were analyzed using the chi-squared test to compare the descriptive data between the experimental and control groups, the independent samples t-test was used to determine the correlation between normally distributed data, and the Mann–Whitney U test was used to determine the correlation between non-normally distributed numeric data. The Mann–Whitney U test was used to compare hematoma, ecchymosis, and pain measurement results of the groups, whereas the Friedman test (15th min, 4th, 48th, and 72nd hour) in repeated measures and the Wilcoxon rank sum W-test as posttest were used. The results were evaluated at a confidence interval of 95% and significance was at a level of $P < 0.05$.

3. **Results**

Gender, age, body mass index (BMI), medical history, drug use status, and previous angiographic status of the patients in the experimental and control groups were similar and there was no significant difference between the groups ($P > 0.05$; Table 1). No significant difference was found between the patients in the experimental and control groups in terms of the type of PCI, catheter number, duration of PCI, duration of catheter dwell time, withdrawal time of the catheter, heparin dosage used during PCI, Plavix loading dose, and APTT, PT, hemoglobin, erythrocyte, hematocrit, platelet, and calcium laboratory values before catheter withdrawal ($P > 0.05$; Table 1).

When the experimental and control groups were compared in terms of color change at the catheter entry site after the femoral arterial catheter was withdrawn, a statistically significant difference was found at the 4th, 48th and 72nd hour ($P < 0.05$; Table 2).

Statistically significant ($P < 0.01$) ecchymosis surface area and hematoma size were observed in the control group than in the experimental group at the 48th hour and 72nd hour (Table 3). When the experimental and control groups were compared in terms of pain rates, a statistically significant difference was found at the 15th minute and 4th to 72nd hour ($P < 0.01$). The experimental and control groups were similar in terms of numbness and hemorrhage characteristics at all time intervals.

4. **Discussion**

Nurses play an important role in preventing complications from admission to discharge. Early recognition and prevention of complications after PCI are key. However, the number of studies related to nursing interventions that are effective, feasible, and validated for vascular complications is limited [14,15,26]. For this reason, it was found to be useful to carry out research on practices that would prevent vascular complications after PCI. In this study, the effect of a 15-min application of cold on the femoral artery region after catheter withdrawal was evaluated in patients undergoing PCI. The study determined that the application of cold decreased hematoma, ecchymosis, and pain (Table 2).

According to this study, it was found that the application of cold to the femoral artery region after catheter withdrawal decreased the incidence of drowsiness in the region, although not significant. In Lunden’s study (2006), it was reported that there was leg numbness, including the femoral artery region, after coronary angiography [40]. It can be said that this situation is related to deterioration in the circulation of the leg that has been inactive for a long time. Many studies evaluating hemorrhage after the withdrawal of the femoral arterial catheter have reported it to occur as a minor [21,47]. Among the factors that increase hemorrhage, there are studies showing that drug use is effective in reducing coagulation [9,30,42,48]. In this study, it was suggested that the reason for the low rate of hemorrhage was that the study did not include patients who used thrombolytic drugs and glycoprotein 2b/3a. In addition, blood coagulation was within normal limits, and this may explain the low rate of hemorrhage (Table 1).
Catheter withdrawal from the femoral artery region creates a trauma effect, often resulting in extravasation of blood and color change [49]. In addition, the thickness of the catheter is a factor in trauma effect, often resulting in extravasation of blood and color change [49]. In this study, it was found that the application of cold decreased hematomas as well as ecchymosis formation [35]. Although there is no study evaluating the hematoma associated with the application of cold applied to the femoral artery region after coronary angiography. King’s study showed that the application of cold compress was an effective and tolerable method in the treatment of hematoma developing after coronary angiography [35]. In addition, studies investigating the effect of the application of cold on hematoma formation reported that 2-min ice application to the region after subcutaneous heparin administration was effective in decreasing hematomas as well as ecchymosis [50] supports the results of this study.

In this study, it was found that the application of cold decreased the frequency of ecchymosis formation in the femoral arterial catheter site, and the size of the ecchymoses developing after the application of cold was smaller. These results confirm the conclusion that ecchymosis formation was prevented by the physiological effects of the application of cold [36–39]. Although there is no study evaluating the hematoma associated with the application of cold applied to the femoral artery region after coronary angiography. King’s study showed that the application of cold compress was an effective and tolerable method in the treatment of hematoma developing after coronary angiography [35]. In addition, studies investigating the effect of the application of cold on hematoma formation reported that 2-min ice application to the region after subcutaneous heparin administration was effective in decreasing hematomas as well as ecchymosis [50] supports the results of this study.

In this study, it was found that the application of cold decreased the frequency of ecchymosis formation in the femoral arterial catheter site, and the size of the ecchymoses developing after the application of cold was smaller. These results confirm the conclusion that ecchymosis formation was prevented by the physiological effects of the application of cold. Although there is no study to date that includes the application of cold to reduce ecchymosis formation after coronary angiography, there are studies on subcutaneous injection sites. In Küçükgüçlü and Okumuş’s study, it was found that the frequency of ecchymosis statistically significantly decreased at the site where cold was applied before 2 min after...
the subcutaneous injection of an anticoagulant drug, and the size of the ecchymoses was smaller in patients who had cold applied [51]. In another study, it was determined that the 2-min application of cold on areas of ecchymosis after subcutaneous injection led to a decrease in the size of ecchymoses, and ecchymosis did not occur in 50% of the patients [50]. The result of the present study indicated that the rate of ecchymosis formation was low and the area was smaller after the application of cold, which was performed for 15 min. Effective results may have been obtained because the amount of subcutaneous tissue in the femoral artery region was small, the fat layer was thinner, and the application time of cold was 15 min.

In this study, it was seen that the application of cold after PCI decreased the incidence of pain in the femoral artery region. In other studies, pain associated with coronary angiography developed mostly on the back during catheter withdrawal and at rest [2,14,32,52,53]. In addition, the patients reported that the use of a sandbag and staying in bed for a long time was disturbing and painful [35]. In our study, pain occurring in the femoral artery region after catheter withdrawal decreased with the application of cold. The application of cold induces local anesthesia by stimulating cold receptors in the skin and inhibiting pain formation [36–39]. Using this information, many studies have been conducted to measure the effect of cold on pain. The results of these studies [39,50,54] indicating that the application of cold performed after subcutaneous heparin administration increases the loss of

Table 2
Comparison of numbness, hemorrhage, color change, ecchymosis, hematoma and pain occurring in patients [n %].

| Characteristics of Catheter Entry Site | Experimental Group (n = 100) | Control Group (n = 100) | χ² | P |
|---------------------------------------|-----------------------------|------------------------|----|---|
| **Numbness**                          |                             |                        |    |   |
| At 15th min                           | 0 (0)                       | 1 (1)                  |    |   |
| At 4th hour                           | 0 (0)                       | 1 (1)                  |    |   |
| At 48th hour                          | 0 (0)                       | 1 (1)                  |    |   |
| At 72nd hour                          | 0 (0)                       | 0 (0)                  |    |   |
| **Hemorrhage**                        |                             |                        |    |   |
| At 15th min                           | 0 (0)                       | 1 (1)                  |    |   |
| At 4th hour                           | 2 (2)                       | 4 (4)                  |    |   |
| At 48th hour                          | 0 (0)                       | 3 (3)                  |    |   |
| At 72nd hour                          | 0 (0)                       | 2 (2)                  |    |   |
| **Color change**                      |                             |                        |    |   |
| At 15th min                           | 1 (1)                       | 3 (3)                  | 1.020 | 0.312 |
| At 4th hour                           | 7 (7)                       | 16 (16)                | 3.979 | 0.046 |
| At 48th hour                          | 12 (12)                     | 45 (45)                | 6.721 | <0.001 |
| At 72nd hour                          | 20 (20)                     | 48 (48)                | 18.542 | <0.001 |
| **Ecchymosis**                        |                             |                        |    |   |
| At 15th min                           | 1 (1)                       | 3 (3)                  | 1.020 | 0.312 |
| At 4th hour                           | 7 (7)                       | 16 (16)                | 3.979 | 0.046 |
| At 48th hour                          | 12 (12)                     | 45 (45)                | 6.721 | <0.001 |
| At 72nd hour                          | 20 (20)                     | 48 (48)                | 18.542 | <0.001 |
| **Hematoma**                          |                             |                        |    |   |
| At 15th min                           | 0 (0)                       | 1 (1)                  |    |   |
| At 4th hour                           | 2 (2)                       | 4 (4)                  |    |   |
| At 48th hour                          | 0 (0)                       | 3 (3)                  |    |   |
| At 72nd hour                          | 0 (0)                       | 2 (2)                  |    |   |
| **Pain**                              |                             |                        |    |   |
| During removal of the catheter        | 99 (99)                     | 99 (99)                |    |   |
| At 15th min                           | 14 (14)                     | 43 (43)                | 20.636 | <0.001 |
| At 4th hour                           | 1 (1)                       | 23 (23)                | 22.917 | <0.001 |
| At 48th hour                          | 0 (0)                       | 18 (18)                | 19.780 | <0.001 |
| At 72nd hour                          | 0 (0)                       | 17 (17)                | 18.579 | <0.001 |

Note: χ² – Chi-Square.

Table 3
Comparison of ecchymosis, hematoma and pain average in patients.

| Characteristics | Experimental Group (n = 100) | Control Group (n = 100) | z | P |
|-----------------|-------------------------------|-------------------------|---|---|
| **Ecchymosis (mm²)** |                               |                         |    |   |
| At 15th min     | 1.0                          | 0.0                     |    |   |
| At 4th hour     | 200.0                        | 62.0                    |    |   |
| At 48th hour    | 116.0                        | 19.8                    | 296.0 | <0.001 |
| At 72nd hour    | 300.0                        | 2.0                     | 17.0  | 85.0  | <0.001 |
| **Hematoma (cm)** |                               |                         |    |   |
| At 15th min     | 2.0                          | 1.5                     |    |   |
| At 4th hour     | 2.0                          | 3.0                     | 3.0   | 19.80 | <0.001 |
| At 48th hour    | 0.5                          | 1.5                     | 3.0   | 4.873 | <0.001 |
| At 72nd hour    | 1.0                          | 0.5                     | 1.0   | 4.873 | <0.001 |
| **Pain**        |                               |                         |    |   |
| At 15th min     | 8.0                          | 0.0                     | 5.0   | 4.211  | <0.001 |
| At 4th hour     | 2.0                          | 0.0                     | 4.0   | 4.736  | <0.001 |
| At 48th hour    | 0.0                          | 0.0                     | 4.0   | 4.432  | <0.001 |
| At 72nd hour    | 0.0                          | 0.0                     | 2.0   | 4.344  | <0.001 |

Note: z – Mann-Whitney U test.

(2 min with 4 min total) the subcutaneous injection of an anticoagulant drug, and the size of the ecchymoses was smaller in patients who had cold applied [51]. In another study, it was determined that the 2-min application of cold on areas of ecchymosis after subcutaneous injection led to a decrease in the size of ecchymoses, and ecchymosis did not occur in 50% of the patients [50]. The result of the present study indicated that the rate of ecchymosis formation was low and the area was smaller after the application of cold, which was performed for 15 min. Effective results may have been obtained because the amount of subcutaneous tissue in the femoral artery region was small, the fat layer was thinner, and the application time of cold was 15 min.
sensation at the injection site, provides adequate analgesia, and decreases the perceived pain also supported the results of our study.

5. Study limitations

The limitation of this study is that it was conducted on patients with PCI in the Coronary Intensive Care Unit of Thoracic and Cardiovascular Training and Research Hospital affiliated with Health Sciences University. For this reason, the results of this study can only be generalized to similar settings.

6. Conclusion

This study found that a 15-min application of cold along with the routine application of a sandbag had a positive effect on decreasing vascular complications. Evaluations at the 15th minute and 4th hour and on the 2nd and 3rd days showed that the frequency and size of hematoma, ecchymosis, and pain formation decreased significantly at the femoral arterial catheter site. In addition, hematomas and ecchymoses formed after the application of cold were found to be smaller in size.

Conflicts of interest

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijnss.2019.09.005.

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