



## Comparison of Sandbag, Close Pad, and Cold Application Combined with Sandbag in Preventing Peripheral Vascular Complications After Cardiac Catheterisation

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### Research Article

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### ABSTRACT

**Objective:** This study was conducted to compare the effectiveness of sandbag method, close pad application, and cold application plus sandbag in preventing peripheral vascular complications after coronary procedure.

**Methods:** 120 patients were included in this experimental study. Three different methods were used following coronary procedure within the scope of the planned study. Only sandbag was used for 40 patients, only close pad for 40 patients and cold application plus sandbag for 40 patients. In all groups, the presence of hematoma, haemorrhage, ecchymosis, and pain was evaluated at the 15th minute, 4th hour, on 1st, and 2nd days after removal of the catheter. The data were collected using the Personal Information Form, the Individual Observation Form and the Visual Analogue Scale.

**Results:** In the second day follow-up after coronary intervention, it was found that ecchymosis was higher for the close pad method, but it was similar in the sandbag group and sandbag plus cold application group ( $p = 0.047$ ). At the 4th hour follow-up after coronary intervention, the pain in the sandbag plus cold application method was less than the close pad and sandbag methods ( $p = 0.04$ ).

**Conclusions:** It was concluded that the methods applied in the present study were effective in preventing peripheral vascular complications. In this context, it was thought that the present study may guide the more comprehensive randomised controlled studies to be planned in the future.

**Keywords:** Coronary intervention; Peripheral vascular complication; Sandbag; Close pad; Cold application.

## Kardiyak Kateterizasyon Sonrası Periferik Vasküler Komplikasyonları Önlemede Kum Torbası, Close Ped ve Kum Torbası ile Kombine Soğuk Uygulamanın Karşılaştırılması

#### Süreç

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### Öz

**Amaç:** Bu çalışma koroner işlem sonrası periferik vasküler komplikasyonları önlemede kum torbası yöntemi, close ped uygulaması ve kum torbası ile birlikte soğuk uygulamanın etkinliğini karşılaştırmak amacıyla yapılmıştır.

**Dizayn:** Deneysel nitelikteki bu araştırmaya 120 hasta dahil edilmiştir. Planlanan çalışma kapsamında koroner işlem sonrası kapama yöntemi olarak üç farklı metod kullanılmıştır. 40 hastaya sadece kum torbası, 40 hastaya sadece close ped ve 40 hastaya da kum torbası ile birlikte soğuk uygulama yöntemi kullanılmıştır.

**Metod:** Tüm gruplarda, hematoma, kanama, ekimoz ve ağrı varlığı kateterin çekilmesinden sonraki 15. dakika, 4. saat, 1. ve 2. günlerde değerlendirilmiştir. Veriler; Kişisel Bilgi Formu, Birey Gözlem Formu ve Görsel Analog Skala kullanılarak toplanmıştır.

**Bulgular:** Koroner girişim sonrası 2. gün takibinde ekimoz close ped yönteminde daha fazla iken, kum torbası ve kum torbası ile birlikte soğuk uygulama gruplarında benzer bulundu ( $p=0,047$ ). Koroner girişim sonrası 4. saat takibinde kum torbası ile birlikte soğuk uygulama yönteminde ağrının close ped ve kum torbası yöntemlerine göre daha az olduğu görüldü ( $p=0,04$ ).

**Sonuç:** Çalışmamızda uygulanan yöntemlerin periferik vasküler komplikasyonları önlemede etkin oldukları, ancak close ped uygulamasının ekimozu önlemede diğer yöntemlere nazaran daha az etkin olduğu ve kum torbası ile birlikte soğuk uygulama yönteminin ağrı kontrolünde daha etkili bir yöntem olduğu sonucuna varılmıştır. Bu bağlamda çalışmamızın ileride planlanacak daha geniş kapsamlı randomize kontrollü çalışmalara yol gösterici olacağı düşünülmektedir.

**Anahtar sözcükler:** Koroner girişim; periferik vasküler komplikasyon; kum torbası; close ped; soğuk uygulama.

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## Introduction

Cardiovascular diseases are the most common cause of morbidity and mortality in developed countries and are responsible for 1/3 of total deaths<sup>1</sup>. Cardiac catheterisation is applied for the diagnosis and treatment of coronary artery disease (CAD). Cardiac catheterisation is divided into two groups as coronary angiography and percutaneous coronary intervention<sup>2</sup>. The mostly preferred peripheral vascular insertion site for cardiac catheterisation is the femoral artery<sup>3</sup>. However, like any interventional procedure, cardiac catheterisation also causes a set of complications. These complications can be examined in 2 groups as major and minor. Major complications include death, myocardial infarction, and stroke. Minor complications are classified as arrhythmias, transient ischemic attack, vascular access site complications, renal failure, and contrast agent-related allergic reactions<sup>4,5</sup>. Among the minor complications, vascular complications are seen more commonly compared to others. Frequently seen vascular complications are hematoma, ecchymosis, haemorrhage, and pain<sup>6-8</sup>. The studies have indicated that peripheral vascular complications following cardiac catheterisation range from 2.9% to 65%<sup>9,10</sup>. The vascular complications causing an increase in morbidity and mortality also cause patients to undergo additional diagnostic and treatment procedures, thus prolonging hospital stays and increasing hospital costs<sup>11</sup>. Nurses being an inevitable person in the healthcare team, have important responsibilities in preventing and reducing possible complications after cardiac catheterization.

Today, the classical sandbag method is widely used in controlling vascular complications after coronary procedures [12]. However, the studies have reported that sandbag application causes more pain and discomfort, thus it is a less tolerable method for patients<sup>12,13</sup>. Vascular closure and compression devices can also be used in various brands and models in addition to the sandbag method in controlling vascular complications<sup>14-16</sup>. Recently the pneumatic compression device (close pad) has been increasingly used instead of the sandbag method<sup>15</sup>. Close pad is a new pneumatic compression device developed to maintain pressure on the femoral artery after short-term manual pressure. The close pad, which has a transparent-looking window and a balloon pouch, is ensured to provide pressure on the area by being placed on the intervention site.

Another method to prevent vascular complications is cold application. Cold application is widely used because of its physiological effects such as vasoconstriction, slowing of tissue metabolism, increase in blood viscosity and local anesthesia<sup>17</sup>. Cold application controls bleeding by reducing capillary blood flow and capillary permeability through vasoconstriction of arterioles, and also increases blood clotting by decreasing blood flow rate and increasing viscosity. Thus the development of bleeding, ecchymosis and hematoma reduce<sup>18</sup>. Cold application, also one of the non-pharmacological pain control methods, elevates the pain threshold, reduces the conduction velocity of small-diameter unmyelinated nerve fibres that carry painful stimuli from the periphery

to the centre by affecting on the peripheral nerves, and has an analgesic effect by closing the pain control gate<sup>19,20</sup>. Bayındır et al., reported that the application of ice packs to the femoral region was effective in reducing the pain caused by removal of femoral catheter in patients undergoing percutaneous coronary intervention<sup>20</sup>. Cold application also provides some other advantages such as ease of application, absence of serious side effects and low cost<sup>21</sup>. In addition, it has been emphasised that cold application is more effective and better tolerable method than the sandbag used in the management of femoral hematoma<sup>22,23</sup>.

Since the literature was reviewed, there has been no study comparing the effectiveness of sandbag method, close pad application and cold application plus sandbag in preventing peripheral vascular complications. In this context, the present study aimed to determine the effectiveness of these three methods in preventing peripheral vascular complications after coronary procedures.

## Materials and Methods

### Type of the Study

This is a randomised controlled study conducted to compare the effectiveness of sandbag, close pad, and cold application plus sandbag in preventing peripheral vascular complications in patients subjected to coronary intervention.

### Location and Time of the Study

The study was conducted in the adult cardiology service and cardiology intensive care unit of a training and research hospital between September 2016 and February 2017.

### Population and Sample of the Study

The study population consisted of patients who underwent coronary intervention at the adult cardiology service and cardiology intensive care unit of the hospital between September 2016 and February 2017. Power analysis was used to determine the sample size and 40 individuals were included in each group provided that statistical power was 80% at  $\alpha=0.20$  confidence level. A total of 120 patients who met the inclusion criteria were included.

### Inclusion Criteria

The inclusion criteria were as follows; (1) undergoing coronary intervention in the relevant clinic, (2) being conscious and cooperative, (3) having no plegia, (4) being over 18 years of age, (5) having coronary intervention site as the femoral artery, (6) having no peripheral vascular complication such as hematoma and ecchymosis at the femoral region before sheath removal, (7) receiving no thrombolytic, glycoprotein 2b / 3a antagonists, warfarin and new generation anti-coagulants, (8) having no previously known coagulation disorder, (9) having platelet counts within the normal values (150,000-450,000 / mm<sup>3</sup>), (10) being hospitalised for 2 days or longer, and (11) agreeing to participate in the study.

### Exclusion Criteria

The exclusion criteria were as follows; (1) undergoing no coronary intervention; (2) being unconscious and uncooperative; (3) having plegia; (4) being 18 years of age or younger; (5) having coronary intervention site as the radial artery; (6) having peripheral vascular complications such as hematoma and ecchymosis at the femoral region before sheath removal; (7) receiving thrombolytic, glycoprotein 2b/3a antagonist, warfarin, and a new generation anti-coagulant; (8) having previously known coagulation disorder; (9) having platelet counts out of normal values; (10) being hospitalised for less than 2 days; and (11) rejecting to participate in the study.

### Research Hypothesis

H<sub>1</sub>: There is no difference in effectiveness between the methods in preventing peripheral vascular complications after coronary intervention.

H<sub>2</sub>: Sandbag method is superior than close pad and sandbag plus cold application methods in preventing peripheral vascular complications after coronary intervention,

H<sub>3</sub>: Close pad method is superior than sandbag and sandbag plus cold application methods in preventing peripheral vascular complications after coronary intervention

H<sub>4</sub>: Sandbag plus cold application method is superior than close pad and sandbag methods in preventing peripheral vascular complications after coronary intervention.

### Data Collection Tools

The Personal Information Form and Individual Observation Form, and Visual Analogue Scale (VAS) were used as data collection tools in the study.

### Personal Information Form

The form consists of a total of 10 questions, including the patient's age, gender, body weight, smoking status, medical diagnosis, chronic diseases, presence of any previous coronary interventional procedures, medical treatments received, pre-procedure hemogram, biochemistry and coagulation parameters.

### Individual Observation Form

This form consists of two parts. The first part includes 9 questions about the type of the interventional procedure applied in the clinic, the size of the catheter used, the time of the catheter removal, the application of manual pressure, and the pressure method planned to be applied. The second part includes questions about the follow-up of peripheral vascular complications.

### Visual Analogue Scale (VAS)

Visual Analogue Scale (VAS) was first used in the 1970s. VAS has been used in many studies evaluating different parameters after the 1990s, and has recently been used in the measurement of special conditions such as pain. It is a scale where the patient can mark his/her own pain on a ten-centimetre ruler with no pain

on the left end and the worst pain (unbearable pain) on the right [24]. VAS is used to digitise some values that cannot be measured numerically. Two extreme definitions of the parameter to be evaluated are written on both ends of a 100 mm line and the patient is asked to indicate where his condition is appropriate by drawing a line or placing a point or marking on this line. The length of the distance from the place where there is no pain to the point marked by the patient indicates the patient's pain. The most important advantage of the test is that it does not have a language and is easy to implement. Regardless of being horizontal or vertical or its length, it does not affect the measurement result.

### Research Application

Patients who underwent coronary intervention and eligible for the study were randomised into three groups according to the simple randomization results generated in the computer environment: the sandbag group, the close pad group, and the sandbag plus cold application group. Patients who met the inclusion criteria were informed about the study both verbally and in written, and their informed consent were obtained. The researcher informed the patients about VAS and explained how to use it. Three different methods were used on 120 patients within the scope of the planned study; group 1: the sandbag alone for 40 patients, group 2: a close pad alone for 40 patients, and group 3: cold application plus sandbag for 40 patients. In the study, after the coronary intervention, 120 patients were continued to apply manual pressure for 15 minutes immediately after the catheter removal. Then, in group 1, pressure to the femoral area for 4 hours using a sandbag were applied; in group 2, the nurse placed the close pad with a balloon pouch at the femoral region, the balloon pouch of the close pad was inflated with 40-50 cc of air with the help of a syringe, thus allowing pressure on the intervention site, and the pressure was continued on the femoral area for 3 hours with the close pad; in group 3, the researcher placed the cold pack pad, which was set at 15-18 ° C in the deep freezer for cold application, on the femoral area in a way not to contact the skin directly and finally sandbag was applied on this pack, and the stopwatch was set to 15 minutes, and when the time expired, the cold pack pad was taken from the bottom of the sandbag and the area was checked, and pressure was maintained with a sandbag for 4 hours. Cold pack pad was applied only once in 4-hour pressure application period.

In this process, for all patients, the presence of hematoma, haemorrhage, ecchymosis and pain in the femoral intervention area was evaluated by the researcher at 15<sup>th</sup> minute and 4<sup>th</sup> hour, and the patient was mobilised gradually after 4 hours. The femoral intervention site was evaluated again by the researcher in terms of hematoma, haemorrhage, ecchymosis and pain on the first and second days of hospitalisation.

The physician of the patient and the follow-up researcher decided jointly whether or not patients developed peripheral vascular complications after coronary intervention based on clinical observation. In all groups, the presence of local complications in the

intervention area at the 15<sup>th</sup> minute and the 4<sup>th</sup> hour and on the 1<sup>st</sup> day and 2<sup>nd</sup> day after sheath removal was examined and recorded.

### Evaluation of Hematoma

The researcher defined hematoma as a non-pulsatile mass on palpation after removal of the sheath. Hematomas were divided into two groups according to the hematoma size; major for those > 10 cm<sup>2</sup> and minor for those < 10 cm<sup>2</sup>. A tape measure was used to measure the size of hematoma. After determining the width and length of the hematoma in centimetres with a tape measure, the area was calculated using a calculator and the hematoma was expressed in cm<sup>2</sup>.

### Evaluation of Ecchymosis

When ecchymosis occurred in the intervention area, the ecchymosis was surrounded by polyethylene millimetric plastic film (opside flexigrid) and the borders of the ecchymosis were drawn with an acetate pen over it. The size measurement was calculated in square millimetre (mm<sup>2</sup>).

### Evaluation of Haemorrhage

It was decided by clinical observation whether or not there was any haemorrhage in the procedure area, and haemorrhage requiring transfusion was expressed as 'major' and haemorrhage not requiring transfusion was expressed as 'minor' haemorrhage.

### Pain Assessment

The responsible researcher evaluated the pain by VAS at the 15<sup>th</sup> minute and 4<sup>th</sup> hour and on 1<sup>st</sup> and 2<sup>nd</sup> days after the removal of the catheter. The patients participating in the study were informed that the number "0" on the scale means no pain; the greater the numbers are, the greater the level of pain is; and the number "10" means most severe pain. They were asked to mark the level of the current pain. In pain measurement using VAS, the following values were determined; 0 = no pain, 1-3 = mild pain, 4-7 = moderate pain, and 8-10 = severe pain.

### Data Assessment

The compliance of the data to normal distribution was evaluated by histogram, q-q graphs and Shapiro-Wilk test. Homogeneity of variance was tested with the Levene's test. Mann-Whitney U test and independent two sample t test were used for quantitative variables in comparisons between paired groups. One-way analysis of variance and Kruskal Wallis tests were used for comparisons between more than two groups. Comparisons between measurements were evaluated by Cochran's Q test. Pearson  $\chi^2$  analysis was used for comparisons of categorical data. Dunn-Bonferroni test was applied for multiple comparisons. The data were

evaluated with IBM SPSS 22 program. Significance level was accepted as  $p < 0.05$ .

### Ethical Considerations

Prior to the application of the study, written permission was obtained from the local ethics committee of the hospital (date: 14.07.2015; number: 2015-07/01). Informed consent was obtained from the patients participating in the study. The study was conducted in accordance with the Principles of Declaration of Helsinki.

### Results

The study included 120 patients. 36 patients were female (30%) and 84 patients were male (70%). Table 1 summarises the distribution of data on the individual characteristics of the patients. In this context, no statistically significant difference was found between the pressure methods and the variables of gender, age, weight, height, body mass index (BMI), systolic and diastolic blood pressure, smoking, history of previous coronary intervention and comorbidity, and all groups had similar characteristics ( $p > 0.05$ ) (Table 1). Additionally, there was no statistically significant difference between groups in terms of haemoglobin, leukocyte count, platelet, coagulation tests and biochemical parameters ( $p > 0.05$ ).

**Table 1.** The Distribution of Individual Characteristics of Patients According to Pressure Methods

	Sandbag (n=40)	Close Pad (n=40)	Sandbag + CA (n=40)	p value
Gender (Female/Male)	11/29	13/27	12/28	0,888
Age (years)*	59,28±9,86	62,75±8,62	60,3±10, 54	0,263
Weight (kg)*	76,55±9,02	78,00±10,51	76,37±12, 19	0,756
Height (cm)*	166,87±6,45	167,72±6,92	167,10±7, 23	0,849
BMI (kg/m <sup>2</sup> )*	27,49±3,34	27,69±4,33	27,44±4, 30	0,959
Systolic blood pressure*	124,75±11,7 6	129,75±17,6 1	132,00±1 4,17	0,083
Diastolic blood pressure*	77,75±9,47 17(42,5)	79,50±10,61 14(35)	81,00±9, 00	0,329 0,191
Smoking, n(%)	19(47,5)	21(52,5)	22 (55)	0,875
Coronary intervention history, n(%)	37(92,5)	34(85)	36(90)	0,136
Comorbidities* , n(%)				

\* mean ± SD \*\* Diabetes mellitus, Hypertension, Hyperlipidemia CA; Cold Application BMI; Body Mass Index

With regard to hematoma, haemorrhage, and ecchymosis variables, a statistical significance could not be obtained, but these complications were seen more in the close pad group at 15<sup>th</sup> minute (respectively,  $p = 0.329$ ;  $p = 0.202$ ;  $p = 0.105$ ) (Table 2). In addition it was determined that moderate and severe pain were more common in the sandbag and close pad methods, but no severe pain was observed in the sandbag plus cold application method (Table 2).

**Table 2.** The distribution of peripheral vascular complications detected at the 15<sup>th</sup> minute after coronary procedure

	Sandbag (n=40)	Close Pad (n=40)	Sandbag + CA* (n=40)	p value
Hematoma, n (%)	4 (10)	6 (15)	2 (5)	0,329
Hemorrhage, n (%)	4 (10)	8 (20)	3 (7,5)	0,202
Ecchymosis, n (%)	6 (15)	11 (27,5)	4 (10)	0,105
Pain, n (%)				
- Mild	7 (17,5)	5 (12,5)	4 (10)	
- Moderate				0,336
- Severe	4 (10)	4 (10)	2 (5)	
	4 (10)	3 (7,5)	0 (0)	

\* CA; Cold Application

When examined in terms of hematoma, haemorrhage, and ecchymosis variables, respectively, it was determined that these complications were seen more in the close pad group at the 4<sup>th</sup> hour after coronary intervention, however a statistical significance could not be obtained ( $p = 0.329$ ;  $p = 0.131$ ;

$p = 0.105$ , respectively) (Table 3). The most important finding of the present study was that the pain felt in the femoral intervention area at the 4<sup>th</sup> hour follow-up after the coronary intervention was less in the sandbag plus cold application method ( $p = 0.04$ ), which was statistically significant (Table 3).

**Table 3.** The distribution of peripheral vascular complications detected at the 4<sup>th</sup> hour after coronary procedure

	Sandbag (n=40)	Close Pad (n=40)	Sandbag + CA* (n=40)	p değeri
Hematoma, n (%)	4 (10)	6 (15)	2 (5)	0,329
Hemorrhage, n (%)	0 (0)	2 (5)	0 (0)	0,131
Ecchymosis, n (%)	6 (15)	11 (27,5)	4 (10)	0,105
Pain, n (%)				
- Mild	10 (25)	9 (22,5)	3 (7,5)	
- Moderate				<b>0,04</b>
- Severe	4 (10)	2 (5)	0 (0)	
	0 (0)	0 (0)	0 (0)	

\* CA; Cold Application

Since it was examined in terms of ecchymosis variable on the 1<sup>st</sup> day after coronary procedure, it was determined that it was seen less in the sandbag plus cold application method, but statistical significance was not obtained ( $p = 0.105$ ) (Table 4). When it was examined in terms of hematoma variable on the first day, this complication was seen more in the sandbag

group, but statistical significance could not be obtained ( $p = 0.591$ ) (Table 4). In addition, on the 1<sup>st</sup> day, no pain was observed at the femoral intervention area in sandbag plus cold application method, while mild pain was detected in the close pad and sandbag methods ( $p = 0.06$ ), but statistical significance was not obtained (Table 4).

**Table 4.** The distribution of peripheral vascular complications detected on the 1<sup>st</sup> day after coronary procedure

	Sandbag (n=40)	Close Pad (n=40)	Sandbag + CA* (n=40)	p value
Hematoma, n (%)	3 (7,5)	2 (5)	1 (2,5)	0,591
Hemorrhage, n (%)	0 (0)	0 (0)	0 (0)	NA
Ecchymosis, n (%)	6 (15)	11 (27,5)	4 (10)	0,105
Pain, n (%)				
- Mild	4 (10)	1 (2,5)	0 (0)	
- Moderate	0 (0)	0 (0)	0 (0)	0,066
- Severe	0 (0)	0 (0)	0 (0)	

\* CA; Cold Application

NA: Not Applicable

While ecchymosis was more common in the close pad method on the 2<sup>nd</sup> follow-up day after coronary intervention, a similar rate of ecchymosis was observed

in sandbag and sandbag plus cold application methods ( $p=0.047$ ) and was found to be statistically significant (Table 5).



**Table 5.** The distribution of peripheral vascular complications detected on the 2<sup>nd</sup> day after coronary procedure

	Sandbag (n=40)	Close Pad (n=40)	Sandbag + CA* (n=40)	p value
Hematoma, n (%)	0 (0)	0 (0)	0 (0)	NA
Hemorrhage, n (%)	0 (0)	0 (0)	0 (0)	NA
Ecchymosis, n (%)	4 (10)	11 (27,5)	4 (10)	<b>0,047</b>
Pain, n (%)				
- Mild	0 (0)	0 (0)	0 (0)	
- Moderate	0 (0)	0 (0)	0 (0)	NA
- Severe	0 (0)	0 (0)	0 (0)	

\* CA; Cold Application

NA: Not Applicable

## Discussion

Since the femoral artery is the most commonly used arterial intervention site for coronary intervention, it is also the most common site for peripheral vascular complications after diagnostic or therapeutic procedures<sup>25</sup>. When the literature is reviewed, it is reported that the frequency of peripheral vascular complications varies between 0.9% and 65%<sup>10, 26, 27</sup>. These differences between the results of the studies are thought to originate from the reasons such as methods of achieving and maintaining haemostasis, mobilisation time, intervention characteristics, and evaluation of complications<sup>28</sup>. In the present study, it was found that the frequencies of hematoma, haemorrhage, ecchymosis, mild pain, moderate pain and finally severe pain were 10%, 12.5%, 17.5%, 13.3%, 8.3%, and 5.8%, respectively.

In the literature, the frequency of ecchymosis is 35.0-68.6%<sup>29,30</sup>. In the present study, in which we aimed to demonstrate the effectiveness of all three methods in preventing peripheral vascular complications, the frequency of ecchymosis was higher in the close pad method on the 2nd day after coronary intervention, while it was found to be similar in the sandbag and sandbag plus cold application groups. The results of different studies in the literature are parallel to results of the present study. After the sheath was removed, pressure with sandbag and mechanical compression devices in femoral intervention site were not superior over another in achieving hemostasis<sup>31-33</sup>. In the study by Roberts et al., close pads were used in 101 patients who had coronary intervention, and they indicated that these devices were very effective and reliable in preventing vascular complications<sup>34</sup>. Although ecchymosis was more common in the close pad method in our study, statistical significance was obtained only in the 2nd day evaluation (Table 5). In addition, it was thought that due to the high rate of complications seen in the close pad method, the cost increased and patient discomfort and dissatisfaction were high. However, in our study, ecchymosis formation was seen less in the cold application plus sandbag method compared to the close pad and sandbag methods (Table 2,3, and 4). In the study of Kucukguclu and Okumus, it was reported that the cold application reduced the frequency of ecchymosis significantly<sup>35</sup>. In another study, it was determined that 2 minutes of cold application after subcutaneous

injection caused a reduction in the size of ecchymoses and finally ecchymosis did not occur in 50% of the patients<sup>36</sup>. These results confirm the result that ecchymosis formation is prevented by the physiological effects of cold application. At the same time, we believe that the amount of subcutaneous tissue in the femoral artery region and the duration of cold application affect the results positively.

Approximately half of the haemorrhage that occurs after the coronary procedure is observed in the arterial intervention area. The severity of the haemorrhage can vary from minor haemorrhage to retroperitoneal haemorrhage with a mortal course<sup>37</sup>. Ginanjar et al., reported that cold application and early ambulation showed the same efficacy as sandbag in preventing bleeding<sup>2</sup>. In the present study, haemorrhage was seen less in the cold application plus sandbag group (7.5%), but it was 10% in the sandbag group and 20% in the close pad group at the 15th minute evaluation. This difference in the cold application plus sandbag group can be explained by the fact that cold application controls bleeding by reducing capillary blood flow and capillary permeability through vasoconstriction of arterioles<sup>18</sup>.

Another complication seen after cardiac catheterization is hematoma. In the studies, it is emphasized that cold application is a more effective and better tolerable method than sandbag method used in the prevention of peripheral vascular complications after coronary intervention<sup>2,22,23</sup>. King et al. compared sandbag and cold application in 50 patients who developed femoral hematoma after cardiac catheterization and revealed that cold application is a much more effective approach than sandbag method<sup>22</sup>. According to Kurt and Kasıkcı's study, cold application to the catheter area after the coronary procedure has been shown to be an effective method in reducing hematoma formation and size<sup>38</sup>. Rani et al., reported in their study that 11% of the patients developed hematoma after coronary angiography<sup>39</sup>. In our study, although there was no statistical significance with regard to hematoma rates, it was found to be lower in cold application plus sandbag than the other groups (Table 2 and 3). This difference can be explained by the fact that cold application decreases blood flow, increases coagulation by increasing viscosity, and controls bleeding by reducing metabolic requirements<sup>18</sup>.

The most important finding of the present study is that the pain felt in the sandbag plus cold application method was less than the close pad and sandbag methods at the 4<sup>th</sup> hour follow-up after coronary intervention (Table 3). Pain can negatively affect the healing process by causing anxiety and fatigue in patients. Pain causes the release of catecholamines, thereby increasing both cardiac workload and oxygen consumption, which can lead to the development of arrhythmia, ischemia, acute heart failure, and acute myocardial infarction in patients with coronary artery disease<sup>20,40</sup>. Therefore, it is important to control pain before it starts during invasive interventions. In order to reduce the patient's analgesic needs, non-pharmacological methods such as cold application should be considered as an alternative for pain control. In a study, it was shown that cold application to the interventional procedure area significantly controlled the pain in 100 patients who underwent cardiac catheterization<sup>41</sup>. According to the study of Kurt and Kasikci, it has been shown that cold application to the catheter area after coronary procedure is an effective method in reducing hematoma, ecchymosis and pain<sup>38</sup>. Wicaksono et al. have shown in their study that the highest pain score was in the sandbag group<sup>42</sup>. The data of our study are similar to the literature. While mild, moderate and severe pain was seen more in sandbag and close pad methods, severe pain was not observed in cold application plus sandbag method (Table 2). In addition, while no pain was observed in the femoral intervention area with cold application plus sandbag method on the 1st day, whereas mild pain was detected in close pad and sandbag methods (Table 4). Based on these findings, we can say that cold application is an important non-pharmacological nursing intervention in the management of peripheral vascular complications. In addition, in other studies, cold application was found to be more relaxing by the patients and was also emphasized as a preferred method by the staff<sup>11,28</sup>.

#### Limitations of the Study

This experimental study has some limitations: (1) approximately 50% of the cases had the history of coronary intervention, (2) the number of patients included in the study was limited, (3) there were cultural and individual differences in the definition of pain, (4) possible anxiety related to intensive care environment and the procedure, and (5) the study was conducted in a single centre.

#### Conclusion

Peripheral vascular complications after coronary intervention can lead to serious morbidity and moral damage. The purpose of nursing practices is to prevent possible complications, to ensure early mobilisation of the patient, to reduce pain, and to enhance the quality of life. It was determined that all 3 methods applied in the present study were effective in preventing peripheral vascular complications. Although no significant statistical difference was found, peripheral

vascular complications were more common in close pad group compared to the other groups. In addition, the sandbag plus cold application method showed a difference in providing pain control and no severe pain was observed in any of the patients in this group. In this context, it is thought that the present study may guide the randomised controlled studies to be planned in the future.

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