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The effect of the local cold application on low back pain and vascular complications of patients undergoing coronary angiography

Fariba Ebrahimi-Shalmani[1], Farideh Hasavari[1], Salman Nikfarjam[2], Ehsan Kazemnejad Leili[3], Nazila Javadi-Pashaki[*4,5]

[1]Cardiovascular Diseases Research Center, Rudsar Shahid Ansari Hospital, Guilan University of Medical Sciences, Rasht, Iran
[2]Department of Cardiology, Cardiovascular Diseases Research Center, Heshmat Hospital, School of Medicine, Guilan University of Medical Sciences, Rasht, Iran
[3]Department of Biostatistics, School of Nursing and Midwifery, Guilan University of Medical Sciences, Rasht, Iran
[4]Department of Nursing, Social Determinants of Health Research Center (SDHRC), Guilan University of Medical Sciences, Rasht, Iran
[5]Department of Nursing, Cardiovascular Diseases Research Center, School of Nursing and Midwifery, Guilan University of Medical Sciences, Rasht, Iran

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ABSTRACT

Coronary angiography due to the risk of vascular complications and low back pain development can lead to undesirable outcomes. This clinical trial was performed on 110 patients undergoing CAG through the femoral artery in 2019. Low back pain was assessed by VAS at baseline, 2, 4, 6 and 24 hours after angiography and vascular complications were investigated 9 times in this period. Results of group and time interaction analysis revealed that pain and vascular complications were significantly different between these two groups (P <0.001). After controlling for individual, clinical and technical variables, the scores of low back pain were associated with the intervention group compared to the control group (P <0.001), Body Mass Index (P=0/035) and INR (P <0.001). The extent of hematoma was associated with group (P = 0.003) and also the extent of ecchymosis was associated with group (P = 0.002), education (P = 0.44) and BMI (P = 0.035). In this study, the local cold was effective in back pain and vascular complications in patients undergoing CAG.

*Corresponding Author

Name: Nazila Javadi-Pashaki
Phone:
Email: n.javadip@gmail.com

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INTRODUCTION

Cardiovascular disease are the leading cause of disability and death worldwide (Joseph *et al.*, 2017). According to the World Health Organization reports, deaths due to heart disease are expected to become the most common cause of death in 2030 (Resolution UGA, 2015). The burden of cardiovascular diseases (CVD) will increase steeply in Iran over 2005–2025, mainly because of the ageing population (Sadeghi *et al.*, 2017).

Due to the high mortality and disability of coronary artery diseases, quick and accurate and rapid diagnosis and treatment are crucial (Neishabory *et al.*, 2010). Currently, coronary angiography (CAG) is an important key diagnostic procedure for assessing the coroner and heart anatomy and physiology, confirmation or ruling out the coronary artery diseases, and gathering information to decide on the need for invasive or non-invasive treatment approaches. In fact, CAG is a routine diagnostic tool worldwide (Libby *et al.*, 2007). According to the American Heart Association, these procedures have been increased by 45 percent from 2008 to 2013 (Shafiee and Ebrahimi, 2016; Hejazi *et al.*, 2013).

Although CAG can play an important role in the diagnosis of coronary artery disease, it has serious implications that need to be considered. The patient's experience during this procedure has an important role in the quality of their life and their willingness in taking follow-ups (Darvishpour *et al.*, 2016). Vascular complications are one of the most common adverse effects of CAG with an estimated prevalence of 0.7 to 28 percent (Woodhead, 2008). Hematoma with 47.5% and hemorrhage with 43.4% are the most common complications (Chair *et al.*, 2003; Yousefi *et al.*, 2011; Bakhshi *et al.*, 2014). Prolonged rest in the supine position and the pressure resulting from the sandbag can impair the patient's comfort (Botti *et al.*, 1998; Rezaei-Adaryani *et al.*, 2009). Patients tend to change their position regularly to relieve low back pain and increase perceived comfort (Gianakos *et al.*, 2004). This frequent switching might cause vascular damage. Since pain leads to patient's anxiety, fatigue, impatience, discomfort and also sleep disturbances during hospitalization, it can have adverse effects on treatment and their recovery (Javadi *et al.*, 2015). On the other hand, the efficacy of using sandbags in reducing vascular complications has been questioned (Chair *et al.*, 2003). Although our literature review demonstrated a positive effect of cold on reducing vascular complications (Bayındır *et al.*, 2017; Shimaa, 2016), comprehensive studies on the effect of the cold application on the prevention of low back pain in patients undergoing angiography are few (Shimaa, 2016). One of the important goals of nursing is to reduce the potential complications after diagnosis and treatment procedures during hospitalization which in turn will improve the quality of care and patients satisfaction (Darvishpour *et al.*, 2016). Therefore, it seems necessary to find a suitable, effective and safe solution for the patients undergoing CAG. On the other hand, considering the limited number of studies on the effect of cold on low back pain, and emphasize on further studies to select the best care strategy with minimal complications in these patients, this study aimed to determine the effect of the local cold application on the site of femoral sheath insertion on low back pain and vascular complications in patients undergoing CAG.

METHODS

This study is a randomized clinical trial performed on 110 patients undergoing elective CAG, referred to a teaching hospital in the north of Iran during March - September 2019. Patients were selected base on inclusion criteria including signing written informed consent, older than 18 years old, performing angiography via the femoral artery, not being sensitive to cold, no active hemorrhage in the femoral area during the procedure and before the catheter withdrawal, not experiencing lower back pain before hospitalization, ability to understand Persian language, no psychiatric disorders, not having any vision and hearing problems, not having a history of treatment with thrombolytic drugs and also hemorrhage disorder for less than 6 months, having a normal coagulation test results and not using sedative drugs during the last 24 hours.

Then, they were randomly allocated in two groups intervention (n = 55) and control (n = 55), by using the random block program on the computer (block size of 4).

In the intervention group, the cold pack was used for hemostasis. In the control group, the routine procedure (sandbag) was used. Sample size was determined based on the results of the study by cureek with parameters d=0.25, P2 = 42%, α = 0.05, β = 0.2, P1 = 27.9% using the following formula (Chair *et al.*, 2004).

n=

$$\frac{(Z1-\frac{\alpha}{2}+Z1-\beta)^2\,[P1(1-P1)+P2(1-P2)]}{\alpha^2}$$

Exclusion criteria were the occurrence of any conditions that may lead to impairment in the care process (Myocardial infarction, changes in consciousness level, vasovagal shock, etc.) and diastolic or systolic blood pressure higher than 110 and 190 mm Hg before removing the sheath.

The data collection tools consisted of 5 sections: demographic, clinical, technical information, also the visual analogue scale for pain assessment (VAS) and vascular complications assessment form. Demographic information included age, gender, education, Body Mass Index (BMI), marital status, smoking history, height and weight. Clinical information included: a history of anticoagulant use (drug name, dose), results of the coagulation studies (latest PT, PTT, INR, platelet count and hematocrit), history of comorbidities (hypertension, diabetes, hyperlipidemia). The technical information included: angiographic duration, sheath size, location and number of venipunctures for catheterization and duration of hemostasis after sheath removal. Low back pain was assessed by VAS. Forms of assessment of vascular complications included: type of complication, amount of hemorrhage, the extent of hematoma and extent of ecchymosis. The amount of hemorrhage was obtained by weighing blooded gases with a precise scales (Standard Feutre, China), with a sensitivity of 0.01 g and an automatic calibration, based on the difference between the weights of dry gas and blooded one. Any palpable mass at the catheter insertion site that protrudes from the body's normal surface was considered as a hematoma. A standard flexible ruler was used to measure these hematomas. The extent of hematoma was calculated by multiplying the large diameter by the small diameter in centimetres. Any discoloration (blue-violet) caused by hemorrhage under the skin in the catheter entry site was considered as ecchymosis. The extent of ecchymosis was obtained by multiplying the size of the largest and the smallest diameter in centimeters.

Patients in both groups underwent cardiac monitoring and their vital signs were controlled, after transfer to the post-angiography ward. The sheath was removed and the duration of hemostasis was recorded by the researcher using a chronometer. After hemostasis control and dressing installation, in control group sandbags weighing 3-4 kg were placed on the position for 4 hours and in the intervention group, cold packs in dimensions similar to sandbag (18 $\times$ 14 cm) with a flexible structure which could gain the body's shape, were installed.

The cold packs were placed on the position 4 times, each time for 20 minutes at 10-minute intervals for a period of 2 hours. Patients in both groups were advised to lie in a supine position for 6 hours and not to move the foot under catheterization. The pack's temperature was in the range of 15-18 °C which could be maintained for 30 minutes. A laser thermometer was also used to monitor the temperature of the pack. Low back pain was assessed by VAS at baseline, 2, 4, 6 and 24 hours after the onset of intervention. Vascular complications including Hemorrhage, hematoma, and ecchymosis were assessed 9 times, before installing dressing, every 15 minutes in the first hour, every 30 minutes in the second hour and after, every hour up to 3 hours. Waterproof markers were used to determine the area of vascular complication, and a flexible transparent ruler was used to measure its extent.

Ethical considerations

This study was performed after receiving written approval of the Research Ethics Committee of Guilan University of Medical Sciences under IR.GUMS.REC.1397.340 and registered in IRAN Registry of Clinical Trials under IRCT 20180701040297N1. Before starting the sampling, the necessary explanations of the research objectives, methods, rights, and expectations were presented to each subject, if desired, they signed a written informed consent to participate in the study.

Data analysis

The data were analyzed by applying descriptive and inferential statistics using SPSS software (version 22). To determine the normal distribution of variables, the Shapiro-Wilk test was used. Chi-square, T-test, and Mann-Whitney U test was used for intergroup comparisons, Repeat measure ANOVA to compare the mean changes of pain scores in the two groups, Bonferroni test to compare pairs of means between the time points, Repeated measures ANCOVA to assess the correlation between the pain scores and intervention type in order to moderate the impact of the confounding variables. The significance level was considered as $P < 0.05$.

RESULTS

The majority of the subjects in the intervention (61.82%) and control (51.73%) groups were over 60 years of age. The demographic, clinical and technical characteristics of the research subjects are presented in Table 1. Our results showed that the intervention and control groups were matched for age, sex, anticoagulant use, history of diabetes, hyperlipidemia, PT, PTT, platelet count and hematocrit (Table 1). Although, there was not any difference in mean of low back pain between the two groups at the onset of the study, a statistically significant difference at other time points was observed ($P< 0.001$).

The assessments of group and time interactions showed a significant difference in low back pain between these two groups ($P< 0.001$) (Table 2). Investigations on vascular complications showed that there was a significant difference in mean hemorrhage at all time points except for the first 15 minutes and also 3 hours after the sheath removal ($P <0.001$). There was a statistically significant difference between the two groups at all evaluation times in their hematoma and ecchymosis ($P <0.001$). The assessments of group and time interactions showed a significant difference in hematoma and ecchymosis ($P <0.001$) (Table 3). Repeated measures ANCOVA test showed a significant effect of the

Table 1: Characteristics of research subjects

Variable		Test N=55 (%)	Control N=55 (%)	P-Value	Variable		Test N=55 (%)	Control N=55 (%)	P-Value
Age (years)		62.36 ±9.59	61.16 ±10.78	0.628^{a}	PTT(Seconds)		33.78 ±5.91	36.40 ±6.37	0.058^{c}
Sex	Female	16 (29.09)	17 (30.91)	0.835^{b}	PT(Seconds)		12.27±0.71	12.30 ±0.66	0.612^{c}
	Male	39 (70.91)	38 (69.09)		INR(Seconds)		1.18 ±0.20	1.03 ±0.10	<0.001^{c}
Educ-ation	illiterate	25 (45.45)	35 (63.64)	0.017^{b}	Platelet count		2.18±54456.13 19218	36.36 ±75.52	0.219^{c}
	High school	19 (34.55)	21 (38.18)		Duration of angiog-raphy	Less than 20 minutes	5 (9.09)	(0)0	<0.001^{d}
	Diploma	1 (1.82)	9 (16.36)			20-30 minutes	50 (90.91)	30 (54.55)	
Smoking	Yes	31 (56.26)	10 (18.18)	0.013^{b}		More than 30 minutes	(0)0	15 (45.45)	
	No	24 (43.64)	41 (74.55)						
BMI		27.09 ±2.32	25.20 ±1.67	<0.001^{a}	Sheath size	6F	15 (27.27)	15 (45.45)	0.047^{b}
						7F	40 (72.73)	25 (45.45)	
Blood Pres-sure	Yes	43 (78.18)	33(60)	0.039^{b}	HCT (%)		38.96 ±4.16	30 (54.55)	0.306^{c}
	No	12 (21.82)	22(40)		anti-coagulant	Yes	15 (27.27)	39.61 ±3,80	0.113^{b}
Diabetes	Yes	20 (36.36)	14 (25.45)	0.216^{b}		No	40 (72.72)	27 (49.09)	
	No	35 (63.64)	41 (74.55)		Duration of home-ostasis	10-15 minutes	1 (1.82)	28 (50.91)	<0.001^{b}
Hyperlipi-demia	Yes	27 (49.09)	25 (45.45)	0.702^{b}		15-20 minutes	54 (98.18)	24 (43.64)	
	No	28 (50.91)	30 (54.55)			20-25 minutes	0	11(20)	

a-Independent t-test
b-Chi-square test
c- Manvitni U test
d-Fisher's exact test

Table 2: Comparison of low back pain at different time points in control and intervention groups

Evaluation time	Test group		Control group		P-Value
	Mean ± SD	median	Mean ± SD	median	
T0	4.22 ± 1.98	4	4.78 ± 1.06	4	0.059
T1	4.75 ± 1.71	4	7.84 ± 1.01	8	<0.001
T2	5,22 ± 1.34	5	7.98 ± .0.87	8	<0.001
T3	5.80 ± 0.99	5	8.11 ± 0.63	8	<0.001
T4	3.91 ± 1.97	3	8.04 ± 1.29	8	<0.001
P (Time effect)[a]	<0.001		<0.001		
P (Group effect)[a]	<0.001				
P (Time and group interaction)[a]	<0.001				
Test strength = 0.999	Eta squared correlation coefficient = 0.642				

P values are based RM ANOVA
[b] Mann-whitey U Test

cold pack (P <0.001), BMI (P = 0.035) and also the result of their last INR (P <0.001) on low back pain controlling for individual, clinical and technical variables, (Table 4). Furthermore, repeated measures ANCOVA test showed the amount of hemorrhage was not affected by any of these variables. Cold pack had a significant effect on the extent of hematoma (P = 0.003) and ecchymosis (P = 0.002). Also, it was found a significant effect of education (P = 0.44) and BMI (P = 0.035) on ecchymosis.

DISCUSSION

The findings of this study showed that local cold administration after arterial sheath removal at the catheter site is effective in decreasing low back pain and vascular complications after angiography. In this study, the average low back pain in both groups had an increasing trend for 6 hours after angiography and then declined 24 hours later. The average score of pain was lower in the intervention group compared to the control group at all time points. Our results showed that in the control group (sandbag), low back pain scores increased from 1.5 at the beginning of the intervention to 4.1 at the end which was in line with research conducted by Çürük *et al.* (2017). Also, changes in Back Pain scores in the intervention group (cold pack) increased from 2.5 at the beginning of the intervention to 3.4 at 4 hours (Çürük *et al.*, 2017). Similarly, in the Fathi et al. study, the maximum score of low back pain was at the third hour after sheath removal, and the minimum was at 24. The sandbag removal caused a decrease in the pain in the third hour (Fathi *et al.*, 2017). The possible explanation for the gradual increase in low back pain score is that sleeping in a fixed position causes pressure on the tissues beneath which, in turn, puts pressure on the vasculature and causes an interruption on blood flow, resulting in ischemia and pain (Botti *et al.*, 1998; Rezaei-Adaryani *et al.*, 2009). The increased low back pain in the control group may be due to the fact that the sandbag puts continuous pressure onto the low back muscles, especially the lumbar muscles, causing an increase in their resistance to gravity, decreased strength, and fatigue. Muscle fatigue and decreased blood flow together leads to reduced adenosine triphosphate (ATP) and decreased glycogen supply that can increase lactic acid, which eventually results in low back pain (Chair *et al.*, 2004).

Our results showed that low back pain was associated with the intervention group compared to the control, BMI and also the result of the last INR. Although in a study led by Chair et al. there was a significant relationship between the subject's weight and their low back pain (P = 0.006) (Chair *et al.*, 2004). However, it is believed that weight gain leads to biomechanical and inflammatory changes, causing vertebral disc impairments and an increase in the pressure on the disc's surface (Sheng *et al.*, 2017). To our knowledge, there is not any study regarding the association between low back pain and INR or other coagulation tests; therefore, we recommend further investigations to explain this phenomenon.

Our results showed that maximum hemorrhage in the intervention group was occurred in the first 15 minutes and in the control group, 1.5 hours after dressing installation. The average hemorrhage in the intervention group was lower than the control group at all time points. Hemorrhage in the test group reached zero, 3 hours and in the control group, 5 hours after dressing installation which indicates the effectiveness of the cold pack in preventing hemorrhage. In the Fathi et al. study, the maxi-

Table 3: Comparison of vascular complications at different time points in control and intervention groups

Evaluation time	Hemorrhage			Hematoma			Ecchymosis		
	Test	Control	P-Value	Test	Control	P-Value	Test	Control	P-Value
T0	5.71 ± 4.78	6.18 ± 1.90	0.034	2.36 ± 0.83	5.27 ± 1.36 36/1±27/5	<0.001	1.32 ± 2.49	4.81 ± 1.38	<0.001
T1	6.07 ± 1.31	6.61 ± 4.95	0.547	3.38 ± 3.27	4.22 ± 2.05	<0.001	1.87 ± 2.92	3.76 ± 2.13	<0.001
T2	5.46 ± 1.42	7.50 ± 4.76	<0.001	2.36 ± 2.83	4.77 ± 3.22	<0.001	2.35 ± 2.58	4.12 ± 3.6	<0.001
T3	4.95 ± 1.74	8.10 ± 4.80	<0.001	2.09 ± 2.83	5.45 ± 3.28	<0.001	2.02 ± 2.62	5.18 ± 2.96	<0.001
T4	4.32 ± 2.05	8.76 ± 5.07	<0.001	1.98 ± 2.70	6.80 ± 8.65	<0.001	1.95 ± 2.55	5.65 ± 3.29	<0.001
T5	1.36 ± 2.90	9.21 ± 5.22	<0.001	1.39 ± 2.43	5.80 ± 3.45	<0.001	1.64 ± 2.44	5.83 ± 3.40	<0.001
T6	11.28 ± 2.90	5.30 ± 9.35	<0.001	0.99 ± 2.16	5.97 ± 3.59	<0.001	1.22 ± 2,26	5.98 ± 3.60	<0.001
T7	0.00 ± 0.00	0.51 ± 1.61	0.023	0.52 ± 1.69	6.03 ± 3.73	<0.001	0.71 ± 1.91	6.13 ± 3.59	<0.001
T8	0.00 ± 0.00	0.47 ± 1.52	0.023	0.43 ± 1.58	6.17 ± 3,87	<0.001	0.62 ± 1.83	6.12 ± 3.74	<0.001
T9	0.10 ± 0.71	0.00 ± 0.00	0.317	0.43 ± 1.56	6.19 ± 3.91	<0.001	0.62 ± 1.81	6.23 ± 3.83	<0.001
P(Time effect)[a]	<0.001	<0.001		<0.001	<0.001		<0.001	<0.001	
P(Group effect)[a]	<0.001			<0.001			<0.001		
P(Time and group interaction)[a]	<0.001			<0.001			<0.001		
Test strength	0.999			0.999			0.999		
Eta squared correlation coefficient	0.194			0/721			0/296		

Data are presented as mean ± SD.
P values are based RM ANOVA
[c] Mann-whitey U Test

Table 4: The effect of the intervention group compared to the control on the level of low back pain

Variable	The sum of the squares	Degrees of freedom	Mean squares	F-Statistic	P-value
Constant values	257.719	1	257.719	44.656	0.000
Effect of intervention compared to control	423.377	1	423.377	73.360	0.000
Angiography Duration	21.718	2	21.718	1.882	0.158
Sheath Size	3.584	1	3.584	0.621	0.433
Duration of homeostasis	2.700	2	2.700	0.234	0.792
Education	1.685	1	1.685	0.292	0.590
Smoking	0.195	1	0.195	0.034	0.854
BMI	26.434	1	26.434	4.580	0.035
Blood Pressure	0.651	1	0.651	0.113	0.738
Latest PTT results	1.666	1	1.666	0.289	0.592
Latest INR	78.480	1	78.470	13.599	0.000
Level of error	559.807	1	5.771		

P values are based on Repeated measures ANCOVA

mum Hemorrhage was at the baseline and the minimum was at 24 hours after angiography. In their study hemorrhage was increasing in the first 6 hours which is in line with our results (Fathi *et al.*, 2017). In curick's study, hemorrhage was lower in the local cold (3.8%) than the sandbag group (8%) which was statistically significant (P = 0.0143) (Çürük *et al.*, 2017). In our study, the average hematoma in the intervention group increased for the first 15 minutes and then decreased until the end of the study. In the control group, there was an increasing trend at all time points. Shimaa's study also showed a significant difference (p = 0.001) between these two groups (Shimaa, 2016).

In our study, the average ecchymosis increased up until the second 15 minutes of the study and then gradually decreased in the intervention group. Conversely, in the control group, it decreased for the first 15 minutes and then increased until the end of the study. There was a statistically significant difference in ecchymosis between the two groups. In Kurt's study in line with our study local cold application for 15 minutes after sheath removal, reduced the size of the ecchymosis in the next 4 hours (Kurt and Kaşıkçı, 2019). Fathi et al. observed that in the sandbag group, the extent of ecchymosis decreased from the beginning, for 3 hours and then gradually increased until the sixth hour. This trend was similar to our control group results (Fathi *et al.*, 2017). In Curuk et al. study, the frequency of ecchymosis in the intervention group (7.6%) was lower than that of the sandbag group (18%) and there was a significant difference between these two groups (P = 0.0143) (Çürük *et al.*, 2017). Also in the study of Küçükgüçlü and Okumuş showed that the frequency of ecchymosis statistically significantly decreased at the site where cold was applied before 2 min after (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 (Küçükgüçlü and Okumuş, 2010).

After controlling for confounding variables (individual, clinical, and technical), the hemorrhage was not affected by any of these variables and the groups. Our finding was in line with the results of Curuk's study aimed to determine the effect of the sandbag and local cold application on post-angioplasty vascular complications (Çürük *et al.*, 2017). The extent of hematoma was only in association with the group (cold pack compared to sandbag), which is in line with the study of Kurt and Kasıkcı in angioplasty patients. 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 (King *et al.*, 2008). Furthermore, the extent of ecchymosis was associated with the group, education level, and BMI. Presumably, Lower education levels may cause a lack of accurate understanding to adhere to the instructions which emphasize on inactivity and also bending the corresponded foot after catheter removal leading to an increase in the risk of hemorrhage and subsequent ecchymosis. On BMI, A study conducted by Williams et al. showed a significant increase in the odds of vascular complications associated with increased BMI (AOR 1.1, 95% CI 1.0–1.2). Obese people have deeper femoral arteries which are more difficult to access. This can increase the probability of damage to these arteries while trying to access (Williams *et al.*, 2018). Therefore, we may conclude that ecchymosis also might be in association with obesity.

In general, complications such as hemorrhage, hematoma, and ecchymosis may occur after angiography because of trauma to the vessel. Differences in the reported vascular complications in different studies can be due to the definition of complications and factors associated with post-angiographic vascular implications such as sheath size, anticoagulant use, age, sex, comorbidities and the type of intervention to control the hemostasis (Chair *et al.*, 2003; Rezaei *et al.*, 2009; Mohammady *et al.*, 2014). Our results showed a significant difference between the intervention and control groups in the vascular complication occurrence. We can conclude that local cold can cause vasoconstriction, decreased blood flow, and increased coagulation which, in turn, result in decreased hemorrhage, that can ultimately reduce the hematoma and ecchymosis (Shimaa, 2016). Decreased vascular complications in the intervention group ensure greater safety of using cold packs compared to sandbag.

One of the limitations of this study is the lack of evaluation of vascular complications after the 24 hours period following cold pack application which its evaluation is suggested in future studies. In this study, we made an effort to recruit a fixed physician, however, it was not possible to use a fixed nurse to remove the sheath and to control manual pressure applied to establish hemostasis. It is recommended to use a piece of standard equipment for homeostasis control in future studies to ensure gaining constant pressure on the position. Also, it was not possible to blind the researcher for this study.

CONCLUSION

Our Findings showed that patients who received hemostasis with cold pack had less low back pain and vascular complications compared to patients receiving sandbags. According to the results of this study, it can be stated that applying local cold is effective on low back pain and vascular complications in patients undergoing coronary angiography. Therefore, it can be considered as a safe intervention that provides comfort to patients undergoing angiography. It is recommended that policy-makers and clinical nurses consider this procedure as a practical approach to provide comprehensive care.

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Conflict of Interest

The authors declare that they have no conflict of interest for this study.

REFERENCES

Bakhshi, F., Namjou, Z., Andishmand, A., Panabadi, A., Bagherinasab, M., Sarebanhassanabadi, M. 2014. Effect of Positioning on Patient Outcomes After Coronary Angiography: a single-blind randomized controlled trial. *Journal of Nursing Research*, 22(1):45–50.

Bayındır, S. K., Çürük, G. N., Oguzhan, A. 2017. Effect of Ice Bag Application to Femoral Region on Pain in Patients Undergoing Percutaneous Coronary Intervention. *Pain Research and Management*, pages 1–7.

Botti, M., Williamson, B., Steen, K., McTaggart, J., Reid, E. 1998. The effect of pressure bandaging on complications and comfort in patients undergoing coronary angiography: A multicenter randomized trial. *Heart & Lung*, 27(6):360–373.

Chair, S. Y., Li, K. M., Wong, S. W. 2004. Factors that Affect Back Pain among Hong Kong Chinese Patients after Cardiac Catheterization. *European Journal of Cardiovascular Nursing*, 3(4):279–285.

Chair, S. Y., Taylor-Piliae, R. E., Lam, G., Chan, S. 2003. Effect of positioning on back pain after coronary angiography. *Journal of Advanced Nursing*, 42(5):470–478.

Çürük, G. N., Taşcı, S., Elmalı, F., Oguzhan, A., Kalay, N. 2017. The Effect of Ice-Bag Applied to Femoral Region of Individuals with Percutaneous Coronary Intervention on Local Vascular Complications and Low Back-Pain. *Journal of Nursing and Health Science*, 6(1):136–144.

Darvishpour, A., Pashaki, N. J., Salari, A., Nejad, M. T., Barari, F. 2016. Comparing the Quality of Life in Patients with Cardiovascular Diseases Before and After Coronary Angioplasty. *Journal of Mazandaran University of Medical Sciences*, 26(137):206–210.

Fathi, M., Valiee, S., Mahmoodi, P. 2017. Effect of changing the duration of keeping sandbag over catheter insertion site on the coronary angiography acute complications: A controlled clinical trial. *Journal of Vascular Nursing*, 35(4):193–200.

Gianakos, S., Keeling, A. W., Haines, D., Haugh, K. 2004. Time in Bed After Electrophysiological Procedures (TIBS IV): A Pilot Study. *American Journal of Critical Care*, 13(1):56–58.

Hejazi, F., Hosseinzadeh, F., Rad, L. I., Bagheri, A., Vahedian, M., Damanpak, V. 2013. Effectiveness of Celox Powder and Standard Dressing in Control of Angiography Location Bleeding. *Journal of Babol University Of Medical Sciences*, 15(4):30–36.

Javadi, N., Darvishpour, A., Mehrdad, N., Lakeh, N. M. 2015. Survey of Sleep Status and its Related Factors among Hospitalized Patients with Heart Failure. *The journal of Tehran Heart Center*, 10(1):9–17.

Joseph, P., Leong, D., McKee, M., Anand, S. S., Schwalm, J.-D., Teo, K., Mente, A., Yusuf, S. 2017. Reducing the Global Burden of Cardiovascular Disease, Part 1: the epidemiology and risk factors. *Circulation Research*, 121(6):677–694.

King, N. A., Philpott, S. J., Leary, A. 2008. A randomized controlled trial assessing the use of compression versus vasoconstriction in the treatment of femoral hematoma occurring after percutaneous coronary intervention. *Heart & Lung*, 37(3):205–210.

Küçükgüçlü, Ö., Okumuş, H. 2010. The Effects of The Applicatıon of The Ice to The Injection Site, on The Patients Who Are Administered Anticoagulant Therapy. *Dokuz Eylul University School of Nursing Electronic Journal*, 3(4):182–186.

Kurt, Y., Kaşıkçı, M. 2019. The effect of the application of cold on hematoma, ecchymosis, and pain at the catheter site in patients undergoing percutaneous coronary intervention. *International Journal of Nursing Sciences*, 6(4):378–384.

Libby, P. P., Bonow, R. O., Mann, D. L., Zipes, D. P. 2007. Braunwald's Heart Disease: A Textbook of Cardiovascular Medicine. Philadelphia. 8th Edition. Philadelphia: Elsevier Science. .

Mohammady, M., Heidari, K., Sari, A. A., Zolfaghari, M., Janani, L. 2014. Early ambulation after diagnostic transfemoral catheterisation: A systematic review and meta-analysis. *International Journal of Nursing Studies*, 51(1):39–50.

Neishabory, M., Ashke-E-Torab, T., Alavi-Majd, H. 2010. Factors Affecting Back Pain among Patients after Cardiac Catheterization. *Iran Journal of Nursing*, 23(63):60–67.

Resolution UGA 2015. Transforming our world: the 2030 Agenda for Sustainable Development: Resolution adopted by the General Assembly on 25 September 2015.

Rezaei, M. A., Ahmadi, F., Asghari-Jafarabadi, M. 2009. The effect of changing position and early ambulation after cardiac catheterization on patients' outcomes: A single-blind randomized controlled trial. *International Journal of Nursing Studies*, 46(8):1047–1053.

Rezaei-Adaryani, M., Ahmadi, F., Mohamadi, E., Asghari-Jafarabadi, M. 2009. The effect of three positioning methods on patient outcomes after cardiac catheterization. *Journal of Advanced Nursing*, 65(2):417–424.

Sadeghi, M., Haghdoost, A. A., Bahrampour, A., Dehghani, M. 2017. Modeling the Burden of Cardiovascular Diseases in Iran from 2005 to 2025: The Impact of Demographic Changes. *Iranian journal of public health*, 46(4):506–516.

Shafiee, H., Ebrahimi, M. 2016. Accurate Prediction Of Coronary Artery Disease Using Bioinformatics Algorithms. *Qom University Of Medical Sciences Journal*, 10(4):22–35.

Sheng, B., Feng, C., Zhang, D., Spitler, H., Shi, L. 2017. Associations between Obesity and Spinal Diseases: A Medical Expenditure Panel Study Analysis. *International Journal of Environmental Research and Public Health*, 14(2):1–11.

Shimaa, E. 2016. The Effectiveness of Using Ice Application on Vascular Access Site Complication after Cardiac Catheterization. *Journal of Nursing and Health Science*, 5(1):8–16.

Williams, T., Khan, A., Savage, L., Condon, J., Boyle, A. J., Collins, N., Inder, K. J. 2018. Femoral vascular complications following cardiac catheterisation. *British Journal of Cardiac Nursing*, 13(12):593–599.

Woodhead, J. M. 2008. Comparison of Radial and Femoral Approaches for Coronary Angiography with or without Percutaneous Coronary Intervention in Relation to Vascular Access Site Complications.

Yousefi, A. A., Madani, M., Azimi, H. R., Farshidi, H. 2011. The factors relevant to the onset of vascular complications after coronary intervention in Shahid Rajaei Cardiovascular Center in Tehran, Iran. *Tehran University Medical Journal*, 69(7):445–450.

