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Original Article

Effects of position change on lumbar pain and discomfort of Korean patients after invasive percutaneous coronary intervention: a RCT study

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Abstract. [Purpose] This study sought to examine the effects of position change on lumbar pain and discomfort of Korean patients after invasive percutaneous coronary intervention. [Subjects and Methods] The participants consisted of 48 patients (experimental: n=24, control: n=24) who underwent invasive coronary intervention (Percutaneous Coronary Intervention) in K hospital, Seoul, Korea. A randomized controlled trial design was used. Position changes as the experimental treatment were sequenced as follows: supine position for one hour after removal of the catheter; 30-degree bed-elevated lateral position for one hour; 30-degree bed elevation for one hour; and finally 30-degree bed-elevated lateral position for one hour. The thirty degree bed-elevated lateral position was intended to press on the surgical site. Measures used were the general characteristics form, Visual Analogue Scale for lumbar pain, and discomfort scale. [Results] There were significant differences on lumbar pain and discomfort of Korean patients after invasive coronary intervention between the experimental and control groups. [Conclusion] Position change was an effective intervention for decreasing lumbar pain and discomfort of Korean patients after invasive coronary intervention. Health professionals need to consider an array of methods including position change for patients after invasive coronary intervention.

Key words: Position change, Lumbar pain, Discomfort

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INTRODUCTION

Ischemic heart diseases such as angina, cardiac infarction, heart failure, and cardiac arrest are caused by a lack of oxygen in the cardiac muscles. With the increase in the morbidity and mortality rates of ischemic heart diseases, the demand for medication therapy and invasive coronary intervention (Percutaneous Coronary Intervention) is also increasing[1)]. There were 36,476 cases in 2006, up by 59.5% to 58,186 in 2010[2)]. Coronary intervention is a procedure for improving coronary artery blockage[3)]. A tube is inserted into the blood vessel in the arm or femoral region to treat the narrowed coronary artery[4)]. In general, patients suffer pain and discomfort after coronary intervention[5, 6)].

In previous studies, patients' lumbar pain and discomfort level decreased when they sat on a bed with the upper part elevated[7, 8)], or when they were in a lateral position after a coronary intervention[9)]. Their position change did not induce complications such as bleeding and hematoma in the femoral artery puncture area, but femoral arterial catheterization and the administration of an anticoagulant to prevent blood clotting could cause vascular complications such as bleeding, hematoma, and false aneurysm in the femoral arterial puncture site[8, 10–12)]. According to clinical guidelines[13)], patients are moved to the ward with their catheters intact from the pathology laboratory to prevent bleeding or hematoma development. Their catheter is removed four hours after the procedure, and the surgical site is manually compressed for 15–20 minutes with the patient's

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legs extended straight. A compressive dressing is applied on the surgical site before a sand bag is put on it for several hours to stop the bleeding while the patient is in a still position. The patient takes a bed rest in a still position with his or her legs extended straight for six to eight hours after the surgery[13]. According to a survey on the absolute rest period after coronary interventions in South Korea, the mean period was about 20 hours[11]. The method of compressing the puncture area, the absolute rest period, and the types of nursing care modalities varied according to the clinician and the protocol[14]. For example, the absolute rest period ranged from 6 to 24 hours.

Due to the still position to prevent vascular complications in the catheterization site after a coronary intervention, patients experience lumbar pain[13, 15] and difficulty in eating and urination[16, 17]. To prevent bleeding complications and for fast recovery, various hemostatic appliances such as vascular closure devices have been developed[18]. Compared with manual compression, these appliances help reduce the risks of bleeding and vascular complications[4, 19]. In addition, the use of the hemostatic appliances shortened the bleeding time to 3–6 hours and reduced the risk of vascular complications as well as the rest period after the surgery[20, 21]. Nevertheless, patients should still have bed rest for three hours with their legs extended straight, which results in discomfort associated with lumbar pain, leg numbness, and surgical site pain[5]. Moreover, the pain and discomfort associated with the still position and the supine position after the intervention can affect the patient's vital signs and recovery[4, 9, 18].

Therefore, the minimization of bleeding complications after a coronary intervention is the focal point of nursing care, and practical and effective methods that can be used in clinical cases must be prepared. Studies[4, 7, 8] on position change after a coronary intervention have been conducted in many countries, but only a few of them were on relieving discomfort after hemostatic appliance applications. In previous studies, Fowler's position did not cause bleeding complications but relieved lumbar pain and discomfort[7, 8, 20]. However, no studies on the lateral position have yet to be reported. In this study, the effects of the lateral position and a 30-degree-elevated position for the effectiveness of bleeding complications, lumbar pain, and discomfort in patients who had been in a still position for three hours after invasive coronary intervention and hemostasis, were investigated for clinical applications.

SUBJECTS AND METHODS

This study used a randomized controlled trial design. Participants were a total of 48 patients (experimental: 24 samples, control: 24 samples) who underwent invasive coronary intervention (Percutaneous Coronary Intervention) in K hospital, Seoul, Korea. The participants were secured through random sampling using a coin toss. During the toss coin, heads meant the subject becomes a participant of the experimental group in this study. Eligibility criteria included those aged 25 to 75 years old after invasive coronary intervention that consented to engage in this study, no lumbar pain before invasive coronary intervention, and no bleeding and hematoma during and after invasive coronary intervention. Average age of the study participants was 63.2 ± 4.6. Sample size adequacy (N=34) was estimated based on an alpha level of 0.05, medium effect size of 0.5, and power of 0.80[22]. Therefore, the sample size of this study was appropriate.

The method of changing positions used in this study was based on the results of the study of Chair et al.[9] that targeted coronary angiography patients, and on the study of Kim et al.[23] on hemostasis using hemostatic appliances in coronary intervention patients. The experimental treatments in this study were conducted with the patient in a supine position for one hour, and then in a 30-degree bed-elevated lateral position for another hour. The position change was finalized after preliminary experimental treatments. Position changes in the experimental group were sequenced as follows: supine position for one hour after removal of the catheter; 30-degree bed-elevated lateral position for one hour; 30-degree bed elevation for one hour; and finally 30-degree bed-elevated lateral position for one hour. At this time, thirty degree bed-elevated lateral position was intended to press on the surgical site. The details of the position change in the control group were to maintain bed rest in a supine position for three hours with the legs extended straight after removal of the catheter.

A questionnaire was designed to measure general characteristics, lumbar pain, discomfort, existence of bleeding and hematoma. General characteristics consisted of gender, age, marital status, education, religion, experience of PCI for a total of six items. Lumbar pain was measured using Visual Analogue Scale (VAS). VAS was the assessment instrument of lumbar pain relief by means of a scale with a range from 0–10, where 0 represented no pain and 10 the most pain. Although VAS is a subjective tool, it is widely applied and is a valid instrument for pain assessment[24, 25]. The discomfort scale developed by Kim[16] and revised by authors was used to measure the level of discomfort of the participants. It consisted of a total of 9 questions using the Likert 4 scores scale. The possible score range was 9–36, and the higher the score of respondent was, the higher the level of his or her discomfort. The reliability of this instrument was Cronbach's α=0.95. Criteria of existence of bleeding and hematoma were done on the basis of Rein et al.[26] Yes in bleeding means more than one 4 × 4 gauze, and No in bleeding means there was less than one 4 × 4 gauze. Yes in hematoma means above 1 cm ×1 cm ×1 cm in size, and No in hematoma means below 1 cm ×1 cm ×1 cm in size.

Approval for this study was obtained from the IRB committee of K medical center in University (Kyung Hee University Medical Center Institutional Review Board, KMC IRB: 1205–05). Participants who formulated the cases were informed about the aim and methodology of the study and were asked to participate. All cases were anonymous. Participants were reminded that they could disengage from the study at any time and without the need to give a reason. The researchers received accomplished written consent forms from those who agreed to participate in the study. Participants were screened

Table 1. General characteristics and homogeneity test (N=48)

Characteristics		Experimental group (n=24)	Control group (n=24)	χ^2
Gender	Male	11 (45.8)	12 (50.0)	0.083
	Female	13 (54.2)	12 (50.0)	
Age (years)	<50	1 (4.2)	0 (0.0)	4.467†
	50–60	8 (33.3)	4 (16.7)	
	60–70	14 (58.3)	16 (70.9)	
	70–75	1 (4.2)	3 (12.4)	
Marital status	Married	24 (100.0)	23 (95.8)	1.021†
	Single	0 (0.0)	1 (4.2)	
Education	Elementary school below	5 (20.8)	6 (25.0)	1.239
	Middle school	14 (58.4)	13 (54.2)	
	High school above	5 (20.8)	5 (20.8)	
Religion	Protestant	9 (37.5)	12 (50.0)	1.392†
	Buddhism	5 (20.8)	4 (16.7)	
	Other	10 (41.7)	8 (33.3)	
Experience of PCI	Yes	13 (54.2)	13 (54.2)	0.000
	No	11 (45.8)	11 (45.8)	

Values are shown as the n (%): frequency and percent.
†Fisher Exact Test, χ^2: χ^2 test

Table 2. Homogeneity test of study variables between two groups (N=48)

Study variables		Experimental group (n=24)	Control group (n=24)	t/χ^2
[a]Lumbar pain		4.00 ± 0.66	3.71 ± 0.62	1.574
[a]Discomfort		21.79 ± 1.50	21.04 ± 2.27	1.348
[b]Bleeding	Yes	0 (0.0)	0 (0.0)	-
	No	24 (100.0)	24 (100.0)	
[b]Hematoma	Yes	0 (0.0)	0 (0.0)	-
	No	24 (100.0)	24 (100.0)	

Values are shown as the mean ± SD, and n (%): frequency and percent
*Significant difference between two groups ($p<0.05$): [a]t-test, [b]χ^2 test

after the purpose and study procedures were explained. The double blind method was used and a research assistant was trained for error decline. A researcher recruited subjects and applied the intervention, while the research assistant measured the lumbar pain, discomfort, and existence of bleeding and hematoma. General characteristics and study variables were measured immediately after invasive coronary intervention (Percutaneous Coronary Intervention) in the experimental and control groups. Also, study variables were measured after applying experimental intervention in experimental groups, and for the control group, study variables were measured after experimental intervention was not applied. Position change as the experimental treatment was applied to study participants by a researcher. Data were collected by a research assistant from March to October 2013.

The collected data were analyzed using SPSS version 21.0. The general characteristics of the study participants were analyzed using descriptive statistics with frequency, percentage, mean, and standard deviation. The homogeneity between two groups was analyzed using χ^2 test and independent t-test. Effects of position change were analyzed using repeated measure ANOVA.

RESULTS

The general characteristics of participants and the homogeneity test are shown in Tables 1 and 2. The 48 subjects were assigned either to the experimental group (with 24 subjects, including 11 (45.8%) males and 13 (54.2%) females) and the control group (with 24 subjects, including 12 (50%) males and 12 (50%) females). 58.3% of the subjects in the control group were in their 60s, and 70.9% in the experimental group. All the subjects in the experimental group were married, and 95.8%

Table 3. Effect of position change on lumbar pain (N=48)

	SS	df	MS	Source	F
Between subject					
Intercept	2,984.6	1	2,984.6		2,201.5*
GRP	76.3	1	76.3	Group	56.2*
Error	62.4	46	1.4		-
Within subject					
Lumbar pain scores	0.9	3	0.3	Time	1.6
GRP × Lumbar pain scores	50.1	3	16.7	Group × Time	86.0*
Error (Lumbar pain scores)	26.8	138	0.2		-

*Significant difference ($p<0.05$): F test

Table 4. Effect of position change on discomfort (N=48)

	SS	df	MS	Source	F
Between subject					
Intercept	8,644.2	1	8,644.2		5,606.3*
GRP	638.0	1	638.0	Group	41.4*
Error	709.3	46	15.4		-
Within subject					
Discomfort scores	2.8	3	0.9	Time	0.7
GRP × Discomfort scores	416.0	3	138.7	Group × Time	99.3*
Error (Discomfort scores)	192.7	138	1.4		-

*Significant difference ($p<0.05$): F test

in the control group. In terms of educational level, 58.4% of the subjects in the experimental group finished Grade 9, and 54.2% in the control group. In both the experimental and control groups, 54.2% of the subjects had a history of coronary intervention. Between the two groups, there were no significant differences in general characteristics and pre-experimental dependent variables (Tables 1 and 2).

The effects of position change are shown in Tables 3 and 4. There were statistically significant differences in lumbar pain ($F=86.046$, $p<0.001$) and discomfort ($F=99.305$, $p<0.001$) between the two groups. Lumbar pain and discomfort in experimental group were decreased more than them of control group. Also, there were no existence of bleeding and hematoma in both groups (Tables 3 and 4).

DISCUSSION

First, in terms of the effects of the position changes on lumbar pain, no significant difference in the pain scores was seen immediately after the procedure. The pain score of the experimental group was 4.00 (0.66) and 3.71 (0.62) for the control group. After the position changes, the pain score of the experimental group decreased to 3.50 (0.78), 2.96 (0.69), and 2.79 (0.83), whereas that of the control group without a position change increased to 4.54 (0.59), 4.83 (0.57), and 5.21 (0.78), corresponding to results of previous studies[7, 8, 20]. Lumbar pain increased due to the lumbar tension caused by the still position that was maintained for 30 minutes to three hours after the procedure to prevent bleeding complications. In the group with change in position, lumbar flexibility was well-maintained with a decrease in the tension level, which prevented an increase in lumbar pain. These results corresponded to those of the studies of Nam[20] and Tavris et al.[4] The still position and a decrease in lumbar flexibility caused muscle tension, and the position change helped relieve lumbar tension and pain. In the control group, the pain score gradually increased up to four hours after the procedure. The trend of the pain score in this study corresponded to that in the study of Kim et al.[23], in which the pain score increased until three hours after the procedure before it abruptly decreased. This important outcome may be used to determine the timing of intervention in a patient who had undergone manual compression. In the study of Nam[20], there was no significant difference in the lumbar pain score immediately after the procedure, but the scores in the experimental group decreased 10 minutes, one hour, and two hours after the position change, whereas those in the control group increased, as in this study. These results also correspond with those of the study of Chair et al.[9], which confirmed a decrease in the lumbar pain in coronary angiography patients who were initially in a supine position, followed by a 30-degree right lateral position, a 30-degree left lateral position, and finally, supine position at an interval of one hour.

Second, the discomfort score immediately after the procedure in the experimental group was 21.79 (1.50), and in the control group, 21.04 (2.27), reflecting no significant difference. In contrast, the discomfort score in the experimental group, which underwent position changes, tended to decrease to 19.75 (2.19), 18.40 (1.89), and 17.54 (1.86) one, two, and three hours after the procedure, respectively. In the control group, which did not undergo position changes, the discomfort score increased to 22.67 (2.50), 23.79 (2.65), and 24.67 (2.58), respectively. In summary, the discomfort levels of the groups according to their position changes immediately after their invasive coronary intervention were similar, but those in the experimental group decreased more significantly as time passed than did those in the control group, which confirms the effect of position changes on reducing discomfort. These results correspond with those of the study of Ki[11], which confirmed growing discomfort with an increase in the absolute rest period after a coronary intervention, and with those of the study of Kim et al.[23], which confirmed the relationship between a position change and the discomfort level after coronary angiography. These results also correspond with those of the study of Kim et al.[23], which were obtained from coronary angiography patients who assumed a lateral position at one-hour intervals with gradual elevations of 15 and 30 degrees, and with those of the study of Nam[20], which were obtained from patients whose bed was elevated to up to 45 degrees. In this study, most of the subjects who did not change their position complained of lumbar pain, leg pain, and numbness, as well as difficulties in food intake and urination as time passed after the procedure. In previous studies[20, 27–29], the lumbar pain levels of the control groups that did not undergo the intervention increased. This implies that lumbar pain and the discomfort level after a coronary intervention increase as time passes, which confirms the need for active nursing interventions to relieve pain and discomfort.

Third, regarding the possibility of developing bleeding complications after an invasive coronary intervention, no bleeding and hematoma after position changes was observed in both groups. Between the groups with various bed rest periods and position changes, similar to results of previous studies there was no significant difference in vascular complication developments in the puncture site after the invasive procedure[7, 17, 19, 20]. In the study of Kim et al.[23], only one case of Grade I (less than 100 ml) bleeding without hematoma was reported three hours after patient arrival in the experimental group, and one case of the same Grade I bleeding without hematoma one hour after patient arrival in the control group was reported. There were no bleeding complications because coronary intervention patients who showed bleeding upon arrival were excluded from this study due to their risk of developing hematoma or bleeding complications. In the study of Rein et al.[26], bleeding was defined as when one or more 4 × 4 gauzes were used. Accordingly, 'no' bleeding was observed in both groups without hematoma, as three cases of less than one 4 × 4 gauze bleeding were observed in the experimental group, and two cases of less than one 4 × 4 gauze bleeding in the control group. Therefore, position change after an invasive coronary intervention was confirmed as a safe procedure because it does not cause bleeding complications. However, further observations on hematoma and bleeding developments in patients who had used hemostatic appliances after a coronary intervention may be needed.

The limitation of this study involves the samples' degree of representation and generalizability. The samples used in this study were recruited only from one hospital in a metropolitan area in South Korea, limiting the characteristics of the resulting data. However, the main aim of this study was not to produce generalizable results, but rather to provide information on which to build future investigations. Further studies with larger sample sizes on physiological responses such as blood pressure and pulse rate may be needed in the future.

In conclusion, the changes from a 30-degree bed-elevated lateral position on the surgical site to a 30-degree bed-elevated position at one-hour intervals during the absolute rest period of patients who underwent invasive coronary interventions were confirmed to have been effective in relieving lumbar pain and discomfort without causing bleeding complications. This has significant implications in clinical practice in overcoming lumbar pain and discomfort for patients after invasive coronary interventions.

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