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Effect of Positioning and Early Ambulation on Coronary Angiography Complications: a Randomized Clinical Trial

Ali Akbar Abdollahi [1], Shahzad Mehranfard [2*], Nasser Behnampour [3], Abdol Mohamad Kordnejad [4]

[1]*Department of Nursing, Ischemic Disorders Research Center, Golestan University of Medical Sciences, Golestan, Iran*
[2]*Department of Nursing, Faculty of Nursing & Midwifery, Dezful University of Medical Sciences, Dezful, Iran*
[3]*Department of Biostatistics, Golestan University of Medical Sciences, Golestan, Iran*
[4]*Department of Angiography, Ganjavian Hospital, Dezful, Iran,*

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ABSTRACT

Introduction: After coronary angiography to prevent potential complications, patients are restricted to 4-24 hours bed rest in the supine position due to the complications. This study was designed to assess the effect of changing position and early ambulation on low back pain, urinary retention, bleeding and hematoma after cardiac catheterization.

Methods: In this clinical trial, 140 patients by using a convenience sampling randomly divided into four 35-individual groups. The patients in the control group were in the supine position for 6 hours without a movement. Change position was applied to the second group (based on a specific protocol), early ambulation was applied to the third group and both early ambulation and change position were applied to the fourth group. Then, severity of bleeding, hematoma, back pain and urinary retention were measured at zero, 1, 2, 4, 6, and 24 hours after angiography. The data was collected through an individual data questionnaire, Numerical Rating Scale (NRS) of pain and Kristin Swain's check list was applied to evaluate the severity of bleeding and hematoma.

Results: None of patients developed vascular complications. Incidence of urinary retention was higher in the control group, although this difference was not significant. The mean of pain intensity in the fourth and sixth hours showed a significant difference.

Conclusion: Based on the findings of this study, changing patients' position can be safe and they can be ambulated early after angiography.

Introduction

Cardiac catheterization is widely used for diagnostic evaluations in patients with cardiac diseases.[1] Annually, approximately 3 million cardiac catheterizations are performed in the United States.[2] For performing cardiac catheterization, the access to heart is established through a catheter which in more than 95% of cases perform through the percutaneous femoral artery using Seldinger technique.[3] Like any other invasive procedures, the access to heart through femoral artery have complications, such as: arrhythmias, vascular access complications (including bleeding and hematoma), myocardial ischemia, coronary artery rupture, hemodynamic collapse, cerebrovascular accident including TIA Transient Ischemic Attacks), contrast material allergy and acute renal failure.[4] The most common complications after coronary angiography are vascular complications.[5]

Generally, the incidence of vascular complications has been reported 1.5 to 9%.[6]

Studies indicated that after angiography, to avoid possible complications caused by the arterial trauma, the patients will be limited to

* Corresponding Author: MehranfardSh (MSc), email:mehranfardshahzad@gmail.com.
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bed-rest with absolute immobility of foot and using a sandbag weighted 2.5-4 Kg on the location.[3,7-9]

The request for complete bed rest of patients immediately after coronary angiography leads to their intolerance, discomfort and permanent complaint of back pain.[3,10] Chair states that back pain after cardiac catheterization causes of the complaints of pain in 35.8% patients.[11] In addition, the patients who undergo cardiac catheterization may develop urinary retention due to the various reasons.[12] Urinary retention may be transient, but if untreated can cause damage to the urinary system.[13]

Recent information indicates the heterogeneity in the patterns and standards related to the nursing care of people who are undergoing coronary angiography[14] and since most of the instructions for this care have been experimental not evidential, accordingly the nurses require a safe protocol based on research and evidence to take care of such patients.[15] In the meantime, nursing intervention aimed at decreasing patient discomfort due to prolonged bed rest are feasible to implement. The identification of additional comfort measures expands nursing knowledge about caring for post coronary angiography patient and may also decrease the amount of pain medication needed.[7] But current care causes pain and urinary retention that is inconsistent with patient comfort. Since the nursing intervenetions are aimed at improving patient comfort without an increase in vascular complications after coronary angiography, care should be intervening in such a way that without complications, provide patient comfort and satisfaction. Shorter rest in bed provides the possibility of early discharge and will resulting in reduced costs. Early ambulation, provided conditions to patients who need an extra bed in intensive care units (ICUs), able to use this facility, and the time required for implementation of medication to reduce pain and care for the patient complete bed rest and thus reduced the loss of manpower and since patient comfort is an important nursing concern, research that examines optimal care for post coronary angiography is needed. So the researchers were motivated to investigate the effect of change position and early ambulation on the complications after coronary angiography to examine possibility and safety of these interventions after angiography.

Materials and methods

The present research is a double-blind clinical trial that was performed on 140 patients referred for elective coronary angiography to Dr. Ganjavian Hospital of Dezful in 2011-2012. According to the results of similar studies and at the significance level of 0.05 and the power of 0.85, 128 patients were assigned to four groups of 32 persons. To make results more reliable 140 people in four groups of 35 persons were selected. Patients were selected through convenience sampling and were randomly divided into four groups.

To prevent contact with other ones, at the end of each group sampling, next group was sampled. Two patients due to the chest pain, were transferred to CCU ward and excluded from the study. For the first group (routine group), six hours of complete bed-rest with the supine position without any movement was applied. In the second group, positioning was intervened. That is, in the first hour after coronary angiography, the patients were in the supine position with elevation of the head of the bed to 15^0, in the second hour, the patients were in the supine position with elevation of the head of the bed to 30^0, the third hour they were in the supine position with elevation of the head of the bed to 45^0; then, the sand bag was removed and the patient rested for half of an hour on the right side and for half of an hour on the left side at the desired angle (15- 45^0) and at the end of the sixth hour, if there were no complications, the patient was helped to leave the bed gently. The intervention in the

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third group was only early ambulation at the fourth hour and the intervention in the fourth group was both change position and early ambulation. That is, the intervention of the change position was performed according to the approach of the second group and at the end of the fourth hour, if there were no complications; the patient would be helped to leave the bed gently (Table 1). After angiography the arterial sheath was removed by one person and then pressure by hand was performed on access site until homeostasis was achieved.

After homeostasis, three gases 10 × 10 cm and 5 gr was placed on the site. In the three intervention groups, sand bags were put on the location for three hours. In all patients (in the four groups), the severity of bleeding, hematoma, back pain and urinary retention were measured at the zero, 1st, 2nd, 4th and 6th hours as well as in the morning after the angiography.

The inclusion criteria included: age between 18-65 years, BP less than 180/100 mm Hg, no active hemorrhagic disorders, PT under 16 seconds and PTT under 90 second, no history of diabetes associated with sensory problems, on the risk of peripheral arterial disease, no history of back pain and no history of urination difficult. The exclusion criteria of the study included: need for cardio pulmonary resuscitation during angiography, femoral artery rupture during angiography, chest pain with new electro cardiogram (ECG) changes, incidence of active bleeding along with hemodynamic disorder and need for blood transfusion, dangerous rhythm disorder immediately after catheterization, heparin injection during or after the procedure, using of sedative, occurrence of hemodynamic disorder during study and the patient's sense of dissatisfaction.

The data collection tools in this study included demographic questionnaire (Table 2, Demographic Characteristics), experiment record sheet and patients' clinical profile form, numerical rating scale (NRS) to measure pain intensity, and Kristin Swain's checklist for checking bleeding and hematoma.[16]The numerical rating scale (NRS) is generally used to evaluate pain intensity.

The scale is 10 cm line that shows severity of pain and patient determines pain on a scale of 0 to 10. 0 means no pain and 10 means sever pain. The reliability and validity of this scale were approved in the Mounes et al., study.[17] In this study, the Spearman correlation coefficient for NRS was measured r=0.83. In Chair research, a significant correlation was obtained between the numerical rating scale and the visual analogue scale of pain (r=0.84–0.95). In addition, the validity and reliability of this instrument are examined and approved in different studies.[3,7,11,17] In order to assess the bleeding and hematoma investigation tools, at the time of bleeding and hematoma occurrence, they would be diagnosed by two nurses with five years of experiences in Post Angio ward and confirmed by the angiography performer cardiologists. The reliability of this tool determined as r=0.91 in the study of Chair.[7] This tool has been also used in various studies.[3,7,18] In this tool, hematoma larger than 5 cm as a significant hematoma and bleeding more than 100 ml as a significant bleeding have defined. Ruler was used to determine the diameter of hematoma, and digital was used to weigh blood gases; as increasing gas weight in per gram equals 1 ml of bleeding was considered.

Tools were used in this study with valid brands available in Iran and calibration of digital were in order to measure the reliability of the scale. The urinary retention was asked the patients during the study. The coronary angiography was performed for all patients through femoral artery by a single physician using 6 French catheters, because a physician's expertise is one of the important factors affecting the vascular complications. The material of the mattresses and the type of beds which may also impact on the patients' comfort and pain levels were selected the same for all. Prior to angiography, patients

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emptied their urinary bladder. They stopped taking warfarin tablet 48 hours before angiography.

Data analysis was performed using descriptive statistics of mean, standard deviation and inferential statistics of Kruskal-Wallis, Mann-Whitney, chi-square, analysis of variance using SPSS ver 11.5. In the applied statistical tests, the significance level was considered 0.05.

The project has approved by the ethics committee.

Results

The results showed the 45.7% of the participants were female and 54.3% were male with the average age of 55.77 (7.87) (Table 2). In this study, the variables of age, gender, BMI, angiography time, hemostasis time, and history of back pain, coronary angiography, smoking as well as diabetes and hypertension were classified into four groups.

This study demonstrated that there was no bleeding and hematoma in any of the subjects in four groups. The study results regarding urinary retention indicated that six people (15.3%) in the routine group, two people (5.7%) in change position group at the second hour, one person (2.9%) in early ambulation group in the fourth hour, and one person (2.9%) in the group with both change position and early ambulation at the first hour, developed urinary retention. This made no significant difference among the groups using chi-square statistical test, but the numbers in the routine group were more.

Compare four groups with average pain intensity using Kruskal-Wallis statistical test indicated that there was a significant difference between the studied groups in the mean of pain intensity at the fourth hour (P=0.001) (Table 3).The paired comparison of groups using the Mann-Whitney test showed that at the fourth hour after angiography, there was a significant difference between the average pain intensity in the routine group and the fourth group (P= 0.012), the second group and the third group (P= 0.015), the third group and the fourth group(P= 0.001) (Table 4), and at the sixth hour, between the routine group and the fourth group(P=0.041) (Table 5).

Based on the 0–10 numerical scale, the most severe back pain is associated with the sixth hour and the score six was reported in the routine group (Figure 1). The Mann-Whitney statistical test indicated that there was no significant difference among the four studied groups in the average pain intensity of the subjects immediately after entering the ward after angiography and on the day after the angiography.

Table 1. Positioning protocols and assessment methods in the groups

Control groups	1st hr	2nd hr	3th hr	4th hr		5th hr	6th hr	7th hr	Next morning
	Supine	Supine	Supine	Supine		Supine	Supine	OOB	Routinely
Change position g.	Supine, HOB 15^0 El	Supine, HOB 30^0 El	Supine, HOB 45^0 El	Right side (30 minutes)	Left side (30 minutes)	Desired position	Desired position	OOB	Routinely
Early ambulation g.	Supine	Supine	Supine	Supine		OOB			Routinely
Change position and early ambulation g.	Supine, HOB 15^0 El	Supine, HOB 30^0 El	Supine, HOB 45^0 El	Right side (30 minutes)	Left side (30 minutes)	OOB			Routinely
Low back pain assessment	✓	✓	✓	✓			✓		✓
Bleeding and hematoma assessment	✓	✓	✓	✓			✓		✓
Urinary retention assessment	✓	✓	✓	✓			✓		✓

CC: Coronary Catheterization, HOB: Head of Bed, EL: Elevation, OOB: Out Of Bed

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Table 2. Demographic and clinical characteristics of the participant

Groups(n=35) Variable	Control	Change position	Early ambulation	Change position and early ambulation	P
Age (years)‡	55.4(7.81)	56.1(8.23)	55.5(7.40)	55.7(7.87)	0.8*
Gender (M/F) n	19.16	19.16	19.16	19.16	1.0**
Marriage (S/Ma) n	2.33	3.32	4.31	0.35	0.9**
BMI‡	27.7(3.68)	27.4(3.49)	27.6(3.05)	27.9(3.12)	1.0**
Hypertension(+)¥	17 (48.6)	17 (48.6)	17 (48.6)	17 (48.6)	1.0**
Diabetes Mellitus(+)¥	2 (5.7)	3 (8.6)	4 (11.4)	2 (5.7)	0.9**
Smoking(+)¥	3 (8.6)	3 (8.6)	3 (8.6)	3 (8.6)	1.0**
Time of angiography‡	17.28(4.75)	16.85(3.85)	17.28(5.19)	16.57(3.79)	0.9**
Time of homeostasis‡	5.31(1.10)	5.05(0.33)	5.34(1.21)	5.11(0.40)	1.0**

‡mean(SD), ¥ n (%), *one- way Anova, **Chi-square test, M: male, F: female, S: single, Ma: married, BMI: body mass index, n: number

Table 3. Comparing the mean of intensity of low back pain in each groups after angiography

Time after angiography	Group (n=35)	Low Back Pain Mean (SD)	P
1st hr	Control	1.69 (0.77)	0.310
	Change position g.	1.63 (0.57)	
	Early ambulation g.	1.25 (2.16)	
	Change position and early ambulation g.	0.40 (1.33)	
2nd hr	Control	0.88 (1.8)	0.310
	Change position g.	1.62 (2.75)	
	Early ambulation g.	1.65 (2.55)	
	Change position and early ambulation g.	1.83 (0.74)	
4th hr	Control	0.88 (2.01)	0.001*
	Change position g.	0.34 (1.16	
	Early ambulation g.	1.51 (2.58)	
	Change position and early ambulation g.	0.33 (0.051)	
6th hr	Control	0.68 (2.12)	0.140
	Change position g.	0.14 (0.84)	
	Early ambulation g.	0.17 (0.85)	
	Change position and early ambulation g.	0.00 (0.00)	

The results of Kruskal - Wallis test showed a significant difference in the fourth hour

Table 4. The mean pain intensity fourth hour between all groups

Group(n=35)	Low Back Pain (rating pain intensity)	P
Control	37.91	0.11
Change position g.	33.09	
Control	33.64	0.32
Early ambulation g.	37.36	
Control	39.07	
Change position and early ambulation g.	31.93	0.012
Change position g.	31.39	0.015
Early ambulation g.	39.61	
Change position g.	36.54	
Change position and early ambulation g.	34.46	0.28
early ambulation g.	40.61	0.001
Change position and early ambulation g.	30.39	

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Table 5. The mean pain intensity sixth hour between all groups

Group(n=35)	Low Back Pain (rating pain intensity)	P
Control	37.01	0.16
Change position g.	33.99	
Control	36.57	0.36
Early ambulation g.	34.43	
Control	39.50	
Change position and early ambulation g.	33.50	0.04
Change position g.	35.01	0.56
Early ambulation g.	35.99	
Change position g.	36.00	
Change position and early ambulation g.	35.00	0.31
Early ambulation g.	36.50	0.15
Change position and early ambulation g.	34.50	

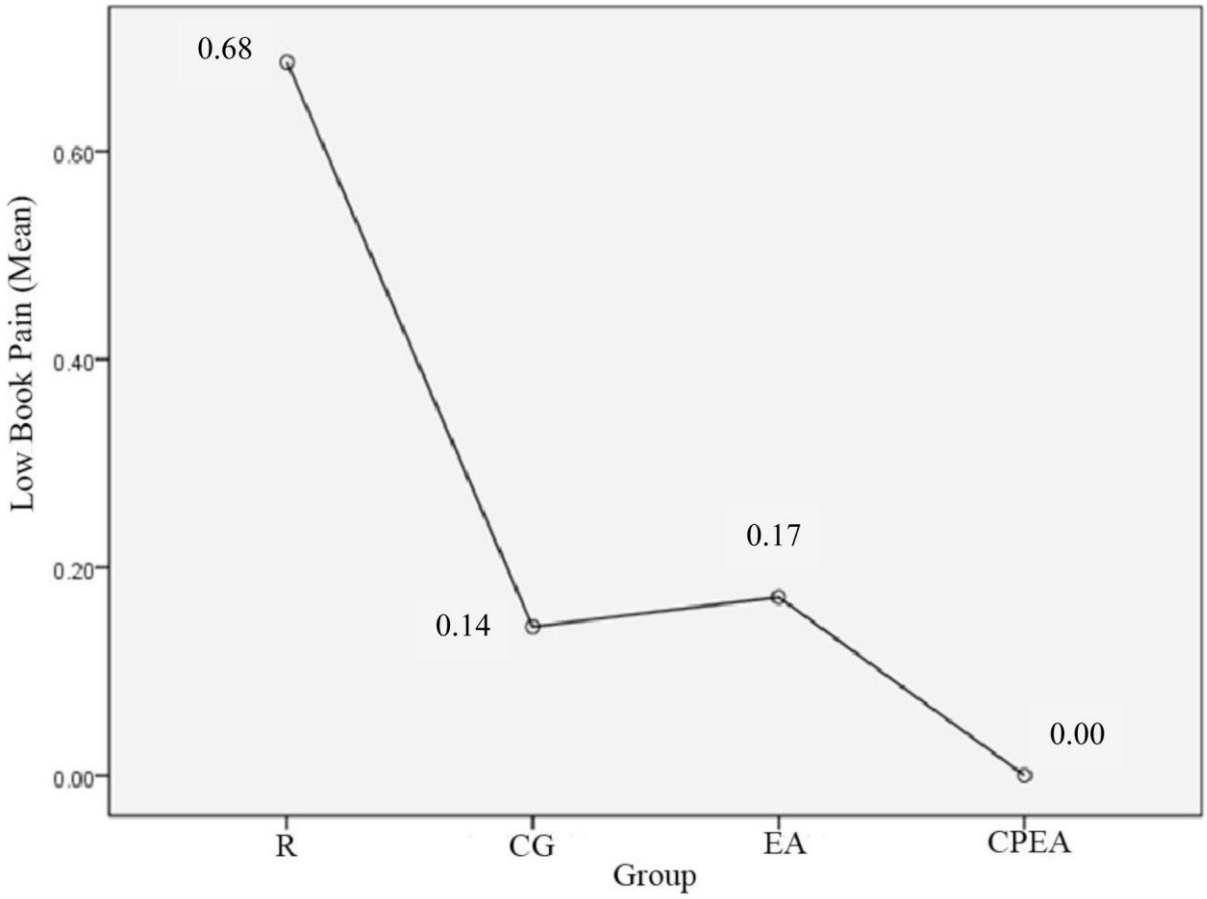

Figure 1. The mean pain intensity of participants 6th hour after angiography

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Discussion

The results obtained in this research indicated that none of the subjects experienced bleeding or hematoma. Similar studies also indicate no significant difference between control group and intervention group in the incidence of hematoma and bleeding complications at the access site after angiography.[3,5,9,11,18,19] Chair in a study reported that none of their patients had hematoma, but four patients in the control group and only one patient in the intervention group had severe bleeding that needed to pressure for create homeostasis. However, there was no significant difference between two groups of the vascular complications.[7] Oley reported that development of hematoma in the control group was 7.1% and in the intervention group was 6.9%, that in total, there was no significant differences between two groups.[20] The Boztosun et al., had investigated the effect of early ambulation after the diagnostic cardiac catheterization, in patients who had been out of bed 2 hours after the procedure, 12 patients (7%) developed a hematoma and 25 patients (16%) had minor bleeding after ambulation.[21] According to Pollard et al., in the group of patients who were ambulated 4.5 hours after the procedure, the incidence of vascular complications were 14.9% and in patients who were ambulated 2.5 hours after angiography, 19.2% reported, that there was no significant difference (P=0.1).[9]

In respect of the urinary retention problem, there was no significant difference between the four groups from this aspect. These results are consistent with the results of the research by Neishaboori;[18] in his study, Neishaboori demonstrated that five subjects (7.7%) in the control group and eight subjects (12.3%) in the intervention group reported urinary difficulty during first 6 hours after cardiac catheterization, which indicated no significant difference (P=0.38). The results of the present study are almost similar; although there was no significant difference; the number of samples that developed urinary retention were more than the routine group.

The comparison of the four groups indicated a significant difference in backache intensity at the fourth hour (P=0.00). Since at the fourth time, the patients were not out of bed, the significant difference of average backache intensity between the groups at the fourth hour can be due to effect of the change position intervention and remove sand bags. The results of the research by Chair et al., conducted to review the impact of change position on the backache after angiography and illustrated that backache intensity in the intervention group has been significantly less than the control group.

The study of Pollard et al.,[9] also showed that the increase of bed angle after one hour with early ambulation after 2.5 hours is similar in safety comparison with the increase of bed angle after 4.5 hours. The study of Yalmaz et al.,[5] titled "minimizing short-term complications in patients undergoing cardiac invasive procedures "that investigated the effect of change position and sand bag on complications, indicated no significant difference between the groups in vascular complications and the patients whose position were changed and their beds were raised, reported lower backache that is consistent with our study; also from the second hour, intensity of back pain showed significant differences between the groups that is inconsistent with the present study. Because in Yalmas study, sand bags were located on access site (30 minute– 2 hours) but in our study, sand bags were located for three hours. The results of Chair et al., study[3] to examine the effect of early ambulation after cardiac catheterization, showed that backache was higher in the control group and it was significantly different from the intervention group. In a study on 1,009 patients undergoing diagnostic catheterization,

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Doyle et al.,[22] indicated that the patients ambulated one hour after the procedure and increased vascular complications; were the ambulation of patients from the bed is safe. In addition, no significant difference was observed in this study among the four studied groups in backache intensity in the day after angiography. It is consistent with the results of the study by Ashktorab and Neishaboori suggesting that there was significant difference between the two groups in pain intensity in the day after angiography.[18] However these results are inconsistent with Chair[3,7] reporting high pain intensity in the day after angiography.

This difference may be due to the long-term bed-rest, which is 8-24 hours in the above studies, kind of mattresses and ethnic Chinese patients participated in these studies that can affect the feeling of pain.

In addition, paired comparison of the groups indicated that up to the fourth hour the patients whose position has been changed are significantly different in pain intensity with other patients whose position has not been changed. It has been presented at several studies that change position in bed reduces the backache intensity. Changing the position is one of the nursing tasks which be used as one of the non-invasive and non-pharmacological solutions to relieve pain. In addition, backache is caused tension of the pain-sensitive structures that press or stimulate the nerve endings which may be directly associated with continuous period of immobility or tension of the lower spinal ligaments.

Conclusion

According to the presented protocol, it is safe and feasible to change the patients' position and to permit early ambulation after coronary angiography. In addition, body change position prevents a backache and reduces its intensity and consequently increases a physical comfort. It also eliminates the possible negative attitudes of patients towards coronary angiography.

Moreover, this positioning method avoid wasting nurses' time on explaining the reason of patients' complete bed-rest, prescribing analgesics as well as massaging the patient's back in order to relieve the pain.

Limitations of study: Since bleeding and hematoma were observed in any groups, more samples were needed.

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Ethical issues

None to be declared.

Conflict of interest

The authors declare no conflict of interest in this study.

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