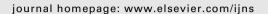


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### The effect of changing position and early ambulation after cardiac catheterization on patients' outcomes: A single-blind randomized controlled trial

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#### ABSTRACT

Background: Cardiac catheterization is the gold standard diagnostic test for coronary heart diseases. In order to minimize the post-procedure complications, patients are restricted to prolonged bed rest that is always accompanied by fatigue and discomfort.

Objective: The aim of this study was to assess the effect of changing position and early ambulation on the level of comfort, satisfaction, and fatigue and on the amount of bleeding and hematoma after cardiac catheterization.

Participants: A sample of 70 patients, who had undergone a non-emergency 6-French cardiac catheterization via the femoral artery from September to November, 2006.

Methods: In a single-blind randomized controlled trial, each patient was randomly assigned to either the control or experimental group. The patients' position in the experimental group was intermittently changed during the first 6 h after catheterization. Seven hours after the procedure, they were allowed to be ambulated and to undertake their self care activities. A pillow was placed under the patients' bodies. Patients in the control group were managed as routine; they were restricted to a 10-24 h bed rest bed rest in supine position with the affected leg straight and immobilized and a sand bag on the puncture site for at least 8 h. The levels of comfort, satisfaction and fatigue, and the amount of bleeding and hematoma were measured at regular intervals after the procedure.

Results: The patients in the experimental group had significantly higher comfort and satisfaction and lower fatigue levels than the control group at 3, 6, 8 h and the next morning after catheterization (P < 0.01). Changing patients' position according to the current protocol in the experimental group produced no significant increase in the amount of bleeding and hematoma when compared with the control group (P > 0.05).

Conclusion: The results of this study showed that the levels of comfort, satisfaction and fatigue after catheterization are related to the duration of bed rest and patients' position in bed. Changing patients' position accompanied by early ambulation after cardiac catheterization are associated with increasing comfort and satisfaction levels and decreasing the level of fatigue without increasing the amount of bleeding and hematoma. © 2009 Elsevier Ltd. All rights reserved.

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### What is already known about the topic?

- After cardiac catheterization, prolonged bed rest is prescribed to minimize the vascular complications. This prolonged bed rest is often associated with pain and discomfort for patients.
- Changing patients' position and early ambulation after cardiac catheterization may decrease the level of back pain.

### What this paper adds

- Changing patients' position and early ambulation after cardiac catheterization increase the levels of comfort and satisfaction and decrease the level of fatigue.
- Changing patients' position and removing the sand bag from the puncture site early at the post catheterization period does not increase the risk of vascular complications.

### 1. Introduction

Cardiac catheterization [CC] is widely used for diagnostic evaluations in patients with cardiac diseases (Woods et al., 2005). Despite progressive improvements in noninvasive techniques, CC remains a key clinical tool for the assessment of anatomy and physiology of the heart and its associated vasculature (Kasper et al., 2005). Currently, CC has become a routine diagnostic procedure performed in many hospitals in Iran. Although it can be performed through brachial, radial or femoral arteries (Woods et al., 2005), most (>95%) CCs are performed through the percutaneous femoral technique (Kasper et al., 2005; Chair et al., 2007). However, CC is not entirely free from the risk of complications (West et al., 2006). Vascular complications such as bleeding, hematoma, distal embolization and arterial thrombosis are major complications after CC that could be resulted from a trauma to the femoral artery (Chair et al., 2003; Steffenino et al., 2006). Due to the potential vascular complications, all patients are restricted to bed rest in supine position with the affected leg immobilized for 6-24 h after the procedure to prevent bleeding from the groin site, which usually occurs in 0.43-4% of patients (Chair et al., 2003, 2007; Benson, 2004). Bearing such a prolonged bed rest in supine position, however, is difficult for many patients, and it is often associated with discomfort for them (Fowlow et al., 1995; Lundén et al., 2006). Studies show that this type of positioning is based on tradition rather than on research (McCabe et al., 2001). The most uncomfortable part of hospital admission for these patients is the time required to lie in flat position after procedure that often results in back pain (Vlasic, 2004). Pain can increase the fatigue level and dissatisfaction of patients (Louville et al., 2003; Morton and Fontaine, 2005). Early ambulation, changing position in bed, and reducing the length of bed rest, may decrease patients' pain (Chair et al., 2003, 2007; Benson, 2004) and significantly decrease the nursing staff workload, reduce in-hospital stay and also enable the patients to meet self care needs such as eating, drinking, and voiding (Roebuck et al., 2000; Tengiz et al., 2003; Rosenstein et al.,

2004). Many patients find it difficult to use bedpan or urinal in the supine position during the bed rest (Chair et al., 2007) and due to special religious and cultural beliefs, this is a highly conflicting and unpleasant problem for the Iranian patients. In spite of these facts, many hospitals are requiring their patients to remain in prolonged bed rest from 18 to 24 h after procedure usually until next morning to prevent complications. The possibility and safety of changing patients' position and early ambulation after cardiac catheterization in our country have not yet been investigated. Furthermore, the effect of changing position and early ambulation on comfort, satisfaction and fatigue has not been investigated yet. Therefore, this study was conducted with the aim of investigating the effect of changing patients' position in bed and an early ambulation on the levels of comfort, satisfaction, fatigue, and vascular complications including bleeding and hematoma after diagnostic cardiac catheterization.

### 2. Methods

### 2.1. Participants

Patients aged 18-20 years, who had undergone a nonemergency 6 French diagnostic CC via the femoral artery, were recruited from September to November 2006. All patients meeting the criteria were approached during the recruitment period. Sample size was calculated based on the results of our pilot study (20 patients in each group). The variable "comfort" was considered as the primary endpoint for calculating the sample size. Finally, with an effect size of 0.7, an alpha of 0.05, and a power of 0.80, 70 patients (35 in each group) were selected. The patients in the pilot study were also included in the final study. The exclusion criteria included the use of anticoagulant agents within previous 24 h before procedure, the known coagulation abnormality, the diastolic or systolic blood pressures higher than 100 and 180 mmHg respectively, the known chronic lower back pain, any complications developed during cardiac catheterization, and a partial thromboplastin time [PTT] higher than 90 s.

### 2.2. Research design and procedure

A single-blind randomized controlled trial was used to perform this study in a non-teaching general hospital in Tehran. Using a table of random numbers, the patients were randomly allocated to either the control or the experimental group. The control group received the routine care; including 10-24 h complete bed rest in supine position with the affected leg straight and immobilized and a sand bag on the puncture site for at least 8 h. Relying on the previous studies (Fowlow et al., 1995; Pooler-Lunse et al., 1996; Logemann et al., 1999; Butterfield et al., 2000; Chair et al., 2003; Pollard et al., 2003), a new method was developed for positioning the patients in the experimental group. The patients in the experimental group were positioned as follows (Table 1): in the supine position with the head of bed [HOB] 15° elevated during the first and second hours, in the supine

Table 1
Positioning protocols and assessment methods in the groups.

	After CC	1 h	2 h	3 h	4 h	5 h	6 h	7 h	8 h	Next morning
Position in Exp. G	Supine, HOB 15 El, pillow (R/L)	Supine, HOB 15 El, pillow (R/L)	Supine HOB, 30 El, pillow (R/L)	Supine, HOB 45 El, pillow (R/L)	Right side, HOB 15 El	Left side, HOB 15 El	Fowlers	OOB	OOB	Routinely
Position in Cont. G Routine positioning, including 10–24 h bed rest in supine position with the affected leg immobilized										
Fatigue, comfort and satisfaction assessment	<b>~</b>	<b>1</b>	-	~	-	-	~	-	~	~
Bleeding and hematoma assessment		~	-	~	_	_	~	-	~	~

Exp G: experimental group; Cont. G: control group; HOB: head of bed; R/L: right or left; OOB; out of bed; El: elevated.

position with HOB 30° elevated during the third hour, in the supine position with HOB 45° elevated during the fourth hour, and respectively in the right and left lateral positions with HOB 15° elevated in the fifth and sixth hours, and in Fowler's position in the seventh hour. After that, the patients were allowed to come out of bed [OOB]. to sit on the chair beside the bed for 10-15 min and then to walk around and undertake self care activities. In the experimental group, the sand bag was taken away 3 h after the procedure. While the patients in the experimental group were in supine position in the first 3 h, they were given a thin supportive pillow  $(4 \text{ cm} \times 40 \text{ cm} \times$ 100 cm) under one side of their body, either left or right, from the shoulder to the gluteus area. We changed the place of the pillow every half hour in the right or the left side of the body. The flow diagram of the study is depicted in the Fig. 1. All patients both in the control and the experimental groups were blinded to the positioning methods.

### 2.3. Data collection

All patients were assessed for fatigue, comfort, satisfaction, bleeding and hematoma at regular time points. These points included the time immediately after coming to the post catheterization ward (T1), at 1 h (T2), 3 h (T3), 6 h (T4), 8 h after cardiac catheterization (T5) and finally the next morning at 06:00 h (T6). To measure the levels of fatigue, comfort and satisfaction, we used three different visual analogue scales (VAS), each of which consisted of a 100-mm long line with the left anchor representing 'no fatigue/comfort/satisfaction', and the right anchor representing 'the highest possible fatigue/comfort/satisfaction'. Visual analogue scales are frequently used to assess subjective feelings such as fatigue, comfort and satisfaction (Mundermann et al., 2002; Louville et al., 2003; Chen et al., 2006; Kos et al., 2006; Rezaei-Adaryani et al., 2009). To measure the amount of bleeding and hematoma, a twodimensional ruler with 1 cm<sup>2</sup> precision was used. The borders of hematoma was first determined by palpation technique and then measured by the ruler. For bleeding, after observing the dressing on puncture site, we measured the surface area of bleeding on the dressing by this ruler. The reliability for this measurement was established using the inter-rater (inter-observer) method. The correlation coefficient was equal to 0.96.

### 2.4. Data analysis

All data analyses were carried out according to a preestablished analysis plan. The Statistical Package for the Social Sciences, SPSS 11.5 for Windows, was used for the analysis. Statistical analysis involved all patients who were randomly allocated to the groups; in other words the attrition rate was equal to zero. Demographic data for all patients were compared using the Chi-square test, Fisher's exact test, and the independent sample t-test to confirm the matching of the groups. Main variables (comfort, satisfaction, and fatigue) were measured by VAS. The VAS scale should be treated as an ordinal scale and analyzed with non-parametric methods (Jakobsson, 2004). Therefore, the Mann-Whitney U test was used to compare these

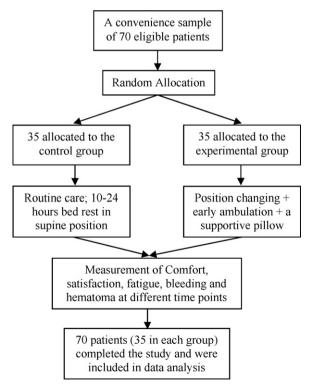


Fig. 1. Flow diagram of a trial of positioning patients after cardiac catheterization.

**Table 2** Patients' demographic data.

Variable	Control G	Experimental G	P-value
Age (years)	$55.82 \pm 11.34$	$59.74 \pm 11.05$	0.14+
Height (cm)	$166.91\pm7.01$	$163.28 \pm 9.69$	0.59 <sup>+</sup>
Weight (kg)	$76.10\pm10.05$	$77.48 \pm 11.75$	0.07
PTT (s)	$33.18 \pm 5.83$	$33.60 \pm 8.94$	0.81
Gender (M/F) n	24/11	17/18	$0.09^{\dagger}$
History of CC (N/Y) n	29/6	29/6	$1.00^{\dagger}$
Marriage (S/Ma) n	1/34	2/33	1.00 <sup>‡</sup>

M: male; F: female; S: single; Ma: married; Y: yes; N: no; n: number.

- <sup>+</sup> The results of the independent sample *t*-test.
- † The results of the Chi-square test.
- <sup>‡</sup> The results of the Fisher's exact test.

variables between groups. Variables "bleeding" and "hematoma" had many zero values and a severely asymmetric shape; hence these two variables were also analyzed using the Mann–Whitney U test. Friedman's rank test was also used to compare the levels of comfort, satisfaction and fatigue at different time points within each group. The level of significance was set at less than 0.05 (P < 0.05).

#### 3. Result

### 3.1. Demographic characteristics

A total of 70 patients participated in the study; 35 patients in each group, with no attrition. The patients' demographic data are shown in Table 2. The results of the independent sample *t*-test for the quantitative variables (age, weight, height, PTT), and the Chi-square test and

Fisher's exact test for the categorized variables (gender, previous history of CC, and marriage status) showed no statistically significant difference between the groups before intervention (P > 0.05, Table 2).

## 3.2. Comparison of the levels of comfort, satisfaction and fatigue between groups

The results of the Friedman's rank test for the within subjects factor of time showed that the variables of comfort, satisfaction and fatigue differed significantly across the six times point in each group (P < 0.001).

Table 3 and Figs. 2–4 represent the levels of comfort, satisfaction and fatigue in the groups at the six-time points. To compare the difference in the levels of comfort, satisfaction and fatigue between groups at each time points, six Mann–Whitney *U* tests were performed. Except for the time immediately after the procedure and the time 1 h after the procedure (i.e. T1 and T2), the levels of comfort and satisfaction in the experimental group were significantly higher than the control group at the other four time points (T3–T6, Table 3). On the other hand, the levels of fatigue in the experimental group were significantly lower than the control group at that four time points (T3–T6, Table 3).

These differences are more obvious in the figures; Figs. 2 and 3 show that the levels of comfort and satisfaction decreased from T1 to T3 in both groups. After that, comfort and satisfaction levels increased in the experimental group. In the control group, however, those variables continued to decrease until 8 h after the procedure (T5), i.e. when the sand bag was taken away from the puncture site, and then began to increase until the

 Table 3

 Comparing the level of comfort, satisfaction and fatigue in each groups (the result of Mann-Whitney U test).

Time	Comfort (Med $\pm$ IQR)			Satisfaction (Med $\pm$ IQR)			Fatigue (Med $\pm$ IQR)		
	Group								
	Control	Exp.	P-value	Control	Exp.	P-value	Control	Exp.	P-value
After CC (T1)	9 ± 2	9 ± 2	0.76	9 ± 2	9 ± 2	0.44	1 ± 2	2 ± 2	0.76
1 h after CC (T2)	$8\pm3$	$8\pm 2$	0.95	$8\pm3$	$8\pm 2$	0.46	$2\pm1$	$2\pm2\pm$	0.81
3 h after CC (T3)	$5\pm2$	$8\pm2$	< 0.0001	$6\pm2$	$8\pm2$	< 0.0001	$4\pm2$	$2\pm3$	0.002
6 h after CC (T4)	$4\pm3$	$9\pm 2$	< 0.0001	$4\pm3$	$9\pm 2$	< 0.0001	$7\pm3$	$1\pm1$	< 0.0001
8 h after CC (T5)	$4\pm3$	$10\pm1$	< 0.001	$4\pm3$	$10\pm1$	< 0.0001	$7\pm4$	$1\pm1$	< 0.0001
Next morning after CC (T6)	$9\pm1$	$10\pm 0$	< 0.0001	$9\pm1$	$10 \pm 0$	< 0.0001	$3\pm 3$	$0\pm 1$	< 0.0001

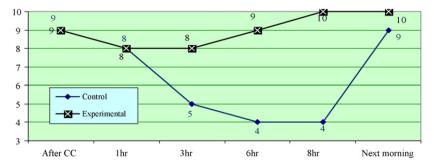


Fig. 2. The levels of comfort in different time points after CC.

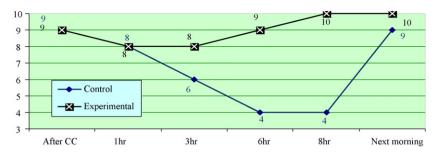


Fig. 3. The levels of satisfaction in different time points after CC.

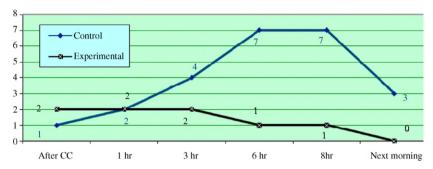


Fig. 4. The levels of fatigue in different time points after CC.

next morning (T6). Fig. 4 shows that the changing trend in the levels of fatigue has been in the opposite direction of the trend which was observed in the levels of comfort and satisfaction. In other words, the level of fatigue in the control group increased from the time immediately after CC (T1) to the time point 8 h after the procedure (T5) when it began to decrease until the next morning.

## 3.3. Comparison of the amounts of bleeding and hematoma between groups

Due to the trace amounts of bleeding and hematoma at each time point, we summed up the bleeding/hematoma amount of each time point all together and made two new variables, i.e. "overall bleeding" and "overall hematoma". The Mann–Whitney U test showed that there is no statistically significant difference between groups regarding the amounts of overall bleeding (P = 0.35) and overall hematoma (P = 0.94).

### 4. Discussion

The results of this study showed that regarding the levels of comfort, satisfaction and fatigue, there were no significant differences between the groups. This shows the matching of the groups before starting the positioning. The main findings of this study were that the levels of comfort, satisfaction and fatigue are related to the duration of bed rest and patients' position in the bed. The longer the patients are required to remain complete bed rest [CBR] in supine position after CC, the lower the levels of comfort and satisfaction and the higher levels of

fatigue they will experience. Patients in the control group complained of discomfort and fatigue and had the desire to move from one side to the other side. Previous studies show that prolonged bed rest in the supine position is difficult for many patients who have undergone cardiac catheterization (Fowlow et al., 1995; Chair et al., 2003, 2007; Benson, 2004; Vlasic, 2004; Lundén et al., 2006). The results show that patients in the experimental group, who received a new way of positioning accompanied by ambulation 8 h after CC, experienced significantly less discomfort and fatigue and more satisfaction. The figures show that from T5 to T6, the levels of comfort and satisfaction have increased and the level of fatigue have decreased in the control group; these changes in the patients' outcomes in the control group are related to taking the sand bag away from the site and giving permission to them to change their position in bed after 8-10 h post CC. The findings also show that the patients in the experimental group did not experience more vascular complications at the puncture site like bleeding and hematoma than the control group. This implies that changing patients' position in bed within the first 8 h after CC and ambulation 8 h after CC do not result in a significant increase in the femoral puncture site bleeding and hematoma formation.

### 5. Limitations

While we attempted to make considerable efforts to design a sound research, the study had several limitations. Although a high inter-rater reliability was established for the measurement of bleeding and hematoma, data for

these two variables were obtained by observation and palpation techniques, where the presence of bias is probable. Second, as we used a combination of methods for positioning patients in the experimental group, it was not completely clear that which intervention (HOB elevation, changing position, or early ambulation) produced more effect on the outcome variable. However, we at least can attribute the variations in the outcome variables to the combination of interventions. Moreover, the assessor was not blinded to the study.

### 6. Conclusion

The findings of this study recommend that changing patients' position in the bed after CC is probably safe, and they can be ambulated earlier in the post CC period than the current practice protocols recommend. Changing patients' position after CC may also lead to higher levels of comfort and satisfaction and lower levels of fatigue. This study showed that how a very simple and cost free nursing intervention can effectively improve the patients' outcome after cardiac catheterization.

#### 7. Recommendations

Further research is needed to determine the best positioning protocol and the minimum time period that patients are required to remain CBR in supine position after CC. In addition, as people are used not to completely expressing their subjective feelings, such as discomfort and fatigue, developing subtler tools to assess comfort, satisfaction and fatigue may be indicated.

### **Conflicts of interest**

None declared.

### **Funding**

This study was supported by Research administration of Medical Faculty of Tarbiat Modares University, Tehran, Iran.

### Ethical considerations

The study was approved by the research council affiliated with a regional university. The council reviewed the study and corroborated its ethical considerations. We explained the aim, advantages and disadvantages of the study for the patients. They were completely free to whether participate in, decline participation or withdraw from the study at any time throughout the study. The patients were assured of the confidentiality of their personal data. Subsequently, they provided the written informed consent form.

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