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Research Article

Effect of position change on back pain and bleeding complications in Hajj Pilgrims Undergoing Percutaneous Coronary Intervention

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Abstract

Background: Although extended bed rest in the spinal posture has become a tradition, it can have unfavorable outcomes. To prevent transfemoral artery problems, various measures such as therapeutic positioning of the patient, elevation of the head of the bed, and early ambulation, have been suggested. This study aimed to assess the effect of positional change on back pain and bleeding complications following percutaneous coronary intervention during the Hajj season.

Methods: Quasi-experimental study was conducted in king Abdullah medical city. The researchers employed a tool to gather data from the participants. Sixty patients were selected using a convenient sampling method. After percutaneous coronary intervention, patients in the control group received routine treatment and the intervention group of patients underwent a series of positional changes following the procedure. The categorical variables as age, sex, past medical history was represented using numerical values and percentages, whilst the continuous variables as back pain was represented using the mean and standard deviation. Fisher's exact test was used to determine if there are associations between the demographic data, health relevant data and laboratory investigation of the control group and hematoma and bleeding' occurrence. The Mann-Whitney U test was used to compare differences between two groups (control and intervention).

Results: There was a highly statistically significant difference in low back pain after percutaneous coronary intervention between the groups (p=0.000). Moreover, 3.3 %of the patients in the control group experienced hematomas' occurrence with no statistically significant difference between the intervention and control groups.

Conclusion: Changing the patients' position following femoral percutaneous coronary intervention decreases back pain without causing any vascular complications compared with routine methods. Additionally, changing positions during the first six hours is safe.

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INTRODUCTION

Percutaneous coronary intervention (PCI) has emerged as a commonly employed therapeutic procedure for diagnosing coronary heart disease (CHD). It is a minimally invasive procedure that involves the use of a catheter to expand or dilate coronary arteries that have been narrowed due to the presence of atherosclerosis or thrombosis. This is achieved through the deployment of either a balloon or stents (Ahmad et al., 2024).

During this time frame, there has been notable progress in the development of devices and techniques, which have played a crucial role in enhancing patient outcomes (KANDAN, 2019). Percutaneous coronary intervention has become a progressively significant approach in the care of coronary heart disease, either as an emergent, scheduled, or rescue procedure (Shin et al., 2019).

Catheters can be introduced during PCI through either the radial artery or the femoral artery. Recent guidelines recommend radial access for patients with ST-elevation myocardial infarction due to a lower risk of vascular complications. However, transfemoral PCI is still a common procedure in some nations, including Brazil and there are still gaps in the research regarding the duration of limb immobilization following PCI (Ibanez et al., 2017). Approximately 3 million PCI angioplasty procedures are conducted annually in the United States, with femoral arteries accounting for about 95% of those procedures (Nakhaie , Ebrahimzadeh, Salehi & Karimpour, 2018).

Transfemoral coronary angiography is frequently chosen over transradial coronary angiography (TCA) because it allows for unlimited puncturing repetition, simple access, less radiation, and less contrast. TFA, on the other hand, is linked to both acute and chronic problems. Back pain, for example, is a typical consequence of TFA and is linked to immobility and limited positioning after the surgery (Anjum et al., 2017; Fereidouni , Morandini & Kalyani, 2019). Moreover, Trauma to the femoral artery can also cause substantial complications during cardiac catheterization, including bleeding, hematoma, distal embolization, and arterial thrombosis (Abdollahi et al., 2015; Christakopoulos et al., 2015).

To avoid potential problems, it is recommended that patients adhere to a period of supine bed rest lasting 612 hours following transfemoral artery (TFA) procedures. The lengthy period of bed rest may potentially lead to increased patient discomfort, as well as the development of groin and back pain. Furthermore, it could result in elevated treatment costs and a prolonged duration of hospitalization. Other outcomes of traumatic femoral artery injury include hematoma formation, bleeding, and urinary retention (Abdollahi et al., 2015; Fereidouni , Morandini & Kalyani, 2019).

The practice of extended bed rest in a spine position has become a tradition, nevertheless, it can result in adverse consequences. The current body of literature lacks a sufficient number of comprehensive studies that examine the impact of different postural changes on vital signs, vascular issues, and back pain in the post-percutaneous coronary intervention (PCI) nursing care process. Various strategies, including therapeutic positioning of the patient, elevation of the head of the bed, early ambulation, and application of a weight to the catheter insertion site, have been recommended for the prevention of transfemoral artery complications. However, the effectiveness of these strategies remains a subject of debate (Naseri et al., 2017).

There is a need for further research to determine the optimal positioning of patients during the procedure, as well as the impact of position change on post-procedure back pain and bleeding complications. Many studies, focused on early ambulation and placement on back discomfort, have tried to relieve pain and bleeding complications in patients receiving transfemoral coronary angiography. So, this is the first study conducted in Saudi Arabia to assess the impact of position change on back pain and, bleeding complications following percutaneous coronary intervention during hajj season.

MATERIALS AND METHODS

Study Design

The current quasi-experimental study involved two groups (control and intervention) and carried out in 2022 during hajj season.

Study Setting and Participants

This study was conducted in king Abdullah medical city which is one of Saudi Arabia's largest medical cities with 390 active beds capacity in Makkah. The sample included 60 conscious cardiac patients who performed transfemoral percutaneous coronary angiography after removing the femoral arterial sheath. Patients who have hemophilia and other coagulation disorders, history of previous low back pain, deterioration of the patient's health, such as pain greater than 7, active hemorrhage, and unstable vital signs, vascular complications as dissection, perforation, arteriovenous fistula, and embolism were excluded from the study.

Sample Size Calculation

The convenience sampling approach was used to choose the samples, which were then randomly divid -ed into two groups: the control group and the intervention group. The sample size was calculated using G*Power to ensure that the study had adequate statistical power to detect a clinically significant difference between the intervention and control groups. We used a two-tailed test with a significance level (α) of 0.05 and a power ($1-\beta$) of 0.80, which are standard thresh-olds in clinical research. Based on previous studies examining the effects of positional change on back pain and bleeding complications, an effect size of 0.5 was anticipated.

Using these parameters, a total sample size of 60 patients was required, with 30 patients in each group (intervention and control) to detect differences between the groups with a 95% confidence interval. This sample size is sufficient to ensure reliable statistical comparisons while accounting for potential variability in patient responses.

Data Collection

After getting official permission from the King Abdullah Medical City, Holy Makkah (KAMC) IRB registered at the National BioMedical Ethics Committee, King Abdulaziz City for Science and Technology, with approval number 20-931, and the study was done accordingly. Informed consent forms were signed by patients who met the trial's inclusion criteria and expressed interest in taking part in the study. The researchers employed a tool for gathering data from patients. patients were selected using a convenient sampling method. The study evaluated vascular problems and back discomfort at six specific time intervals: immediately after the surgery, at the fifth minute, and at the first, third, and every subsequent hour for the following six hours following the transfemoral coronary angiography.

Control Group

Patients in the control group received standard care following percutaneous coronary intervention, which included having their heads elevated by 15○ to 30○, having their legs kept straight, and staying in bed for four to six (4-6) hours as directed by the physician in accordance with hospital policy.

Intervention Group

In the context of the intervention group, the researcher executed the repositioning procedure under the guidance of the physician' supervision. The intervention group of patients underwent a series of positional changes following the procedure. Specifically, in the fifth minute after the procedure, Patients were positioned on their backs with the head of the bed raised by 15 degrees. In the first hour, patients were positioned in a low Fowler's position, with the head of the bed elevated between 15○ and 30○. In the third hour, patients were placed in a semi-high Fowler's position, with the head of the bed elevated between 30○ and 45○. Finally, in the fourth hour, patients were positioned in a left or right lateral position, with the head of the bed elevated between 30○ and 45○. The patient was placed in the Low Fowler's position during the fifth hour, with the head of the bed elevated between 15 and 30 degrees. Subsequently, during the sixth hour, the patient was positioned in the regular Fowler's position, with the head of the bed elevated between 45 and 60 degrees (Mert & Öztekin, 2019).

Data collection tool

The data was gathered with a tool that included a three-part. Patient demographic information is presented first. Part one is based on a review of the literature of Abdollahi et al, 2015 and includes patients' demographic and health information that was culled from their medical records, such as age and sex, ad-mission diagnosis, history of back pain, use of anti-thrombosis, aspirin, and pain medication drugs, pro-thrombin time (PT), partial thromboplastin time (PTT), International normalized ratio (INR), hemoglobin, and hematocrit levels.

Part two: Numeric Pain Intensity Scale. This section was adapted from McCaffery 1989 to measure back pain intensity for the sample. The numerical representation consists of eleven points arranged in a horizontal line, with each point corresponding to a number ranging from 0 to 10. The numerical scale ranging from zero to ten is utilized to assess pain severity, with zero representing the absence of pain and ten indicating the most intense level of pain. The individual selects a numerical value that represents the level of pain experienced (Naseri et a.,2017). Part three: Bleeding complications occurrence after transfemoral coronary angiography. This section has been adopted from Christenson's guidelines for the evaluation of hematoma and bleeding. According to the Christensen scale, a mild hemorrhage is defined as having a measurement ranging from 2 to 5 cm2, and a large hematoma is characterized by a measurement equal to or exceeding 5 cm2. Gianakos et al conducted measurements of the greatest and smallest diameters of an irregularly shaped hematoma and approximated the area of the hematoma by multiplying these diameters together (McCaffery,1989).

The term s̈ignificant bleedingẅas operationally defined as a blood loss above 100ml, while ïnsignificant bleedingẅas operationally defined as a blood loss anticipated to be 100ml or less. Major bleeding was defined as the loss of 2 g/dL or more of hemoglobin -bin, or the need for transfusion of 2 or more units of red blood cells, or both. The assessment of bleeding problems was conducted by categorizing them as either p̈resentör äbsent.¨ The questionnaire's reliability was found to vary between 0.86 and 0.95, as reported by Spielberger in 1983.

Ethical Considerations

Upon obtaining formal approval, all participants were required to complete written informed consent forms. The study's objective, along with the potential risks and advantages associated with participation, was thoroughly explained to all patients. Furthermore, the patients were provided with information regarding the potential adverse consequences associated with altering their position during transfemoral angiography, including the risks of bleeding and hematoma formation, among others. The participation was voluntary and anonymous. The study took into account the principle of secrecy, ensuring that all patients' information was securely stored in a closed file cabinet with restricted access. In addition, it is important to note that every patient is assigned a unique code number for identification purposes.

Statistical analysis

The study's data was coded and then translated into coding sheets. The results underwent verification. Subsequently, the data was inputted into the SPSS system files, utilizing the SPSS package version 26. A series of procedures were implemented after the data entry phase in order to ensure accuracy and prevent any potential errors. Subsequently, the data underwent processing and interpretation. The categorical variables as age, sex, past medical history was represented using numerical values and percentages, whilst the continuous variables as back pain was represented using the mean and standard deviation. Fisher's exact test was used to determine if there are associations between the demographic data, health relevant data and laboratory investigation of the control group and hematoma and bleeding' occurrence. The chi-square (x2) was used to determine the level of significance between control and intervention group. The Mann-Whitney U test was used to compare differences be-tween two groups (control and intervention). Statistical significance was set at p 0.05.

RESULTS

Sample description

Table 1 shows that 13 patients (43.3%) in the intervention group and 20 patients (66.7%) in the control group were more than sixty years old with no statistically significant difference between both groups. It was also noted that 18 patients (60.0%) in the intervention group and 17 patients (56.7%) in the control group of were male with no statistically significant difference between them. Furthermore, cardiovascular disorders were found to be the highest percentages of the past medical history of both groups (70% and 96.7 % respectively), with no statistically significant difference between both groups. As for the current medications received, it can be seen that 8 patients (43.3%) in the intervention group and 17 patients (56.7%) in the control group received anti-platelets medications with no statistically significant difference between them.

Table 2 demonstrates that the majority of patients in both groups have normal laboratory investigations nearly the same with no statistically significant difference between both groups.

Bleeding complications' occurrence

Table 3 illustrates that only one patient (3.3%) in the control group experienced hematomas' occurrence with no statistically significant difference between the intervention and control group. The patient who experienced hematomas was diagnosed with the minor hematoma type. It was observed that one patient (3.3%) in control group had insignificant bleeding compared with 100 % of patients in intervention group with no bleeding with no statistically significant difference between them. Furthermore, there was no incidence of major bleeding in both groups.

Table 4 shows that there is a highly statistically significant difference in low back pain after percutaneous coronary interventions between both group p=0.000 except in T1(5th min after the procedure).

Table 5 demonstrates that there is no statistically significant relationship between the demographic, the health relevant data and laboratory investigation of the control group and the hematoma and bleeding' occurrence.

DISCUSSION

Prolonged immobilization in the supine position following transfemoral PCI may have adverse effects and lead to discomfort among a majority of patients. These effects manifest as many symptoms, including back pain, fatigue, and general discomfort (Lu & Chuang, 2018). One of the most efficient methods to relieve back pain after coronary artery angiography is early ambulation and positioning changes for the patient. These two interventions, as opposed to standard treatments, can be used to decrease back discomfort following PCI. Patients' back pain is decreased by using early ambulation between 2-4 hours after angiography, changing the patients' position, and using modified positioning (Fereidouni , Morandini & Kal- yani , 2019).

The present study Findings showed that there was no statistically significant difference between groups in relation to hematoma and bleeding' occurrence. This may be due to the use of angio-Seal as a closure device to prevent bleeding after angiography procedures instead of manual compression. This finding is supported by the studies conducted by Utami et al, Türen et al, Mert, Ibdah et al and Mohmmed et al which indicated that the positioning of patients does not have a significant impact on the occurrence of arterial bleeding and hematoma.

Furthermore, Cha and Sok revealed that transitioning patients 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 period of absolute rest effectively alleviated lumbar pain and discomfort (Cha & Sok, 2016). Importantly, this intervention did not result in any bleeding complications. The result of this study contradicts Santos et al who concluded that there was a higher incidence of small to medium-sized hematomas in the intervention group, but no associated clinical complications were observed (Santos et al.,2019).

Findings of the current study revealed that changing position after PCI decreases low back pain. This may be related to early ambulation that can decrease back pain. This result is matched with Manueke et al and Mohmmed et al who concluded that changes in position within six hours of PCI can reduce the incidence of back pain that patients experience (Manueke , Trisyani & Nurlaeci , 2019; Mohmmed et al., 2022). Further-

Table 1: Distribution of the intervention and control groups in relation to the demographic and health relevant data. (n= 60)

Demographic data	Control group (n=30)		Intervention group(n=30)		Sig.
	No	%	No	%	
Age (years):<18	1	3.3	0	0.0	X2= 5.15P= 0.16
18- <40	1	3.3	1	3.3	
40 - <60	8	26.7	16	53.3	
≥ 60	20	66.7	13	43.3	
Sex: Male	17	56.7	18	60.0	X2= .069P= 0.793
Female	13	43.3	12	40.0	
Past medical history: Cardiovascular disorder	29	96.7	21	70.0	X2= 11.2 P=0 .010
Respiratory disorder	1	3.3	0	0.0	
Renal disorder	0	0.0	1	3.3	
No	0	0.0	8	26.7	
Current medications: Thrombolytic Anticoagulants Anti-platelets	4917	13.330.056.7	18178	16.740.043.3	X2= 1.07 P=0.58

Table 2: Comparison between the control and intervention groups in relation to the laboratory investigations. (n= 60)

Laboratory investigations	Control group (n=30)		Intervention group(n=30)		Sig.
	No	%	No	%	
Platelet count Normal	29	96.7	30	100.0	X2= 1.01 P= 0.31
Decrease	1	3.3	0	0.0	
Increase	0	0.0	0	0.0	
PTNormal	29	96.7	28	93.3	X2= 3.01 P= 0.22
Decrease	0	0.0	2	6.7	
Increase	1	3.3	0	0.0	
PTTNormal	30	100.0	28	93.3	X2= 2.06 P=0.15
Decrease	0	0.0	0	0.0	
Increase	0	00	2	6.7	
INRNormal	30	100.0	30	100.0	
Hemoglobin levels Normal	28	93.3	22	73.3	X2=5.00 P=0.082
Decrease	2	6.7	5	16.7	
Increase	0	0.0	3	10.0	
Hematocrit levels Normal	28	93.3	24	80.0	X2=2.59 P=0.273
Decrease	2	6.7	5	16.7	
Increase	0	6.0	1	3.3	

Table 3: Comparison between the control and intervention groups regarding bleeding complications' occur-rence.

	Control group (n=30)		Intervention group(n=30)		Sig.
	No	%	No	%	
Hematomas' occurrence No hematoma	29	96.7	30	100.0	X2= 1.01 P= .313
Minor	1	3.3	0	0.0	
Major	0	0.0	0	0.0	
Bleeding' occurrence No bleeding	29	97.7	30	100.0	X2= 1.01 P= 0.31
Insignificant <100 ml	1	3.3	0	0.0	
Significant >100 ml	0	0.0	0	0.0	
Major bleeding No	30	100.0	30	100.0	

more, Niknam et al reported that adopting a semi-seated position after the procedure is both effective and safe in alleviating pain, while not posing an increased risk of vascular complications (Niknam, Farsi, Butler & Pishgooie , 2021).

Neishabouri et al and Valiee et al conducted studies to examine the effects of modifying position and adopting early mobilization on back pain and vascular side

Table 4: Comparison between the control and intervention groups in relation to low back pain after percutaneous coronary interventions.

Low back pain assessment	Group	Mean±SD.	Sig.
T1 (5th min: HOB is elevated 15○ SP)	Control	0. 000± 0.000	Z=0.00 P=1.00
	Intervention	0. 000± 0.000	
T2 (1st h: HOB is elevated 15-30○ LFP)	Control	0.33± 0.80	Z=2.31 P=0. 02*
	Intervention	0. 000± 0.000	
T3 (3rd h: HOB is elevated 30-45○ SHFP)	Control	0.80 ± 0.86	Z=4.57 P=0.000**
	Intervention	0. 000± 0.000	
T4 (4th h: HOB is elevated 15○ R+LLP)	Control	0.96 ±0.99	Z= 4.75 P=0.000**
	Intervention	0. 000± 0.000	
T5 (5th h: HOB is elevated 15-30○ LFP)	Control	0.93 ± 1.01	Z= 4.57 P=0.000**
	Intervention	0. 000± 0.000	
T6 (6th h: HOB is elevated 45-60○ SFP)	Control	0.96±1.03	Z= 4.57 P=0.000**
	Intervention	0. 000± 0.000	

Z: Mann-Whitney Test * significant at P <0.05
HOB: head of bed, S: spine position, LFP: low fowler's position, SHFP: semi high fowler's position, R+LLP: left or right lateral position, LFP: low fowler's position, SFP: standard fowler's position.

Table 5: Relationship between the demographic data, health relevant data and laboratory investigation of the control group and hematoma and bleeding' occurrence. (n= 30)

Patients' demographic data	Hematomas and bleeding' occurrence				Sig.
	Yes		No		
	No	%	No	%	
Age (years)<18	0	0.0	1	100	FEP=1.00
18- <40	0	0.0	1	100	
40 - <60	0	0.0	8	100	
≥ 60	1	3.3	19	97.7	
Sex Male	0	0.0	17	100	FEP=0.417
Female	1	7.7	12	92.3	
Laboratory investigations: Platelet count Normal	1	3.4	28	96.6	FEP=1.00
Decrease	0	0.0	1	100	
PT Normal	1	3.4	28	96.6	FEP=1.00
Increase	0	0.0	1	100	
PTT Normal	1	3.3	29	96.7	
INR Normal	1	3.3	29	96.7	
Hemoglobin Normal	1	3.6	27	96.4	FEP=1.00
Decrease	0	0.0	2	100	
Hematocrit Normal	1	3.6	27	96.4	FEP=1.00
Decrease	0	0.0	2	100	
Current medications Thrombolytic	0	0.0	4	100	FEP=1.00
Anticoagulants	0	0.0	9	100	
Anti-platelets	1	5.9	16	94.1	

FET: Fisher Exact Test, P-value <0.05 is statistically significant, PT: Prothrombin Time, PTT: partial thromboplastin time. INR: International Normalized Ratio

effects in individuals who underwent coronary angiography . Their findings indicated that recent modifications in position and early mobilization techniques have the potential to mitigate the occurrence of back pain and alleviate its intensity (Neishabouri , Haghighi, Gilvari , & Haghighat, 2020). In contrast, Santos et al found no statistically significant differences in pain outcomes when the duration of affected limb immobilization during bed rest in the supine position was reduced from 4 to 2 hours after sheath removal subsequent to transfemoral urgent/emergency PCI (Santos et al.,2019).

The main limitation of our study is that it was not possible to determine whether the variation in the incidence of vascular problems was due to differences in the expertise and skills of the cardiologists who intervened during the femoral route coronary angiography.

CONCLUSION AND RECOMMENDATION

In conclusion Changing the patients' position following femoral percutaneous coronary intervention de-creases back pain without causing any vascular complications compared with routine methods. Additionally, changing positions during the first six hours is safe. It is imperative for healthcare personnel to im-part knowledge

to patients regarding the significance of adhering to appropriate positioning and minimizing excessive movement in the afflicted region during the recovery process. In order to enhance the generalizability of the findings, it is recommended to do a replication of this study using a bigger sample size.

AUTHOR CONTRIBUTION

All authors equally contributed to the research and provided final approval for the manuscript.

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