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Effect of Early Ambulation; Three versus Five hours after Transfemoral diagnostic Cardiac Catheterization: A randomized clinical One-arm Study

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Abstract:
Background: *Cardiac catheterization is a golden standard diagnostic test for coronary heart diseases. The most common complications are bleeding and hematoma. In order to minimize the post-procedure complications, patients are restricted to bed for 8-24 hours in flat position.*
Aim: *The aim of this study was to investigate the effect of early ambulation; three versus five hours after transfemoral diagnostic cardiac catheterization on vascular complications and level of pain.*
Methods: *In a random clinical trial, 164 adult male and female patients, who had undergone transfemoral diagnostic cardiac catheterization were randomly assigned into two equal study groups . The first group (G1)ambulated at 3 hours after sheath removal. The second group (G2) ambulated 5 hours after sheath removal. The study was conducted at cardiac catheterization unit in cardiology department of the Specialized Medical Hospital at Mansoura University Hospital .The intensity of pain, the level of bleeding and hematoma were evaluated at ambulation time and after the seventh day of catheterization.*
Results: *There was no statistically significant difference between two study groups in vascular complications and pain intensity(P>0.05).There was statistically significant difference between two study group in occurrence of vascular complication at time of ambulation and seven days of catheterization.*
Conclusion: *It's safe for Patients to ambulate earlier after diagnostic cardiac catheterization. Both early ambulation (3 hrs) and (5 hrs) after cardiac catheterization had a similar and low rate of vascular complications.*
Key words: *Cardiac catheterization, Early ambulation, vascular complications*

I. Introduction

Coronary heart disease is the leading cause of death in the United States today. Treatment options include medical management, coronary interventions, and cardiac revascularization .[1,2] In Egypt, according to the latest annual statistics of the national heart institute in Cairo (2010), approximately 1.3 million input cardiac catheterizations are performed annually, half of those patients have percutaneous cardiac interventions and about 400,000 undergo coronary artery bypass graft operations .[3]Cardiac catheterization is widely used for diagnostic evaluations in patients with cardiac diseases and is the gold standard diagnostic test for coronary heart diseases.[4] 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**.**[5]

Cardiac catheterization is an extremely valuable diagnostic procedure for obtaining detailed information about the structure and function of the cardiac chambers, valves, and coronary arteries. The procedure may include studies of the right or left sides of the heart, as well as the coronary arteries **.**[6]Catheterization is normally performed by skin puncture under local anesthesia. This procedure can lead to a variety of complications ranging from mild to severe hematoma, hemorrhage, acute thrombosis, and bruising. The procedure also incurs significant financial costs **.**[7,8] The most common complications are bleeding and hematoma, which usually appear within 12 hour after the intervention, and which may lead to localized pain **.**[7]

To reduce possible vascular complications at the groin site, all patients are prescribed strict immobilization and bed rest in the supine position **.**[4] And manual or mechanical application of firm pressure above the puncture site is needed. Moreover, prolonged bed rest in recumbent position and immobilization of the affected leg are also required for those patients after sheath removal **.**[5,9] The involved leg is immobilized for 2–24 hours after the procedure to prevent vascular complications **.**[10,11,12] Bleeding and hematoma are normally

formed in the soft tissue of the upper thigh and disappear a few days after catheterization. [7] It is therefore important to identify safe and feasible approaches to promote patient comfort without increasing the risk of vascular complications including hematoma and bleeding .[5] The most frequent complaints from patients during prolonged bed rest are back pain and urinary discomfort .[4, 7, 13]

To relieve these discomforts caused by prolonged bed rest, early ambulation can reduce discomfort without any statistically significant increase in the incidence of post catheterization complications and its effectiveness has also been examined by various studies .[4,14,15] The suggested early ambulation from these studies ranges from 1 hour to 6 hours with the sheath size from French 5 to 8. It has shown that the suggested time for early ambulation in different studies is safe and associated with low rates of vascular complications .[4,14,15] The aim of the study was to investigate the effect of early ambulation; three versus five hours after transfemoral diagnostic cardiac catheterization on vascular complications (hematoma & bleeding) and level of pain.

II. Methods

Study Design

A Randomized clinical research design has been utilized in this One-arm Study

Research Hypothesis

To fulfill the aim of the study the following research hypothesis were formulated:-

***H1*:** Both study groups who ambulated early at (3 hrs) and (5 hrs) after cardiac catheterization had a similar and low rate of vascular complications (hematoma & bleeding) .

***H2*:** Both study groups who ambulated early at (3 hrs) and (5 hrs) after cardiac catheterization had similar and reduce back pain intensity.

Setting

This study conducted at cardiac catheterization unit in cardiology department of the Specialized Medical Hospital at Mansoura University Hospital. The collection of data lasted for a period of three months, starting from February to April 2015. Data were collected three days a week from 8.00 am to 10.00 pm.

Study population

Purposive sample of all adult male and female patients, agreed to participate in the study aged above (18-60 years old) who are admitted for performing diagnostic cardiac catheterization through femoral artery during a period of three months were eligible for inclusion in the study .They were randomly assigned into two equal study groups, the first group allowed to ambulate 3 hours after catheterization. The second group ambulated 5 hours after catheterization. The levels of pain, the amount of bleeding and hematoma were measured at regular intervals after the procedure.

The patients were selected based on the following criteria

***The inclusion criteria included**:* Age between +18-60 years ,BP less than 180/100 mm Hg, All patients undergoing cardiac catheterization had a sheath size range from six to nine French sheath, Hemodynamic stability.

The exclusion criteria of the study included: Coagulation abnormalities, chronic lower back pain, transradial coronary angioplasty. Patients are scheduled for non-emergency percutaneous coronary intervention (PCI), history of diabetes associated with sensory problems.

Data collection tools

***Demographic and Clinical Data Sheet*:**

Developed by the researcher to record patient's demographics, diagnosis, medical history and sheath size.

***Hematoma Formation Scale*:**

According to Simon (2010) hematoma was defined as an accumulation of blood at skin level with bruising or swelling in the area of the artery punctures during the period of sheath insertion through 6-12 hours following sheath removal.[16] The scale designed for measurement of hematoma size. It was adopted from Al Sadi et al. (2010).It classified hematoma into four categories according to surface area: No hematoma (<2cm2 in diameter), Small hematoma (2≤ 5cm2 in diameter),Medium hematoma(5≤ 10 cm2 in diameter) and Large hematoma (≥ 10 cm2 in diameter).[17]

Bleeding Scale:

The scale designed for measurement any leakage of blood from the puncture site. It was adopted from Black (2008). It classified oozing into four categories according to surface area soaked with blood : No oozing (dry dressing), Mild oozing (< 2cm 2 in diameter dressing soaked with blood),Moderate oozing (2≤ 5cm 2 in diameter dressing soaked with blood) and Severe oozing (5≤ 10 cm 2 in diameter dressing soaked with blood).[18] For hematoma formation, and bleeding scales, it was filled by the researchers immediately at 3 and at 5 hours post homeostasis and after one week.

***Pain Intensity Numeric Scale*:**

It was adopted from Puntillo et al. (2001).The scale determines the level of pain intensity ranging from no pain (scored = 0), to worst (scored = 10). [19]

Content validity*:* The tools were tested for content related validity by jury of 5 specialist in the field of medical-surgical nursing and coronary medicine from Mansoura University and the necessary modifications were done.
A pilot study was conducted on 10 patients from each group after explain the nature and purpose of the study to test the feasibility and applicability of the tools.

Reliability: Reliability testing was done using split half methods and Cronbach's alpha that measures the degree of reliability for the entire form. Both techniques showed high reliability of the final version of the tool.(Alpha = .85).

Ethical consideration

After obtaining the permission from Ethical Committee of Faculty of Nursing Mansoura University, An Official approval was obtained from hospital administrative authority to collect the necessary data after explanation of the aim and nature of the study. The researcher emphasized participation was absolutely voluntary and confidential. Anonymity, privacy, safety and confidentiality were absolutely assured throughout the whole study as well as the right to withdraw from the study at any time. Participant signed on written consent.

Procedure

Preparatory phase:

The patient admitted early in the morning at the catheterization unit. The researcher was obtained demographic and clinical data from the patient medical record as well as directly from the patient such as the patient age, sex , medical history and measuring weight and height to calculate body mass index. Heart rate and mean arterial pressure were measured. Peripheral pulse was measured. The levels of pain and the amount of bleeding and hematoma were measured at regular intervals after the procedure. A scale was used to measure the size of hematoma and bleeding was carried out through observing the dressing. All patients were trained on how to use pain intensity numeric scale before angiography procedure and rated their intensity of site pain compression experience at the observation time.

Implementation phase

After the invasive procedure at the catheterization laboratory, patients returned to the unit and sheath removed immediately post cardiac catheterization by doctor. Homeostasis was achieved by 15 minutes of manual compression, followed by a compression bandage. In the first group, patients started to ambulate in 3 hours post homeostasis after sheath removal. During immobilization period the patient was allowed to elevate the head of the bed to 45°.In the second group, the patients started to ambulated 5 hours post homeostasis after sheath removal.

Statistical analysis

Data was collected and analyzed by computer programmed SPSS (ver.16) Data were presented using descriptive statistics in the form of frequencies and percentages for qualitative variables, and means and standard deviations for qualitative variables. Qualitative variables were compared using chi-square test to determine significance for non-parametric variables. The critical value of the tests "P" was considered statistically significant when P less than 0.05.

III. Results

Table 1**.** : Shows the socio-demographic characteristics of the two study groups. As regards to Age of the first study group, (50.0%)of them aged ranged from 50 to 60years, with a mean age 50.32± 7.71 years, while nearly half of the second study group (47.6%) aged ranged from 40 to 49 years, with a mean age 48.49±7.62 years. No statistical significant differences were detected between two study groups regarding their age (x^2=2.284 , p=0.319). Males were more prevalent in the studied sample. They constituted (56.1%) of the first study group, and (54.9%) of the second study group, with no significant differences between the two groups (x2= 0.025, p= 0.875).

The majority of patient in the two study groups (79.3% and75.6%) respectively were married. No significant difference was detected between the two groups regarding marital status (x^2=0.381, p= 0.826). Concerning medical payment, nearly three quarter of the first study group was totally reimbursed (74.4%) & more than three quarter of the second study group (76.8%) was totally reimbursed .No significant difference was detected between the two groups (x^2=0.482, p=0.786).

Concerning level of education, no formal education prevailed among 39.0% of the first study group and 45.1% of the second study group .While 30.5% of the first study group and 40.2% of the second study group were read and write. No significant difference was detected between the two groups regarding education level (x^2= 6.656, p= 0.084)..Regarding occupation, about more than one third of the two study group 37.8% was house wives and 32.9% of the first study group was employee .While 47.6% in the second study group was practical work. There is significant difference was detected between the two groups (x^2=9.341, p=0.009)

Table 1. Comparison between the two study groups in relation to socio demographic data .

Socio demographic data	G1 Ambulated after 3 hours		G2 Ambulated after 5 hours		Total		Pearson Chi-Square X2 test (P)
	No=82	%	No=82	%	No=164	%	
Age (in years)							
30-39	11	13.4	11	13.4	22	13.4	**2.284**
40-49	30	36.6	39	47.6	69	42.1	**(0.319)**
50-60	41	50.0	32	39.0	73	44.5	
Mean± SD	**50.32± 7.71**		**48.49±7.62**				
Sex							**0.025**
Male	46	56.1	45	54.9	91	55.5	**(0.875)**
Female	36	43.9	37	45.1	73	44.5	
Marital status							
Married	65	79.3	62	75.6	127	77.4	**0.381**
Widowed	13	15.9	16	19.5	29	17.7	**(0.826)**
Divorced	4	4.9	4	4.9	8	4.9	
Educational level							
No formal education	32	39.0	37	45.1	69	42.1	
Read& write	25	30.5	33	40.2	58	35.4	**6.656**
Primary	12	14.6	4	4.9	16	9.8	**(0.084)**
Secondary	13	15.9	8	9.8	21	12.8	
University &above	0	0.0	0	0.0	0		
Occupation							
Practical work	24	29.3	39	47.6	63	38.4	
Employee	27	32.9	12	14.6	39	23.8	**9.341**
House wife	31	37.8	31	37.8	62	37.8	**(0.009)***
Medical payment							
Totally reimbursed	**61**	**74.4**	**63**	**76.8**	**124**	**75.6**	**0.482**
Partially reimbursed	**13**	**15.9**	**10**	**12.2**	**23**	**14.0**	**(0.786)**
Totally self paid	**8**	**12.2**	**9**	**11.0**	**17**	**10.4**	

* Significant, at p< 0.05

Table 2**.** Shows health relevant data among the two study groups. It is noticed that, angina was the most common diagnosis among the two study groups (72.0% and 68.3% respectively). With significant difference were detected between the two groups (x^2= 9.745, p=0.021) .Concerning the present of symptoms, it was evident that Chest pressure and difficulty in breathing were the main symptoms in the first study group (52.4%). While Chest pain radiating to shoulder and neck was the main symptoms in the second study group (48.8%). No significant difference was detected between the two groups (x^2=4.512, p=0.105).Regarding family history, there is no family history in more than half in the first study group (52.4%). while nearly two third of the second study group was presence of family history (65.9%). There is significant difference was detected between the two groups (x^2=5.588, p=0.018).Regarding obesity, more than half of the two study groups were overweight (68.3% and 62.2% respectively). While nearly one quarter of the two study groups were obese (20.7% and 24.4% respectively). No significant difference was detected between the two groups (x^2=0.677, p=0.713).

Table 2. Health relevant data of the two study groups

Items	Ambulated after 3 hours G1		Ambulated after 5 hours G2		Total		Pearson Chi-Square X2 test (P)
	No=82	%	No=82	%	No=164	%	
Diagnosis							
Angina	59	72.0	56	68.3	115	70.1	9.745
Myocardial infarction	13	15.9	13	15.9	26	15.9	(0.021)*
Hypertensive HD							
Valvular heart disease	10	12.2	5	6.1	15	9.1	
	0	0.0	8	9.8	8	4.9	
Symptoms							
Chest pain	12	14.6	11	13.4	23	14.0	
Chest pain radiate to Shoulder &neck	27	32.9	40	48.8	67	40.9	4.512 (0.105)
-Chest pressure &difficulty in breathing	43	52.4	31	37.8	74	45.1	
Family history							
Yes	43	52.4	28	34.1	71	43.3	5.588
No	39	47.6	54	65.9	63	56.7	(0.018)
Body mass index							
Under weight	0	0.0	0	0.0	0	0.0	0.677
Normal weight	9	11.0	11	13.4	20	12.1	(0.713)
Over weight	56	68.3	51±	62.2	107	65.3	
Obese	17	20.7	20	24.4	37	22.6	
Mean± SD	**28.682 ± 2.136**		**28.109 ± 3.046**				

Table 3**.** Shows comparison of the complications of cardiac catheterization of two study groups at ambulation and after one week from ambulation. Regarding hematoma , The majority of the study sample in the two study groups was non hematoma formation at the time of ambulation (90.2% & 92.7%) respectively. And The majority of the study sample in the two study groups was non hematoma formation after one week from ambulation (87.8 % & 93.9%) respectively. No significant difference was detected between the two groups (x^2= 0.312 , p= 0.576) & (x^2=2.860, p=0.239).

In relation to bleeding , The majority of the study sample in the two study groups have no bleeding at the time of ambulation (89.0% & 93.9%) respectively. And The majority of the study sample in the two study groups have no bleeding after one week from ambulation (93.9% & 97.6 %) respectively. No significant difference was detected between the two groups (x^2= 1.799, p= 0.407) & (x^2=1.343, p=0.246).Concerning back pain, the majority of the study sample in the two study groups was no pain at the time of ambulation (76.8% & 79.3%) respectively. And The majority of the study sample in the two study groups have no pain after one week from ambulation (96.3% & 98.8 %) respectively. No significant difference was detected between the two groups (x^2= 0.564 , p= 0.754) & (x^2=1.025, p=0.311).

Table 3. Complications of cardiac catheterization of two study group at ambulation and after one week from ambulation

data	Ambulated after 3 hours G1				Ambulated after 5 hours G2				Pearson Chi-Square X2 test (P)[a]	Pearson Chi-Square X2 test (P)[b]
	At ambulation		After one week		At ambulation		After one week			
	No= 82	%	No= 82	%	No=82	%	No=82	%		
Hematoma formation										
Non hematoma	74	90.2	72	87.8	76	92.7	77	93.9		
Small hematoma	8	9.8	8	9.8	6	7.3	5	6.1	0.312	2.860
Moderate hematoma	0	0.0	2	2.4	0	0.0	0	0.0	(0.576)	(0.239)
Large hematoma	0	0.0	0	0.0	0	0.0	0	0.0		
Bleeding										
No bleeding	73	89.0	77	93.9	77	93.9	80	97.6		
Mild bleeding	8	9.8	5	6.1	5	6.1	2	2.4	1.799	1.343
Moderate bleeding	1	1.2	0	0.0	0	0.0	0	0.0	(0.407)	(0.246)
Sever bleeding	0	0.0	0	0.0	0	0.0	0	0.0		
Back Pain										
No pain	63	76.8	79	96.3	65	79.3	81	98.8		
Moderate pain	11	13.4	3	3.7	9	11.0	1	1.2	0.564	1.025
Worst pain	8	9.8	0	0.0	8	9.8	0	0.0	(0.754)	(0.311)

Pearson Chi-Square X2 -test (P) [a]: comparing two study groups at time of ambulation.
Pearson Chi-Square X2 -test (P) [b]: comparing two study groups after one week.
* Significant, at p< 0.05 .

Table 4**:** Describe relation between body mass index of two study group and complications of cardiac catheterization at the time of ambulation, The occurrence of hematoma, bleeding and pain increased in both study groups at the time of ambulation in over weight and obese patients and was statistically significant in hematoma and bleeding where P values = (0.007) ,(0.000) & (0.000) respectively**.**

Table 5. Relation between body mass index of two study groups and complications of cardiac catheterization after one week from ambulation, The occurrence of hematoma, bleeding and pain increased in both study groups after one week from ambulation in over weight and obese patients that was statistically significant in hematoma and bleeding where P values = (0.003) ,(0.000) & (0.042) respectively.

Table 4. Relation between body mass index of two study groups and vascular complications of cardiac catheterization at the time of ambulation

Body mass index	Ambulated after 3 hours G1		Ambulation after 5 hour's G2	
	Occurrence of hematoma	Occurrence of bleeding	Occurrence of hematoma	Occurrence of bleeding
	No= 8	No= 9	No= 6	No= 5
BMI				
Normal weight	1	1	0	0
Over weight	2	4	0	0
Obese	5	4	6	5
Pearson Chi-Square X2 test (P)	**9.912 (0.007)***	**5.291 (0.259)**	**20.068 (0.000)****	**16.506 (0.000)****

Table 5. Relation between body mass index of two study group and vascular complication of cardiac catheterization after one week from ambulation

Body mass index	Ambulated after 3 hours		Ambulation after 5 hours	
	Occurrence of hematoma	Occurrence of bleeding	Occurrence of hematoma	Occurrence of bleeding
	No= 10	No= 5	No= 5	No= 2
BMI				
Normal weight	1	0	0	0
Over weight	4	1	0	0
Obese	5	4	5	2
Pearson Chi-Square X2 test (P)	**6.315 (0.177)**	**11.425 (0.003)****	**16.506 (0.000)****	**6.355 (0.042)***

* Significant, at p< 0.05

IV. Discussion

The aim of this study was to investigate the effectiveness of three versus five hours early ambulation after diagnostic cardiac catheterization through the femoral artery on vascular complications (hematoma & bleeding) and level of back pain. It was hypothesized that the two study groups had a similar and low rate of vascular complications (hematoma & bleeding), and less back pain intensity .

It is obvious from the present study that the majority of the first group were in age group 50 to 60 years old and the majority of the second group were in age group 40 to 49 and most patient in both groups were males .This can be attributed to the higher exposure to life stress, and female hormones protect female from CAD. This in line with abdollahi (2015) 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).[20]The results have shown that patients in the two study groups were similar in their age, gender and body mass index with no statistically significant differences among them. These parameters were important to be equally distributed among the two study groups because of their possible relations to the occurrence of vascular complications. This is in congruence with Hamner (2010) who have reported that age, height and weight, as well as sex are known to be predictive of vascular complications.[21] And also congruence with Kobrossi (2014) who reported that There were no differences between the two groups with respect to age, gender, body mass index .[22]

The results showed that early ambulation after femoral cardiac catheterization had no statistically significant effect on the incidence of vascular complications including bleeding and hematoma in two study groups. This findings come in accordance with Mohammady (2014) who reported that patients can be ambulated after 2–3 h following transfemoral catheterization, and that early ambulation had no significant effect on the incidence of vascular complications[23]& this also congruent with Mahgoub (2013) who reported that, no significant statistical differences were put into evidence between both studied groups in regards to vascular complication. And early ambulation is safe and feasible for patients undergoing PCI and CA.[24] additionally Sabzaligol (2010) reported that There was no statistically significant difference between the intervention and control groups in the level of bleeding after 6 hours, 24 hours, and seven days of catheterization (P>0.05).[25]

Back pain is an issue for patients who are required to remain on bed rest post femoral cardiac catheterization. The results showed that, early ambulation was associated with a lower level of back pain intensity in the 3 hours category versus the 5 hours category. This is in congruence with Burn (2012) who reported that early mobilization prior to four hours is safe and has a proven effect on back pain reduction .[26] This also congruence with Mohammady (2014) who reported that Early ambulation was associated with a lower level of back pain intensity in the 2–4 hrs category vs. the 6 hrs category after 2, 4 and 6 hrs follow-up.[23] And also congruence with Sabzaligol (2010) who reported that Back pain intensity was lower in the intervention group than the control one after 6 and 24 hours of catheterization (P<0.001).[25]

V. Conclusion

This study supports our hypothesis that the two study groups had a similar and low rate of vascular complications (hematoma & bleeding), and less back pain intensity. Moreover, Early ambulation after diagnostic cardiac catheterization had no significant effect on the incidence of vascular complications including bleeding, hematoma. However, early ambulation was associated with a lower level of back pain intensity. And The results of this study suggest that patients can be ambulated 3-5 hours after sheath removal.

Conflict Of Interest

The authors declare that they have no conflict of interests.

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Implications For Practice

Cardiac catheterization unit need to encourage early ambulation policy post cardiac catheterization to improve**.** patient comfort and early patient discharge from the hospital**.** Further nursing studies should investigate the longer term effects of early vs late ambulation by expanding the follow up period.

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