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RESEARCH ARTICLE

THE EFFECT OF EARLY MOBILIZATION AFTER DIAGNOSTIC CORONARY ANGIOGRAPHY ON THE VASCULAR COMPLICATIONS AT AHMED GASIM CARDIAC AND RENAL TRANSPLANTATION HOSPITAL 2017-2019

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ABSTRACT

Coronary catheterization is a minimally invasive procedure to access the coronary circulation and blood filled chambers of the heart using a catheter to recognize occlusion, stenosis and thrombosis. This procedure is commonly performed through the femoral artery, which may induce possible complications like bleeding or hematoma. These complications led to restricting of patient movement, so the patient has to lie in bed in a supine position for at least 6 hours after angiography. This is an experimental case control study, conducted to evaluate the effect of early mobilization on vascular complications. A sample of 300 adult patients was selected by a random sample technique. They were randomly allocated for 100 patients in the experimental group and 200 patients in the control group. The study was conducted from March/2017- March/2019 at Ahmed Gasim Cardiac Surgery and Renal Transplantation Hospital in Khartoum State, Sudan. The experimental group was mobilized early at 4 hours and the control group was placed on routine bed rest of 6 hours post sheath removal. Both groups received usual care. A structured questionnaire and checklist were used to collect data. Data was analyzed by using Statistical Packages for Social Sciences (SPSS). The result revealed that the majority of population did not develop bleeding after mobilization, (97.0%) in the cases and (99.0%) in the controls. While in the control (1%) had hematoma. This study concluded that early mobilization did not increase vascular complications and further studies should be done to decrease bedrest post diagnostic coronary angiography to 3 hours or less.

Key words: Bleeding, Hematoma, Femoral artery, Bed rest.

INTRODUCTION

Coronary heart disease (CHD) is considered as a main cause of cardiovascular disease (CVD) and heart failure, reaching nearly 30 % of the total cardiovascular disease in Sudan. Throughout 2016, the available data from all the country showed that: 585 patients underwent coronary artery bypass grafting (CABG), 1377 had percutaneous intervention (PCI) in the form of single or multiple stents and 4694 had diagnostic catheterization (Khalil, 2019). Interventional cardiology procedures are constantly increasing in numbers and in quality, especially in developing countries. During 2010-2015 at Egypt around 55,000 procedure was done (Magdy *et al.*, 2017). 17.9 million person died from cardiovascular disease in 2016 representing 31% of all global deaths, 85% are due to heart attack and stroke. Out of the 17 million premature deaths (below the age of 70) due to non-communicable disease in 2015, 82% are in low and middle income countries and 37% are caused by cardiovascular disease (WHO, 2017). Coronary heart disease is main cause of deaths worldwide (Perviz and Darred, ?). Coronary heart disease (CHD) is the single largest cause of death in the developed countries and is one of the main causes of disease burden in developing countries as well. In 2001, there were 7.3 million deaths and 58 million disability adjusted life years (DALYs) lost due to Coronary heart disease CHD worldwide (Thomas *et al.*, 2010).

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Coronary artery disease causes declined blood flow in the arteries that supply blood to the heart. Coronary artery disease is the more common form heart disease affecting approximately 16.5 million Americans over the age of 20 and is the leading cause of death of both men and women in the United States, it is estimated that every 40 seconds, someone in the United States has heart attack (Stacy *et al.*, 2018). The first cardiac catheterization performed in Sudan was in January 1976. The service continued till 1988 and stopped due to financial constraints and loss of trained technical staff to the Gulf States. By the turn of this century cardiac catheterization was resumed in Sudan primarily in the main cardiac centers of Sudan Heart Center, Ahmed Gasim Hospital and AlShaab Teaching Hospital as well as other public and private centers (Suliman, 2013). A coronary catheterization is a minimally invasive procedure to access the coronary circulation and blood filled chambers of the heart using a catheter. It is performed for both diagnostic and interventional purposes (Proudfit *et al.*, 1966). Coronary angiography is a common procedure that rarely causes serious problems. Possible complications may include bleeding, allergic reactions to the contrast dye, infection, blood vessel damage, arrhythmias, blood clots that can trigger a heart attack or stroke, kidney damage, and fluid buildup around the heart. The risk of complications is higher in persons who are older or who have certain conditions like chronic kidney disease or diabetes (<https://www.nhlbi.nih.gov/health-topics/coronary-angiography>). This procedure is commonly performed in Sudan through the femoral artery and may induce possible complications like bleeding or hematoma. These complications lead to restricting

the patient to lie in bed in a supine position for at least 6 hours after angiography. Routine bed rest is practice based on empirical reasoning and tradition and is associated with back pain, urine retention, discomfort, and made leads to negative feeling towards the procedure (Gozalian, 2008). Major complications from cardiac catheterization are uncommon and occur in less than 2% of the population, with mortality of less than 0.08% (Morteza *et al.*, 2012). Many studies were designed to study decreasing these complications without exposing the patients to any vascular complication by early mobilization. Randomized experimental study conducted on 120 patients, the finding showed that bleeding happened in 2 patients in the control group and one in the cases group. Also there was no incidence of large pre-ambulation hematoma in the control group, and there was one case in the experimental group, study concluded that ambulation 2 hours after angiography through the femoral site is feasible and safe also can shorten hospital stay (Farmanbar *et al.*, 2015). Another prospective study which had a big number of participants (4294) reported that no significant difference in the incidence of hematoma formation or bleeding following 6 or less than 6 h of bed rest (OR 0.82; 95% CI 0.59, 1.16) (Ying and Chair. E. Ruth, 2003). Another study work revealed that the incidence of vascular complications after femoral sheath removal following a percutaneous coronary intervention occurs between (5%-30%). The study objective was to determine which subject characteristics and co morbidities contribute to vascular complications post percutaneous coronary intervention procedure Age was significantly associated with ecchymosis, whereas hypertension was associated with a decreased level of ecchymosis. Body surface area significantly influenced hematoma formation (Sabo *et al.*, 2008).

MATERIAL AND METHODS

An experimental case control study was conducted at Ahmed Gasim Cardiac Surgery and Renal Transplantation hospital in Khartoum State, Sudan. This hospital is a governmental tertiary hospital receiving referral cases from all Sudan. From March 2017- March 2019. The inclusion criteria were adult patient's males and females who underwent diagnostic coronary angiography through the femoral artery and who were willing to take part in the study. The exclusion criteria were use of a Vascular Closure Device, use of radial access, patients having intervention (PCI), Emergency case, patients with high blood pressure before mobilization, patients who had bleeding or hematoma before mobilization and patients refusing to participate. The sample size was measured by Slovenes' formula ($n = N / 1 + N(e)^2$) Where: N=1200 is total number of patients who had diagnostic coronary angiography at Ahmed Gasim Cardiac and Renal Transplantation Hospital in 2017. So $1200 / 1 + 1200(0.05)^2$ gave a sample size of 300. A random sample technique was used to select the sample of 100 patients in the experimental group and 200 patients in the control group. The data collection tools were. Questionnaire: developed by the researcher to record patient's demographic characteristics including (age, weight), medication use, hemostasis and sheath size used. Checklist: to record patient's blood pressure, hematoma: measured using classified hematoma into four categories according to surface area and bleeding: Using (visual analogue scale (VAS) according to WHO bleeding scale. Data was analyzed by using Statistical Packages for Social Sciences (SPSS). In the analysis of the research findings; numeric values, numbers, and percentage

distribution have been employed. The significance level has been determined as $p < 0.05$. Analysis using chi-square test and T. test as statistical tests.

Pilot study: After obtaining formal administrative approval from the concerned authority, the tools was pre-tested to check for the clarity of items and feasibility. The reliability of the tools was tested on 20 patients.

Procedure of data collection: Data was collected five days a week from 8.00 am to 10.00 pm, starting from March to May 2018. A qualified Nurse with more than a year experience in the post-angiography wards assisted the researcher in collecting the data after she was trained. The researcher listed all adult patients registered for coronary angiography, after the procedure the first one who met the criteria was assigned for the experimental group and second one for control group. But unfortunately a lot of patients refused to be part of the experimental group. Those who refused were included in control group. Therefore, the number in the control group was larger than the experimental group. The investigator introduced her and explained the purpose of the study. Doctors, staff Nurses and ward in-charge Nurses who worked in the catheterization laboratory and the post cardiac catheterization wards department, were informed about the purpose of the study. The patients were randomized to mobilize early at 4 hours (experimental group) and the second group was placed on routine bed rest of 6 hours post sheath removal (control group). Otherwise the two groups received usually care. Blood pressure checked and recorded, then sheath removed immediately. Hemostasis was achieved by manual compression for all populations by using three fingertips, applied direct pressure at the groin puncture site. The time of compression average 10-20 minutes to achieve hemostasis, dressing was applied over puncture site by sterile gauze and securing by the tape. Groin sites were inspected for vascular complications (hematoma, bleeding) before mobilization time (cases & control) and frequently until patients discharge. Sandbag used to control the possible bleeding and hematoma for high risk patients their characteristics included (high BP, obese, old age, on rapid heparin, noncompliance and hemostasis time delayed more than 20 minutes, blood pressure checked again before mobilization and record). Bleeding check at one hour and two hours after mobilization for two groups. Final assessment was made at patient discharge. For the experimental group the vascular complications (bleeding, hematoma) was checked at the night of operation and at the morning of the next day by telephone because the hospital allowed discharge of the diagnostic catheterization patients on the same day of the operation.

Ethical consideration: The study proposal was submitted to relevant Research and Ethics Committees in Alzaiem Alazhari for ethical approval and then it was submitted to the Federal Ministry of Health. Ethical approval was obtained from the ethical committee of Ahmed Gasim Hospital. Each participant was well informed about the aim and potential benefits of the study, their written consent was taken and confidentiality was ensured

RESULTS

Demographic data was obtained from the patient's files; personal data was obtained by questionnaire and check list.

The result displayed as the following: The results explained that most of participant's age among the cases and controls was 51 – 70 years (61-61%- and 132-66%- respectively), and the most of the patients were above 70kg, this was specifically 55.0% in the cases and in the controls (52.0%) and there are some medications usually described for patients who have coronary heart diseases, the majority of the population in this study were on anti-platelet (81%) in the cases and in the controls (92.5%). Majority of the patients achieved hemostasis after sheath removal at 10 minutes in (97.0%) in the cases and in the controls in (84.5%), but among the control some patients was took up to 15minutes (13.5%). Then sheath size used for the population in this study ranged between 5-6 and 7, majority of the patients used size 5F (81.0% in the cases and in the controls (66.5%) but the size 6F was used more among controls (32.0%) Table (1).

Regarding blood pressure after mobilization the majority of patients have normal blood pressure (80.0%) in the cases and in the controls (82.5%) Table (2). The majority of the study population did not develop bleeding at one hour after mobilization (97.0%) in the cases and in the controls (99.0%) insignificant p value = (0.202) table (3). Regarding hematoma at one-hour no one in the cases developed a hematoma but in the controls (1%) had hematomas, however in significant difference between the two groups p value= (0.316) table (4). Table (5) Showed no one of population had bleeding or hematoma after two hours from mobilization in both groups, 100 (100.0%) &200 (100.0%) respectively. Therefore the difference between the two groups was significant p value = (0.00). No one developed bleeding or hematoma at the night of the operation day or the next day after the operation for cases Table (6).

Table 1. Distributions of patient's personal data in cases and control groups

Demographic Characteristics	Study population	
	Control group n = 200	Experimental group n=100
Age	18 - 30 years	1 (0.5%)
	31 - 50 years	57 (28. 5%)
	51 - 70 years	132 (66%)
	Above 70 years	10(5%)
Weight	40-50 kg	4 (2.0%)
	51-70 kg	92 (46, 0%)
	Above 70kg	104 (52.0%)
Size of sheath use	5F	133 (66.5%)
	6F	65 (32.5. %)
	7F	2(1.0%)
Hemostasis time	10minutes	169(84.5%)
	15minutes	27(13.5%)
	20minutes	3(1.5%)
	More than 20minutes	1(0.5%)
Medication	Thrombolytic	18(9. %)
	Anti-coagulant	46(23%)
	Anti platelet	185(92.5%)

Table 2. Comparison between blood pressure in cases and controls after mobilization

Blood pressure	After mobilization		P value
	Control	Cases	
normal BP	165 (82.5%)	80 (80.0%)	0.565
abnormal BP	21 (10.5%)	13 (13.0%)	
abnormal systole	10 (5.0%)	3 (3.0%)	
abnormal diastole	4 (2.0%)	4 (4.0%)	
Total	200 (100%)	100 (100%)	

Table 3. Occurrence of bleeding in cases and controls at one hour after mobilization

Vascular complication/Bleeding	At one hour after mobilizations(5 th for cases & 7 th hours for control)		P value
	Control	Cases	
No	198 (99.0%)	97 (97.0%)	0.202
Yes	2 (1.0%)	3 (3.0%)	
Total	200 (100%)	100 (100%)	

Table 4. Occurrence of hematoma in cases and controls at one hour after mobilizations

Vascular complication/ hematoma	After one hour from mobilization (5 th for cases & 7 th hours for control)		P value
	Control	Cases	
No	198 (99.0%)	100 (100%)	0.316
Yes	2 (1.0%)	0 (0.0%)	
Total	200 (100%)	100 (100%)	

Table 5. Occurrence of vascular complication in cases and controls at two hours after mobilizations

Vascular complication/ Hematoma& bleeding	At two hours from mobilization(6 th for cases, for control 8 th hours)		P value
	Control	Cases	
Yes	0 (0%)	0 (0%)	-
No	200 (100%)	100 (100%)	
Total	200 (100%)	100 (100%)	

Table 6. Occurrence of vascular complication in cases (At night & Next day of operation by telephone)

	At night & Next day of operation by telephone		P value
	Control	Cases	
Yes	-	0 (0%)	-
No	-	100 (100%)	
Total	-	100 (100%)	

DISCUSSION

Today with the increasing number of coronary angiography proceeded and evolving technology, Nurses are facing a great challenge. They are in the front line, and play significant role in the decrease or prevention of vascular complications after femoral sheath removal. This study aimed to evaluate the effect of early mobilization after diagnostic coronary angiography through femoral artery after sheath removal on the vascular complications among adult patients. According to the finding of this study, there was no major difference in the demographic data and others variables (medications used, sheath size used, hemostasis achieved) between the two groups. We found that sheath size 6 French was more frequently used in the control group (32.0%) compared to (19%) in experimental group but did not increased the incidence of bleeding through control group. The majority of the population achieved hemostasis at 10 minutes, but among the control group there was delayed more 15 minutes, and this still it was in the hemostasis time range. Blood pressure after mobilization showed no change between the two groups.

Regarding vascular complications after mobilization; bleeding occurred in a small number (3.0% in the cases and 1.0% in the controls) which was not significant P. value= 0.202. Hematoma was (1.0%) in controls only, which was also not significant p value=0.316. Therefore we found that early mobilization post coronary angiography was not associated with increase in vascular complications. Our results were similar to many researchers' findings that examined the effectiveness of early mobilization on vascular complication. Farmanbar *et al.* in their study, found similar result, that bleeding occurred in one patient among the cases and 2 patients among the control and no hematoma occurred (Farmanbar *et al.*, 2015). Another study done by Höglund, J supported our result (hematoma 5.8 & 3.8 in case and in control respectively and concluded that early ambulation after coronary angiography is safe, without affecting the incidence of vascular complications, and decreases the patients' pain, both during and after the bed rest (Johan *et al.*, 2011). The same was found by Gozalian, M, who found that (bleeding was (1.7%) in experimental group and (3.3%) in control) and concluded that early mobilization is safe especially with the increasing numbers of patients and restricted hospital facilities (Gozalian, 2008). Another study done by Augustin, A .C. Showed that bleeding was (1.7% in cases and 0.6% in control

p=0.31) (Augustin, 2010). Tamim *et al.* showed similar result among their study in which the incidence of vascular complication was (2.7%-2.6% in control group p value =0.97) (Semaanand and Dakik, 2014). Study done by Gillane, O and Pollard, M, were concluded that complication rates through 500 patients were higher in patients on aspirin and clopidogrel (17.4%) compared with those who were not (12.8%; p=0.38); and in patients with high BP (14.2%) compared with patients with normal BP (13%; p=0.75), females low than males (Gillane and Pollard, 2009). In our study the vascular complications were measured until the next day, while in the study done by A.Elhamed, R *et al.*, they measured the vascular complication up to a week after patient discharge (Elhamed *et al.*, 2015). On the other hand, Farmanbar, R *et al.* made the observation up to month. But all of them reported no vascular complications during all the follow up time (Farmanbar *et al.*, 2015).

Conclusion

Patient undergoing diagnostic cardiac catheterization through femoral access with manual compression can be mobilized early at 4hours without increase in the incidence of vascular complications.

Recommendation

Further studies should be done to decrease bed rest post diagnostic coronary angiography to 3hours or less.

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