Predictors of Post -Cardiac CatheterizationFemoral Artery Hematoma and Bleeding

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Abstract: Cardiac catheterization is performed routinely in hospitals all around the world. Extensive analyses of complications have been performed in the 1980s and early 1990s, showing a relatively stable mortality rate between 0.1% and 0.2% and an overall complication rate between 0.8% and 1.8%. However, there are few data about procedural complications of cardiac catheterization. Complication rate may be significantly lower in recent years because advanced catheter technologies have improved cardiac catheterization significantly. the incidences of vascular access complications alone have been reported to be anywhere from 0.1% to 61%, depending on the definition of complications and covariates, including the type of procedure, anticoagulation, closure devices, age, sex, and co morbidities. Nurses need to develop safe protocols of care for patients post CC and PCI that are research and evidence based. **Aim of the study:** The aim of the present study was to determine incidence of post cardiac catheterization hematoma and bleeding and investigate the significance of risk predictors for these complications. **Methods:** The study was carried out at coronary care unit at the main university hospital, Alexandria University. Included 100 patients and an assessment tool was used to investigate the patients. It consisted of 3 parts Patients˴ characteristics, information of Cardiac catheterization and risk factors. **Results:** It was found that hematoma occurred with 31% of the studied sample. In addition diabetes mellitus was risk factor for the occurrence of hematoma with significant difference 0.038. Sex, age, smoking, hypertension, hypercholesterolemia, myocardial infarction, indication, type of procedure, BMI, French sheath size, PCI and compression time cannot be considered risk factors for the occurrence of hematoma. **Conclusion:** Cardiac catheterization staff and nurses caring for these patients must work together to prevent complications, when possible, and treat complications when they occur. Diligent assessment and monitoring are required to meet these goals. Nurses with specialized training are needed to assess, identify and manage vascular.

1. Introduction

Cardiac catheterization is considered the gold standard for the diagnosis, evaluation, and treatment of cardiac diseases. Although it has reduced morbidity and mortality for cardiovascular disease, this invasive procedure is not free of complications [1].

In 1929, Werner Forssmann [2] was the first to advance a catheter into the heart. Nowadays, cardiac catheterization is performed routinely in hospitals all around the world. Extensive analyses of complications have been performed in the 1980s and early 1990s, showing a relatively stable mortality rate between 0.1% and 0.2% and an overall complication rate between 0.8% and 1.8% [2-5]. Because all cardiac catheterizations involve the insertion of foreign objects into the circulatory system, it should not be surprising that a variety of adverse events can ensue.

Post cardiac complications range from minor problems with no long-term sequelae (e.g., transient bradycardia during coronary contrast injection) to major problems [e.g., cardiac perforation, abrupt closure of a coronary artery during percutaneous transluminal coronary angioplasty (PTCA)] that may require immediate surgical attention or cause irreversible damage (e.g., stroke, myocardial infarction, renal failure, or even death) [6].

The American College of Cardiology's benchmark for the incidence of all complications, major adverse cardiac events, stroke, death, renal failure (RF), and vascular complications is no more than 1% for diagnostic CC and 3% for PCI[7,8]. However, the incidences of vascular access complications alone have been reported to be anywhere from 0.1% to 61%, depending on the definition of complications and covariates, including the type of procedure, anticoagulation, closure devices, age, sex, and comorbidities[9,10].

Vascular complicationsinclude bleeding at the access site, hematoma, retroperitoneal bleeding, and pseudoaneurysms or arteriovenous fistulaformation [11]. Local complications at the sheath introduction site are among the most common problems seen after cardiaccatheterization procedures [12].Bleeding, bruising, or hematoma at the sheath site can occur if sufficient pressure is notapplied manually, with a mechanical compression device, or with vascular closure devices [13].

Bleeding isblood loss at the site of arterial or venousaccess. It may be due to perforation of a traversed artery or vein requiring transfusion and it prolongs the hospital stay, and it may cause a drop in hemoglobin of greater than 3.0 gm/dl. Bleeding attributable to the vascular site could be local hematoma >10 cm, or external entry site bleeding. The use of anticoagulants to minimize clot formation during the cardiac catheterization and the use of platelet inhibition agents to decrease stent restenosis raise the risk of groin bleeding complications post procedure [14].

A hematoma is a collection of blood within the soft tissues of the upper thigh or lower abdomen. Signs and symptoms of hematoma formation at the groin site are identified by swelling and pain at the site [5, 15]. Knowledge and assessment of these early signs and symptoms of bleeding at the access site are pivotal in minimizing vascular complications. Hematoma characteristics vary widely from patient to patient. Variations include covert bleeding into subcutaneous tissue, which may be difficult to assess, and/or obvious bleeding from the site with additional signs and symptoms of compromised vascular flow (e.g., weak or absent pedal pulses)[7].

Factors that influence vascular complications including patient characteristics, interventional cardiologist technique, medications used during the catheterization, use of manual and/or mechanical compression at the access site, use of closure devices, and nursing care [2,7].

Nurses play a critical role in the management of patients after cardiac catheterization. Early detection and management of vascular complications are keys to minimizing complications. Nurses need to develop safe protocols of care for patients post CC and PCI that are research and evidence based. Patient outcomes can be improved if there is a greater quantity or quality of nursing care (bleeding and hematomas).

The start of safe, quality care begins with a thorough review of the patient's history and physical, current medications, risk factors for development of complications, and summary of the events in the cardiac catheterization lab [16].So, the aim of the present study was therefore to investigate predictors of post cardiac catheterization hematoma and bleeding.

Aim of the study:

The aim of the present study was to determine predictors of post cardiac catheterizationfemoral artery hematoma and bleeding.

2. Methods:

Design:

This study haddescriptive design.

A-Settings:

The study was carried out at coronary care unit at the main university hospital, Alexandria University.

B- Study population:

One hundred patients were involved in this study.

C- Tool of data collection:

An assessment tool was developed by the researcher and used to investigate patients. It consisted of 2 parts.

Part I: Patients' characteristics:

This part consisted of patient name, sex, age, body mass index and medical history.

Part II: information of Cardiac Catheterization:

This part consisted of indications of cardiac catheterization, type of procedure, sheath size, usage of anticoagulants, PCI status, femoral artery involved, number of sheath utilized, number of catheter changed

Data collection:

Permission to conduct the study was obtained from the director of the chosen setting. The tool was tested by 5 experts in critical care nursing and cardiology medicine for content validity (97%).The study was explained to every patient and patient's consent was obtained before starting this study. A pilot study was carried out on five patients to check and ensure the clarity and applicability of the tool.

All patients undergoing diagnostic or therapeutic cardiac catheterization at the CCU of the Main university hospital Alexandria University were involved in this study. Each patient was examined by research immediately before the procedure to detect any vascular complication for any previous catheterization. Any patient with previous vascular complication was excluded from this research.

In all patients, the clinical variables recorded included patient age, sex, height and weight, and the presence or absence of clinically detectable peripheral vascular complication. The procedural parameters recorded included the type of catheterization procedure performed, the size of the arterial and venous sheaths, the peri- or post procedural use of anti-platelet, anticoagulant or fibrinolytic therapy,

Patients undergoing outpatient diagnostic procedures were examined for evidence of access site complications prior to discharge from the catheterizing institution and before patient's discharge from CCU(after 6 hours for CA and after 12 for PCI) and were then interviewed 72 hours to 1 week later.

D-Data analysis:

Data were analyzed using the Statistical Package for Social Science (SPSS version 16). The obtained data were coded, analyzed and tabulated. Descriptive analysis was performed in this study including frequencies, percentage, Pearson X^2 test and odds ratio.

3. Results:

Figure I show prevalence of post cardiac catheterization within studied sample it was found that hematoma occurred for 31% of the studied sample, bleeding occurred for 1%.

Table I reveals Frequency distribution of patient's characteristics and its relation with hematoma. It can be noticed that the age of the majority of the studied patients was between 40- 50. Moreover, indication of cardiac catheterization for the majority of studied patients 80% was valvular disease. In relation to sex it was found that 67.2% of male and 72.7% did not have hematoma.

As regard to past history it can be observed that 69.4 % of the studied patients were smokers and 70% of them had hypertension while 61% of studied sample were diabetics and 39% of diabetic patient had hematoma. In addition diabetes mellitus was risk factor for the occurrence of hematoma with significant difference 0.038. Furthermore, the majority of studied sample had myocardial infarction 71% and 69% of them do not have hypercholesterolemia. It was found that all of the previous factors including Sex, age, smoking, hypertension, hypercholesterolemia, myocardial infarction, indication and type of procedure cannot be considered risk factors for the occurrence of hematoma.

Table II reveals frequency distribution of procedural risk factors and its relation with hematoma. It can be observed that the majority of patients were 45 obese with no incidence of hematoma 73.3%. Furthermore, most of studied patients 89 patients used 6 French sheath size with 71.9 with no incidence of hematoma. In addition most of patients who used 7 French heath size had hematoma.

Also, the majority of studied patients 70 % were admitted for performance of CA. The common femoral artery were used more frequency than superficial femoral artery included 57 patients with low incidence of hematoma for both 31.6% and 30.2% respectively.
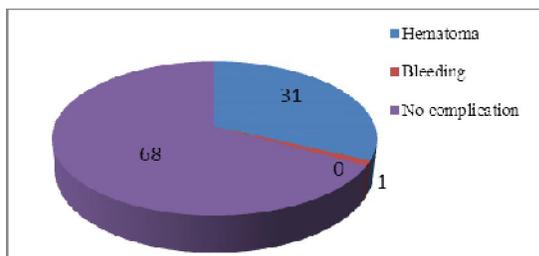
Figure I: Prevalence of post cardiac catheterization complications:

In relation to number of sheath which was used it was found that the smaller size 6 French was used for most of patient 98 patient with 69.4% of them had no incidence of hematoma. Also, 3 catheters were used during the procedure for the majority of patients 61 patients with low incidence of hematoma 37.7. Regarding time of compression it was found that most of patients 47 patients received the longest period of time 15-30 minutes and the majority had no hematoma 74.5 %. Moreover all of the previous factors cannot be considered risk factors for the occurrence of hematoma.

X^2 Tests between the demographic and procedural variables and the presence of any complication in (Tables I, II) were performed to identify variables that should be included in the logistic regression analysis (Table III). Diabetes mellitus, size of sheath and compression time could be identified the most significant risk factors. It can be observed that DM was associated with increased risk ratio of hematoma (OR=2.42%; 95%C.I. = 6.34-1.23), size of sheath increase ratio of hematoma (OR=3.6%; 95%C.I. = 13.95-1.2) and compression time increase risk of hematoma (OR= 0.55%; 95%C.I. = 1.12-.99).

Discussion:

It had been reported in previous studies that vascular access complications occurred from 0.1% to 61% [8, 9] of studied patients. In this study the most common complication was hematoma (Figure I)it occurred for 31% of studied patients. It was reported in previous study that the rate of hematoma was 12%[17].

Numerous studies have focused on identifying risk factors associated with complications of cardiac catheterization. Risk factors associated with vascular complications include being older and female, small stature, obese, coexisting condition of hypertension and/or renal failure, use of a large sheath, prolonged sheath time and excessive coagulation[10, 11, 18].

An increased risk of hematoma has been found with females but in this study there was no significant difference between men and women. It has been noted in previous study that women are at significantly higher risk than men [19].The reason for this high risk in women in not well understood, although various contributing causes have been suggested, such as hormonal factors or small vessel size. If small vessel size is an important factor, it may be that the insertion of sheaths that are too large for the vessel plays a role, and if so, the use of smaller sheaths in these cases could help to ameliorate the problem. This information may already be appreciated by practitioners, as indicated by data from this study which show that catheterizing physicians have a tendency to use smaller sheath size 6Fr.

In addition it was found in previous studies that advanced age > 70 years old was an independent risk

factor for vascular complication related to the presence of atherosclerotic blood vessels[20]. It is contradictory with the finding of this study as age was not an independent factor for hematoma because the age of our patient do not exceed 70 years old(Table I). It was not proven by this study that smoking was risk factors for post catheterization vascular complications (Table I). But, small artery size associated with current and former smoking, the presence of peripheral vascular disease, advanced atherosclerosis of the aorta and the iliacal arteries as seen in smokers are related to this increased risk of post catheterization complications[21].

Table I: Frequency distribution of demographic risk factors for vascular complication:

| Patient's characteristics | Total | Hematoma | | P |
| | | No | Yes | |
		No %	No %	
Age <40	6	4 66.7	2 33.3	0.922^
40-	20	15 75	5 25	
50-	51	34 66.7	17 33.3	
60+	23	16 69.6	7 30.4	
Sex Male	67	45 67.2	22 32.8	.572
Female	33	24 72.7	9 27.3	
Indication Myocardial ischemia	95	65 68.4	30 31.6	0.585!
Valvular disease	5	4 80	1 20	
Past history 1-Smoking				
No	64	44 68.8	20 31.3	0.943
Yes	36	25 69.4	11 30.6	
2-Hypertension No	30	20 66.7	10 33.3	0.714
Yes	70	49 70	21 30	
3-DM No	41	33 80.5	8 19.5	0.038*
Yes	59	36 61	23 39	
4-Hypercholesterolemia No	79	55 69.6	24 30.4	0.795
Yes	21	14 66.7	7 33.3	
5-MI No	38	25 65.8	13 34.2	0.587
Yes	62	44 71	18 29	

*P: Pearson X^2 test ^: p value based on Mont Carlo exact probability! P value based on Mont Carlo exact probability * P < 0.05 (significant)*

Table II: Frequency distribution of procedural risk factors and vascular complication:

Risk factors	Total	Hematoma		*P*
		No	Yes	
		No %	No %	
BMI				
Normal	12	8 66.7	4 33.3	
Overweight	43	28 65.1	15 34.9	0.695
Obese	45	33 73.3	12 26.7	
Procedure				
CA	70	49 67.1	23 32.9	0.580^
PCI	30	20 71.4	8 28.6	
Artery involved				
Superficial femoral artery	43	30 69.8	13 30.2	0.885!
Common femoral artery	57	39 68.4	18 31.6	
French sheath size				
6	89	64 71.9	25 28.1	0.073!
7	11	5 45.5	6 54.5	
No of sheath inserted				
1	98	68 69.4	30 30.6	0.557!
2	2	1 50	1 50	
No of catheters used				
1	8	6 75	2 25	
2	31	25 80.6	6 19.4	0.184
3	61	38 62.3	23 37.7	
Compression time (min)				
7-9	8	3 37.5	5 62.5	
10-14	45	31 68.9	14 31.1	0.113
15-30	47	35 74.5	12 25.5	

CA: coronary angiography, PCI: percutaneous coronary intervention. *P: Pearson X^2 test ^: p value based on Mont Carlo exact probability! p value based on Mont Carlo exact probability * P < 0.05 (significant)*

Table III: Predicting factors for occurrence of post cardiac complications:

Common risk factors	B	S.E.	OR	95%C.I.for OR	
				Lower	Upper
DM	.88	.49	2.4	1.23	6.34
Size of sheath	1.28	.69	3.6	1.2	13.95
Compression time	-.6	.36	0.5	.99	1.12
Constant	-7.8	4.21	0.0		

OR: odds ratio, SE: standard error, B: regression coefficient
CI: confidence interval

A previous study reported conflicting results on other associations with vascular complications, such as myocardial infarction, diabetes mellitus and hypertension[22]. Diabetes mellitus arose in this study to be

the only an independent risk factor for hematoma (Table I) and it was associated with high odds ratio for hematoma (Table III). This finding support previous research done by Groome[23] it was related to the effect of Diabetes mellitus on vascular integrity. Furthermore, our results are in certain contrast with previous study which found hypertension as a risk factor. Hypertension also came as an independent risk factor probably due to the difficulty in compressing an artery with an elevated intra-luminal pressure[24]. Although most of patients had past history of MI and the most of them had MI (Table I). But MI was not found as a risk factor in the contrary of the results of previous study which found MI as an independent risk factor especially when they received thrombolytic therapy [22].

In this study the development of hematoma was not common in patients with valvular heart disease because the number of these patients was so little 5 patients only (Table I). Other author has reported an increased incidence of post catheterization complications in these patients particularly when receiving concomitant anticoagulation therapy [23]. Another risk factor was predicted in previous study and did not consider an independent risk factor in this study. It was a high body weight. This may not come as a surprise since may be more difficult in obese patients[25].

Fewer femoral complications have been noted in patients undergoing elective PCI than CA. The reason is that groin sheaths after diagnostic procedure are usually removed immediately after the procedure by catheter lab nurses whereas after PCI, the sheath is removed in the resident in the ICU, usually with greater care. But it was found in this study low incidence of hematoma with CA as the same as PCI (Table II). It may be related to high experience level of nurses.

Bleeding has been reported as a complication in individuals who are fully heparinized and coumadinized as well as patients who receive enoxaparin. Most patients are given heparin at the start of the procedure but only a minority of operators orders an activated clotting time (ACT) test before removing the groin sheath after the diagnostic angiography. It may be necessary in some patients to reverse the effects of heparin with protamine [26]. Also, it can be added that risk of bleeding is increased with a high femoral puncture. This has been demonstrated by Gabriel et al who found that the risk of vascular complications was 8.7% with puncture of the SFA compared to 3.1% with CFA puncture[27]. That explains the reason of low incidence of bleeding in this study. The common femoral artery was used to insert the sheath and the puncture site (Table II). It

was appropriate for applying enough pressure in the majority of patients.

In fact, the strongest preventable risk factors for hematoma formation were sheath size and compression time. The dataof this research show that the size of the catheter was one of the most important risk factor (Table III). Difficulty of femoral artery catheter insertion due to artery size has been implicated as one risk factor. This could be important information in the consideration of what sheath size to use. If so, the shift to smaller devices may be at least partially responsible for this improvement. Failure to decrease the sheath size appropriately, as needed, could result in vessel injury such as laceration or dissection, and resulting bleeding.

At the same time it must be realized that there is almost certainly a limit to how much the sheath size can reasonably be reduced in an effort to reduce the probability of local vascular complications of cardiac catheterization. This is because reducing the sheath size too much would probably reduce the chances of angiographic success. Therefore, an appropriate balance should be sought between a sheath size large enough to maximize the likelihood of angiographic success, while simultaneously small enough to minimize the risk of local vascular complication. It was found the catheter size of importance. Furthermore, similar results were obtained by Messina *et al.,* who reported a relation between sheath size and the incidence and significance of complications.

In relation to compression time, it must be above the puncture site directly for approximately 20 minutes. Manual compression requires the use of the two or three fingers compressing 1 to 2 cm. Our data show that compression time was one of the most important risk factor (Table III). Although the majority of our patients received more than 20 minutes of compression time but hematoma was occurred. One study reported reduction in hematoma rate from 12% to 1% through performance improvement projects which include an average manual compression rate of 24 minutes. Hematoma can occur if the sheath is removed prior to proper hand positioning and timely compression or prior to sheath removal if multiple attempts were made for vascular access. It can be noticed that the majority used 3 catheters during procedure with one sheath which increase liability for hematoma (Table II).

Conclusion:

It can be concluded from this study that hematoma was common complication among studied patients and it is a complication can occur while the sheath is in place, during removal, or hours later. Risk factors associated with hematoma according to the finding of this study were D.M, large sheath size and

compression time. Nurses with specialized training are needed to assess, identify and manage hematoma.

Recommendation:

1- Nurses have to use a specific protocol in a post catheterization unit.

2- Great cautious should be applied to high risk patients for post catheterization complications especially for diabetic patients.

3- Proper assessment and monitoring are required to identify, and manage hematoma and bleeding.

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