

Assessment of femoral access site hematoma formation incidence and risk factors among post cardiac catheterization patients in 2024

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ABSTRACT

Background: An invasive cardiovascular procedure's frequent and potentially serious complication is hematoma formation at the femoral access site.

Aims: To assess the incidence and risk factors of hematoma formation at femoral access site among patients post cardiac catheterization.

Design: Descriptive research design was used.

Subject and setting: All available adult patients (200), aged 18-65 years old, from both sexes who were attend to cardiac Catheterization unit at Makkah Hospital, Saudi Arabia for a diagnostic procedures or interventional cardiac catheterization within 6 months' period.

Tools: two tools were used (I) Patient interview questionnaire, and (II) risk factors assessment list.

Results: Incidence of femoral access hematoma formation over six months was (20%)percentage. Regarding medical data more than half of the studied patients had hypertension (61.5%), majority had a history of previous hospitalization (84.0%), large portion of them performed cardiac catheterization for diagnostic purposes and were smokers (39.0%). Regarding the modifiable risk factors, obesity was the 29(14.5%), position change during compression 31(15.5%), Number of artery puncture (25%) Renal dysfunction 19(9.5%), Early ambulation 27(13.5), Use of anticoagulant 17(8.5%). Regarding the non-modifiable risk factors were found among 29(14.5%) of the studied patients who were advanced in age 29(14.5%) and male gender was 27(13%) While, thenon-modifiable risk factors were 14.5 1.5 and 9.5% including advanced age and hypertension among male patients.

Conclusion: There was A hematoma formation among patients after cardiac catheterization. There was correlation between medical data, modifiable risk factors & non-modifiable risk factors.

Recommendations: Developing a standardizing protocol about hemostasis, sheath removal for providing education and training to healthcare providers to identify and manage such risk factors.

Keywords: Cardiac catheterization, Femoral access, Hematoma, prevalence & Risk factors

INTRODUCTION

In order to diagnose or treat some heart diseases, such as clogged arteries or irregular heartbeats, a thin, flexible tube called a cardiac catheter is directed through a blood vessel to the heart. Doctors can learn vital information about the heart's blood arteries, heart valves, and heart muscle through cardiac catheterization (Roy et al., 2022). The most frequent side effect following cardiac catheterization operations is hematomas. Usually, hematomas develop after poorly managed hemostasis after sheath removal. The majority of hematomas are benign and self-limiting, but big, quickly growing hematomas may induce hemodynamic instability and necessitate blood and fluid resuscitation. Transradial access considerably lowers the incidence of this problem (Gleich et al., 2021).

Hematoma is a localized collection of blood outside the blood vessels, usually caused by bleeding from the punctured site of the artery or vein during the catheterization procedure. Hematomas could be ranged from small

bruises to large collections of blood that could cause significant pain, swelling, and other complications (Chaurasia et al., 2023).

Risk factors for femoral access site hematoma are the use of complex techniques during Percutaneous cardiac intervention (PCI), insufficient hemostasis after PCI, use of antiplatelet or anticoagulant drugs during or after the procedure, application of a long catheter to the femoral artery and/or long duration of catheter stay (Ignatavicius et al., 2020).

In patients with transfemoral access, retroperitoneal bleeding should be suspected if there is a sudden change in the patient's hemodynamic stability with or without back pain, as there may not be any visible swelling in the groin for some of those patients. It is important to monitor patients for signs and symptoms of hematoma formation after cardiac catheterization, as prompt recognition and management could help to prevent further complications. Patients who develop symptoms should seek immediate medical attention (Roy et al., 2022).

The incidence of hematoma among such group of patients is less than 0.2%. Strong clinical suspicion along with immediate imaging, usually with a CT scan, helps to diagnose this problem. Identification of the bleeding source is essential for patients with continued hemodynamic deterioration. These life-threatening bleeds are more frequent when the artery is punctured above the inguinal ligament (Gleich et al., 2021).

Prevention of hematoma formation at the femoral access site is essential to reduce the risk of complications and improve patient outcomes. Appropriate patient selection, careful arterial access technique, and the use of closure devices could help to minimize the risk of hematoma formation. Prompt recognition and management of hematomas are also critical to prevent further complications (Roy et al., 2022).

Cardiac catheterization is usually done by an interprofessional cardiac care team that includes an interventional cardiologist with assistance from nurses and radiologic technologists. During the procedure, a nurse is dedicated to the monitoring of the vital signs. After the procedure, the nurse is also responsible for ensuring that the access site is not bleeding, and the distal extremity pulses are intact. In addition, the nurse monitored the urine output to ensure that there has been no adverse reaction of the dye to the kidney. Interprofessional collaboration and open communication was provide significant benefits when performing cardiac catheterization (Munir et al., 2020).

Significance of the study

Cardiac catheterization had become a routine diagnostic procedure performed in many hospitals (Sasaki et al., 2023). Patients admitted to the cardiac catheterization unit of Al- azhare University Hospital around 600 patients per year performed either diagnostic or interventional cardiac catheterization (Hospital record, 2020). Hematoma considers the most common vascular access site complication after cardiac catheterization, so this study was conducted to assess the incidence and risk factors of femoral site hematoma formation.

Aims of the study

To assess the incidence and risk factors of hematoma formation at femoral access site among patients post cardiac catheterization, through:

1. Determine the incidence of post cardiac catheterization femoral site hematoma.
2. Identify the modified and non-modified risk factors of hematoma formation at the femoral access site among patients post cardiac catheterization.

Research questions

- 1- What is the incidence of post cardiac catheterization femoral site hematoma?
- 2- What are the risk factors of femoral site hematoma formation?

Patients and Methods

Research design

A descriptive research design was used to conduct the study.

Settings

This study was carried out in Cardiac Catheterization Unit and Coronary Care Unit, at Makkah hospital, Saudi Arabia

Study Sample

All available adult patients (200), aged from 18-65 years old, from both sex who admitted cardiac catheterization unit at Makkah hospital, Saudi Arabia for diagnostic or interventional cardiac catheterization within 6 months period.

Exclusion criteria

Patients with; peripheral vascular disease, congenital malformation, or bleeding disorder all was excluded from the study.

Study tools

Two tools were used for Data collection: Tool I: Patient interview questionnaire:

It developed by the researcher after reviewing the current relevant literatures, it included 2 parts

Part 1: Demographic data: Age, sex marital status, education level , occupation, and residence.

Part 2: Medical data: which included medical diagnosis, indications of catheterization, past health history, purpose of catheterization and patient habits.

Tool II: Risk factors assessment list: this tool include both modifiable risk factors of femoral access site hematoma formation among patients post cardiac catheterization as: obesity, previous catheterization at the same site, anticoagulants, prolonged procedure duration, large sheaths, early ambulation puncturing below the femoral bifurcation, sheath time, method of compression (manual), using of steroids ,position change during compression, number of artery, puncture time compression, heparin uses, low platelet count, lower body surface areas-low body weight, hypertension and renal dysfunction. While, and non modifiable include older age, gender.

Scoring system

The presence of the factor was given (1 mark) While absence of it was given (zero mark).

Ethical considerations

- Research proposal was approval from ethical committee .
- There was no risk for study subject during application of research .
- The study followed the common ethical principles in clinical research .
- Oral consent was obtained from patients who were willing to participate in study, after explaining the nature and purpose the study .
- Confidentiality and anatomy were assured .
- Study subject had the right to refuse to participate and or withdraw from the study without any rational and at any time .
- Study subject privacy was considered during data collection.

Procedure

- An official approval was obtained
- Content validity was done by 5 expertise from the staff of nursing and medical fields and necessary modifications were done .
- A pilot study was conducted on (10%) 20 patients of sample in the selected setting to test the feasibility and applicability of the tools (were added to the main sample later), as well as to estimate the time needed to fill in the data collection tools, and then the tools were modified according to the results of the pilot study.
- Patient's agreement for voluntary participation was obtained and purpose and nature of the study was explained to them.
- Patients were assessed for demographic data, and medical data before cardiac catheterization using (tool I), It took about 30 minutes.
- Patients were assessed for risk factors of femoral site hematoma formation during and post cardiac catheterization using tool (II), It took about 30 minutes.
- Each patient was interviewed for 10 minutes either before or after cardiac catheterization.
- The number of patients differ from day to day depending on the number of patients performed cardiac catheterization in the operation list as ranged from 0to 8 patients per day.
- Patients were followed by the researcher for hematoma formation during hospitalization and after discharge for 5 days post cardiac catheterization either through telephone contact or some patients return to the outpatient clinic in case of any complications appears.
- Data were collected in the morning and afternoon shifts.
- Data were collected from cardiovascular department and catheterization unit during the period from January to June 2024.

Statistical analysis

Collected data was analyzed and tabulated. The researcher used an appropriate statistical analysis method and testes for analysis of the result. The statistical package for (SPSS) version (23) was used to analyze data. Descriptive statistics were used for the quantitative data. It included frequencies, percentage, mean \pm SD. Person

correlation (correlation is significant at the 0.05 level). The level of significant for this study was set at ($P < 0.05$) to detect any indication of differences found in the data available.

RESULTS

Table (1): Distribution of participant patients demographic characteristics (n=200)

Table 1: The patients in the study had a mean age of 52.58 ± 6.91 years, were all married, and the majority of them were male (58.0%), had a secondary education (54.5%), were housewives (42.0%), and came from a rural area (83.0%).

Demographic characteristics	N.	%
Gender		
Male	116	58.0
Female	40	02.4
Age(Mean\pmSD)	52.58 \pm 6.91	
Marital status		
Single	0	0.0%
Married	200	100
Education level		
Illiterate	9	4.5
Read and write	19	9.5
Primary education	11	5.5
Secondary education	109	54.5
High education	52	26.4
Occupation		
Farmer	3	1.5
Skilled worker	76	38.0
Office work	37	18.5
Housewife	84	42.0
Residence		
Rural	166	83.0
Urban	40	17.0

Table (2): Distribution of the studied patients regarding their medical data (n=200):

Table 2: revealed that 61.5% of the participants in the study had hypertension and 49.0% had diabetes mellitus. Additionally, 84.0% of patients underwent cardiac catheterization for diagnostic purposes, 39.0% smoked, and 52.0% had a history of prior hospitalization. Patients with diabetes mellitus, hypertension, prior hospitalization, and hematoma formation showed statistically significant differences.

Medical data	Total No%	Hematoma				P. value
		Not present		Present		
		N.	%	N.	%	
Chronic diseases						
-Diabetes mellitus	84(49%)	40	02.4	40	%0.4	0.04*
-Hypertension	123(61.5%)	446	04.4%	40	8.5%	.01*
-Chronic obstructive pulmonary disease	5(2.5%)	0	2.4%	4	0.5%	.413 ns
-Dyslipidemia	13(6.5%)	44	5.0%	4	1.5%	.128 ns
-Others(renal failure-peptic ulcer)	0 (2%)	0	2.4%	4	4	.402 ns
Previous hospitalization	104 (52.0%)	89	44.5%	15	7.5%	.025*
Purpose of catheterization:						
-Diagnostic	168 (84.0%)	404	76.5%	40	7.5%	.196 ns
-Therapeutic	32 (16.0)	20	13.5%	0	2.5%	
Personal habits						
-Smoking	78 (39.0%)	04	36.5%	0	2.5%	.132 ns

Table (3): Assessment data during and post cardiac catheterization among the studied patients (n=200):

Table 3: demonstrated that 192 (96%) of the patients in the study had a normal puncture site, whereas 6 (4.0%) had a low puncture site. It was discovered that 140 (70%) of the patients in the study had a low time number of

puncture trials. 200 (100%) of the study participants had active clotting times. Additionally, every patient in the study wears French sheath size (6). The majority of the 198 patients (99.0%) in the study had the longest compression times, which ranged from 15 to 30 minutes. Additionally, the majority of the patients in the study—197, or 98.5%—had the longest sheath time.

Assessment data	Total	Hematoma				P. value
		Not present		Present		
		N.	%	N.	%	
Site of puncture						0.001**
- High	2	4	4	2	% 4.4	
- Normal	192	400	% 44.0	40	% 0.0	
- Low	6	4	% 4.0	4	% 4.0	
Number of artery puncture						.001**
- Once	33	44	% 46.0	4	4	
- Twice	140	440	% 60.4	6	3.0%	
- 3times	27	44	% 6.0	40	7.0%	
Sheath time						.272 ns
- 15-<30mintes	197	404	89.0%	48	9.5%	
- 30-45mintes	3	2	1.0%	4	0.5%	
Compression time						.905 ns
- 15-<30mintes	198	408	89.9%	48	9.5%	
- 30-45mintes	2	4	0.5%	4	0.5%	
Pain						.096 ns
- Mild	179	408	79.5%	24	10.0%	
- Moderate	21	24	10.5%	4	4	

Fig (1): Displayed that distribution of Incidence of hematoma among femoral access, showed that the majority of the patients didn't had any hematoma.

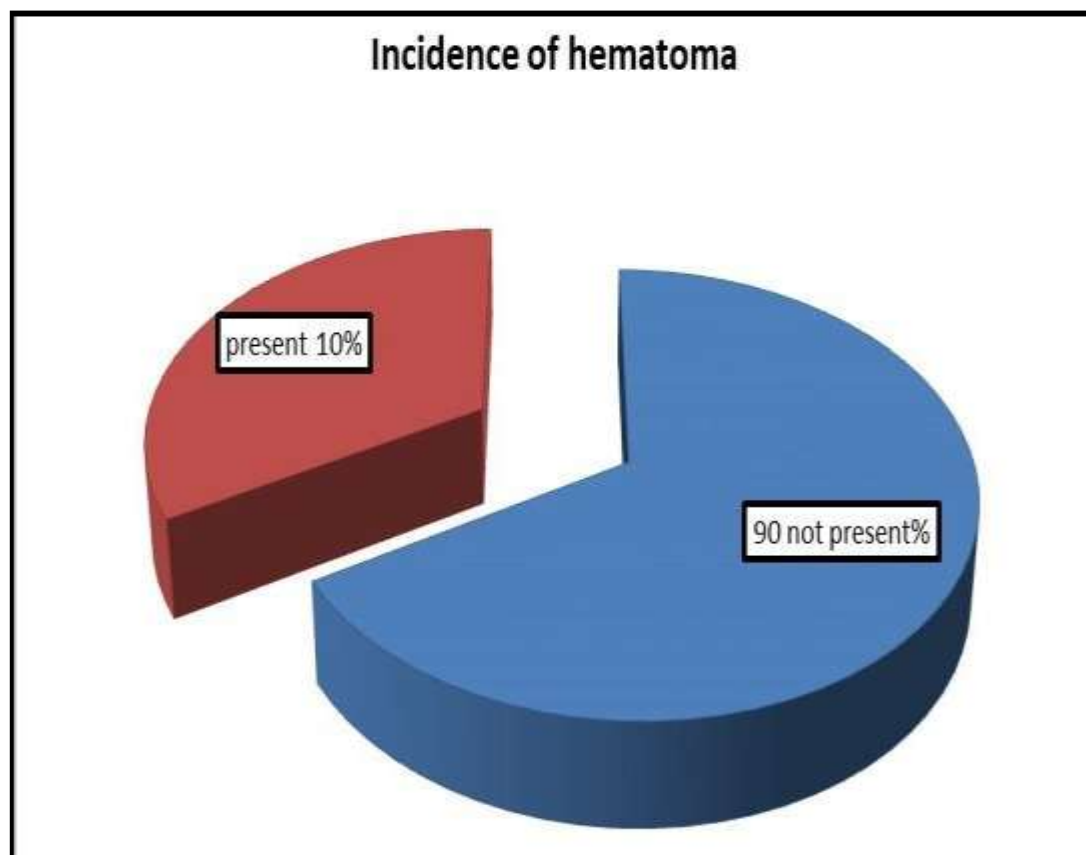


Figure 1: Incidence of hematoma formation among the studied patients (n=200):

Table (4): Modifiable risk factors for femoral access sit hematoma formation among the studied patients

(n=200):

Table 4: Reported that modifiable risk factors among the studied patients included; obesity 29 (14.5%), As well as hypertension was found among 25 (12.5%), renal dysfunction was found among 19 (9.5%). A small number of patients 17 (8.5%) use anticoagulation's that may participate in hematoma formation in the groin area, and that could be a modified factors which may be the cause of hematoma formation among the large sheath 17 (8.5%), also early ambulation among 27 (13.5) of the studied patients, puncture below the femoral bifurcation among 19 (9.5%), method of compression among 17 (8.5%), 20 (10%) taking steroids, position change during compression among 31 (15.5), number of artery puncture among 25 (12.5%), compression time 30-45 minutes among 25 (12.5%), taken dose of heparin among 22 (11%), perform previous catheterization among 21 (10.5%), low platelet count was among 19 (9.5%), lower body surface area among 19 (9.5%), low body Weight was among 19 (9.5%), incidence of hematoma was among 22 (11%).

Modifiable risk factors	Total	Hematoma				P. value
		Not present		Present		
		N.	%	N.	%	
-Obesity	29	44	5.5%	44	9.0%	0.001
-Hypertension	20	44	5.5%	40	7.0%	0.001
-Renaldys function	48	4	4.0%	44	5.5%	0.001
-Low body weigh	19	44	0.4%	8	0.0%	0.001
-Lower BMI	19	44	0.4%	8	0.0%	0.001
-Use of anticoagulant	17	4	4.0%	8	4.5%	0.001
-Heparindose	22	44	0.4%	42	6.0%	0.001
-Steroids	20	4	4.0%	42	6.0%	0.001
-Low platelet count	19	44	0.4%	8	0.0%	0.001
-Large sheaths	17	4	4.0%	8	4.5%	0.001
-Sheath time	18	8	4.5%	8	0.0%	0.001
-Punctur in below the femoral bifurcation	19	8	4.5%	44	0.4%	0.001
-Number of artery puncture	25	44	6.0%	42	6.0%	0.001
-Method of compression	17	4	4.0%	8	0.0%	0.001
-Position change during compression	31	40	7.0%	40	8.5%	0.001
-Time compression	25	42	6.0%	44	6.0%	0.001
-Previous catheterization at the same sit	21	44	0.4%	44	5.5%	0.001
-Early ambulation	27	44	0.0%	46	8.0%	0.001

Table (5): Non modifiable risk factors for femoral access sit hematoma formation among the studied patients (n=200):

Table 5: Showed that the non-modifiable risk factors were found among 29 (14.5%) of the studied patients, who were advanced in age and gender 27 (12.5%). As The percentage of male gender was 27 (13.5%) and had risk factors of hematoma formation more than the female gender.

Risk factors of hematoma formation more than the female gender:						
Non modifiable risk factors	Total	Hematoma				P. value
		Not present		Present		
		N.	%	N.	%	
-Advanced age	28	40	7.0%	40	7.5%	0.001
-Gender	20	42	6.4%	40	7.5%	0.001

Table (6): Relation between hematoma formation and risk factors (n=200):

Table 6: Reported that appositve correlation between the incidence of hematoma occurrence with both the modifiable and the non-modifiable risk factors.

Risk factors	Hematoma	N.	Mean	Std. Deviation	
- Modifiable risk factors	No present	180	.8944	3.44388	T: -9.160 Sig. 0.001**
	Present	20	9.2000	6.51799	
- Non modifiable	No present	180	.2500	.90853	T: -10.785 Sig. 0.001**
	present	20	2.7500	1.51744	

Table (7): Correlation between hematoma formation and medical data (n=200):

Table 7: Showed that the increased number of trails puncture, presence of diabetes millets, hypertension, previous hospitalization, and number of artery puncture had a positive correlation with hematoma formation.

Variables	Correlation hematomas	
	R	P
- Diabetes mellitus	.140	.048*
- Hypertension	.161	.023*
- Chronic obstructive pulmonary disease	.053	.453 ns
- Dyslipidemia	.115	.105 ns
- Previous hospitalization	.153	.030*
- Number of artery puncture	.445	.001**

DISCUSSION

Hematoma formation at the femoral access site is a common complication following cardiac catheterization. The incidence of hematoma varies depending on hematoma and the patient population studied. The risk of hematoma formation could be minimized by careful patient selection, appropriate procedural technique, and prompt recognition and management of complications (Kurt & Kaşıkçı, 2019). This study aims to assess the incidence and risk factors of hematoma formation at femoral access site among patients post cardiac catheterization.

Regarding the demographic characteristics of patients with cardiac catheterization who underwent cardiac catheterization in this particular study. The majority of them were males. The mean age of the patients was 52.58 years, with a standard deviation of 6.91 years. The researcher point of view that the age group and sex of the studied patients consider a very important variable to be detected. This is in the same line with the finding of a study done by Baljepally et al., (2021) who had shown that men are more likely than women to undergo cardiac catheterization procedures. Also, the finding of a study done by Brida et al., (2021) suggested that the patient population was relatively young and may not be representative of older patient populations who are more likely to develop cardiovascular disease.

Also the finding of a study done by Vincent et al., (2021) suggested that men are more likely than women to undergo cardiac catheterization procedures, and that the average age of patients undergoing the procedure is typically in the mid-of 60 years old.

In the other hand, the finding of a study done by Steenblik et al., (2021) found that women were less likely than men to undergo cardiac catheterization procedures, and that they were also less likely to receive appropriate care for their cardiovascular conditions.

In terms of occupation, the current study revealed that the largest group of patients were skilled workers in fields such as construction, carpentry, and while around half of them were housewives. As well the majority of patients came from rural areas. It's important to note that these demographics may not be representative of the general population due to the specific characteristics of the study population.

The finding of a study done by Yujeong, (2022) who investigated the demographics data of the patients undergoing cardiac catheterization procedures and found that the majority of patients undergoing cardiac catheterization procedures were employed, with a significant percentage working in manual labor jobs. Also, the finding of a study done by Green et al., (2020) found that patients from rural areas were less likely to undergo cardiac catheterization procedures compared to patients from urban areas, which may be related to differences in healthcare access and utilization in rural areas.

In the current study more than half of the studied patients undergoing cardiac catheterization had hypertension, while less than half of them were having diabetes mellitus and fewer percentage were having dyslipidemia. The researcher opinion, people with diabetes are more likely to get high blood pressure, high cholesterol, and obesity, all of which are a major risk factors for cardiovascular diseases. Additionally, diabetes could cause damage to the blood vessels and nerves that control the heart and blood vessels, which can lead to complications such as heart attack, stroke, and peripheral artery disease as mentioned in study of done by Otvos et al., (2023). In this line, the finding of a study done by Stein et al., (2022) found that hypertension, or high blood pressure, is a major risk factor for cardiovascular diseases and is a common comorbidity in patients undergoing cardiac catheterization. Besides, the finding of a study done by Huang et al., (2022) who found other risk factors, such as obesity, smoking, high cholesterol, and a sedentary lifestyle, which could also contribute to the development of cardiovascular diseases and may require further evaluation and management.

In terms of the purpose of the catheterization, the majority of procedures were diagnostic that match with the purpose of the catheterization, diagnostic procedures are more common than therapeutic procedures. The finding of a study done by Yoshihara, (2023) confirmed that purpose of the diagnostic catheterization which involves,

evaluation the structure and function of the heart and blood vessels while therapeutic catheterization, need a specialized instrument, such as balloons or stents, to treat blockages or other abnormalities in the coronary arteries.

Regarding hospitalization history, the finding of a study done by Bonanad et al., (2020) who found that it is not uncommon for patients with a history of cardiovascular diseases or related comorbidities to require hospitalization for management of their condition. Also the finding of a study done by Nielsen et al., (2021) reported that hospitalization may be necessary for a variety of reasons, such as for diagnostic evaluation, treatment of acute symptoms, or for surgical or interventional procedures. While the finding of a study done by Curigliano et al., (2020) reported that patients with a history of hospitalization for cardiovascular disease may have a higher risk of adverse outcomes and may require closer monitoring and follow-up care.

Additionally, the result of the present study showed that a large percentage of the studied patients undergoing cardiac catheterization were smokers. From the researcher's point of view smoking is a well-established risk factor for cardiovascular diseases, and it is not surprising that a significant proportion of patients undergoing cardiac catheterization were smokers.

This confirmed by the finding of a study done by Malakar et al., (2019) who found cigarette smoking could contribute to the development of atherosclerosis, a buildup of plaque in the arteries that can lead to heart attack, stroke, or other cardiovascular complications.

A large portion of patients in the present study underwent cardiac catheterization with a normal site of puncture with no hematoma formation, which is typically the femoral artery in the groin area. A small proportion of patients had a low puncture site or a high puncture site, which may be used in special circumstances such as in patients with peripheral artery disease or in those requiring access to a specific coronary artery. The researcher's view that due to that all patients in the present study underwent cardiac catheterization, the size of the sheath varied among patients, with a range of 6 French. The number of trials, or attempts to gain access to the artery, also varied among patients, with a large number of patients requiring two trials and the majority had a mild pain. This matches with the finding of a study done by Annetta et al., (2022) who registered that low incidence of hematoma occurrence was related to a low puncture site, typically in the distal femoral artery, may be used in patients with peripheral artery disease or other conditions that make the femoral artery in the groin area inaccessible.

According to the researcher's view gaining access to the artery can sometimes be challenging and may require multiple attempts. This is not uncommon in cardiac catheterization, as the procedure requires a high level of skill and experience to navigate the complex anatomy of the heart and blood vessels.

The finding of a study done by Cho et al., (2023) showed that multiple attempts to gain access to the artery could increase the risk of complications, such as bleeding or hematoma formation, and could also prolong the duration of the cardiac catheterization. However, the finding of a study done by Mangieri et al., (2023) who mentioned that it is important for the healthcare provider to obtain safe and successful access to the artery in order to perform the necessary diagnostic or therapeutic interventions. Also the finding of a study done by Besli et al., (2021) supported this and found that the majority of patients experienced mild pain or discomfort during the procedure, and that pain scores were generally low at 24 hours after the cardiac catheterization.

Regarding the modifiable risk factors of hematoma formation, the present study found that the majority of patients with hematoma were obese, use of anticoagulant medications, had large sheaths and did not ambulate early after the procedure.

Regarding the modifiable risk factors of hematoma formation, the present study found that the majority of patients with hematoma were obese, use of anticoagulant medications, had large sheaths and did not ambulate early after the procedure.

However, the finding of a study done by Sasaki et al., (2023) who recommended that healthcare providers may take steps such as using smaller sheaths, avoiding multiple punctures, using appropriate compression devices, and encouraging early ambulation to reduce the risk of hematoma formation. Careful monitoring and follow-up after the procedure can help detect and manage any complications that may arise. While the finding of a study done by Cheng et al., (2022) who stated that the strategies to reduce the risk of hematoma include using smaller sheaths, avoiding multiple punctures, using appropriate compression devices, and encouraging early ambulation. Based on the data presented, regarding modifiable risk factors for hematoma after cardiac catheterization the majority of patients with hematoma had renal dysfunction, and hypertension. The researcher's opinion that advanced age may be associated with thinning of the skin and reduced tissue elasticity, which could increase the risk of bleeding or hematoma formation after a cardiac catheterization. While the finding of a study done by Mangieri et al., (2023) who reported that non-modifiable factors cannot be directly modified, so, healthcare providers can take appropriate measures to monitor and manage these risks, such as adjusting medication dosages or using different approaches to reduce the risk of bleeding or hematoma formation. Close monitoring and follow-up after the procedure can also help detect and manage any complications that may arise.

In this regard, the finding of a study done by Jones- Muhammad, & Warrington, (2019) who reported that hypertension - high blood pressure can cause damage to blood vessels which makes them more prone to leaking

and bleeding. This is an important consideration in cardiac catheterization, as prolonged pressure holds could increase the risk of complications such as bleeding or hematoma formation (Bangalore et al., 2021).

This matches with the finding of a study done by Ahmed et al., (2023) who reported that hematoma is a known complication of cardiac catheterization. The researcher views that the presence of a hematoma could increase the risk of bleeding and other complications and may require additional monitoring or treatment.

However, the finding of a study done by Naidu et al., (2021) who recommended that patients should be advised to report any unusual bleeding or bruising after the procedure, as prompt evaluation and treatment may be necessary to prevent complications.

The existing study referencing found a significant correlation between hematoma formation and both modifiable and non-modifiable risk factors, as well as body mass index. Overall, as the researcher opinion, it is important for healthcare providers to consider both modifiable and non-modifiable risk factors, as well as body mass index, when assessing a patient's risk of hematoma formation after femoral access, and take appropriate measures to minimize this risk, such as using appropriate hemostasis techniques and monitoring the patient closely after the cardiac catheterization.

Regarding the finding of a study done by Ali et al., (2018) who investigated the risk factors associated with hematoma formation after femoral artery access for cardiac catheterization. While the finding of a study done by Slogoff et al., (2020) who found a non-significant results associated between certain risk factors and hematoma formation after femoral access. The present study found that, diabetes mellitus, hypertension, previous hospitalization and number of artery punctures increase incidence of hematoma. and showed appositve correlation between incidence of hematoma occurrence and those variables.

While the finding of a study done by Sasaki et al., (2023) who reported that 1,207 patients undergoing percutaneous coronary intervention found that hypertension and diabetes mellitus were significant predictors of hematoma formation after femoral access. The authors recommended that these risk factors should be considered when assessing a patient's risk of hematoma formation after percutaneous coronary intervention.

However, it is possible that some studies may had conflicting results. For example, the finding of a study done by Slogoff et al. (2020) who did not find a significant association between age, gender, hypertension, diabetes mellitus and obesity with hematoma formation after femoral access.

CONCLUSION

From the results of the present study, it could be concluded that the incidence of femoral access hematoma formation after cardiac catheterization at Makkah hospital, Saudi Arabia over six months was (10%). Moreover, a statistical significant difference was found between hematoma formation with both modifiable and non-modifiable risk factors. A positive correlation was found between hematoma formation and diabetes mellitus, hypertension, previous hospitalization, and number of artery puncture.

RECOMMENDATIONS

1. Simple illustrated guidelines about cardiac catheterization and prevention of hematoma formation should be available for patients.
2. Evaluating the effectiveness of different hemostasis techniques in preventing hematoma formation. This could include comparing manual compression with the use of closure devices.
3. Developing and implementing quality improvement initiatives aimed at reducing the incidence of hematoma formation at the femoral access site among patients post cardiac catheterization.
4. Conducting large prospective studies to determine the incidence of hematoma formation at the femoral access site in patients post cardiac catheterization and to identify the risk factors associated with this complication.

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