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Original Article

Others Section

Incidence and Predictors of Post-catheterisation Femoral Artery Access Vascular Complication in North Indian Population

ANIL GUPTA[1], SARITA CHOUDHARY[2], VIJAY PATHAK[3], POOJA PATHAK[4]

Introduction: Coronary Artery Disease (CAD) has been considered one of the major causes of morbidity and mortality in developed countries. Vascular access-site complications following percutaneous interventions done using femoral approach, are an important cause of mortality, morbidity, prolonged stay and greater cost burden.

Aim: To study the incidence and the factors which predict femoral artery access vascular complication after catheterisation in North Indian population.

Materials and Methods: This was a prospective longitudinal observational study conducted at Department of Cardiology SMS Medical College at Jaipur, Rajasthan, India between April 2016 to November 2017. All patients (n=11200) who underwent catheterisation from the femoral approach from April 2016 till November 2017 in the study institute were included. Duplex ultrasound was performed in cases with clinical suspicion of vascular complications. Clinical data and procedural variables were compared with a control group of 100 randomly selected patients. Univariate analysis and a logistic regression model for multivariate analysis for predicting independent variable was performed.

Results: Femoral artery access vascular complication incidence rate was 2.05% (230). Complications rate was higher for interventional procedures (3.6%) than diagnostic procedures (1.25%). The most common vascular complication was haematoma which was seen in 1.29% (145) patients, other complication were femoral artery venous fistula seen in 0.37% (42) patients, pseudo-aneurysm in 0.41% (46) patients, acute limb ischemia in 0.1% (12) and infection in 0.09% (11) patients. It was found that advanced age (>60 years), female gender, obesity and hypertension were predictors of complication. Patients who received thrombolytic agent or low molecular weight heparin prior to procedure, use of large sheath size (7F vs 6F) and multiple puncture to achieve femoral artery access were also independent predictors of vascular complication. Diabetes mellitus and duration of manual compression had no impact on vascular complication.

Conclusion: Femoral artery access vascular complication is not uncommon following diagnostic or interventional cardiac catheterisation. The strongest predictors of vascular complication were advanced age (>60 year), female gender, overweight and obesity, hypertension, use of thrombolytic agent or anticoagulant prior to procedure, large size sheath 7F, and multiple puncture. Use of smaller sheaths, improved access techniques, safer antithrombotic therapy and use of vascular closure devices may be helpful for prevention of these vascular complications.

Keywords: Angiography, Femoral route, Local site complication

INTRODUCTION

Coronary Artery Disease (CAD) has been considered one of the major causes of morbidity and mortality in developed countries [1]. Coronary angiography has become the gold standard for the diagnosis and establishing treatment strategies for atherosclerotic CAD [2]. Coronary angiography can be performed via the femoral, radial or ulnar arteries. The femoral approach is the most commonly used site of vascular access for catheterisation procedures [3].

Access site complications are the most common cause of complications following cardiac catheterisation procedures. Although radial route leads to early ambulation, reduce the discomfort of bed rest, decrease the length of hospitalisation and cuts the cost of the procedure [4].

Vascular complications of cardiac catheterisation and coronary intervention can be divided into minor and major complications. Minor complications include minor bleeding, ecchymosis and stable haematoma. Major complications include pseudo aneurysm, Arteriovenous (AV) fistula, large haematoma requiring transfusion, retroperitoneal haemorrhage, embolism, thrombosis, infection, vessel rupture/perforation and limb ischemia [5,6]. Despite the advances in technology including smaller sheath sizes, less aggressive and more calculated approach in anticoagulation, the use of different vascular closure devices, femoral artery access vascular complication continues to be a nightmare for the interventional cardiologist.

Data suggest that the incidence of complications associated with invasive coronary procedures has decreased [2,7]. The incidence of major bleeding complications after Percutaneous Coronary Intervention (PCI) at the Mayo Clinic had decreased from 8.4% in 1994-1995 to 3.5% in 2000-2005 [6]. The CAD varies in Indian population compared to western nation, the age at presentation is less, there is a high incidence of double and triple vessel disease, with diffuse involvement and significant left ventricular dysfunction at presentation [8,9]. Healthcare infrastructure, access to centre with catheterisation laboratory and affordability is also limited in Indian patients compared to developed countries. One study from India reported that 6.8% of the study population developed complications, among which 4.4% had haematoma. The risk of complications was higher in PCI patients and those with femoral access site [10].

Data regarding these complications from tertiary care centers in India is limited. Hence, this study aimed to detect incidence and factors predicting vascular complication after femoral artery route catheterisation procedure.

MATERIALS AND METHODS

This was a prospective longitudinal observational study conducted at Department of Cardiology SMS Medical College at Jaipur, Rajasthan, India between April 2016 to November 2017. Approval from the Institutional Ethical Committee was obtained vide letter number 2710/MC/EC/2016.

Inclusion criteria: Patients undergoing cardiac catheterisation for diagnostic or percutaneous intervention were included in the study.

Exclusion criteria: Patients who had an access site different from right or left femoral artery, documented coagulation disorders, anticoagulation on warfarin with International Normalised Ratio (INR) >2.0 and peripheral vascular disease patients were excluded from the study.

Total of 14,300 patients who underwent diagnostic and therapeutic intervention in the institute were recruited, out of which 3,100 patients were excluded due to various reasons. Out of total 11200 patients included in the study, 7,400 underwent diagnostic procedure and 3800 underwent therapeutic interventional procedure. Among 330 patients who underwent local site Doppler ultrasound, 230 were found to have various complication.

Methods

- Clinical data of all patients who were included was collected and entered into a database. Body Mass Index (BMI) was calculated according the formula: BMI (kg/m^2)=weight/height^2. Use of single (aspirin or clopidogrel) or dual anti-platelet (aspirin+clopidogrel) or intravenous (i.v) antiplatelet and fibrinolytic or LMWH therapy before the procedure was noted. Intravenous Unfractionated Heparin (UFH) was used in all diagnostic and therapeutic intervention according to standard dose protocol. Type of the procedure whether diagnostic or therapeutic was noted. The artery sheath size ranged from 5-7 French. A modified Seldinger technique was used to cannulate the common femoral artery before the bifurcation.
- Postprocedure, the artery was sealed either by femoral closure device or manual compression. The groin sheath was removed immediately in the case of a diagnostic procedure and removal was delayed until six hours of the interventional procedure after discontinuation of effect of heparin. The femoral sheaths were removed by trained personnel dedicated to the task. Manual compression was used in all patients until the puncture site had been secured of bleeding and then compression bandage kept for another 5-6 hours. All patients were immobile for another 5-6 hour after puncture site had been secured. All patients were examined before and after procedure including auscultation of the groin and palpation of lower limb pulsations.

In all patients suspected of having local vascular complications based on the presence of the following findings at the site of puncture-pain, extensive skin discoloration, palpable or pulsatile mass and thrill or bruit, a doppler scan was done. It was performed using IE-33 Phillips 3D echo machine with linear L11-3, and EPIQ 7C 3 D echo machine with linear L12-3 vascular probe and type of vascular complication were noted. Patients with acute limb ischemia doppler finding were confirmed with lower limb Computed Tomography (CT) angiography. Local site infection was diagnosed on basis of clinical finding, laboratory investigation and blood culture.

To establish a control group, 100 patients were randomly selected without vascular complication. In the control group also, Duplex scan was performed to exclude the presence of vascular complication.

STATISTICAL ANALYSIS

Statistical analysis was performed using the Statistical Package for Social Sciences (SPSS), IBM corporation, New York, USA. Qualitative data was expressed as percentage of proportion and analysed by Chi-square test. Quantitative data was expressed as mean±SD, and analysed by using student t-test. To determine independent risk factor for vascular complication, fisher-exact test was used for univariate analysis. Significance level was kept as p-value <0.05.

RESULTS

A total of 11200 pateints were studied and all the baseline characteristics where noted [Table/Fig-1]. Patients with advanced age, female gender, overweight and obesity and hypertension were at greater risk of complication. Those who had received thrombolytic therapy or low molecular weight heparin prior to the procedure had enhanced risk for vascular complication. Procedure related risk factors were use of large size sheath (7F) and multiple puncture.

Risk factor	Complication group (n=230)	Control group (n=100)	p-value
Age (years)	57.73±10.59	53.85±9.87	
60 year and more	118	29	0.0002
Less than 60 year	112	71	-
Obese (BMI from 30-39.9 kg/m^2)	123 (53.47%)	32 (32%)	0.005
Gender			
a) Female	130 (56.52)	40 (40%)	0.006
b) Male	100 (43.47)	60 (60%)	0.09
History of coronary angiography	79 (34.34%)	30 (30%)	0.12
History of fibrinolytic therapy use	85 (36.95%)	21 (21%)	0.0047
History of taking dual antiplatelet drug	211 (91.73%)	90 (90%)	0.6
Low molecular weight heparin use	178 (77.39%)	45 (45%)	0.0001
Hypertension	158 (68.69%)	37 (37%)	0.0001
Diabetes mellitus	63 (27.39%)	30 (30%)	0.68

[Table/Fig-1]: Baseline clinical characteristics.

Out of 11,200 total patients, 230 (2.05%) were found to have femoral artery access vascular complications. It was found that therapeutic procedures had higher complication rate of 3.6% than the diagnostic procedures 1.25% [Table/Fig-2]. The most common vascular complication noted was haematoma in 145 patients (1.29%) [Table/Fig-3].

Total procedure (N)	Vascular complication (n)	Incidence rate
Total (11200)	230	2.05%
Diagnostic procedure (7400)	93	1.25%
Therapeutic procedure (3800)	137	3.60%

[Table/Fig-2]: Total complication incidence rates.

Complication	Diagnostic (n=7400)	Therapeutic (n=3800)	Total (N=11200)
Haematoma	60 (0.81%)	85 (2.23%)	145 (1.29%)
Pseudoaneurysm	18 (0.24%)	28 (0.73%)	46 (0.41%)
Arteriovenous fistula	20 (0.27%)	22 (0.57%)	42 (0.37%)
Acute arterial occlusion	4 (0.05%)	8 (0.21%)	12 (0.1%)
Infection	3 (0.04%)	8 (0.21%)	11 (0.09%)

[Table/Fig-3]: Incidence of individual vascular complication.

DISCUSSION

Vascular access complications remain an important cause of catheterisation procedure morbidity and mortality [1]. In this study, it was found that local site complication rate was 2.05%. Femoral access-site complications were higher for interventional procedures (3.6%) than diagnostic procedures (1.25%), which is likely related to anticoagulant therapy, greater sheath diameter and prolonged length of procedure. Similar results were found in previous studies. Tavris DR et al., described an overall 3.4% rate of vascular complications following diagnostic cardiac catheterization [11]. Femoral access-site complications were reported to be 1.8% for diagnostic and 4% for interventional procedures by Chandrasekar B et al., [12].

The most common local complication seen in this study was haematoma (1.29%). Yatskar L et al., found that a haematoma is the most frequent complication and can occur in anywhere from 2 to 12% of cases [13].

It was found that advanced age (>60 years), female gender, overweight and obese and hypertensive patients were independent predictor of vascular complication. The increased risk in older patients may be related to age-related changes in the associated arterial wall which is mediated by increasing calcification and loss of elastin and due to increased variability of vasculature in these patients. This finding of the present study is in agreement with that reported by Ortiz D et al., [14]. The greater risk of these complications in females might be explained by small vessel diameter, thus requiring multiple punctures and higher risk of bleeding. This finding is supported by Dencker D et al., study which found that older patients and the female sex were independently associated with major vascular access complications [15]. Increased risk of complication noted in obese patients can be attributed to difficulty in localising femoral artery leading to multiple punctures, difficulty in compressing artery for haemostasis and associated comorbidities. However, the findings of the present study contradicts those obtained by Sulzbach-Hoke LM et al., and Ohlow MA et al., who reported that the BMI did not affect the complication rate [16,17].

Patients who received thrombolytic agent or low molecular weight heparin prior to procedure, use of large sheath size and multiple puncture to achieve femoral artery access also significantly increases risk of vascular complication. These findings are supported by multiple studies [3,18,19] that reported that the use of an arterial sheath with a diameter greater than six french and multiple punctures are independent predictor of vascular complication. Hypertension is also an independent risk factor probably due to the difficulty in compressing the artery with an elevated intra-luminal pressure.

Independent predictors of haematoma include old age, female gender, chronic renal insufficiency, complex coronary lesions, use of GP IIb/IIIa inhibitors and the use of thrombolytics. Risk factors for pseudoaneurysm formation were found to be lower arterial puncture, female gender, old age, diabetes and obesity [20]. Risk of bleeding into the retroperitoneal space is increased with a high femoral puncture (particularly above the inguinal ligament and puncturing the back wall of the vessel) and post-catheterisation anticoagulation [20,21]. If the arterial puncture site is below the bifurcation of femoral artery, compression of the artery is difficult as the pressure is applied here mainly against soft tissue rather than the bone of the femoral head [3,22]. When the puncture is above the inguinal ligament, compression and haemostasis is difficult as here the artery resides in the retroperitoneal space. The risk factors for lower extremity ischemia include the use of larger catheters or sheaths in relatively smaller arteries, peripheral vascular disease, older age, cardiomyopathy, hypercoagulable states and vessel dissection [20].

The incidence of vascular complications has decreased over time due to advancements in anticoagulant and antiplatelet agents and newer generations of arterial closure devices usage. These complications are associated with longer hospital stay, greater cost of treatment, increase in mortality and major adverse cardiac events [13]. Alternative access sites, particularly the radial approach is gaining favour as it is associated with lower complication rates, improved patient comfort and reduced hospital cost. Disadvantages of radial access include a higher incidence of procedure failure that necessitates resorting to the femoral approach, longer procedural times (at least in the 'learning curve' phase), postprocedural radial artery spasm and occlusion [23,24]. Complications associated with brachial artery access are similar to those seen with femoral access, but ischemic complications are generally more common with brachial access [25].

Limitation(s)

Reporting bias could have happened because the complications were self-reported by the investigators and not by a core laboratory, blinded to treatment. Procedures were performed by different operators who may vary in their expertise thus impacting the results. Finally, some complications may have developed after discharge of the patient from the hospital which were not included in the study.

CONCLUSION(S)

Femoral artery access vascular complication is not uncommon and poses a significant challenge for interventional cardiologists. The incidence is generally higher for interventional procedures than for diagnostic procedures. The complication may range from minor ones such as small haematomas to major conditions including AV fistulas, haematomas requiring transfusion, retroperitoneal haemorrhage, arterial dissection and limb ischemia. The strongest predictors of vascular complication are advanced age (> 60 year), female gender, overweight and obesity, hypertension, use of thrombolytic agent or anticoagulant prior to procedure, large size sheath 7F and multiple puncture. Diagnosis of the vascular access-site complications can typically be confirmed by ultrasound. Treatment is dependent upon the complication identified. Complications result in longer hospital stays, additional treatments and higher healthcare costs. Advancements in anticoagulant agents, closure devices and radial approach use offers promise in decreasing vascular access-site complications.

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PARTICULARS OF CONTRIBUTORS:
1. Consultant, Department of Cardiology, SMS Medical College, Jaipur, Rajasthan, India.
2. Assistant Professor, Department of Cardiology, SMS Medical College, Jaipur, Rajasthan, India.
3. Professor, Department of Cardiology, SMS Medical College, Jaipur, Rajasthan, India.
4. Student, Department of Medicine, SMS Medical College, Jaipur, Rajasthan, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Sarita Choudhary,
House No. 18, Bajaj Nagar Enclave Colony, Near Gandhi Nagar Railway Station, Jaipur, Rajasthan, India.
E-mail: drsaritachoudhary@yahoo.com

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