

Complication Following percutaneous coronary intervention via the femoral artery

Experience in Iraqi center for the Heart Disease and Ibn Al-Bitar Hospital for cardiac surgery.

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Abstract:

Background: Vascular complications have been recognized as an important factor in morbidity after diagnostic and percutaneous coronary interventions.

Objectives: This study sought to evaluate vascular complications after diagnostic coronary angiography and percutaneous coronary intervention (PCI) from the common femoral artery.

Patients and methods: This prospective cohort study was carried out over a year period, from February 2008 till January 2009, at the Iraqi Center for the Heart Disease and Ibn Al-Bitar Hospital for Cardiac Surgery. A total number of 2400 patients underwent 3600 procedures, diagnostic coronary angiography (2196) and PCI(1404) via their common femoral arteries were included in this study.

Result: A total 407(11.3%) patients developed different vascular complications (retroperitoneal hematoma, loss of distal pulse, arterial perforation each of them 0.03%, bruises 8.9%, pseudoaneurysm 0.69%, AV fistula 0.03%, hematoma ≥ 10 cm 0.3% and < 10 cm 1.2%). We identified multiple factors associated with increased frequency of vascular complications like age, gender and past medical history. We have more frequent minor complications and more attendance to treat our complications surgically.

Conclusions: This study has shown that the vascular complications continue to occur post PCI and diagnostic coronary angiography.

Keywords: Vascular complications, femoral artery, percutaneous coronary intervention (PCI).

*Fac Med Baghdad**2016; Vol.58, No.4**Received: Sept.2016**Accepted: Nov.2016***Introduction:**

The most common catheterization problem involved is the initial access to the circulation. Femoral artery cannulation is the most common form of arterial access for diagnostic coronary catheterization and percutaneous coronary intervention (PCI) (1).

Entry into the circulation is generally the only painful part of the diagnostic coronary angiography procedure; pain during entry into the vessel may cause a vagal reaction or spasm, prolonging the procedure and potentially causing more significant complications(2).

Seldinger first described the technique for percutaneous common femoral artery vascular access in 1953(3). Applying the typical modified Seldinger's technique helps to perform a safe arterial cannulation. As part of the modified Seldinger's technique, a catheter sheath with its dilator is passed into the arterial lumen over the guide wire(4). The operator advances the sheath-dilator assembly while holding the guide wire straight and stable. The operator introduces the sheath-dilator assembly into the artery by firmly holding it close to the tip, making clockwise and counterclockwise half rotations and

applying firm advancing pressure (reduces forward friction). If resistance is encountered (scar tissue), serial dilators of bigger sizes are used before the final sheath is positioned(4). Then the wire and the dilator are removed all together. Soon the operator should aspirate 2-3cc of blood from the side arm of the sheath and flushes the sheath with heparinized saline solution; thereafter the sheath should be aspirated and flushed after each catheter removal to avoid clotting(5).

The femoral pulse at the inguinal crease is not a reliable landmark for the femoral artery particularly obese, female and elderly patient; whose crease tends to be much lower than inguinal ligament. The skin access point is usually above the inguinal crease and almost always below the inguinal ligament. The operator must realize that the inguinal skin crease is highly variable in relation to the common femoral artery and has been shown to be caudal to the common femoral artery bifurcation up to 75% of patients, especially in obese and multiparas female patients(6).

The operator should attempt to puncture the artery close to the midline of the anterior wall. Puncturing the lateral wall may create a problem in advancing the guide wire or, worse, controlling bleeding after the procedure. A posterior wall puncture increases the risk of bleeding including the

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development of a potentially life threatening retroperitoneal hematoma(7) .

If a venous puncture has been made inadvertently, the needle should be removed and adequate manual pressure held for about 3 min; proceeding directly to arterial puncture without removing the needle and holding pressure increases the chance of arteriovenous fistula formation or simply the bruises. If a venous puncture is planned, it should be made lower than the arterial puncture site to avoid complications(4). Almost always check the distal pulses(popliteal and pedal), and bruits should be auscultated both before and after the procedure, a new bruit or absent of the distal pulses, may indicated vascular complications(8) .

Ninety seven percent of patients have the femoral artery is lying on the medial third of the head of femur; only 3% have their artery totally medial to the femoral head(2). Alternatively, fluoroscopy can be used to locate the femoral head, the entry point on the skin is located over the inferior border of the femoral head(2). Fluoroscopic femoral head is an important landmark, access obtained at the level of the femoral head will help in hemostasis, allowing manual compression of the common femoral artery over the femoral head(7).

Aims of the study

Identify risk factors for vascular complications due to sheath insertion in diagnostic coronary angiography and PCI procedures and to Identify the frequency of local vascular complications after diagnostic and interventional coronary procedures.

Patients and Methods

All patients undergoing diagnostic coronary angiography and percutaneous coronary intervention (PCI) were evaluated for this prospective study which is carried out in two institutional Iraqi Board training interventional cardiology centers; the

Iraqi Center for Heart Disease & Ibn Al - Bitar Hospital for Cardiac Surgery, from February 2008 to January 2009; evaluating the vascular complications that occur after performing diagnostic coronary angiograph (CATH.) and PCI via the common femoral artery access.

A total number of 2400 patients underwent 3600 procedures, in both centers; their database were collected in questioner, based on the age, gender and their body surface area for each patient. For each patient, the femoral artery was routinely examined by palpation and auscultation for bruit, and the pedal pulses were palpated prior and after each examination, and during the night and morning tours after the procedure; any bruit, hematoma or previous vascular complications found prior to our study were excluded from the collected sample. Different diagnostic procedures were used during the study if a vascular complication discovered, ranging from the simple demarcation of hematoma (via a colored pen), local ultrasonography, PCV, WBC, and even CT-scan examination to reach a definitive diagnosis, assess severity and to judge the proper therapy whether conservative or referral to the vascular surgeons. According to ACC/AHA grading of dyspnea, functional classification(F.C.) of the heart failure was determined. The diagnosis of Peripheral vascular disease depend on clinical and Doppler study.

The major vascular complications include Retroperitoneal hematoma, Loss of distal (pedal) pulse and Arterial perforation while the minor complications include Bruises, Pseudo aneurysm, AV fistulas, Hematoma and Infection (abscess).

Statistical analysis: Chi-square test was used to assess the relation of different factors P_ values of less than 0.05 was considered significant.

Results:

Table1: Demographic Baseline Characteristics of Patients by Vascular Complication Outcomes

Patients data	Vascular complication					P-value
	Negative		Positive		Total	
	N	%	N	%		
Age in years						
<50	342	99.7	1	0.3	343	<0.001
50-59	2279	90.4	241	9.6	2520	
60-69	520	78.2	145	21.8	665	
70-79	52	72.2	20	27.8	72	
Gender						
Female	1242	84.5	228	15.5	1470	<0.001
Male	1951	91.6	179	8.4	2130	

Table 2: Vascular Complication Outcomes according to Indications of Procedures

Indications for procedure	Vascular complication					P-value
	Negative		Positive		Total	
	N	%	N	%	N	
Stable angina	2351	99.2	19	0.8	2370	<0.001
Unstable angina	638	83.6	125	16.4	763	
AMI*	80	72.7	30	27.3	110	
Cardiac shock (IABP)	8	44.4	10	55.6	18	
Total	3077	94.4	184	5.6	3261	

*AMI: acute myocardial infarction

Table 3: Vascular complications during study in 2 Centers.

Vascular complications	No.	%
Major vascular complications		
Retroperitoneal hematoma	1	0.03%
Loss of distal (pedal) pulse	1	0.03%
Arterial perforation	1	0.03%
Minor vascular complications		
Bruises	320	8.9%
Pseudo aneurysm	25	0.69%
AV fistulas	2	0.05%
Hematoma ≥ 10cm	11	0.3%
Hematoma < 10cm	43	1.2%
Infection (abscess)	3	0.08%
Total	407	11.3%
Patients need Vascular surgery	29	0.08%

Table 4: Baseline Characteristics of Patients' Medical History by Vascular Complication Outcomes

Patient variable	Vascular complication					P-value
	Negative		Positive		Total	
	N	%	N	%	N	
Smoking habit	1692	93.6	116	6.4	1808	<0.001
Heart failure F.C*. I-II	283	95	15	5	298	<0.001
Heart failure F-C*. III-IV	319	84.6	58	15.4	377	<0.001
Diabetes mellitus	987	89.2	120	10.8	1107	[NS]
Hypercholesterolemia	2070	93	157	7	2227	<0.001
Renal impairment creatinine > 1.2s	127	77.4	37	22.6	164	<0.001
COPD**	169	79	45	21	214	<0.001
Uncontrolled hypertension	317	82.3	68	17.7	385	<0.001
Peripheral vascular disease	319	82.9	66	17.1	385	<0.001
Previous PCI/CATTH	1016	83.9	195	16.1	1211	<0.001
Total	3193	88.7	407	11.3	3600	

* F.C. functional classification

**COPD: chronic obstructive pulmonary disease

Discussion

As the age is increasing (>50yr. old), the risks of vascular complications were statistically significant, (p<0.001). Elderly patients are mostly debilitated, they have lax skin and lost their periarterial connective tissue support. Also their arteries are heavily atherosclerosed, calcified, and increased incidence of peripheral arterial diseases making their arteries less compressible on manual compression method after sheath removal(9,10,11,12). Females reported higher rates of vascular complications (15.5%) in comparison to males(8.4%) (P<0.

001), with a relative risk(1.85) times more than males; since our female patients are mostly obese, they are multiparas, and because of menopaucity, the muscles and skin of their abdomen and pelvic area are lax and folded, making difficult to palpate their femoral artery pulsation. Folded skin increases the incidence of local infections; probably the limited number of female nurses in our centers did limit the manual compression time, after the sheath removal, which lead to the higher incidence rate of hematoma formation among female patients, as in previous studies(13,14,15,16,17).this result

similar to Robert J. et al study when he found that the adverse patients factors included increasing age, female gender(18). The diabetes mellitus (RR=0.94),current smokers(RR=0.4), and hypercholesterolemia (RR=0.39). Although are risk factors for coronary artery disease, our study proved that they had not increased the frequency of vascular complications, yet no addressed correlation with vascular complications(19,20,21),as in previous studies. Uncontrolled hypertension(BP>140/90) sustained more vascular complications(16.7% , P <0.001) because of the higher pressure on the portal of entry , so they did require a special care. The manual compression by hands should be fulfilled for 45 min duration; and avoidance of early ambulation thereafter(9,22,23) in regards to hypertension (HT), our findings were similar to previous studies. The chronic obstructive airway diseases (COPD) were very common(10.3%, P < 0.001) among our studied patients since the cause is unique smoking. Some of those patients, did use steroids as part of COPD therapy control; they did increase the risk of vasculopathies and delayed healing, then vascular complications. COPD increases the risk of vascular complications by 1.97 times relatively to non-COPD(8,24). The results regarding our study were identical to previous studies(25). We noticed that the number of patients with heart failure (F.C I-II) are less than those patients with (F.C III-IV) whom attended interventions. Patients with F.C III-IV heart failure had body edema and cannot tolerate being flat , making them at risk of vascular complications; they had 3.1 times risk to develop vascular complications relatively to F.C I-II(26); our results were similar to the previous studies(25,26). Also peripheral arterial disease interfere with hemostasis after sheath removal and manual compression may interfere with distal circulation in an already diseased femoral artery. Our study did show peripheral vascular disease raises the frequency of vascular complications relatively by 1.62 times(27) which is similar to the previous studies(13,16,28). It is very well known that renal impairment could interfere with hemostasis leading to more complications, via vasculopathy and coagulopathy(20). The rate of vascular complications was significantly higher among those with renal impairment(22.6%)compared to those with normal renal function (10.8%). The risk of developing vascular complications is increased by 2.1 times among renal impairment patients, our results were identical to previous studies(16,25,29). In regards to indications of interventions, cardiogenic shock was the strongest independent predictor of vascular complications in our study (2.5%), P < 0.001,with a relative risk 69.3 times those whom intervention done for stable angina ,probably because of the emergent priority of the procedure, collapsed femoral arteries making their palpation difficult that interferes with safe femoral artery access. Also the anticoagulants, fibrinolytics and antiplatelets which are routinely used prior, during or after the interventions could predispose to complications. The supportive indication for intra-aortic balloon pump (IABP) insertion requires sheaths 8-9F sizes, do increases the complications either directly from large size sheath or the use of heparin to avoid thrombosis.

On the other hand the prolonged sheath indwelling time which frequently noticed during the management of cardiogenic shock is an additional risk factor for the femoral artery complications(25,29,30,31). Acute myocardial infarction and unstable angina indications for the interventions carried significant (p<0.001 for each) incidences for vascular complications due to emergency in sheath insertion and the use of anticoagulants and or fibrinolytics.

In the American College of Cardiology (ACC), National Cardiovascular Disease Registry: emergency procedures and sheath size were found to be independently predictive of vascular complications. Also our results were similar to other studies(25,28). Our study did show that the frequency of major vascular complications was a little bit lower than the rate outside(14,32,33). But we did require vascular surgery more, probably because of the limited conservative treatment such as thrombin local injection and ultrasonographic guided compression. On the other hand, the minor complications were much greater than other studies because our facilities were limited and we enrolled the bruises as a minor complications , which is not usually mention in previous studies (34,35).

Conclusion:

Vascular complications continue to occur post PCI and diagnostic coronary angiography, despite better equipment and good operator experience. Reductions in the prevalence of adverse procedural factors contributed to the decrease in the frequency of vascular complications, suggesting that strategies to reduce vascular complications can be effective in improving the safety of these procedures.

Author contributions:

Salah M. Majeed :Study conception,Study design
Hilal Bahjet Al Saffar : Acquisition of data analysis, Interpretation of data
Amal N .AL -Marayati: Drafting of manuscript ,Critical revision

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