Body Surface Area and Sheath Size as a Risk Factors for Vascular Complications After Coronary Angiography Via Femoral Approach

Salah Mahdy Majeed

ABSTRACT:

BACKGROUND:

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

OBJECTIVE:

This study sought to evaluate vascular body mass index and sheath size as risk factors for vascular complications after diagnostic coronary angiography via femoral approach.

PATIENTS AND METHODS:

This historical prospective cohort study was carried out from February 2012 till January 2013, at the Iraqi Center for the Heart Disease. A total number of 2400 patients underwent 3600 procedures, diagnostic coronary angiography (2196) and PCI(1404) via their common femoral arteries.

Result: Body surface area > 2m2 is a statistically significant factor for vascular complications, and <1.6m2 is also an important statistically significant risk for vascular complications.

The results of the current study according to sheath size show:- during the diagnostic coronary angiograph procedures, sheath size 5F was the least(n=34), in which no reported vascular complications. Sheath size 6F (n = 1661) with (75) 4.5% complicated vs. (1586) 95.5% didn't, sheath size 7F used among (501) patients, vascular complications developed in (171) 34.1% vs. (330) 65.9%. In comparison between the incidence of vascular complications among sheath sizes (6F, 7F) vs. 5F the P value < 0.001 for both.

During the PCI procedures, sheath size 6F was used among (140) patients, with vascular complications in one patient (0.7%). 7F used among (1219), with vascular complications in (115) 9.4%, and 8F used in (45) patients with vascular complications in (45) 100%. By using 6F as a referent, sheaths 7F&8F were statistical significant(p<o.oo1).

CONCLUSION:

Vascular complications were significantly associated with the extreme of body surface area (both obese and slime), there was a direct relationship between sheath size and the occurance of vascular complications in both diagnostic coronary angiography and percutanous coronary intervention procedures.

KEY WORDS: body surface area ,sheath size, vascular complications.

INTRODUCTION:

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 angiograph (procedure; pain during entry into the vessel may cause a vagal reaction or spasm, prolonging the procedure and potentially causing more significant complications[2].

In patients with significant history of claudication, diminished or absent pulses (femoral and or pedal), bruits over ileofemoral area, prior femoral artery graft surgery or total hip replacement; extensive inguinal scaring from previous catheterization and IABP or extensive tortuous or diseased iliac artery; severe backaches and inability to lie flat, patient

Interventional Cardiologist, Medical City, Iraqi Center for Heart Disease.

request or morbid obesity, for all previous states, the physician should use an alternative entry site or use small sheath size in order to avoid access site complications[3].

The sheath has a hemostatic valved end with aside arm. Unvalved sheaths should not be used because the leak and arterial pressure around the catheter cannot be measured through the side arm. A catheter of one French size smaller than the sheath size is necessary for satisfactory sidearm pressure recording. The inside diameter sheaths and (catheters) is measured in French(F)unite; one French is equal to 0.33mm[4].

A sheath size 6F is generally used for diagnostic coronary angiography. Sheaths 4 or 5 F are preferred over larger sheaths in peripheral vascular disease ; sheath size 7 or 8 F are used for acute cases or planned PCI and IABP.13 Sheath >8F used for peripheral and carotid interventions and in ASD occluder (Amplatzer). Long sheaths (24-40)cm are generally preferred over the ordinary sheaths (11cm long) in cases of tortuous common iliac artery, to allow free catheter manipulation[5,6].

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[5].

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[6].

The advantages of a sheath include single arterial entry with increased patient comfort and the limitation of arterial damage by several catheter exchanges through the artery. The sheath also maintains constant arterial access, so that an accidental removal of the wire dose not result in loss of arterial access. Arterial access may be maintained for alternative procedure(s) or later therapeutic intervention (PCI) [7] .

in some cardiac centers, the use of femoral artery Closure Device; they offer the advantages of improved patient comfort, early sheath removal, early mobilization and hospital discharge, and in some patients anticoagulation may be continued without interruption. But they did not decrease vascular complications[6] . During the period of post procedure observation period it is necessary to monitor heart rate, temperature, blood pressure, urine output, distal pulses, and the access site (for pain, bleeding, or hematoma).

The American College of Cardiology/ American Heart Association defined the peripheral vascular complications following sheath insertion both in diagnostic coronary angiography (CATH) and PCI as the following [8,9,10] :

Arteriovenous (AV) Fistula, Pseudoaneurysm and Hematoma, Thrombotic arterial occlusion, Retroperitoneal hemorrhage, Infection(abscess)and Arterial perforation

PATIENTS AND METHOD:

This historical prospective cohort study was carried out from February 2012 till January 2013, at the Iraqi Center for the Heart Disease. A total number of 2400 patients underwent 3600 procedures, diagnostic coronary angiography (2196) and PCI(1404) via their common femoral arteries.

All patients enrolled in the study had their body surface area been identified (BSA= square root of Height X Weight/ 3600; using height in centimeters and weight in kilograms).

The sheath size was an important factor in the procedure; the sheaths are measured in French unite (equal to 0.33mm diameter), had different sizes. Commonly, the 2 institutional centers using sizes 5F,6F, and 7F for diagnostic coronary angiography and 6F,7F and 8F for PCI procedures, with a standard length of 11cm and a hemostasis valve[11].

RESULTS:

Among the baseline characteristics of body surface area is classified into 4 groups BSA >2m², 17.1% developed complications and 82.9% did not with P<0.001 and 95%CI(1.39-2.41); (1.8-2)m², 9.4% had vascular complications and 90.6% without complications; (1.6-1.8)m², 10.4% had complications and 89.6% no vascular complications, P value 0.33 and 95%CI(0.9-1.38);BSA < 1.6m2, 22.6% developed vascular complications and 77.4% without complications, P value < 0.001 and 95%CI(1.73-3.34). BSA > 2m2 is a statistically significant factor for vascular complications, and <1.6m2 is also an important

statistically significant risk for vascular complications.

The results of our study according to sheath size show:- during the diagnostic coronary angiograph procedures, sheath size 5F was the least one used, 0% complicated vs. 100% didn't, in which no reported vascular complications. Sheath size 6F (n = 1661) with 4.5% complicated vs. 95.5% didn't, sheath size 7F used among (501) patients, vascular complications developed in 34.1% vs. 65.9%. In comparison between the incidence of vascular complications among sheath sizes (6F, 7F) vs. 5F the P value < 0.001 for both.

During the PCI procedures, sheath size 6F was used among (140) patients, with vascular complications in one patient (0.7%). 7F used among (1219), with vascular complications in (115) 9.4%, and 8F used in (45) patients with vascular complications in (45) 100%. By using 6F as a referent, sheaths 7F&8F were statistically significant, p<0.001.

Table1:Baseline Characteristics of Patients according to Body Surface Area by Vascular Complication Outcomes.

Vascular complications	Negative		Positive		Total		P- value
	N	%	N	%	N	%	
Body surface area (m2)							
>2	319	82.9	66	17.1	385	100	
(1.8-2)	1237	90.6	128	9.4	1365	100	
(1.6-1.8)	1510	89.6	176	10.4	1686	100	
<1.6	127	77.4	37	22.6	164	100	<0.001
Total	3193	88.7	407	11.3	3600	100	

Table 2: Vascular Complication Outcomes of Diagnostic Coronary Angiography.

Vascular complications during Diagnostic angiograph	Negative		Positive		Total		P- value
	N	%	N	%	N	%	
Sheath size (F)							
5-F	34	100	0	0	34	100	<0.001
6-F	1586	95.5	75	4.5	1661	100	
7-F	330	65.9	171	34.1	501	100	

Table 3: Vascular Complication Outcomes of Percutaneous Coronary Intervention.

Vascular complications during Percutaneous coronary intervention	Negative		Positive		Total		P- value
	N	%	N	%	N	%	
Sheath size (F)							
6-F	139	99.3	1	0.7	140	100	<0.001
7-F	1104	90.6	115	9.4	1219	100	
8-F	0	0	45	100	45	100	

DISCUSSION:

At our study we considered the sheath size 5F is the standard referent for diagnostic coronary angiograph and 6F for the PCI. We noticed that as the sheath size is bigger, the frequency of vascular complications is increased; all results were statistically significant (p<0.001). The relative risks (13.21and140) times for 7F&8F sheaths, respectively, in referent to 6F during PCI .Our observations provide a strong evidence that switching to smaller sheath size, which seem to be wherently safer, resulted in improved safety.

Our study was similar to previous studies carried on the relationship between sheath size and frequency of vascular complications[12]. Both cardiac centers did use larger sizes sheaths (6F,7F) for diag.cor.angio. and (7F and 8F) for the PCI and very rarely used the 5F and 6F sheaths; because of the limited available numbers of these last two

sheaths,or their catheters, increasing the risk of vascular complications[13].

We also found the risk of vascular complications is escalating as the body surface area raised (>2m²) ; and as it decreased(<1.6m²),relatively to BSA(1.8-2)by 1.83 and 2.41 times respectively. The large body surface area makes the finding of femoral artery pulse is so difficult because of the panniculus abdomen , folded inguinal skin, deep location of the femoral artery; all these do interfere with the Seldinger's needle and or sheath advancement; also the large number of bacteria and fungi in the folded skin altogether are predisposing factors for the vascular complications[14,15]. On the other hand , low body surface area (<1.6m²) was an identical risk factor for the vascular complications, since they had superficially located femoral arteries with diffuse pulsation. And again loss of the connective tissue supports around femoral arteries; altogether do raise the possibilities of vascular complications [16].

low body weight is an independent predictor of thrombocytopenia[16] Our results were identical to previous studies[17,18].

CONCLUSION:

Vascular complication after coronary angiography and PCI with the extreme of body surface area (both obese and slim) patients. There were a direct relationship between the size of th esheath and the occurance of vascular complication after diagnostic coronary angiography and PCI via femoral approach.

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