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Rama Kumari N., Bhaskara Raju Indukuri and Aruna Devi M

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RESEARCH ARTICLE

THE IMPACT OF SHEATH SIZE ON VASCULAR COMPLICATIONS AFTER TRANS-RADIAL ACCESS FOR CORONARY ANGIOGRAPHY

Rama Kumari N[1]., Bhaskara Raju Indukuri[2] and Aruna Devi M[3]

[1]Department of Cardiology Nizam's Institute of Medical Sciences, Panjagutta, Hyderabad
[2]Gandhi Medical College, Department of Surgery Interested in Cardio-Thoracic Surgery
[3]Dapartment of Radiology, Nizam's Institute of Medical Sciences, Panjagutta, Hyderabad

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ABSTRACT

Back Ground: The present study was undertaken to compare is to find out the nature and the extent of radial artery complications by high-resolution vascular ultrasound after transradial diagnostic angiography and percutaneous transradial interventions (PCI) with 5F and 6F vascular sheaths.
Methods: A total of 461 patients who are undergoing CAG, PCI through trans radial access with 5-F(n=192), 6-F(n=366)sheaths were studied. Duplex sonography was obtained in each patient before and after discharge and after 1 month those who had Radial Artery Occlusion (RAO).
Results: The radial artery occlusion after coronary angiogram with ultrasound was observed in 26 cases (5.64%). out of which the rate of RAO in 5F sheath group was 10 (5.25%) and in 6F sheath group was 16 (4.37%, p=0.34). On univariate analysis the predictors of post procedural RAO were sex (p<0.032), operator 1 (p<0.034). There was no statistically significant difference between 5 and 6 French sheaths (p=0.34). In multivariate regression analysis all of our results remained unchanged.18 patients out of 28 (who presented with RAO) had severe symptoms and were treated with Low Molecular Weight Heparin (LMWX) for 7-14 days. On follow up after one month none of these patients have re-canalization of the artery. 10 patients who had RAO with no symptoms showed spontaneous re-canalization of the artery on follow up.
Conclusion: The rate of RAO by ultrasound examination is less in this study as compared to previous studies. The use of 5–F sheath for transradial access does not significantly decrease the rate of RAO when compared with 6-F sheath.

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INTRODUCTION

In recent years, radial artery (RA) has been widely used as a progressive access for coronary intervention {1-3}. There are few reports on radial artery injuries after using the transradial approach {4,5}. On the other hand, the radial artery has been established the second position, after the left internal thoracic artery (LITA) in coronary artery bypass graft surgery (CABG) {6}. The recently published multicentric RIVAL (radial versus femoral access for coronary intervention) trial {7} was conducted to compare radial with femoral access in the setting of acute coronary syndromes. The radial access was shown to reduce major vascular complications compared to the femoral access. In the published data, radial artery occlusion (RAO) rates were noticed to lie in broad range from 5%-38% {8-11}. The large variance might be related to the fact that radial artery patency after catheterization was assessed by clinical forearm inspection and pulse palpation rather than vascular ultrasound in the vast majority of studies {12}. The main purpose of the study is to find out the nature and the extent of radial artery complications by high-resolution vascular ultrasound after transradial diagnostic angiography and Percutaneous Coronary Interventions (PCI) with 5F and 6F vascular sheaths.

MATERIAL AND METHODS

Study patients

Four Hundred Sixty One (461) consecutive in-patients with a normal Allen's Test who underwent TRI via the RA at our high-volume tertiary care and training centre were enrolled in this study. Ethical committee approval and informed consent from each patient was obtained. We excluded patients with a negative Allen's test, surgical trauma of the forearm arteries and peripheral vessel disease. **All patients who are undergoing CAG, PTCA through Radial Artery were included.**

***Corresponding author:* Rama Kumari N**
Department of Cardiology Nizam's Institute of Medical Sciences, Panjagutta, Hyderabad

Examination of RA with high-resolution vascular ultrasound:

Colour Doppler Ultrasound study was performed by experienced sonographers in all 461 patients 24 hours after the procedure to examine the radial, ulnar, and brachial arteries of the access forearm with a Vivid 7 Ultra Sonography System (General Electric Medical systems, and over, Massachusetts) featuring a 9-12 MHz multi-frequency vascular probe.

Definitions

The primary objective was to study the incidence of post-procedural RAO. This is confirmed by absence of ante grade flow on high-resolution vascular ultrasound. Secondary objectives were other local access site complications such as bleeding events, pseudoaneurysms and arterio-venous fistulas. Bleeding events were defined as mild, moderate, and severe according to the Global Use of Strategies to Open Occluded Arteries. Symptomatic patients with RAO were treated with low-molecular-weight heparin (LMWH) with a dose adjusted to body weight for 7 to 14 days. Asymptomatic patients received no specific therapy. In patients with RAO, a follow-up was conducted after 7 to 14 days and one month after the transradial catheterization (clinical examination and vascular ultrasound examination).

Procedural Protocol

The right arm was positioned beside the patient's body and the wrist was hyper extended. After local subcutaneous anaesthesia with 1% lidocaine, RA puncture was performed with a 21-gauge angiocatheter needle (Cordis Corporation, USA) and a 0.53 mm (0.021 inch) hydrophilic guide wire was inserted through the needle. Upon removal of the needle, a 11-cm 5F/6F sheath (Cordis Corporation, USA) was passed over the guide wire. After sheath insertion, 0.2mg nitro-glycerine, 200µg verapamil and the bolus of heparin (5000 IU for CAG) were administered through the sheath. After transradial coronary procedure, the arterial sheath was removed immediately and hemostasis was achieved by RA compression with manual compression. All symptoms were carefully recorded. Severity of pain was graded by the visual analogue scale and reported as severe according to the patient's subjective complaint

Statistical Analysis

The Statistical Package for Social Sciences (SPSS) for Windows, version 17.0 (SPSS, Chicago, IL, USA) was used for all analyses. Continuous variables are expressed as mean ± standard deviation, and categorical variables are expressed as frequency. Continuous variables were compared with Student's t-test or variance analysis of a single factor. Categorical data were compared using the chi-square or Fisher's exact test, as appropriate. Potential risk factors for post-procedural RAO were investigated by Univariate logistic regression. A multivariate logistic regression model with all significant variables was established to estimate odd ratios (ORs) inclusive of 95% confident bounds. $P < 0.05$ was considered as significant.

RESULTS

In our study a total of four hundred and sixty one (461) consecutive in-patients were included. The baseline clinical characteristics are summarized in Table1. Among 461 Patients who underwent diagnostic coronary angiogram (Figure1), 5F sheath was used in 192 Patients (Right Radial Artery was used in 188 patients, Left Radial Artery was used in 4 patients) and 6F sheaths was used in 269 patients. Out of 461 patients 97 needed PCI which was done with 6F sheath (Table2).

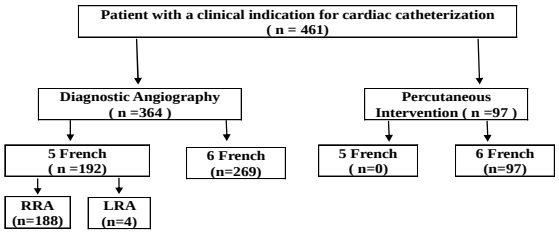

Figure 1: Flow Chart

Table 1: Baseline patient characteristics

Variables	5-F Sheath group	6-F sheath group	P values
Age (years)	55.22 ± 10.94	55.94 ± 11.45	0.50
Body Mass Index	24.14 ± 5.23	24.58 ± 4.01	0.376
Total Cholesterol	158.85 ± 50.22	173.82 ± 42.85	0.046
LDL Cholesterol	90.57 ± 37.16	101.85 ± 33.62	0.06
HDL Cholesterol	39.90 ± 11.63	38.33 ± 17.28	0.55
Triglycerides	149.47 ± 66.51	163.12 ± 80.78	0.28
LVEF	53.94 ± 15.76	51.87 ± 14.04	0.24
Creatinine (mg/dl)	1.17 ± 0.59	1.2 ± 0.31	0.52
Haemoglobin	12.71 ± 1.94	13.31 ± 2.4	0.01
Fluoroscopy Duration	4.07 ± 3.98	9.30 ± 14.22	0.001
Amount of Contrast	49.75 ± 19.42	82.07 ± 48.38	0.000
No of Catheters	1.22 ± 0.48	0.93 ± 0.46	0.81
Risk Factors {n (%)}			
Diabetes	62(35.3%)	113(64.6%)	0.004
Hypertension	113(45.2%)	137(54.8%)	0.22
Smoking	44(34.1%)	85(65.9%)	0.007
Family History of CAD	9(47.4%)	10(52.62%)	0.45
Aspirin	74(36.6%)	140(65.4%)	0.009
Statin	89(34%)	173(66%)	0.01
β Blocker	79(35.9%)	141(64.1%)	0.05
Calcium Antagonist	8(30.8%)	18(69.2%)	0.379
ACEI/ARB	61(37.2%)	103(62.8%)	0.52

Table 2: Procedural Data

	5-F Sheath	6-F Sheath	P value
No. of PCI (%)	0	97 Cases (56.39%)	
Fluoroscopy Duration (Min)	4.07 ± 3.98	9.30 ± 14.22	0.001
Fluoroscopy Duration	4.07 ± 3.98	9.30 ± 14.22	0.001
Amount of Contrast	49.75 ± 19.42	82.07 ± 48.38	0.000
No of Catheters	1.22 ± 0.48	0.93 ± 0.46	0.81
Left Radial Artery	4	0	
Radial Artery Diameter			
Before	2.16 ± 0.45	2.3 ± 0.43	0.04
After	2.01 ± 0.55	1.93 ± 0.53	0.04
Vessel Disease {n (%)}			
1-Vessel	51(37.4%)	96(65.3%)	0.002
2-Vessel	18(34.6%)	34(65.4%)	0.08
3-Vessel	1744.7%)	21(55.3%)	0.56

In 5F sheath group the percentage of diabetics were 62 patients (14.8%), smokers were 44 (10.5%) and hypertensives were 113 (26.9%), like wise in 6F sheath group the percentage of diabetics were 117(28%), smokers were 88(21.1%) and hypertensives were 142(33.8%). In this study the single-vessel disease, two-vessel disease and three-vessel disease in the 5F sheath group and 6F sheath groups were 51(11.8%), 18(4.2%) and 13(3.9%), 90(22.3%), 34(7.9%) , 22(5.1%) respectively.

Vascular complication rates

The radial artery occlusion after coronary angiogram was observed in 26 cases (5.64%). Out of which the rate of RAO in 5F sheath group was 10 (5.25%) and in 6F sheath group was 16 (4.37%, p=0.34). Pseudoeneurysm, Arteriovenous Fistula were observed in 2 cases in 6F sheath group, and mild bleeding was observed in 1(0.52%) case with 5F sheath group, in 2(0.75%) cases with 6F sheath group (p = 0.98). Pseudo aneurysm patient was treated with ultrasound guided graded compression successfully, and patient with arteriovenous fistula patient was lost on follow up (Table 3). There was no moderate or severe access site bleedings according to Global use Strategies to Open Occluded Arteries definitions requiring blood transfusions or surgical repair.

Table 3: Vascular Access Site Complications

	5-F Sheath	6-F sheath	P Value
Total number of access site complication			
Radial artery Occlusion	10(37%)	17(63%)	0.30
Arteriovenous fistula	0	1(0.37%)	0.56
Pseudoeneurysm	0	1(0.37%)	0.77
Moderate severe bleeding	0	0	
Mild bleeding	1(0.52%)	2(0.75%)	0.59
Pseudoeneurysm	0	1	0.56
Operating Doctors			
0 < 1000 Procedures 1 > 1000 Procedures	135 (43.4%) 57(45.2%)	176(56.6%) 69(54.8%)	0.40

Table 4: Vascular Access site Complications in Patients with diagnostic Catheterization only.

	5-F Sheath	6-F sheath	P Value
Total number of access site complication			
Radial artery Occlusion	10(5.25%)	16 (6.42%)	0.34
Pseudoeneurysm	0	1(0.37%)	0.77
Arteriovenous fistula	0	1(0.37%)	0.77
Moderate/severe bleeding	0	0	
Mild bleeding	1(0.52%)	2 (0.75%)	0.98

Predictors of RAO

On Univariate Analysis the predictors of post procedural RAO were sex (p = 0.032) and operator 1 (p = 0.034). There was no statistically significant difference between 5-F and 6-F sheaths with RAO (p=0.34). In multivariate regression analysis all of our results remained unchanged in patients who underwent diagnostic catheterization and PCI.

Figure2 Intimal Dissection and Thrombotic Occlusion of the Radial Artery after Coronary Angiogram through Trans-Radial Route

Clinical course of patients with RAO

18 patients out of 26 (who presented with RAO) had severe symptoms and on ultrasound found to have long segment intimal disruption/dissection and occluded with thrombus (Figure 2). All symptomatic patients were treated with low molecular weight heparin for 7-14 days. On follow up after 1 month none of these patients had re-canalization of the artery. 10 patients who had RAO with no symptoms were found to have short segment 1-2mm intimal disruption/dissection with thrombus, and showed spontaneous re-canalization of the artery on follow up after 1 month.

DISCUSSION

TRI has been shown to have less complications, safe and economic alternative to the femoral approach for the patients [13]. Key factors in the prevention of radial artery occlusion might be anticoagulation[14]and immediate post-procedural sheath removal[15,16].The rate of vascular access site complications after transradial coronary catheterization as monitored by vascular high-resolution ultrasound examination was significantly low in the present study compared to previous studies [17-20].

Routine radial artery ultrasound and the true rate of RAO. In this present prospective study all the patients prior to the TRI underwent ultrasound examination of radial artery, ulnar artery and brachial artery to look for any pre-existing vascular anomalies and vessel diameter to be punctured. Appropriate size sheath according to vessel diameter was used in each patient. The rate of vascular access site complications after transradial coronary catheterization as monitored by vascular high resolution ultrasound. **Effect of sheath size on the RAO rate.**

In this prospective registry the use of 6-F sheaths was not independently associated with an increased rate of post-procedural RAO (p=0.38). In contrast, other studies show higher post procedural RAO with 6F sheath[21].Although it might be obvious that larger sheath diameters lead to increased vascular trauma, the exact pathomechanism explaining this finding remains incompletely understood. There is an influence of the inner diameter of the radial artery and the outer diameter of the sheath on the rate of RAO. Because we measured the pre procedural radial artery diameter and the sheath size was chosen accordingly, the rates of RAO may be less in this study. The stretching effect of the sheath and the passage of the sheath as well spasms of the radial artery might cause intimal flaps leading to RAO. Consequently the mechanisms of RAO in relation to sheath size should be further studied in imaging studies with optical coherence tomography.

Other Patient Related risk factors for RAO

Our study found that women are at higher risk than men for post procedural RAO**.** The complex sympathetic autonomic innervations of the radial artery, which might increase the risk of vascular spasms is thought to be the cause for increased RAO in women. But exact mechanisms of post procedural RAO remains unknown.

Procedure-related risk factors

In the present study the rate of RAO was more with operator with <1000 procedures/year, whereas the rate of RAO is very low with senior interventionists (>10,000 interventions). In contrast to a recently published study [22-23] (in which RAO after transradial catheterization was 10.5%) our study revealed an incidence of RAO after transradial cardiac catheterization is only 5.64%. In the present study our registry represents a real world scenario with a pool of interventionists having different degrees of experience with the transradial approach.

Limitations of the Study

This study was not a randomized comparison and a selection bias cannot be ruled out. Our study represents a single-center experience with a limited number of patients. The third limitation is that we did not study the influence of unfractionated heparin on the incidence of RAO. In the present study all patients with diagnostic angiography received 5000 IU of unfractionated heparin and in total 100 IU/kg body weight when PCI performed.

CONCLUSION

The rate of RAO by ultrasound examination is less in this study as compared to previous studies. The use of 5–F sheath for transradial access does not significantly decreased the rate of RAO when compared with 6-F sheath. The effectiveness of radial access might be linked to expertise and volume. To abbreviate the post-procedural complications of patients with transradial coronary procedures, vascular ultrasound of the access site before and after the procedure might be a valuable, non-invasive tool.

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