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ANATOMICAL OBSTACLES AND SHEATH TO BALLOON TIME WHILE INTERVENING THROUGH TRANSRADIAL APPROACH IN PATIENTS UNDERGOING PRIMARY PCI.

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ABSTRACT

Background: Transradial approach has been considered a safe and useful vascular access site for cardiac catheterization in comparison with the conventional transfemoral approach. However, radial access has many challenges, such as access difficulty related to anatomical variations, radial artery spasm, occlusion, loops, tortuosities, and aberrant origin of radial and subclavian arteries. These factors were ignored in the large randomized trials that might have a significant impact on the outcome. **Purpose:** To determine the predictors of anatomical obstacles and the sheath to balloon time while intervening through a trans-radial approach in patients undergoing primary percutaneous coronary intervention. **Methods & Results:** This was a case-control study comprised of 466 patients who underwent primary percutaneous coronary intervention to determine the predictors of anatomical obstacles Sheath to balloon time was determined in both the groups with and without anatomical obstacles.Patients with and without anatomical obstacles were recruited in a 1:3 ratio. Mean age was 56.45 ± 9.42 years. 78.5% (366) were male and 21.5% (100) were females. Out of them 64.2% (299) were hypertensive. 42.7% (199) were diabetics. Among the anatomical obstacle radial artery spasm was included in 25.9%, Subclavian tortuosity in 40.2%, tortuous configuration in 17%, Radioulnar loop in 12.5% and abnormal loop in 4.5% study population. (Fig 1). Mean sheath to balloon time was 22.19 ± 9.76 minutes. Mean sheath to balloon time was 19.42 ± 6.2 in trans-radial route without anatomical obstacle and 30.92 ± 13.25 minutes in patients with anatomical obstacle. Contrast induced nephropathy was more pronounced in patients with anatomical obstacles (4.5%) as compared to patients without obstacles (0.6%). **Conclusion:** Older age, female gender, and diabetes were found to be the major predictors for anatomical obstacles and hence significantly increasing the sheath to balloon time.

KEYWORDS: radial artery spasm, occlusion, loops, tortuosities.

INTRODUCTION

Acute myocardial infarction (MI) with ST-segment elevation is caused by rupture or erosion of an atherosclerotic plaque, initiating intraluminal thrombosis resulting in occlusion of a coronary artery Primary percutaneous coronary intervention (PCI) is the preferred treatment for MI with ST-segment elevation and is effective in opening the infarct related artery.

Transradial approach has been considered a safe and useful vascular access site for cardiac catheterization in comparison with the conventional transfemoral approach.[1–4] In general, access-site complications are significantly lower in the trans-radial approach than in the transfemoral approach. Furthermore, trans-radial cardiac catheterization (TRCC) shortens hospital stay and improves postprocedure quality of care.[5, 6] The advantages of transr-adial approach has been proved in large clinical randomized trials.

TRCC also has unique technical challenges, such as access difficulty related to anatomical variations[7,8,9], RA spasm[10-13], and RA occlusion.[14,15] Anatomical variations of the RA, such as abnormal RA origin, radioulnar loop, tortuous configuration, and severe RA spasm, occasionally lead to procedural failure. Some previous studies reported that the frequency of anatomical variations of the RA may differ between Asian and Western populations.[9,15] Incidence of these obstacles are known in many studies around 2-10%.

Despite having numerous benefits of trans-radial approach, this technique has few drawbacks especially in STEMI patients undergoing primary percutaneous coronary intervention. Timely intervention is the key in these patients to maintain a door to balloon time. These radial loops, radial artery spasm, abnormal origin, tortousities and subclavian arteytortousities are the delaying factors and increase the sheath to balloon time. Subsequently this impact on outcome. In this study, we will determine the frequency, predictors and their impact on sheath to balloon time and overall outcome.

OBJECTIVE

To determine the frequency and predictors of anatomical obstacles and their impact on sheath to balloon time and overall outcome while intervening through transradial approach in patients with STEMI.

METHODS

This case control study was conducted in Department of Adult Cardiology, NICVD Karachi from 28 January 2021 to 27 July 2021 after the approval of ethical review committee, ERC no:08/2021. A total of 466 patients were included. Patient's baseline characteristics, demographic details, and contact information, were documented on a structured proforma. All patients were managed as per the institutional protocol and recommended guidelines. Patients with STEMI undergoing Primary PCI through transradial approach were included. Patients not meeting the inclusion criteria and refused to give consent were excluded from the study. Anatomical obstacles through transradial approach such as radial artery spasm (defined as 75% stenosis at first radial arteriography after administration of isosorbidedinitrate and heparin), radioulnar loops(the presence of a full 360 loop of the RA distal to the bifurcation of the brachial artery), tortuous configuration (presence of maximum angulation of 90), and subclavian tortuosity were monitored and how these factors influence the sheath to balloon time and the outcome of STEMI patients undergoing Primary PCI was recorded.

Data analysis was performed through IBM SPSS version 21. The continuous variables were summarized as mean ± SD (standard deviation) and categorical response variables were expressed as percentages (%) [Counts]. Stratification was done by patient'sdemographic and baseline characteristics and post stratification Chi-square test was applied. Sheath to balloon time for patients with and without anatomical obstacles was compared by applied independent sample t-test. The criteria for statistical significance were taken as a p-value of less than or equal to 0.05.

RESULTS

A total of 466 patients were included in the study. 78.5% (366) were male. Mean age was 56.45 ± 9.42 years. 64.2% (299) were hypertensive. 42.7% (199) were diabetics. Family history of Cad was documented in 7.1% (33). 27.3% (127) were smokers. 5.8% (27) were obese. (Table 1). Regarding baseline characteristics females have more anatomical obstacle as compared to male (P value 0.035). Patients with Age more than 65 years have more anatomical obstacle during trans radial access as compared to age less than 65 years (P value 0.023). These are shown in detail in (table 1).

Among the anatomical obstacle in Radial artery access Radial artery spasm was included in 25.9%, Subclavian tortuosity in 40.2%, tortuous configuration in 17%, Radioulnar loop in 12.5% and abnormal loop in 4.5% study population. (Fig 1). Mean sheath to balloon time was 22.19 ± 9.76 minutes. Mean sheath to balloon time was 19.42 ± 6.2 in trans-radial route without anatomical obstacle and 30.92 ± 13.25 minutes in patients with anatomical obstacle. (Table 2).

Killip class I was documented in 91.2% (425) and most frequent MI was anterior wall i.e., in 56.4% (263) study population. Single vessel coronary artery disease (SVD) was present in 32.2% (150), Double vessel CAD in 35.4% (165) and 3VCAD in 32.4% (151). Most frequently involved artery was LAD which was documented 57.1% (266) followed by RCA in 31.5% (147) patients. TIMI 0 flow was included in 60.3% (281).

In 11.4% (53) patients there was access switch from radial to femoral site that also increased the sheath to balloon time. Mean EF was 40.73 ± 7.78% in study population. Post Procedural TIMI III flow was achieved in 95.5% (445). Post procedure TIMI III flow was statistically insignificant in both with and without anatomical obstacles 96% (340) vs 93.8% (105). Table 3.

Table 1: Demographic details and risk factors stratified by presence and absence of obstacles

Characteristics	Total	Anatomical Obstacles		p-value
		No	Yes	
Total (N)	**466**	**354 (76%)**	**112 (24%)**	**-**
Gender				
Male	78.5% (366)	80.8% (286)	71.4% (80)	0.035*
Female	21.5% (100)	19.2% (68)	28.6% (32)	
Age (years)	56.45 ± 9.42	55.6 ± 9.45	59.11 ± 8.86	<0.001*
≤ 45 years	16.3% (76)	17.5% (62)	12.5% (14)	0.023*
46 to 65 years	69.7% (325)	70.9% (251)	66.1% (74)	
> 65 years	13.9% (65)	11.6% (41)	21.4% (24)	
Hypertension				
No	35.8% (167)	36.2% (128)	34.8% (39)	0.797
Yes	64.2% (299)	63.8% (226)	65.2% (73)	
Diabetes				
No	57.3% (267)	59.9% (212)	49.1% (55)	0.044*
Yes	42.7% (199)	40.1% (142)	50.9% (57)	

Family history of CAD				
No	92.9% (433)	93.2% (330)	92% (103)	0.652
Yes	7.1% (33)	6.8% (24)	8% (9)	
Smoking				
No	72.7% (339)	72.3% (256)	74.1% (83)	0.711
Yes	27.3% (127)	27.7% (98)	25.9% (29)	
Obesity				
No	94.2% (439)	94.6% (335)	92.9% (104)	0.483
Yes	5.8% (27)	5.4% (19)	7.1% (8)	

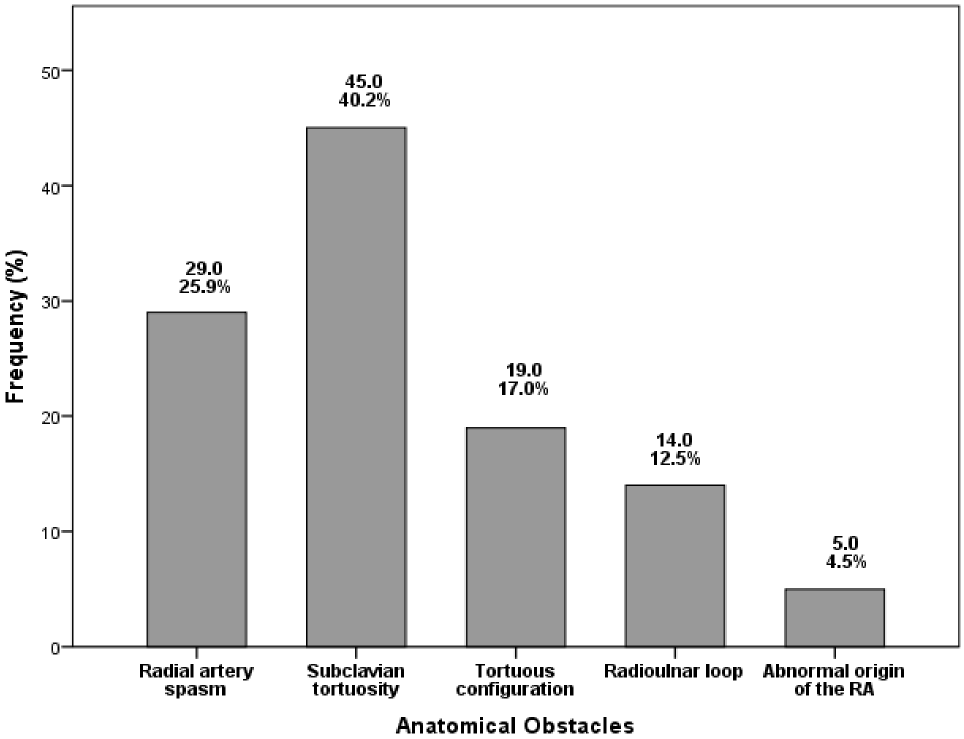

Fig 01: Frequency of various anatomical obstacles shown by Bar Graph.

Table 2: Killip class at presentation, type of MI, and angiographicdetails stratified by presence and absence of obstacles

Characteristics	Total	Anatomical Obstacles		p-value
		No	Yes	
Total (N)	**466**	**354**	**112**	**-**
KILLIP Class				
I	91.2% (425)	91.8% (325)	89.3% (100)	0.411
II	7.9% (37)	7.3% (26)	9.8% (11)	0.398
I	0.4% (2)	0.3% (1)	0.9% (1)	0.389
II	0.4% (2)	0.6% (2)	0% (0)	0.425
Type of MI				
Anterior	56.4% (263)	57.3% (203)	53.6% (60)	0.483
Inferior	34.5% (161)	34.2% (121)	35.7% (40)	0.766
Posterior	5.6% (26)	5.1% (18)	7.1% (8)	0.408

Lateral	3.4% (16)	3.4% (12)	3.6% (4)	0.927
Number of vessels involved				
Single vessel disease	32.2% (150)	33.1% (117)	29.5% (33)	0.479
Two vessel disease	35.4% (165)	36.2% (128)	33% (37)	0.547
Three vessel disease	32.4% (151)	30.8% (109)	37.5% (42)	0.186
Culprit coronary artery				
LAD	57.1% (266)	57.6% (204)	55.4% (62)	0.672
RCA	31.5% (147)	31.6% (112)	31.3% (35)	0.939
LCX	8.6% (40)	7.6% (27)	11.6% (13)	0.190
Ramus	1.7% (8)	2% (7)	0.9% (1)	0.441
Diagonal	0.9% (4)	0.8% (3)	0.9% (1)	0.964
LM	0.2% (1)	0.3% (1)	0% (0)	0.573
TIMI (pre procedural) flow				
0	60.3% (281)	61% (216)	58% (65)	0.574
I	12.2% (57)	11.3% (40)	15.2% (17)	0.275
II	6% (28)	4.8% (17)	9.8% (11)	0.051
III	21.5% (100)	22.9% (81)	17% (19)	0.184
Access Switchover				
No	88.6% (413)	99.7% (353)	53.6% (60)	<0.001*
Yes	11.4% (53)	0.3% (1)	46.4% (52)	
Sheath to Balloon time (min)	22.19 ± 9.76	19.42 ± 6.2	30.92 ± 13.25	<0.001*
LVEDP (mmHg)	17.3 ± 5.67	17.47 ± 6.06	16.75 ± 4.21	0.243
LV Gram (EF)	40.73 ± 7.78	40.56 ± 7.96	41.25 ± 7.22	0.416

Table 3: Post procedure TIMI flow, complicaitons, and outcomes stratified by presence and absence of obstacles

Characteristics	**Total**	**Anatomical Obstacles**		**p-value**
		No	**Yes**	
Total (N)	**466**	**354**	**112**	**-**
TIMI (post procedural) flow				
0	0.2% (1)	0.3% (1)	0% (0)	0.573
I	1.3% (6)	0.6% (2)	3.6% (4)	0.014*
II	3% (14)	3.1% (11)	2.7% (3)	0.817
III	95.5% (445)	96% (340)	93.8% (105)	0.307
Post-procedure complications and outcomes				
CIN	1.5% (7)	0.6% (2)	4.5% (5)	0.010*
Heart failure	2.1% (10)	1.7% (6)	3.6% (4)	0.262
Arrhythmias	3% (14)	2.8% (10)	3.6% (4)	0.751
Hematoma	0.2% (1)	0.3% (1)	0% (0)	>0.999
Radial artery perforation	0.6% (3)	0.3% (1)	1.8% (2)	0.145
All-cause death	1.9% (9)	2% (7)	1.8% (2)	>0.999
Cardiovascular death	0.9% (4)	0.8% (3)	0.9% (1)	>0.999
Rr-infarction	0.2% (1)	0% (0)	0.9% (1)	0.240
Other	0.9% (4)	0% (0)	3.6% (4)	0.003*

Regarding post-operative complications, contrast induce nephropathy was significantly more reported in patients with anatomical obstacle4.5% (5) as compared to those with no obstacle0.6% (2), P value 0.010. No significant difference was found in other complicationsi.e., heart failure, Arrythmias, hematoma, radial artery perforation, all cause death, cardiovascular death & Reinfarction. Table 3.

DISCUSSION

Trans radial route will be used as first option for coronary intervention as recommended by the guidelines and clinical randomized trials. However, thereare severalanatomical obstacles while using trans-radial route increase the sheath to balloon time and may adversely affect the outcome of these patients. This study was performed to focus the frequency of various anatomical obstacles and sheath to balloon time and its effect on the adverse outcome. The main predictors in our study were male gender, advanced age and diabetic patients. These factors were highly associated with switch over to femoral site and increased sheath to balloon time.

Among 53 patients having switched to Femoral site, 52 patients are due to anatomical obstacle. In other words, among 112 patients with anatomical obstacle 52(46.2%) patients switched to femoral site. Switch over have beenreported around 4%–7% in different studies.[16-18] In a study by Louvard et al.[19] the crossover to transfemoral site was 8.9% in their study population. The reason might be because of more patients enrolled in our study and only STEMI patients as compared to them. Also the reason may be because of more octogenarian population. Similarly in Kimet al.[20] crossover rate was 3.5% may be because of of elective cases. Failure to Puncture the radial arteryis first anatomical obstacle during transradial catheterization as radial artery is small in size so very prone to spasm. Also Wrist pain during puncturing radial artery is very important factor causing radial spasm and puncture failure. As puncturing radial artery is first step in tras-radial access so it should be near perfect.

Overall Mean Sheath to Balloon time (min) in our study was 22.19 ± 9.76 minutes. Louvard et al.[19] documented of full fluoroscopy time of 6.0 ± 4.4 min in their trans-radial arm of the study. Its because they have recorded full fluoroscopy time for their procedure while we have more focused on TIMI flow establishing in primary PCI set up that’s why we have recorded the mean sheath to balloon time here. Also usually more patients in acute primary PCI are elderly and they have more frequent anatomical obstacle. In meta-analysis by Plourde et al.[21] reported that fluoroscopy time was morein trans-radial access which has shorten over time because of more expertise. similar findings were also presented by Agostoni et al.[22] and Brasselet et al.[23] because of expertise and refinement in hard wares for trans-radial access. Incidence of radial artery vasospasm were approximately similar as reported in study by Brueck et al.[24] Diabetic patients have more anatomical obstacles through trans-radial route as compare to non-diabetics while attempting primary PCI. And in our study Diabetes was a powerful predictor for radial artery anatomical obstacle. This observation was also reported by multiple studies. The reason may be because of small artery caliber and diffuse atherosclerotic process as compare to non-diabetics.

Hardwaresused Opti-torque(Pre-shaped) catheter for most of the angiography. Judkins Right(JR) Guiding catheter for right coronary arteryand Extra back up Support(EBU) Guiding catheter for Left coronary artery lesions. In other studies, they haven't mention about the diagnostics and guiding catheter. This may have some effect on procdure time. The major limitations of the study were single centre study, low sample size and randomization of the patient groups.

CONCLUSION

Male gender, advanced age and diabetes were found to be the powerful predictors of Anatomical obstacles in this study while using trans-radial access for primary angioplasty. Anatomical obstacles has increased the sheath to balloon time and more switch over to femoral site that have adverse effect on the overall outcome of the STEMI patients. Despite the proven benefits of transradial approach, wise selection of the procedural route may decrease the sheath to balloon time and improve the outcome of STEMI patients.

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