Original Research Article

Feasibility of Radial artery access for primary angioplasty and high risk subgroup analysis - A paradigm shift

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Abstract

Objective: Radial access (RA) for angioplasty is an established technique, with proven benefits. The paradigm shift has made us to evaluate the feasibility of routine use of radial access in primary percutaneous coronary intervention (PCI). Also high risk subgroups (HRG) analysis was done to identify the clinical and procedure-related variables associated with higher complication rates. **Materials and Methods:** Total of 315 patients (112 HRG and 203 non HRG) presenting with ST-segment elevation acute myocardial infarction (STEMI) considered for primary PCI through RA at operator discretion were included in the study. The study analyzed the various risk factors and baseline characteristics in whole cohort and subgroup analysis comparing HRG and non HRG. **Results:** Patient had different spectrum of STEMI, with majority having LV systolic dysfunction. Primary PCI with drug eluting stent was done in majority of patients. Procedural parameters were compared and TIMI- 3 flow was achieved in 86.03%, fluoroscopy time 5-10 min in 90.16% and majority contrast volume used were less than 100 ml. Complications rate was low. **Conclusion:** This study proved the procedural success of RA for primary PCI in patients with various risk factors and baseline characteristics and supports its routine use for primary PCI. It also showed RA can be used in primary angioplasty in different type of HRG cases without any increase in procedural parameters and complications in comparison with non HRG.

Keywords: High risk groups; Primary angioplasty; Radial access

Introduction

Various accesses have been used for angioplasty with varying success rates in clinical practice[1]. The techniques available for angioplasty have its own advantages and disadvantages according to individual expertise[2-4]. Each access is generally at operator preference. A transradial approach (RA), as opposed to a femoral artery (FA) approach, for percutaneous coronary intervention (PCI) has become increasingly popular because of fewer bleeding complications, increased patient comfort, early ambulation, and shorter hospital stay[5-10]. This approach has been successfully employed in primary PCI for acute myocardial infarction (MI).

The trend is changing recently to use radial artery access even in high risk patients[11,12]. The paradigm shift has made to evaluate and compare the RA for primary angioplasty in a large number of cases with various risk factors and conditions. So, the clinical study was aimed to evaluate and compare the ease of access and other related factors for the successful use of RA in all types of conditions.

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The study was aimed to evaluate and compare the feasibility of routine use of RA in primary PCI, and in High Risk Group (HRG) and non-HRG sub groups. It also aimed to identify the clinical and procedure-related variables associated with higher complication rates. The parameters taken into consideration were the baseline characteristics, complications, the procedure-related factors like fluoroscopy time, contrast volume, and angioplasty success rate (TIMI grade).

Materials and methods

Study Design and Participants

The study was prospective, observational and descriptive in nature. It included 315 patients presented with acute ST-segment elevation myocardial infarction (STEMI) who underwent PCI through RA at cardiology department of a tertiary care centre, Thrissur, Kerala. The study period was for one year starting from January 2016. The selection of RA or FA approach was at the discretion of interventionist. Patients who underwent PCI through femoral artery were excluded in this study. The study protocol was approved by the Institutional Ethics Committee (IEC no. 2/16/IEC/JMMC & RI).

Patients were admitted and evaluated for baseline characteristics such as clinical history, physical examination and investigations including ECG, 2D echo and routine laboratory investigation. Then patients were divided into two groups (HRG and non HRG) for subgroup analysis. The HRG included patients with unfavorable characteristics, such as Elderly (>75 years), Cardiogenic shock, Severe Left

Ventricular systolic dysfunction, high degree AV block, Low body surface area (BSA), multi-vessel PCI, diabetes mellitus, Low Body mass index (BMI) and non-HRG included all other patients other than HRG. The procedural parameters, complications and outcomes have been assessed, tabulated and analyzed using descriptive analysis.

Procedure

The interventionist generally preferred right radial artery for transradial PCI. After local anesthesia, patients RA were punctured and A 5 or 6 French (Fr) radial artery sheath was inserted. On insertion of the sheath, 5000 units of heparin were administered. After diagnostic procedure, an additional bolus of 2500 units of heparin was administered just before starting PCI. Engagement of the left coronary artery (LCA) or right coronary artery (RCA) for diagnostic angiography was generally attempted using a Tigar catheter preferably. EBU, JL, JR were used as guiding catheter. The arterial access sheaths were removed following PCI and hemostasis was achieved by manual compression. Patients were permitted for early ambulation if hemodynamically stable and without any complications. Data of all patients were evaluated for baseline characteristics and procedural parameters. Patients were prospectively followed up till discharge, and in-hospital complications (if any) were noted.

Statistical analysis

Data were expressed as the mean, standard deviation (SD) or percentage (%). Intra group comparison was performed among the patients for the successful use of RA. A probability value of less than 0.05 was considered statistically significant.

Results

Demographic and morbidity profile

Out of 315 consecutive patients studied, males were 82% in which 27.3% were under 50 years and 6.7% above 75 years. BMI was calculated and less than 19 kg/m^2 was found in 13%, while above 25 kg/m^2 found in 23.2% (Table-1).

Table 1: Demographic profile in percentage

Variables		High Risk Group (N=112)	Non-High risk Group (N=203)	Total	
				N=315	Percentage
Gender	Male	26.3	55.9	259	82.2
	Female	9.2	8.6	56	17.8
Age	<=40	2.2	3.2	86	27.3
	41-50	6.1	15.9		
	51-60	9.8	24.8	208	66
	61-70	7.6	17.5		
	71-75	3.2	3.2		
	>75	6.7	0		6.7
BMI	Under weight (<19)	5.1	7.9	41	13
	Normal (19-25)	22.9	40.9	201	63.8
	Over weight (>=25)	7.6	15.6	73	23.2

The majority of patients had one or more risk factors for Coronary Artery Disease (CAD), with diabetes mellitus in 42.5%, systemic hypertension in 39.4% and smoking in 28.9% (Table-2).

Table 2: Morbidity profile in percentage- exposed to one or more factors

Risk factors	High Risk Group (N=112)	Non-High risk Group (N=203)	Total (N=315)
DM	13.9	28.5	42.5 (134)
HTN	13.3	26.1	39.4 (124)
DLP	3.8	7.3	11.1 (35)
H/O vascular disease	3.2	3.5	6.7 (21)
F/H/O premature CAD in family	2.5	4.2	6.7 (21)
Smoking	9.5	19.4	28.9 (91)

Clinical and interventional characteristics of patients

At presentation, patients average systolic BP was 140.8 ± 31.6 mmHg and diastolic BP was 83.4 ± 16.1 mmHg. Total Ischaemic time was found to be 6.46 ± 4.74 hrs for the whole study group. On ECG evaluation, AWMI spectrum were present in 48.9%, with QRBBB pattern in 4.5% and IWMI spectrum in 51.1% with 4.4% having RVMI. On echocardiography evaluation, 22.9% had a good LV function (LVEF >50%), 39.4% had mild LV systolic dysfunction (LVEF 40-50%), 18.7% with moderate LV systolic dysfunction (LVEF 30-40%) and 19% with severe LV systolic dysfunction (LVEF<30%). Coronary angiogram was showing SVD in 41.3%, DVD in 31.7%, TVD in 24.8 % and LMCA involvement in 2.2% patients prior to intervention. In the majority of patients (84.8%) Drug Eluting Stent (DES) was used, while Bare Metal Stent (BMS), plain old balloon angioplasty (POBA) and thrombo-suction were done in the remaining patients.

Procedural parameters

Post procedure, TIMI 3 flow was achieved in 86.03% and TIMI 2 in 12.7% and only TIMI 1 in 1.27%. The Majority of patients had fluoroscopy time <10 min (87.6%) for the procedure. The contrast volume used during procedure was ≤100 ml in 83.5%, 100- 150ml in 9.2% and more than 150ml in remaining patient's (Table 3).

Table 3: Comparison of Procedural parameters after randomization in both groups

Parameters		High Risk Group (N=112)	Non-High Risk Group (N=203)	Total (N=315)	P value
TIMI FLOW	Grade 1	3	1	4 (1.27%)	0.120
	Grade 2	17	23	40 (12.7%)	
	Grade 3	92	179	271 (86.03%)	

FLUOROSCOPY TIME	<10	96	180	276 (87.6%)	
	>=10	16	23	39 (12.4%)	0.477
T-Test (Comparison of means of Fluoroscopy time among Risk groups)					
Mean ± SD		6.44±4.18	6.34±3.55		0.817
CONTRAST VOLUME (ML.)	<=100	97	167	264 (83.5%)	0.465
	100-150	7	21	28 (9.2%)	
	>150	8 (34.8%)	15 (65.2%)	23 (7.3%)	
T-Test (Comparison of means of contrast volume among Risk groups)					
Mean ± SD		110.27±27.78	112.32±29.37		0.547

Chi-square and T test showed no significant differences in Procedural parameters among risk groups.

Complications

Patients were followed till discharge and in-hospital complications (if any) were noted. No complications were seen in 80% patients. Local complications were rare, with small haematoma present in 4 patients. Systemic complications were seen in 18.7% patients. Of this, AKI is the most common (62.7%). AKI was mostly contrast induced nephropathy, 21.6% patients were having preexisting CKD. All the patients recovered from AKI, except 2 patients with CKD requiring dialysis. Acute stroke occurred in 4(1.3%) patients and TIA in one patient during the hospital stay. Four patients had resuscitated cardiac arrest with primary VT/VF during post procedure period. Three patients had acute pulmonary oedema (Table 4). Complication rate was higher with the higher killip class at admission time, as expected.

Subgroup Analysis

Out of 315 patients in the study, 112 patients were in HRG. No statistically significant difference was found in procedural variables (fluoroscopy time, TIMI flow, contrast volume) (Table 3) and complications (p value >0.05) after comparison with non-HRG (Table 4). Among complications acute pulmonary oedema and resuscitated cardiac arrest were found more commonly in HRG.

Table 4: Number of cases with systemic complications

Systemic Complications	High Risk Group (N=112)	Non-High risk Group (N=203)	Total (N=315)	Percentage	
None	81	171	252	80	
With local complications	1	3	4	1.3	
With systemic complications	30	29	59	18.7	
Acute Stroke and TIA	3	1	4	6.8	100
Acute pulmonary Oedema	3	0	3	5.1	
AKI	11	16	27	62.7	
AKI with Arrhythmia	1	0	1		
AKI on CKD	3	5	8		
AKI with Cardiac Tamponade	0	1	1		
Resuscitated cardiac Arrest	4	0	4	6.8	
Arrhythmias	2	0	2	3.4	
Stent thrombosis	2	3	5	8.5	
Primary VT, TPI	1	2	3	5.0	
GIBLLED from Hemorrhoids	0	1	1	1.7	

Discussion

The first angioplasty procedure using RA was reported in 1993 by Kiemeneij and Laarman[2]. The radial approach is associated with a reduction in vascular access related complications after PCI[12,13].

Available literature showed that when primary angioplasty was performed via radial route, STEMI treatment resulted in decrease in mortality, bleeding risk and complications, [8,9,14] and these observations supported our study results too. Various studies showed that patients who had PCI done through RA had spent fewer days in hospital and fewer days in the coronary care unit because of lesser complication rate[14-16]. These study results are incongruent to our study observations. Majority of our patients were discharged within 3-5 days post procedure if uncomplicated.In the present study, feasibility of RA for primary angioplasty in patients with different baseline characteristics were assessed and sub-groups analysis were done comparing HRG with non-HRG. Despite the growing evidence on this issue, there remains considerable controversy on the routine use of RA, based on the idea that this approach could affect the success of angioplasty and reperfusion time in specific patient groups (i.e. high risk groups). In this study, no statistical significant difference was found among the HRG and non-HRG in procedural variables and complications rate. The RIVAL trial had excluded the high risk group of patients (i.e. cardiogenic shock), which we have included in our study. Despite this the results and complications were comparable with the RIVAL study[8]. Different studies and meta-analysis showed that HRG have been treated preferably using FA[14]. In Indian scenario the use of RA still is considered difficult procedure because of long learning curve associated with it[13]. Very few Indian studies have been published using RA for PCI but none of them had considered the various HRG patients[11-15]. Only our study considered and analysed HRG sub groups and compared it with non HRG successfully for different parameters.The study by Francisco J, *et al*., 2016 presented the results of a PPCI in 1029 patients, in which more than 93% of PPCI procedures were carried out using RA[6]. Whereas in this study, all our cases we performed through RA. In that study, angioplasty success rate was nearly 96%, and crossover was required in only 3.0%; but in our study, we had success rate of 98.5%. In that study, the use of RA did not affect the success rate of angioplasty or reperfusion time, although the higher crossover rate to FA was observed (10.9% vs 2.6%; P=0.006) in less favorable subgroup. But in our study even in HRG the procedural success rate was same as non-HRG. In the present study, no statistical significant differences were found in procedural parameters like TIMI flow, flouroscopy time and contrast volume on comparing HRG with non-HRG. The systemic complications on comparing HRG and non-HRG, complications were numerically more in HRG, but statistically significant difference were not found. Among systematic complication, acute kidney injury (AKI) was most common. Systemic complications were common in elderly with age more than 75 years compared to less than 60 years. Complications were more in higher killip class as expected. Complication rate were comparable to other major studies on RA PCI[6,8,9]. So present study showed that primary PCI through RA is feasible for all patients including HRG. In available literature search we could not find any large study which compared the HRG with non-HRG through RA. None of the published studies assessed and compared all the parameters (high risk groups)[14,17].There is sufficient evidence that patients with periprocedural bleeding have an unfavorable prognosis with increased

hospital stay and mortality. Although these complications are generally uncommon, several studies shown that RA is associated with a lower risk of developing such complications than FA, with no detriment to reperfusion time [6-10, 14-17]. The present study showed that primary PCI through RA is feasible for routine use in all patients with different base line characteristics and has equal success in HRG compared with non-HRG. Short duration of follow up is one of the limitations as our study followed the patients only during a hospital stay and patients were taken for RA at operator discretion and in relatively small sample size (315 patients). The study also not considered any comparison with other access like FA as majority of cases in our center are done by RA.

Conclusion

The study analysed the RA feasibility in primary angioplasty in patients with one or more risk factors with diabetes, hypertension and smoking being the most common. Family history of premature CAD was more common in patients with less than 50 years. On comparing HRG and NON-HRG, complications were numerically more in HRG, but statistically non-significant (p value > 0.05). There was no significant difference between procedural variables among the two groups. The results of this study support routine use of RA in all types of cases including high risk characteristics. We recommend that more emphasis should be put on rapid spread of expertise in RA (as the learning curve is more for RA than FA). RA may soon become the standard mode of access for all PCI (including HRG) and we recommend the same in the Indian subcontinent where we carried our study.

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