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ORIGINAL ARTICLES

Transradial versus Transfemoral Approach for Primary Percutaneous Coronary Intervention – Single Centre Experience over a Period of Two Years

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Abstract:

Background: Primary percutaneous coronary intervention (PPCI) is preferred over thrombolysis due to its better outcome both in terms of morbidity and mortality. Transradial (TR) PPCI is favored over transfemoral (TF) approach due to several advantages including survival benefit. Only concern of TR PPCI is a possible delay in door-to-balloon (D2B) time which is an important parameter for a better outcome. This retrospective analysis compared various outcome variables including D2B time between TF versus TR groups in order to decide which approach provides better outcome over the other.

Methods: This study was conducted at Ibrahim Cardiac Hospital & Research Institute (ICHRI) on retrospective data collected over a period of 2 years between January 2013 to December 2014. Patients with ST-segment elevation myocardial infarction (STEMI) attending at Emergency Department of ICHRI within 12 hours of chest pain and were sent for PPCI were consecutively included in the study based on predefined enrollment criteria. Demographic, angiographic & angioplasty variables, D2B time, duration of hospital stay and mortality were compared between TF versus TR groups.

Results: Of the 92 patients included in the study, 47(51.1%) patients underwent PPCI through TF access whereas 45(48.9%) patients through TR access. There was an increasing trend of performing PPCI via TR access in 2014 compared to 2013 (64.4% vs. 35.6%). There was no significant difference between the study groups in terms of age and sex. Baseline angiographic & angioplasty variables were almost similar between the groups. The mean D2B time was significantly shorter in TR group than that in TF group (79.0 ± 34.6 vs. 90.3 ± 37.7 min, p=0.021). One patient in each group died from ventilator associated pneumonia after PPCI.

Conclusion: Our single center retrospective analysis showed a statistically significant decrease in the door to balloon time with TR PCI, which makes it an attractive option for PPCI in STEMI.

Key Words: Primary PCI, trans radial.

Introduction:

Rupture or erosion of plaque in a large coronary artery leads to thrombotic occlusion and typically presents with acute ST-segment elevation myocardial infarction (STEMI). Primary percutaneous coronary intervention (PPCI) addresses this life threatening condition by opening up the infarct related artery by angioplasty within 12 hours of onset of symptom. This modality of treatment is replacing thrombolysis, in centers with available resources, as the success rate of opening up the artery with this procedure is over 90% & TIMI grade 3 flow rates of over 70%[15] compared to those with thrombolysis being 60-85% & 50-60% respectively.[16,17,18] As a result PPCI has significantly reduced mortality compared to fibrinolytic therapy (8.9% vs. 1.9%).[19]

Transfemoral (TF) PPCI was the standard modality of approach all over the world including our country. In 1996 Steg and Aubry first reported two transradial (TR) PPCIs

in patients with severe peripheral arterial disease.[20] Since then TR PPCI has become popular as a valid alternative to TF PPCI. This changing paradigm is due to patients' comfort, earlier mobilization, shorter hospital stay, reduced bleeding risk, lower cost and possibly survival benefit[7]. There are reports that TR PPCI may have lower radiation exposure in expert hands[21,22] and may have a mortality advantage.[23,24,25] A recent meta analysis on 11 randomized trial involving 9,202 patients compared TR PCI to TF PCI in ACS patients found significantly reduced risk of major bleeding (OR 0.60; 95% CI, 0.41–0.88; p = 0.008), vascular complications (OR 0.35; 95% CI, 0.28–0.46; p<0.001) and reduced the risk of death (OR 0.70; 95% CI = 0.53–0.94, p = 0.016).[26]

In STEMI "Time is muscle" meaning that the earlier the reperfusion the more myocardium is salvaged.[27] However, there is concern that TR PPCI may prolong an important quality metric of this procedure which is door-to-balloon (D2B) time, especially with new operator. Society of Cardiovascular Angiography and Intervention (SCAI)[28]

has specific recommendation for PPCI. Operators and sites should start performing TR PPCI after performing at least 100 elective PCI cases with a "radial first" approach and their femoral crossover rate should be below 4%. Femoral access for PPCI is recommended if the time to obtain radial access is >3 min, or the time from introducer sheath placement in the radial artery to engaging the infarct related artery with the guide catheter is >10 min.

Ibrahim Cardiac Hospital & Research Institute (ICHRI) started their first TR PCI in the year 2010 and first TR PPCI in 2011. This retrospective study was done to compare the results of TF PPCI versus TR PPCI in our centre.

Methods:

This retrospective study was conducted over a period of 2 years from January 2013 to December 2014. A total of 92 patients based on predefined enrollment criteria were selected out of 108 patients (as some patients' data were incomplete) after taking clearance from ethical review committee. Patients with STEMI attending at Emergency Department of ICHRI within 12 hours of chest pain (between 8 am to 8 pm on each working day according to hospital protocol) and underwent PPCI were included in the study. However patients with shock, advanced renal failure and severe co-morbidities were excluded. The choice of TF or TR access site – right or left and diameter of guide catheter during the procedure were exclusively of operator's choice. Use of thrombus extraction, Intracoronary Glycoprotein IIb/IIIa (IC GPI), Temporary Pacemaker (TPM) depended on the need during the procedure.

The demographic characteristics, risk factors and location of MI on the basis of ECG were recorded. Coronary angiographic findings like single (SVD), double (DVD) or triple vessel disease (TVD) and target coronary vessel of myocardial infarction were noted. Admission time recorded in the hospital database was taken as "door time". Hospital database time corresponds to satellite based standard timing. "Balloon time" was taken from the cath lab station. There was a small difference between cath lab station time with the hospital data base standardized timing. This difference was taken into account while calculating D2B time. Whether drug eluting stent (DES), bare metal stent (BMS) or both types of stent used was also noted. The use of manual thrombus extraction, IC GPI, buddy wire support for stent implantation and peri-procedural TPM were compared between TF and TR groups. Length of hospital stay and in-hospital mortality was also recorded.

Data were processed and analyzed using software SPSS version 11.5. The test statistics used to analyze the data were descriptive statistics, Chi-squared Test (c^2), unpaired t-Test, Fisher's Exact Test, The level of significance was set at 0.05 and p <0.05 was considered significant.

Result:

Of the 92 patients who underwent PPCI, 47(51.1%) were approached through TF, 45(48.9%) through TR routes. The mean age of the patients was 53.4±8.9 and 55.0±11.1 years in TF and TR group respectively and the difference was not statistically significant (p =0.430). Majority of the patients were male, only 10.6% female in TF group & 11.1% female in TR group. In the year 2013 PPCI was performed via TF access in 72.3% cases and via TR access in 35.6% cases. In the year 2014 PPCI was performed via TF access in 27.7% cases and via TR access in 64.4% cases indicating a significantly increasing trend of using TR approach in performing PPCI by the operators (Table I).

Table I shows the distribution of risk factors between the groups. There was no significant difference between TF and TR groups with respect to hypertension (40.4% vs. 44.4%, p = 0.697) and diabetes mellitus (31.9% vs. 46.7%, p = 0.147). However, dyslipidaemia demonstrated its significant presence in the latter group (4.3% vs. 8.2%, p = 0.037).

In TF group, 24(48.9%) patients were presented with acute AWMI, 17(36.2%) with acute IWMI, 1(2.2%) with acute IRVWMI & 5(11.1%) with acute IPWMI. In TR group, 20(44.4%) patients were presented with acute AWMI, 23(51.1%) with acute IWMI and 2(4.4%) with acute IPWMI (Table I).

Table-I

Comparison of demographic characteristic, type of MI and coronary vessels involved between femoral and radial groups

Demographic characteristic, type of MI and coronary vessels involved	Group		p-value
	Femoral(n =47)	Radial(n = 45)	
Age#	53.4 ± 8.9	55.0 ± 11.1	0.430
Sex*			
Male	42(89.4)	40(88.9)	0.942
Female	5(10.6)	5(11.1)	
Year of admission*			
2013	34(72.3)	16(35.6)	<0.001
2014	13(27.7)	29(64.4)	
HTN*	19(40.4)	20(44.4)	0.697
DM*	15(31.9)	21(46.7)	0.147
DL* 2(4.3)	8(82.2)	0.037	
AWMI*	24(48.9)	20(44.4)	0.525
INWMI*	17(36.2)	23(51.1)	0.148
IRVWMI**	1(2.2)	0(0.0)	0.315
IPWMI*	5(11.1)	2(4.4)	0.238
No of vessel involved*			
SVD	21(44.7)	23(51.1)	0.737
DVD	16(34.0)	15(33.3)	
TVD	10(21.3)	7(15.6)	
LAD*	24(51.1)	21(46.7)	0.673
LCx**	6(12.8)	4(8.9)	0.550
RCA*	23(48.9)	21(46.7)	0.828

Figures in the parentheses indicate corresponding %;
* Chi-squared Test (c^2) was done to analyzed the data.
# Data were analyzed using Unpaired t-Test and were presented as mean ± SD.
**Fisher's Exact Test was done to analyzed the data.
Total will not correspond to 100 % for multiple responses.

In TF group, single, double and triple vessel involvements were 21(44.7%), 16(34.0%) & 10(21.3%) respectively, while in the TR group, those were 23(51.1%), 15(33.3%) and 7(15.6%) respectively. There was no statistically significant difference between the groups in terms of number of coronary artery involvement (Table I). The infarct-related arteries (IRAs) were LAD-24, LCx-6 & RCA-23 in TF group and LAD-21, LCx-4 & RCA-21 in TR group respectively.

Mean hospital stay was almost similar in both groups (4.5±2.4 & 4.7±2.1 days, p =0.883), but mean D2B time was significantly longer in TF group than that in TR group (90.3±37.7 min vs. 79.0±34.6 min, p =0.021) (Table II).

Out of 47 patients in TF group, 45 underwent PCI whereas 43 patients underwent PCI in TR group out of 45. Remaining 2 patients in both groups underwent plain old balloon angioplasty (POBA) only. The number stents required in TF group was 55 and that in TR group was 52. Majority of the patients in either group (88.9% in TF and 83.7% in TR group) received DES (p = 0.438). Average stent length & stent diameter were 25.9 ± 12.4 and 2.9 ± 0.4 mm respectively in TF group whereas those were 26.5 ± 8.3 and 2.9 ± 0.5 mm respectively in TR group (Table III). 35 patients required 1 stent and 10 patients required 2 stents during PPCI in TF group whereas 34 patients required 1 stent and 9 patients required 2 stents during PPCI in TR group. The most commonly used stent diameter in TF group 2.75 mm and that in TR group was 3.0 mm (Table IV).

IC GPI were used in 14(29.8%) & 11(24.4%) in TF & TR group respectively. Thrombus aspiration was done in 7(14.9%) & 4(8.9%) cases in TF & TR group respectively. TPM was required in 4(8.5%) cases only in TF group. Buddy wiring was required in 1(2.1%) & 4(8.9%) cases in TF & TR group respectively. The incidence of angiographic no reflow was seen in 2(4.3%) patients only in TF group. One patient died in each group after the procedure related to ventilator associated pneumonia (Table V).

Table-II

Comparison of door to balloon time and length of hospital stay between femoral and radial groups

Time	Group		p-value
	Femoral(n=47)	Radial(n=45)	
Hospital stay (days)	4.5±2.4	4.7±2.1	0.883
D2B Time (minutes)	90.3±37.7	79.0±34.6	0.021

Figures in the parentheses indicate corresponding %;
Data were analyzed using Unpaired t-Test and were presented as mean ± SD.

Table-III

Comparison of stent category & characteristics between femoral & radial groups

Variables #	Group		p-value
	Femoral(n=45)	Radial(n=43)	
No of stents used	55	52	0.545
Stent category			
DES	40(88.9)	36(83.7)	0.438
BMS	3(6.7)	2(4.7)	
DES+BMS	2(4.4)	5(11.6)	
Number of stent			
1 stent	35(77.8)	34(79.1)	0.883
2 stent	10(22.2)	9(20.9)	
Stent Length (mm)	25.9±12.4	26.5±8.3	0.805
Stent diameter	2.9±0.4	2.9±0.5	0.508
Stent per patient	1.2±0.3	1.2±0.4	0.474

Figures in the parentheses indicate corresponding %;
Data were analyzed using Unpaired t-Test and were presented as mean ± SD.

Table-IV

Comparison of different stent diameter between femoral and radial groups

Stent Diameter		Group	
		Femoral(n=45) n=35	Radial(n=43) n=34
1	STENT USED		
	2.25	3 (6.7)	2 (4.7)
	2.5	12 (26.7)	9 (20.9)
	2.75	15 (33.3)	10 (23.3)
	3	7 (15.6)	13 (30.2)
	3.5	5 (11.1)	9 (20.9)
	3.75	1 (2.2)	0 (0.0)
	4	2(4.4)	0 (0.0)
2	STENT USED	n=10	n=9
	2.25	0 (0.0)	2 (12.5)
	2.5	4 (40.0)	2 (11.1)
	2.75	2 (20.0)	2 (11.1)
	3	1 (10.0)	1 (12.5)
	3.5	2 (20.0)	0 (0.0)
	4	1 (10.0)	2 (11.1)

Table-V

Comparison of different procedural details and mortality between femoral and radial groups

Procedural details & mortality	Group		p-value
	Femoral(n=47)	Radial(n=45)	
POBA*	2(4.3)	2(4.4)	0.965
Thrombus aspiration*	7(14.9)	4(8.9)	0.375
GPI*	14(29.8)	11(24.4)	0.565
No reflow**	2(4.3)	0(0.0)	0.258
Buddy wire**	1(2.1)	4(8.9)	0.167
TPM**	4(8.5)	0(0.0)	0.064
Death**	1(2.1)	1(2.2)	0.742

Figures in the parentheses indicate corresponding %;
* Chi-squared Test (c^2) was done to analyzed the data.
**Fisher's Exact Test was done to analyzed the data.

Discussion:

This single-center retrospective study revealed several important findings. First, the use of TR approach is increasingly becoming popular among our intervention cardiologists, which corresponds well with a worldwide trend in the use of TR. Secondly, there were no observed differences in mortality TF and TR PCI. Finally, the door-to-balloon time was significantly decreased with TR which has important implications for future clinical practice.

Two frequently cited randomized trials, The RadIal Vs femorAL access for coronary intervention (RIVAL) and RadIal versus FemoraL randomizEd investigation in ST-Elevation Acute Coronary Syndrome (RIFLE-STEACS), showed a mortality benefit for TR in patients with STEMI.[11,12] The mortality benefit is thought to be due to reduction in bleeding events, as it is known that post-PCI bleeding is independently related to mortality in ACS.[29,30] Although our current study did not show a mortality benefit in TR over TF, it was likely underpowered to show a mortality benefit due to low absolute number of total deaths (1 death in each group). This may have been due to selection of relatively healthy patients and excluding those in shock or renal failure.

When it was first introduced, TR PCI was rarely used in clinical practice. This may have been due to concerns about the difficulty with radial access, navigation of the tortuous arm vasculature to engage the coronary arteries, and inability to use larger thrombectomy catheters. However, given the benefit in mortality and/or bleeding seen on recent studies, there has been increasing adoption of the TR approach globally in recent years and subsequently there has been increasing expertise in this technique.[31,32] This increasing trend in using TR is reflected in our data, which shows a 28.8% absolute increase in the use of TR from 2013 to 2014, which was found to be statistically significant. The changing trend is largely driven by the increasing comfort on the part of the operator.

Despite the growing body of evidence for mortality benefit with TR in STEMI, there have been questions raised regarding whether D2B is delayed in TR. This is a valid concern as D2B time is a well-known parameter for better outcomes and shortened D2B times have been linked to improved survival.[33] Studies that have examined these issues have reported conflicting results. Initially, small single-center studies have shown that D2B times with TR are similar to those with the TF.[34] A 2009 meta-analysis of 12 studies involving 3324 patients showed a slightly reduced D2B time and slightly longer procedural time by <2 minutes in TR approach.[35] More recently, in 2013, data from the Cath PCI Registry examined 294,769 patients undergoing primary or rescue PCI for STEMI and found that TR was associated with longer median D2B time (78 vs. 74 min; $p<0.0001$) but lower adjusted risk of bleeding (odds ratio [OR]: 0.62; 95% CI: 0.53 to 0.72; $p<0.0001$) and lower adjusted risk of in-hospital mortality (OR: 0.76; 95% CI: 0.57 to 0.99; $p=0.0455$).[18]

In the context of above mentioned data, the reduction in D2B time in our study could be considered a significant finding. This is most likely due to the growing operator experience with TR PCI at our institution since 2011, as mentioned earlier that successful TR PCI is largely dependent on operator experience. Procedural time has been shown to decrease with higher volume[15] and low TR volume has been associated with both worse clinical outcomes and access site failure requiring crossover.[11,36]

Additionally, our finding of decreased D2B time was independent of the complexity of the procedure, as there were no statistically significant differences in stent dimensions and number of stents between TR and TF groups.

However, we encountered several limitations which deserve mention. As with any retrospective observational study, it was difficult to adjust for all confounding factors that might have affected D2B time and length of hospital stay. Therefore they may have been hidden factors that may have biased the results in favor of the radial access. Another limitation is the fact that the operators in our trial were skilled in the TR approach and performed a larger volume over the two-year study period. This may not be the case in other centers where operators mainly perform TF approach. Therefore the external validity of this study is limited.

Conclusion:

Our single center retrospective analysis showed a decrease in the D2B time with TR PCI, which makes it an attractive option for PCI in STEMI. Despite the growing evidence for benefit in mortality and bleeding with TR PCI, it continued to be less commonly used in clinical practice. As outcomes with TR PCI are largely dependent on experience, centers and individual operators should continue to develop expertise in the use of the radial technique, and should do so by following the recommended guidelines from SCAI.

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