ORIGINAL ARTICLE

Door-to-balloon time in radial versus femoral approach for primary percutaneous coronary intervention in patients with ST-segment elevation myocardial infarction

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Abstract   Primary percutaneous coronary intervention (pPCI) is considered the preferred reperfusion strategy for patients presenting with ST-segment elevation myocardial infarction (STEMI). This study compares the door-to-balloon (D2B) time between transradial vs. the transfemoral approach in patients presenting with STEMI.

Methods: A retrospectively collected catheterization laboratory database was reviewed for the consecutive patients presenting with a STEMI. Specific time parameters were recorded, and our composite end points were time to revascularization, angiographic success, short term clinical success, and procedural vascular complications.

Results: Radial PCI (r-PCI) was performed in 33 patients (67.3%) and in 16 patients (32.7%) PCI was done through femoral artery (f-PCI). No significant difference was observed in the pre-catheter and catheter laboratory times. Mean times from emergency room door-to-catheter laboratory time for r-PCI vs. f-PCI were 82.48 ± 37.42 and 76.29 ± 34.32 min, respectively ($P = 0.636$). The mean time from patient arrival to the cardiac catheter laboratory-to-balloon inflation was 34.56 ± 14.2 in the r-PCI group vs. 33.12 ± 12.56 min with the f-PCI group ($P = 0.215$). The total D2B time was not significantly different between r-PCI vs. f-PCI groups (100.32 ± 36.3 vs. 97.31 ± 30.37 min, respectively, $P = 0.522$). Angiographic success rates were observed in 92.1% of the patients for

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r-PCI, and in 87.5% for f-PCI (P = 0.712). There were no vascular complications in both groups.

Conclusions: Patients presenting with STEMI can undergo successful pPCI via radial artery without compromising patient care.

1. Introduction

Current practice guidelines consider primary percutaneous coronary intervention (pPCI) the preferred reperfusion strategy for patients presenting with ST-segment elevation myocardial infarction (STEMI), conditional on the timely performance of the PCI procedure.[1] On the basis of current American College of Cardiology/American Heart Association guidelines,[2] door-to-balloon time (D2B) has become a reportable core measure of quality and correlates with outcomes in high-risk and early presentation patients.[3] Periprocedural bleeding remains a major limitation of primary PCI because of the need to administer potent antithrombotic agents.[4] Previous data have established the strong association between major bleeding after PCI and increased mortality.[5–8] Substantial efforts have been made to reduce the occurrence of periprocedural bleeding, from using vascular closure devices to the use of antithrombotic agents associated with a lower bleeding risk.[9,10] Radial access during PCI has emerged as a promising alternative to femoral access, as the primary PCI using the radial approach was associated with a fourfold reduction in major bleeding.[11] Radial artery access for diagnostic cardiac catheterization received interest through the work of Campeau[12] twenty years ago, and subsequently for intervention procedures by Kiemeneij et al.[13] Since then, there has been widespread adoption of transradial techniques outside of the United States.[14] Parts of Europe and Japan do 40% or more of their cases using the radial artery, but in the United States estimates are in the low single digits (2%), although those United States cardiologists and radiologists who have learned the radial technique tend to use it for many, if not most, of their patients.[15] Reasons stated for slow acceptance in the United States include a lack of training in the radial approach, greater difficulty manipulating catheters, difficulty in achieving radial access, uncertain radiation exposure, and a learning curve for performing cardiac catheterization through the wrist.[16] These arguments against the use of the radial artery imply that greater time may be required to perform cardiac catheterization using the radial artery. This importance of time may be greatest for patients presenting with STEMI as survival directly relates to reperfusion times (door-to-balloon).[17–19] For patients undergoing primary PCI for acute STEMI, potential differences between radial PCI (r-PCI) and femoral PCI (f-PCI) in D2B times have not been widely evaluated. This study compares the transradial vs. the transfemoral approach time in the intervention for patients presenting with STEMI.

2. Methods

A retrospectively collected catheterization laboratory database of consecutive patients presenting with a STEMI over a 23 months period (starting from March 2007 till the end of January 2009) at a tertiary care hospital (Cardiothoracic Department, Spedali Civili, Brescia University, Italy) was reviewed for this analysis. We reviewed and studied patients who presented to our hospital by ST-segment elevation myocardial infarction according to the definition of Joint European Society of Cardiology/American College of Cardiology Committee 2007.[20–24] STEMI was identified by ECG either in the hospital or in the field, and cardiac catheterization laboratory staff was directly notified by the emergency medicine physician. All patients received aspirin, clopidogrel, unfractionated heparin, glycoprotein IIb/IIIa (abciximab), and other anti-ischemic medications before or during the procedure according to clinical decision of the attending physician and treating interventionalist.

The study population was stratified according to arterial access used to perform pPCI into 2 groups; radial group and femoral group (r-PCI vs. f-PCI). The choice between femoral or radial artery access was left to the discretion of the operator. Attending operators and technical staff were experienced at the transradial and transfemoral arterial access. The radial approach is the default strategy at the Brescia catheterization laboratory – Spedali Civili. In accordance with institutional policy, the femoral approach was favored for patients with negative findings on the Allen test,[12,25] and for patients with coronary artery bypass grafts (CABG). Radial arterial access was achieved in a standard fashion using commercial micropuncture kits. Intra arterial nitroglycerine (200 mcg) was used as the primary antispasmodic. PCI was performed using 6 Fr guiding catheters. At procedure completion, the sheath was removed immediately and a compression by hemostatic band was installed for 3 h. Femoral procedures were done using vascular sheaths, which were placed using the Seldinger's technique. PCI was performed using 6 Fr guiding catheters. After the end of the procedure, the sheath was removed in the intensive care unit 4–5 h after the procedure and manual compression was performed for a minimum of 15 min or until satisfactory hemostasis had been achieved. This was followed by placement of a compressive bandage for 6 h. Closure devices were not used. Access was considered successful once the sheath was inserted into the artery. Crossover between initial access approaches was also recorded and access was stratified based on the first route of access attempted.

Specific time parameters were recorded: time from emergency room arrival-to-patient arrival in catheter laboratory (cath. lab.), time from patient arrival in catheter Laboratory-to-balloon inflation and total D2B time (interval from the first emergency room arrival-to-the first attempt at opening the artery by aspiration thrombectomy, balloon inflation, or direct stenting in the infarct-related artery "IRA").

American college of cardiology/American heart association task force on performance measures stated that "the goal of pPCI is to restore flow in the IRA".[26] As we sought to determine whether the radial approach was associated with a successful pPCI without increasing the time to revascularization, our composite end points were the time from emergency room door to revascularization, angiographic success, short term clinical success[27] (relief of signs and/or symptoms of

myocardial ischemia after recovery of the patient from the procedure), and procedural vascular complications (defined as access site bleeding, digital ischemia, hematoma, pseudoaneurysm, or AV fistula formation). Angiographic success in our study was defined as a residual stenosis diameter less than 20% in stented segments or < 50% in balloon angioplasty segments, in the presence of TIMI flow grade III (Thrombolysis In Myocardial Infarction[28]) in the target vessel on a lesion-by-lesion basis. Short term clinical success was judged by the absence of ischemic discomfort post pPCI, but it may be unreliable for identifying failed or successful reperfusion, so we used in addition ST-segment resolution on the 12-lead ECG by more than 70% as an evidence of successful reperfusion.[27]

2.1. Statistical analysis

The data was coded and computed on a statistical package for social sciences SPSS version 17 for windows for statistical analysis. Times measured were analyzed using a Student t test and reported as mean values. Mean times are reported in minutes along with one standard deviation from the mean. Demographic information and complications were categorical data, and were analyzed using a chi squared analysis. Significance was defined as $P < 0.05$.

3. Results

Over the study period; 2143 PCI procedures were done in the catheter laboratory, in which 2647 lesions were treated for a total of 1824 patients. Primary PCI for patients with acute STEMI constituted 462 procedures of the total PCI performed, during which 507 coronary lesions were treated for 447 patients. Of these, 49 acute STEMI patients were included in this registry, in which pPCI was done by the authors.

Radial PCI was performed in 33 patients (67.3%) and in 16 patients (32.7%) PCI was done through femoral artery. There was no statistical significant difference between the two groups in age, gender, or coronary artery disease risk factors including, diabetes, stroke, hypertension, smoking, dyslipidemia, or prior MI, PCI, or CABG. Patients in the both groups, who underwent inter-hospital transfer prior to the procedure were statistically non significant (radial: 57.5% vs. femoral: 50.0%, $P = 0.617$). The demographic data of the studied population are listed in Table 1.

In the f-PCI group, arterial access was achieved via the contra lateral femoral artery following initial failure in 2 patients and times recorded were included for the femoral artery access, while there was no crossover from right radial artery access to left radial or femoral artery in the radial group.

Single culprit vessel PCI was performed in all patients of the f-PCI group and in 31 patients (93.93%) for the r-PCI group, $P = 0.63$. Primary PCI was done for 2 vessels in two patients of the radial group. Thirty eight lesions were treated in 33 patients for the radial group, while in the femoral group 16 lesions were intervened upon. Residual stenosis was less than 20% in stented segments or < 50% in balloon angioplasty segments after pPCI occurred in 35 lesions (92.1%) for the radial group vs. 14 lesions (87.5%) in the femoral group, $P = 0.712$ (Table 2).

In the femoral group, 14 lesions presented with TIMI flow 0 (87.50%), 1 lesion with TIMI flow 1 (6.25%) and other one lesion with TIMI flow 2 (6.25%). Pre primary PCI vessel stenosis range was 90–100% of the index luminal diameter of the vessel with a mean stenosis of 99.31 ± 2.50. Post primary PCI, 14 lesions had TIMI flow 3 (87.50%), 1 lesion with TIMI flow 0 (6.25%) and one lesion had TIMI flow 2 (6.25%). Fourteen lesions (87.5%) had a residual stenosis less than 20% in stented segments or < 50% in balloon angioplasty segments (Table 2).

In the radial group, 20 lesions presented by TIMI flow 0 (52.63%), 5 lesions with TIMI flow 1(13.16%), 1 lesion with TIMI 2 (2.63%) and 12 lesions had TIMI flow 3 (31.58%). Pre pPCI vessel stenosis range was 80–100% of the index luminal diameter of the vessel with a mean stenosis of 95.66 ± 6.76. Post pPCI, 37 lesions had TIMI flow 3 (97.37%) and only one lesion had TIMI flow 1(2.63%). Thirty five lesions (92.1%) had a residual stenosis less than 20% in stented segments or < 50% in balloon angioplasty segments (Table 2).

Angiographic success was achieved in 35 lesions (92.1%) in radial pPCI vs. 14 lesions (87.5%) in the femoral pPCI, $P = 0.712$. While short term clinical success rates were observed in 30 patients (90.9%) for the radial group vs. 14 patients (87.5%) for the femoral group ($P = 0.749$) Table 3. There were no procedural vascular complications in both groups.

No significant difference was observed in the pre-catheter and catheter laboratory times. Mean times from emergency room door-to-catheter laboratory time for r-PCI vs. f-PCI were 82.48 ± 37.42 and 72.29 ± 34.32 min, respectively ($P = 0.636$). The mean time from patient arrival to the cardiac catheter laboratory-to-balloon inflation was 34.56 ± 14.2 in the r-PCI group vs. 33.12 ± 12.56 min in the f-PCI group, which is statistically non significant ($P = 0.215$). The total D2B time was not significantly different between r-PCI vs. f-PCI groups (100.32 ± 36.3 vs. 97.31 ± 30.37 min, respectively, $P = 0.522$) Table 4.

4. Discussion

Traditionally, primary PCI has been performed using the femoral approach. The reluctance to use the radial approach has stemmed from the perceived longer vascular access time and the subsequent delay in reperfusion time, despite the findings of fewer vascular complications, such as lower bleeding risk, lower costs, greater patient comfort, shorter post procedural hospitalization time, and lower mortality when transradial artery access is used rather than transfemoral in many studies.[15,29–31]

In the setting of pPCI, more than 2/3 of major bleeding events are attributable to complications at the femoral access site.[32–34] Also, a femoral hematoma requiring transfusion is an independent predictor of one year mortality.[31] Potential strategies to reduce the incidence of bleeding have included tailored and monitored anticoagulant and antiplatelet therapies. Rao et al.[15] reported a significantly lower risk of bleeding complications in patients treated using the radial approach. In a meta-analysis of randomized trials, radial access reduced major bleeding by 73% compared with femoral access.[35]

Table 1 Patients demographics.

	Radial PCI (N = 33 pts)	Femoral PCI (N = 16 pts)	P value
Age (year): range	36.00–86.00	31.00–87.00	
Mean ± SD	62.82 ± 11.94	63.63 ± 16.19	0.85
Sex: male	26 pts (78.79%)	13 pts (81.25%)	0.841
Female	7 pts (21.21%)	3 pts (18.75%)	
Height (cm): range	152.00–190.00	155.00–180.00	
Mean ± SD	169.61 ± 8.79	169.69 ± 7.63	0.98
Weight (kg): range	45.00–130.00	50.00–121.00	
Mean ± SD	82.00 ± 17.06	77.38 ± 13.99	0.35
BSA (m^2): range	1.41–2.45	1.50–2.20	
Mean ± SD	1.93 ± 0.23	1.86 ± 0.18	0.28
Diabetes mellitus, n (%)	25 (75.7%)	13 (81.25%)	0.75
Hypertension, n (%)	27 (81.8)	14 (87.5%)	0.66
Dyslipidemia, n (%)	23 (69.7%)	10 (62.5%)	0.73
Cerebrovascular disease, n (%)	3 (9.1%)	2 (12.5%)	0.81
Smoking, n (%)	20 (60.6%)	9 (56.2%)	0.62
Previous PCI, n (%)	8 (24.2%)	4 (25%)	0.83
Previous CABG, n (%)	0 (00%)	1 (6.2%)	0.77
Previous MI, n (%)	5 (15.1%)	2 (12.5%)	0.89
Inter-hospital transfer, n (%)	19 (57.5%)	8 (50.0%)	0.617

BSA, body surface area; MI, myocardial infarction; PCI, percutaneous coronary intervention; CABG, coronary artery bypass grafting; pts, patients.

Weaver et al.[36] conducted a nonrandomized single center study and he demonstrated that the PCI performed for STEMI using radial artery access could be performed with shorter door to balloon times compared with femoral artery access in a center where a high volume of radial artery procedures is performed (D2B was 76.4 ± 26.4 in r-PCI vs. 86.5 ± 27.6 min in f-PCI, P = 0.008). These results are reassuring in that they suggest the concerns and challenges of adapting transradial techniques that do not appear to translate into actual degradation of door-to-balloon times in the very time sensitive care of STEMI patients.

These results differ from prior observational and randomized studies for acute myocardial infarction, where procedural times were typically not significantly different or were longer when radial access was used.[37–40] However, one meta analysis noted significant heterogeneity in procedural times based upon the experience of the operators with shorter radial procedural times for more experienced operators.[41]

Accessing the radial artery has often been deemed technically more challenging and time consuming.[38] In the present study, we did not observe any differences in either the time from arrival to catheter Laboratory-to-balloon inflation time or the time from emergency door-to-balloon inflation (D2B) in both groups, which were 34.56 ± 14.2 in r-PCI vs. 33.12 ± 12.56 min in f-PCI and 100.32 ± 36.3 in r-PCI vs. 97.31 ± 30.37 min in f-PCI, respectively (P = 0.215 and 0.522).

Also Arzamendi et al.[11] reported no significant effect on key procedural intervals between radial and femoral approaches (Time to puncture 9 ± 5 vs. 9 ± 6 min, Time to revascularization 21 ± 9 vs. 23 ± 10 min and D2B 123 ± 63 vs. 129 ± 81 min, respectively "P = >0.05"). He reported a reduction in 1 year follow-up of major adverse cardiac events (MACE), associated with using the radial approach among patients undergoing primary PCI, which was mainly attributable to a reduction in mortality and target vessel revascularization at 12 months, and this is consistent with the previous data

linking a reduction in mortality to lower bleeding complications among patients undergoing radial access.[42–44] Also he documented a strong association between lower bleeding rates and reduced 12-month mortality among patients undergoing radial-access PCI. The target vessel revascularization rates were also lower in the radial group in his study, possibly because of the better post procedural TIMI flow grade observed in the radial group. Moreover, the greater use of optimal anti-coagulant and antiplatelet therapies among patients undergoing radial PCI might have achieved a more effective antithrombotic milieu, with subsequent improvement in epicardial flow. In our study, we are in agreement with Arzamendi et al.[11] regarding the key procedural intervals, as there was no significant difference between radial and femoral groups. But regarding TIMI flow; post procedure TIMI flow 3 was achieved in 97.37% and 87.50% for both radial and femoral groups, respectively with no significant difference in our study (P = 0.139).

It has been argued that the transradial approach may be associated with lower rates of angiographic and clinical success. However the angiographic and short term clinical success rates in our study for the pPCI in both radial and femoral groups were not significantly different. This latter point might encourage centers with a low volume of radial procedures to increase the number of procedures using this approach, especially in the setting of STEMI. Cruden et al.[45] demonstrated that, the transradial approach is safe and effective in patients with STEMI undergoing rescue PCI following failed thrombolysis by appropriately trained operators.

In some studies, there has been a trend toward higher failure rates at crossing the lesion with a wire in radial access procedures.[36–39] In our study, there was no significant difference in the failure to cross a lesion depending on arterial access used, as we have only one patient in the femoral group, in whom we failed to cross the lesion with a wire in a totally occluded vein graft. So the higher failure rates at crossing the lesion, appears to be an artifact in the literature of operator experience as it

Table 2 Procedural characteristics.

	Radial pPCI	Femoral pPCI	P value
Vascular access crossover, n (%)	0 (00.00%)	2 (12.5%)	0.350
Vessels intervened upon, n (%):			
One vessel	31 pts (93.93%)	16 pts (100%)	0.78
Two vessels	2 pts (6.07%)	0 (00.00%)	0.63
Three vessels	0 (00.00%)	0 (00.00%)	
Lesions intervened upon, n (%):			
Left main artery	1 (2.63%)	0 (0.00%)	0.512
Left anterior descending artery	13 (34.21%)	5 (31.25%)	0.833
Left circumflex artery	5 (13.16%)	2 (12.50%)	0.948
Right coronary artery	19 (50.00%)	8 (50.00%)	1.000
Bypass graft	0 (0.00%)	1 (6.25%)	0.120
Pre pPCI TIMI flow grade, n (%):			
TIMI flow 0	20 (52.63%)	14 (87.50%)	0.015
TIMI flow 1	5 (13.16%)	1 (6.25%)	0.461
TIMI flow 2	1 (2.63%)	1 (6.25%)	0.520
TIMI flow 3	12 (31.58%)	0 (0.00%)	0.011
Post pPCI TIMI flow grade, n (%):			
TIMI flow 0	0 (0.00%)	1 (6.25%)	0.120
TIMI flow 1	1 (2.63%)	0 (0.00%)	0.512
TIMI flow 2	0 (0.00%)	1 (6.25%)	0.126
TIMI flow 3	37 (97.37%)	14 (87.50%)	0.139
Residual stenosis, n (%)			
Yes	35 (92.1%)	14 (87.5%)	0.712
No	3 (7.9%)	2 (12.5%)	
Angiographic success of the pPCI	35 (92.1%)	14 (87.5%)	0.712
Pre pPCI stenosis %	80–100 (95.66 ± 6.76)	90–100 (99.31 ± 2.50	0.14
Post pPCI residual stenosis %	0.00–90.00 (9.97 ± 26.37)	00–100 (11.88 ± 27.80)	0.81
Length of lesion (mm)	8–35 (14.63 ± 5.52)	6–30 (15.13 ± 6.12)	0.77
Balloon diameter (mm)	1.50–3.5 (2.25 ± 0.46)	1.50–3 (2.20 ± 0.37)	0.71
Balloon length (mm)	10–20 (14.84 ± 2.88)	12–20 (15.40 ± 2.67)	0.52
Bare metal stent diameter (mm)	2.25–4 (3.15 ± 0.45)	2.50–3.5 (3.05 ± 0.38)	0.50
Bare metal stent length(mm)	12–28 (17.35 ± 4.48)	8–28 (16.29 ± 4.38)	0.45
Contrast volume (ml)	162–275 (213.9 ± 62)	158–260 (205.8 ± 41)	0.37

n, number; pts, patients; pPCI, primary percutaneous coronary intervention; TIMI, thrombolysis in myocardial infarction flow, Residual Stenosis, <20% in stented segments or <50% in balloon angioplasty segments; mm, millimeter.

does not seem to be present when operators with more radial artery access experience performed the procedure.[40]

Radial artery access has been associated with a greater access crossover rate, which reported to be 4–7% in previous studies.[38–47] The crossover rate in our study was (12.5%) in the femoral group, while there was no crossover in the radial group. The greater rate of success in radial approach in our study could be attributed to the greater experience in the radial access, as it is the default access in all the elective and emergency procedures in catheter laboratory of Spedali Civili, Brescia University, Italy. Weaver et al.[35] stated that crossover rates, which are typical component of many comparisons between radial and femoral techniques, are associated with the experience level of the operator and expert in both techniques may reduce time delays regardless of initial access site used when problems arise.

5. Conclusions

The results of this study support that, patients presenting with STEMI can undergo successful PCI via the radial artery without compromising patient care. Door to balloon time is not increased by radial artery access compared with femoral artery access, where the operator has a considerable experience using the radial artery for coronary intervention.

Table 3 Clinical presentation of the studied population before and after PCI.

	Radial pPCI	Femoral pPCI	P value
Systolic BP before pPCI (mmHg)	80–190 (132.33 ± 20.68)	80–160 130.00 ± 21.53)	0.96
Diastolic BP before pPCI (mmHg)	60–110 (77.88 ± 12.93)	50–110 (78.13 ± 15.48)	0.95
Systolic BP after pPCI (mmHg)	80–160 (124.55 ± 13.94)	90–150 (123.13 ± 16.62)	0.76
Diastolic BP after pPCI (mmHg)	60–100 (74.85 ± 9.06)	50–100 (72.81 ± 11.54)	0.50
Angina after pPCI, n (%):			
No	30 pts (90.91%)	15 pts (93.75%)	0.733
Yes	3 pts (9.09%)	1 pt (6.25%)	
Resolution of ST segment in ECG, n (%):			
>70%	30 pts (90.9%)	14 pts (87.5%)	
<70%	3 pts (9.1%)	2 pts (12.5%)	0.749

BP, blood pressure; pPCI, primary percutaneous coronary intervention; pts, patients.

Table 4 Procedural and process times measured from door to balloon inflation.

	Radial pPCI	Femoral pPCI	P value
ER door-to-Cath. Lab. time (min)	14–231 (82.48 ± 37.42)	15–210 (76.29 ± 34.32)	0.636
Arrival to Cath. Lab.-to-balloon inflation time (min)	27–45 (34.56 ± 14.2)	25–43 (33.12 ± 12.56)	0.215
ER door-to-balloon inflation time (min)	49–269 (100.32 ± 36.3)	47–245 (97.31 ± 30.37)	0.522

ER, emergency room; Cath. Lab., catheter laboratory.

5.1. Study limitations

There are some important limitations in this study. First, it is a single-center study. Second, it should be emphasized that, this study was a retrospective, non-randomized in patients undergoing primary PCI with acute STEMI. These, could only be overcome by a prospective randomized controlled trial.

Conflict of interest

The authors have no conflict of interest.

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