

Original Article

Outcomes of transradial primary percutaneous intervention from a tertiary cardiac centre in Turkey

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Received May 16, 2015; Accepted May 31, 2015; Epub July 15, 2015; Published July 30, 2015

Abstract: Objectives: The aim was to study transradial approach (TRA) and transfemoral approach (TFA) in terms of feasibility, effectiveness, usefulness, and procedure characteristics in patients having ST-segment elevation myocardial infarction (STEMI) and undergoing primary percutaneous coronary intervention (PCI). Along with the said aim, major adverse cardiovascular events (MACE) at follow-up were also compared. Methods: The present study was conducted on 344 consecutive patients having ST-segment elevation myocardial infarction and qualifying for PCI. Patients were classified into two groups according to radial and femoral approaches. Patients were followed-up for MACE. Results: PCI was found to be successful in all patients. In TRA group the time between the end of the intervention to removal of the sheath, and duration of mobilization and hospitalization were significantly shorter when compared to TFA group (12 ± 2 minutes vs. 240 ± 12 minutes; $P = 0.001$, 13 ± 2 hours vs. 22 ± 2 hours; $P = 0.001$, and 96 ± 45 hours vs. 125 ± 55 hours; $P = 0.001$, respectively). In TRA group, two patients had hematomas greater than 2 cm while fourteen patients in TFA group had hematomas greater than 5 cm (1% vs. 8%; $P = 0.002$). TRA group had lower in-hospital MACE rates (5% vs. 11%; $P = 0.036$). The long terms MACE rates of the groups were similar (23% vs. 22%; $P = 0.888$). Conclusions: In patients with STEMI, PCI via TRA had the same effectiveness as TFA. Moreover, Time to ambulation and rates of bleeding complications were reduced by TRA, which allowed early rehabilitation. TRA reduced the incidence of in-hospital MACEs.

Keywords: Transradial approach, transfemoral approach, primary percutaneous coronary intervention, st-segment elevation myocardial infarction

Introduction

Today, coronary angiography (CAG) examinations and interventional procedures by the transfemoral approach (TFA) are employed by many institutions. TFA is preferred more as it is easier for physicians. However, high rates concerned with local complications have led researchers seek alternative ways of intervention [1]. Moreover, despite improvements in technique, equipment and medical agents, bleeding still remains the major factor in morbidity and mortality in STEMI [2]. Due to lower incidence of complication in vascular access site, relatively high procedural effectiveness, lower hospital costs and improved patient satisfaction when compared to TFA, transradial approach (TRA) has been used widely [1-5]. Primary PCI via TRA decreases the incidence of

major bleeding and provides a lower mortality rate too [6].

Our aim was to study TRA and TFA in terms of feasibility, effectiveness usefulness and procedure characteristics in patients having ST-segment elevation myocardial infarction (STEMI) and undergoing primary percutaneous coronary intervention (PCI). Along with the said aim, major adverse cardiovascular events (MACE) at follow-up were compared too.

Methods

Study population

385 consecutive patients admitted to the emergency unite of Mevlana University Hospital within six hours from the onset of their symptom and undergoing primary PCI were included

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Table 1. Baseline characteristics of the patients

Variable	Radial (n: 174)	Femoral (n: 170)	P value
	Group I	Group II	
Age (years)	63 ± 11	64 ± 12	0.184
Gender (men)	145 (83%)	134 (79%)	0.335
Hypertension	49 (28%)	40 (24%)	0.394
Diabetes mellitus	69 (40%)	59 (35%)	0.373
Smoking	50 (29%)	40 (24%)	0.322
Family history	26 (15%)	22 (13%)	0.645
Pain to balloon time (hour)	3.9 ± 1.8	3.9 ± 1.7	0.305
HR at admission (beats/min)	78 ± 16	79 ± 14	0.108
SBP at admission (mm Hg)	130 ± 28	133 ± 26	0.100
DBP at admission (mm Hg)	88 ± 15	89 ± 14	0.224
Glucose (mg/dl)	159 ± 81	155 ± 67	0.535
Total Cholesterol (mg/dl)	194 ± 51	201 ± 45	0.438
Triglycerides (mg/dl)	158 ± 73	171 ± 74	0.116
HDL (mg/dl)	39 ± 9	40 ± 8	0.145
LDL (mg/dl)	131 ± 32	127 ± 34	0.216
White Blood Cell (10 ³ /μL)	11.2 ± 3.5	10.7 ± 3.0	0.144
Hemoglobin (g/l)	14.2 ± 2.7	13.9 ± 1.9	0.265
Mean Platelet Volume	9.9 ± 0.8	9.9 ± 0.9	0.754
Neutrophil/Lymphocyte ratio	4.2 ± 2.9	4.3 ± 3.1	0.726
Infarction localization			
Inferior	73 (42%)	67 (39%)	0.631
Infero-postero-lateral	17 (10%)	18 (11%)	0.802
Anterior	84 (48%)	85 (50%)	0.749

Data are expressed as mean ± standard deviation for normally distributed data and percentage (%) for categorical variables; HR-heart rate; DBP-diastolic blood pressure; SBP-systolic blood pressure.

in the present study. A total of forty one patients composed of those lost to follow-up, those having no documented follow-up after primary PCI (n = 33), those necessitating an intra-aortic balloon pumping (n = 2) and those having a height below 150 cm (n = 1) were excluded from the study. The final study population was 344 patients divided into two groups. In group I, there were one hundred seventy four patients undergoing coronary angiography and PCI via TRA (age 63 ± 11, 145 men) and group II consisted of 170 patients via TFA (age 64 ± 12, 134 men). Before the procedure was started, modified Allen test where the adequate collateral blood flow was assessed using a pulse oximeter was used. When an abnormal result was obtained in the right upper limb, modified Allen test was repeated on the left one. TFA was performed when the modified Allen test failed to present normal results in both of the extrem-

ities. Radial artery puncture was performed using a 21 G needle and 0.021 inch wire while femoral artery puncture was performed using an 18 G needle and 0.035 inch wire. Standard 5 F Judkins diagnostic catheter and 6 F vascular sheath were used for coronary angiography.

After receiving intravenous heparin (100 U/kg) and 600 mg loading dose of clopidogrel, the patients underwent balloon pre-dilation with coronary balloon and stent (bare metal or drug-eluting stent) implantation. In the radial group, the vascular sheath was removed following the procedure while the radial artery was compressed for 1 to 2 hours using a Terumo Band. In femoral group, the vascular sheath was removed after 4-6 hours by taking into account the value of the activated coagulation time (ACT). Regarding the study protocol, an approval was obtained from the medical ethics committee of Selcuk University. An informed consent was taken from all the patients.

Laboratory analysis

Antecubital venous blood samples required for the laboratory analysis were obtained from all the patients at baseline. The measurements of routine blood parameters were carried out within 5 minutes of sampling using Sysmex K-X-21N auto analyzer.

Follow-up, adverse cardiovascular events and definitions

Follow-up data was obtained from the hospital records and through interviews with the patients, their families or their primary care physician. Obtaining a TIMI 3 flow rate was considered as a successful PCI. Clinically overt blood loss with a 3 g/dL decrease in hemoglobin, intracranial, intraocular, or retroperitoneal hemorrhage, any decrease in hemoglobin > 4 g/dl without overt bleeding, and transfusion requirement of ≥ 2 units of blood products were defined as the major bleeding complications.

Non-fatal myocardial infarction, in-stent thrombosis, cardiovascular mortality during the in-hospital or long-term follow-up period, and

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Table 2. Angiographic results of the patients

Variable	Trans Radial group I	Trans Femoral group II	P value
<i>Number of narrowed coronary arteries (n, %)</i>			
1	96 (55%)	92 (54%)	0.661
2	56 (32%)	44 (26%)	
3	22 (13%)	34 (20%)	
<i>Infarct-related artery (n)</i>			
Left anterior descending artery	84	85	0.829
Circumflex coronary artery	17	18	0.724
Right coronary artery	68	62	0.661
Safen vein graft	5	5	1.000
<i>Narrowed vessels (n)</i>			
Left main coronary artery	2	2	1.000
Left anterior descending artery	113	113	0.821
Circumflex coronary artery	62	73	0.186
Right coronary artery	90	88	0.992
<i>Initial TIMI flow grade (n, %)</i>			
0	149 (87%)	152 (87%)	0.774
1	17 (10%)	18 (11%)	
2	5 (3%)	3 (2%)	
<i>Final TIMI flow grade (n, %)</i>			
1	5 (3%)	4 (2%)	0.422
2	14 (8%)	20 (12%)	
3	155 (89%)	147 (86%)	
Activated coagulation time (second)	272 ± 60	271 ± 60	0.873
Glycoprotein IIb/IIIa antagonist (n, %)	41 (24%)	50 (29%)	0.224
Volume of contrast (ml)	125 ± 25	120 ± 17	0.975
Stent implantation (n, %)	174 (100%)	170 (100%)	1.000

Data are expressed as mean ± standard deviation for normally distributed data and percentage (%) for categorical variables. TIMI-Thrombolysis in Myocardial Infarction.

stroke were defined as the major adverse cardiovascular events (MACE). A total occlusion documented by angiography was the proof of in-stent thrombosis. Non-fatal myocardial infarction was defined as recurrent chest pain and/or new electrocardiographic changes along with a ≥ 20% rise in cardiac biomarkers after recurrence. Cardiovascular mortality was defined as deaths due to myocardial infarction, cardiac arrest or other cardiac causes. The total procedure time was the time passing between arrivals to the catheter laboratory to the removal of catheter from the sheath.

Statistical analysis

Continuous variables were expressed as mean ± standard deviation and categorical variables were defined as percentage and compared using Chi-square test. Differences between the

two groups were checked for significance with the two-tailed Student's t-test for independent variables. $P < 0.05$ was considered significant. SPSS Statistical Software (version 15.0 for Windows; Chicago, IL) was used in all the statistical analysis.

Results

The mean follow-up period was 13 months (1-20 months). Baseline characteristics of the patients are given in **Table 1**. Demographic features, cardiovascular status on admission, risk factors for coronary heart disease and MI localization in ECG did not show any difference between the groups.

The groups did not show any difference in terms of angiographic data either (**Table 2**). Following PCI, TIMI 3 flow was maintained in 89% and

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Table 3. Time intervals during coronary angiography and PCI

Variable	Radial (n = 174) group I	Femoral (n = 170) group II	P value
Arrival in the Catheter lab time (minutes)	19 ± 6	19 ± 8	0.316
Total procedure time (minutes)	38 ± 7	37 ± 8	0.327
Time of fluoroscopy (minutes)	10.8 ± 6.7	10.6 ± 5.9	0.824
The time until the end of the intervention to remove the sheath (minutes)	12 ± 2	240 ± 12	0.001
Hospitalization ± SD (hours)	96 ± 45	125 ± 55	0.001
Mobilization (hours)	13 ± 2	22 ± 2	0.001

Data are expressed as mean ± standard deviation for normally distributed data and percentage (%) for categorical variables.

Table 4. In-hospital and long term follow up and MACE

Variable	Radial (n = 174) group I	Femoral (n = 170) group II	P value
Major bleeding	0 (0%)	1 (0.6%)	0.495
Minor bleeding	4 (2%)	14 (8%)	0.013
Fatal bleeding	0 (0%)	0 (0%)	1.000
Requiring transfusion	0 (0%)	1 (0.6%)	0.495
Drop in hemoglobin > 3 g/dL	3 (2%)	6 (4%)	0.336
Intracranial hemorrhage	0 (0%)	0 (0%)	1.000
Minor hematoma	3 (2%)	10 (6%)	0.043
Hematoma > 5 cm	2 (1%)	14 (8%)	0.002
Aneurysm	0 (0%)	3 (2%)	0.078
In-hospital MACE	8 (5%)	18 (11%)	0.036
Acute thrombosis	4 (2%)	10 (6%)	0.094
Nonfatal MI	5 (3%)	10 (6%)	0.146
Cardiovascular mortality	3 (2%)	3 (2%)	1.000
Stroke	0 (0%)	0 (0%)	1.000
Repeated revascularization	5 (3%)	4 (2%)	0.750
Long term MACE	40 (23%)	38 (22%)	0.888
Instent restenosis	31 (18%)	33 (19%)	0.807
Nonfatal MI	13 (8%)	10 (6%)	0.345
Cardiovascular mortality	5 (3%)	5 (3%)	1.000
Stroke	0 (0%)	0 (0%)	1.000

MACE: Major adverse cardiovascular events, MI: Myocardial infarction.

87% patients in group I and group II, respectively ($P = 0.460$). Tirofiban were administered at similar rates in both groups (24% vs. 29%, $P = 0.224$). The volume of contrast and time of fluoroscopy did not show any significant difference between the groups. Similarly, the groups did not differ in terms of time of arrival to the catheter laboratory and the total procedure time in catheter laboratory (**Table 3**).

In hospital and long-term follow-up results

TRA group had a significantly shorter time to mobilization (13 ± 2 h vs. 22 ± 2 h; $P = 0.001$) and length of hospitalization (96 ± 45 h vs. 125

± 55 h; $P = 0.001$). Blood transfusing was required in none but one patient in TFA group due to severe bleeding. Minor bleeding complications were significantly lower in TRA group (2% vs. 8%; $P = 0.015$). When both groups were compared, the long-term MACE rates were similar (23% vs. 22%; $P = 0.888$) while TRA group had lower in-hospital MACE rates (5% vs. 11%; $P = 0.036$) (**Table 4**).

All those having complaints on radial or femoral access sites after PCI underwent ultrasonography. Two patients in TRA group had a total occlusion of the radial artery without any ischemic events. Ultrasonographic examination revealed minor hematomas in three and ten patients in TRA and TFA groups, respectively (1.7% vs. 5.9%; $P = 0.005$). Two patients in group I had hematomas greater than 2 cm while fourteen patients had hematomas greater than 5 cm in group II (1.1% vs. 8.2%; $P = 0.002$). Three patients in TFA group had pseudo-aneurysm (0% vs. 2%; $P = 0.078$).

Arteriole-venous fistula present in none of the patients in the study population.

Discussion

In our study we showed that TRA was safe, feasible, and at least as effective as TFA and has the advantages of shorter hospital stays and lower hospital complication rates.

TRA, allowing early ambulation and shorter hospital stay, has been shown to reduce rates of vascular complications and access-site bleeding but increase access-site crossover or primary failure [1-4, 6-10]. It has gained popularity

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and started to be used worldwide in recent years [3, 11, 12]. Radial access is used in less than 10% of all coronary angiographic procedures worldwide. This could be related with the assumptions that there is an excessive failure rate and the procedure takes a longer time in TRA. Gathering more data on this issue may lead interventional cardiologist to change their practices [13, 14].

The use of TRA has been limited by the technical difficulties and the long learning curve too. Moreover, procedural success has been shown to be associated with the procedural volume and expertise of the physician [15, 16]. All the studies have also shown the necessity of a learning curve [1, 12, 17]. New generation hydrophilic sheaths and novel pharmacological cocktails decreasing radial artery spasm have increased the success rates associated with TRA. Additionally, thinner guiding catheters which have been used progressively through the years simplified the coronary engagement and balloon or stent delivery greatly [18-22]. Despite beliefs that radial artery access is more difficult and time consuming when compared to femoral artery access, the procedure has become relatively easier due to increased surgeon expertise and newly diagnosed catheters and equipment. In a study employing meta-analysis in heterogeneous groups, Agostoni et al. showed that there was no significant difference between transradial and transfemoral groups in terms of procedure time [1]. They showed that the average coronary procedure time was 35 minutes in transradial group and 33.8 minutes in transfemoral group, while the average fluoroscopy time was 8.7 minutes in transfemoral group and 9.8 minutes in transradial group [1]. Chodór *et al.* found that the total procedure time was 58.3 min and 55.1 min in TFA and in TRA, respectively [23]. Similar to the previous findings, we did not find any significant difference in terms of procedure time.

Obtaining TIMI 3 flow in STEMI patients is accepted as the main angiographic evidence for the success of the procedure. It was found in TENMPURA study, conducted on 151 patients, that primary stent implantation by TRA was feasible when compared to TFA [17]. In the RADIAL-AMI study conducted on 50 patients having MI and undergoing PCI with TRA (25 patients) or TFA (25 patients), Cantor et al. investigated TRA resulted in earlier ambulation,

improved patient and fewer vascular complications. They found that primary and rescue PCI could be performed with high success rates and low complication rates using either radial or femoral access [24].

In a RADIAMI study conducted on 100 STEMI patients, TRA and TFA groups were compared in terms of their success rates and length of hospital stay [23]. 88% of the TRA patients were observed to have TIMI 3 flow while the said ratio was 92% in TFA patients. TIMI 2 flow was obtained in 12% and 65 of TRA and TFA patients, respectively. TRA and TFA groups did not show any difference in terms of duration of hospitalization (6.26 ± 3.86 d vs. 6.75 ± 4.02 d, $P = 0.772$).

In our study, we conducted a retrospective study on 344 patients with STEMI who had undergone primary PCI by using similar numbers of patients in the TRA and TFA groups. Although it was not statistically significant, our study also showed that more patients in TRA group reached TIMI 3 flow (89% TRA vs. 87% TFA, $P = 0.460$). The stent was placed successfully after performing PTCA in all patients in both TRA and TFA groups. High and similar TIMI 3 flow values were obtained in both groups. Early patient mobilization and short hospitalization were the most important advantages in TRA group (patient mobilization: 13.3 ± 2.1 h vs. 21.9 ± 2.2 h; $P = 0.001$), (duration of hospitalization: 96 ± 45 h vs. 125 ± 55 h, $P = 0.001$). These results are consistent with the results obtained in previous studies. Based on our findings, we believe that TRA has a major advantage in terms of low cost and effectiveness.

When compared to TRA, major complications experienced in puncturing of the artery are not more prevalent in TFA, as confirmed by randomized studies [2-4, 14, 23, 25]. Bleeding complications are decreased in TRA due to early removal of the vascular sheath from the radial artery, using smaller sheaths and administering heparin rarely after the procedure. It has been established by some several studies that bleeding complications are less and thus the mortality rates are lower in TRA when compared to TFA [2, 6, 13, 26].

In the TEMPURA study, those in the transfemoral group had bleeding complications but the difference between the groups in terms of such

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complications was not statistically significant (3% vs. 0%; $P = 0.14$) [17]. Similarly, Cantor et al. did not observe any major bleeding complications in either group [24]. It was reported in the RIVAL trial that the transradial group had lower access site complication rates (1.4% vs. 3.7%, $P < 0.0001$) while the groups did not show any difference in terms of incidence of major bleeding [2]. Consistent with the previous studies, minor bleeding complications occurred less frequently in the transradial group than in the transfemoral group (2.3% vs. 8.2%; $P = 0.015$). Severe bleeding cases requiring blood transfusion were observed only in TFA group.

20-50% of STEMI patients undergoing PTCA develop MACE during follow-up [25, 27-29]. Recently published RIVAL trial studied whether TRA was superior to TFA in patients having ACS and found that both TRA and TFA were effective and safe for PCI. More than seven thousand patients were enrolled in the said study and 28% were STEMI. Transradial and transfemoral groups did not show any significant difference in terms of primary endpoints (death, myocardial infarction, stroke, major bleeding) (3.7% vs 4%, $P = 0.5$). The sub-group analysis revealed that the primary endpoints were lower in TRA group in patients with STEMI (3.1% vs. 5.2%, $P = 0.026$). The groups were similar in terms of in-hospital mortality, too.

In our study, the groups were similar regarding repeated revascularization of the IRA (3.4% vs. 2.4%; $P = 0.750$). In-hospital MACE rate was lower in TRA group (5% vs. 11%; $P = 0.036$), while long-term MACE rates did not show any difference (23% vs. 22%; $P=0.888$). Having decreased morbidity and mortality in transradial approach has been thought to be related with decrease in venous thromboembolic/pulmonary embolism due to early ambulation, decrease in nasocomial infections as a result of early discharge, decreased renal failure due to decreased periprocedural renal embolism, or unknown reasons.

Conclusion

In STEMI patients, PCI with transradial approach can be performed as successfully as TFA when done by expert hands. Transradial approach also has the advantages of shorter duration of hospitalization and lower incidence of in-hospital adverse cardiovascular events.

Disclosure of conflict of interest

None.

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