

Comparison of Transradial versus Transfemoral Approach for Primary Percutaneous Coronary Intervention in Patients with ST-Elevation Myocardial Infarction

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Abstract

Background: Transradial approach has been used widely around the world for its unique advantages, but its use for primary percutaneous coronary intervention (pPCI) remains controversy. This study was conducted to explore the difference of major adverse cardiovascular and cerebral events (MACCE) and bleeding complications between transradial and transfemoral approach for pPCI in patients with ST-elevation myocardial infarction (STEMI).

Methods: Patients underwent pPCI for STEMI from January 2002 to December 2009 in Beijing Friendship Hospital were recruited in our study. Patients were divided into two groups: transradial intervention group (TRI) and transfemoral intervention group (TFI) according to the different interventional approaches.

Results: A total 661 eligible patients were recruited in this retrospective observational study. TRI was used in 340 STEMI patients and TFI in 321 patients. There was no statistical difference in baseline characteristics between the two groups. More patients in TRI group crossed over to transfemoral access than TFI group crossed over to transradial access [4.41% (TRI) vs 1.24% (TFI), $p < 0.05$]. MACCE, especially all-cause deaths, in TFI group during in-hospital and one-month follow up were more than in TRI group [MACCE, 2.94%(TRI group) vs 6.54%(TFI group), $p < 0.05$; death, 3.82%(TRI group) vs 7.47%(TFI group), $p < 0.05$]. Major bleeding between the two groups has no statistical difference, but access site complications, especially hematoma, were more frequent in TRI group than in TFI group [access site complications, 1.76%(TRI group) vs 5.6%(TFI group), $p < 0.01$; hematoma, 1.17%(TRI group) vs 3.73%(TFI group), $p < 0.05$]. At the same time, TRI shortened the hospitalization days compared to TFI group [5.4±2.6(TRI group) vs 7.1±3.7(TFI group), $p < 0.01$].

Conclusions: Transradial approach for pPCI in patients with STEMI is associated with less vascular access site complications, especially hematoma, and MACCE, especially death, and shorter hospitalization time than transfemoral approach.

Keywords: Transradial intervention; Transfemoral intervention; ST-elevation myocardial infarction

Introduction

Percutaneous coronary intervention (PCI) is an integral part of treatment for ischemic heart disease. Coupled with evidence-based pharmacological strategies, the use of PCI in appropriate patients reduces morbidity and mortality across the spectrum of risk [1]. Continual evolution of antithrombotic therapy and device technology has resulted in the application of PCI to a wider population of patients [2]. Procedural success rates are high and ischemic complications relatively rare [3], thus, attention has turned to periprocedural bleeding complications [4].

Bleeding events and the consequent need for transfusion are independent determinants of survival in acute coronary syndromes. Their relation to short- and long-term mortality has been demonstrated in major randomized trials as well as through the evaluation of registries. [5-8] Clinical trials evaluating new pharmacological strategies have focused on reducing this risk [9,10]; however, absolute reductions in bleeding risk have been modest across most studies. A growing body of evidence suggests that a procedural strategy-using the transradial rather than the transfemoral approach for PCI- is associated with comparatively larger reductions in bleeding complications than those achieved with any anticoagulant strategy.

Patients with ST-elevation myocardial infarction (STEMI) very frequently require potent adjunctive antithrombotic therapy, including

glycoprotein IIb/IIIa inhibitors and hence, are especially at risk for access site related bleeding complications [11]. Recent studies has further indicated that transradial approach is safe and efficacious for elective coronary angiographic studies of outpatients [12], elective left main coronary intervention [13]. So currently, the transfemoral and transradial approach are the most popular vascular access routes for PCI worldwide. While the safety and efficacy of the transfemoral approach for acute myocardial infarction (AMI) patients undergoing primary PCI have been extensively discussed [14,15], relevant issues for using the transradial approach for primary PCI have not been fully investigated [16] in an era when transradial approach for primary PCI is already daily practice in some medical centers [17,18]. A lot of

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experiences and studies from single centers have been reported the efficiency and safety of transradial approach for primary PCI, but the results are not consistent with each other [16,19-26]. Therefore, our study aimed to compare the clinical results and bleeding complications of primary percutaneous coronary intervention (pPCI) in patients with STEMI through transradial and transfemoral approach.

Methods

Study population

Ours was a retrospective observational study. Data on consecutive STEMI patients at Beijing Friendship Hospital who underwent pPCI within 12 hours of the onset of symptoms were retrospectively collected from January 2002 to December 2009. The diagnosis of STEMI was based on the following: > 30 minutes of continuous chest pain; ST elevation > 2.0 mm in ≥ 2 contiguous electrocardiographic (ECG) leads. There were not any exclusion criteria in our study. The study protocol was reviewed and approved by the ethical committee at Beijing Friendship Hospital. Informed consent to participate in this study was obtained from all patients.

The patients were initially divided into two groups based on interventional approaches. The patients underwent pPCI via transradial approach were transradial intervention group (TRI), who underwent pPCI via transfemoral approach were transfemoral group (TFI).

Coronary intervention

All patients received an intravenous (IV) bolus injection of 2,000 U of heparin, 300mg aspirin and 600mg clopidogrel before angiography. Diagnostic coronary angiography was performed via the femoral or radial approach using the Judkins technique. Approach cross-over occurred when the initial approach failed during coronary angiography or PCI, such as failed puncture, tortuous road, and difficult guiding catheter (GC) engagement and failed PCI for insufficient backup of GC. After an additional IV or intra-arterial bolus injection of 6,000 U of heparin, PCI was performed. Primary PCI was done using the conventional technique, and coronary stents were used without restrictions. The infarction related artery (IRA) was the only target of the procedure. Intra-aortic balloon counterpulsation (IABP) was performed in cases of hemodynamic instability and temporary pacemaker was implanted when necessary. Usage of glycoprotein IIb/IIIa inhibitors was determined by the operators before March 2005 and glycoprotein IIb/IIIa inhibitors was used as a routine way to antithrombotic strategy after March 2005 when tirofiban- a kind of glycoprotein IIb/IIIa inhibitor- was clinically used widely in China. When visible thrombus was found, thrombus aspirator was used for thromboectomy during PCI. TIMI grade 3 coronary flow in the treated vessel with a residual stenosis < 20% was considered successful PCI. Patients received conventional drug treatment according to individual need, which was determined by the attending physician. The patients with stents received anticoagulation with a clopidogrel and aspirin regimen (clopidogrel 75 mg once a day and aspirin 100 mg once a day).

Echocardiography analysis

A two-dimensional echocardiogram was performed in-hospital follow up for the evaluation of left ventricular (LV) wall motion and LV ejection fraction (LVEF). The analysis was carried out by two observers blinded to the clinical and angiographic data.

Clinical follow up

Clinical follow-up data were obtained from out-patient examinations or by the investigators who made telephone contact with patients at about 1 month post PCI. In-hospital and 1-month complications included major adverse cardiovascular and cerebral events (MACCE) including all-cause death, myocardial infarction, target lesion revascularization (TLR) and cerebrovascular accident. Bleeding complications were also followed up at the same time. Major bleeding was defined as one of the following: fatal bleeding, intracranial hemorrhage or bleeding associated with a ≥ 3 g/dL hemoglobin drop or requiring transfusion or requiring surgery (pseudoaneurysms requiring thrombin injection or ultrasound compression were excluded). In-hospital days, radial occlusion and vascular access site complications (minor bleeding, hematoma, pseudoaneurysm and artery-venous fistula) were collected by the follow-up doctors.

Statistical analysis

Data are expressed as mean \pm SD. Continuous data were analyzed using the t-test and categorical data were analyzed using the chi-square test or fisher's exact test. Statistical analysis was performed using SPSS software, version 15.0 (SPSS, Inc., Chicago, Illinois). Statistical significance was defined as $P < 0.05$.

Results

Baseline clinical characteristics

A total of 661 consecutive eligible pPCI cases were performed from January 2002 to December 2009, among whom 321 were performed by the transfemoral approach and 340 by the transradial approach. Baseline clinical characteristics of the patients grouped by interventional approaches are provided in Table 1. There were no

	TRI group	TFI group
Number of patients [n (%)]	340(51.56)	321(48.43)
Age (years)	64.5 \pm 9.74	65.9 \pm 12.8
Male gender [n (%)]	264(77.64)	253(75.7)
Systemic hypertension [n (%)]	176(51.76)	163(50.77)
Diabetes mellitus [n (%)]	115(33.82)	104(32.39)
Hypercholesterolemia [n (%)]	100(29.41)	97(30.21)
Current smoker [n (%)]	191(56.17)	180(56.07)
Previous MI [n (%)]	21(6.17)	19(5.91)
Location of MI		
Anterior [n (%)]	188(55.29)	171(53.27)
Inferior or posterior [n (%)]	152(44.7)	150(46.72)
Killip Class		
I [n (%)]	215(63.23)	201(62.61)
II [n (%)]	79(23.23)	73(22.74)
III or IV [n (%)]	46(13.52)	47(14.64)
Concomitant therapy		
Aspirin [n (%)]	335(98.52)	318(99.06)
Clopidogrel [n (%)]	336(98.82)	319(99.37)
Beta-blocker [n (%)]	311(91.47)	296(92.21)
ACEI/ARB [n (%)]	298(87.64)	274(85.35)
Statin [n (%)]	322(94.7)	299(93.14)

Values are presented as mean \pm standard deviation or n (%).

*Denotes statistical difference ($p < 0.05$) compared to normal group.

TRI,transradial intervention;TFI,transfemoral intervention; MI, myocardial infarction; ACEI, angiotensin converting enzyme inhibitor; ARB,angiotensin receptor blocker

Table 1: Baseline characteristics of study population.

differences between the groups in term of the indices collected in the Table 1 (details in Table 1).

Coronary angiographic and PCI outcomes

More patients in TRI group crossed over to transfemoral access than in TFI group crossed over to transradial access [4.41% (TRI group) vs 1.24% (TFI group), $p < 0.05$]. No significant difference was found between the two groups in other indices (details in Table 2).

Clinical results, echocardiographic outcomes and access complications

Compared with TFI group, less MACCEs happened in TRI group in hospital and at one-month follow up [in hospital, 2.94% (TRI group) vs 6.54% (TFI group), $p < 0.05$; one-month, 3.82% (TRI group) vs 7.47% (TFI group), $p < 0.05$]. More patients of TFI group died in hospital and at one-month follow up than TRI group[in hospital, 1.17% (TRI group) vs 3.73% (TFI group), $p < 0.05$; one-month follow up, 1.47% (TRI group) vs 3.73% (TFI group), $p < 0.05$] and hospitalization time was longer in TFI than in TRI group [5.4 ± 2.6 (TRI group) vs 7.1 ± 3.7 (TFI group), $p < 0.01$]. There were no difference of major bleeding between the groups, but significant difference was observed in vascular access site complications [1.76% (TRI group) vs 5.6% (TFI group), $p < 0.01$],

especially hematoma [1.17% (TRI group) vs 3.73% (TFI group), $p < 0.05$]. Of course, there were more occluded radial artery in TRI than in TFI group [4.11% (TRI group) vs 0.31% (TFI group), $p < 0.01$]. (details in Table 3 and Figure 1-3).

Discussion

The use of transradial access for PCI has increased dramatically since the first report of transradial cardiac catheterization in 1989 and PCI in 1993. As expertise has evolved and technical hurdles have been overcome, an increasing number of operators have adopted this approach as default. It offers the benefit of rapid mobilization postprocedure and is favored by many patients who have undergone cardiac catheterization and PCI procedures from both the transfemoral and transradial approaches in the past. Potential benefits include ease of in-laboratory sheath removal, early ambulation, and facilitated discharge as well as cost savings. Furthermore, the ability to detect and control access site hemorrhage promptly is facilitated and is especially relevant with the substantial anticoagulation and antiplatelet regimens used during and after PCI, which potentially benefits patients at high risk of thrombosis, such as, acute coronary syndrome (ACS).

	TRI group	TFI group
Time from onset to reperfusion (h)		
	6.5±2.4	6.4±3.5
Access site crossover	15(4.41)	4(1.24)*
Number of narrowed coronary arteries		
0 [n (%)]	2(0.58)	1(0.31)
1 [n (%)]	173(50.88)	161(50.15)
2 [n (%)]	98(28.82)	100(31.15)
3 [n (%)]	67(19.7)	59(18.38)
Pre-PCI TIMI flow		
0 [n (%)]	284(83.52)	277(86.29)
1 [n (%)]	27(7.94)	19(5.91)
2 [n (%)]	18(5.29)	15(4.67)
3 [n (%)]	11(3.23)	10(3.11)
Post-PCI TIMI flow		
0 [n (%)]	2(0.58)	2(0.69)
1 [n (%)]	7(2.05)	5(1.55)
2 [n (%)]	23(6.76)	20(6.23)
3 [n (%)]	308(90.58)	294(91.58)
IRA		
LM[n (%)]	7(2.05)	11(3.42)
LAD[n (%)]	178(52.35)	171(53.27)
LCX[n (%)]	44(12.94)	37(11.52)
RCA[n (%)]	113(33.23)	106(33.02)
GP IIb/IIIa antagonist [n (%)]	254(74.7)	237(73.83)
Contrast dose(ml)	110±29	105±38
Devices used in PCI		
Thrombus aspirator [n (%)]	259(76.17)	232(72.17)
IABP[n (%)]	12(3.52)	17(5.29)
Temporary pacemaker[n (%)]	22(6.47)	19(5.91)
Stent [n (%)]	330(97.05)	316(98.44)
DES [n (%)]	309(90.88)	299(93.14)
Underwent secondary PCI of non-IRA[n (%)]	56(16.47)	48(14.95)

Values are presented as mean ± standard deviation or n (%).

*Denotes statistical difference ($p < 0.05$) compared to normal group.

TRI, transradial intervention; TFI, transfemoral intervention; PCI, percutaneous coronary intervention; IRA, infarction related artery; DES, drug eluting stent; IRA, infarction related artery; IABP, intraaortic balloon pump; LAD, left anterior descending; LCX, left circumflex; RCA, right coronary artery; GP, glucoprotein

Table 2: Coronary angiographic and percutaneous coronary interventional outcomes

	TRI group	TFI group
Success rate of PCI [n (%)]	308(90.58)	294(91.58)
In-hospital		
MACCE [n (%)]	10(2.94)	21(6.54)*
Myocardial infarction[n (%)]	3(0.88)	7(2.18)
Death [n (%)]	4(1.17)	12(3.73) *
LVEF(%)	53.2±11.4	52.6±13.7
At one-month follow up		
MACCE [n (%)]	13(3.82)	24(7.47)*
Myocardial infarction[n (%)]	5(1.47)	10(3.11)
Death [n (%)]	5(1.47)	12(3.73) *
LVEF (%)	54.5±10.6	53.2±16.5
Hospitalization time(days)	5.4±2.6	7.1±3.7**
Major bleeding[n (%)]	4(1.17)	10(3.11)
Vascular access site complications [n (%)]	6(1.76)	18(5.6) **
Hematoma[n (%)]	4(1.17)	12(3.73) *
Pseudoaneurysm[n (%)]	1(0.29)	3(0.93)
Artery-venous fistula[n (%)]	1(0.29)	3(0.93)
Radial occlusion[n (%)]	14(4.11)	1(0.31) **

Values are presented as mean ± standard deviation or n (%).

*Denotes statistical difference ($p < 0.05$) compared to normal group; **Denotes statistical difference ($p < 0.01$) compared to normal group.

TRI,transradial intervention;TFI,transfemoral intervention;PCI,percutaneous coronary intervention;MACCE,major adverse cardiovascular and cerebrovascular events; LVEF, left ventricular ejection fraction.

Table 3: Clinical results, LVEF and access complications.

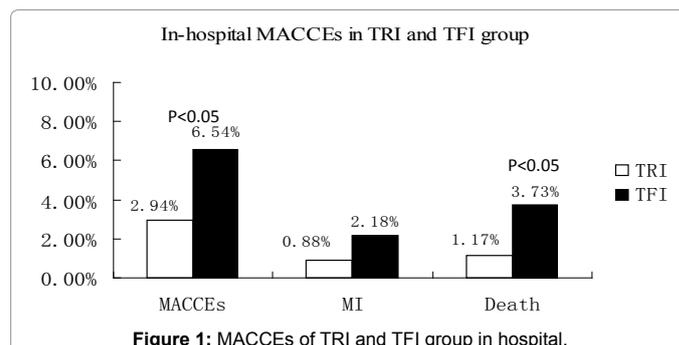


Figure 1: MACCEs of TRI and TFI group in hospital.

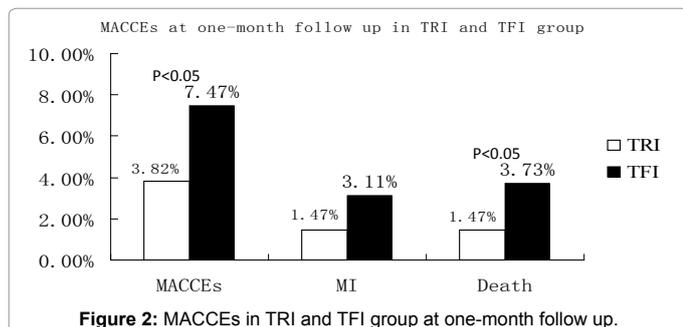


Figure 2: MACCEs in TRI and TFI group at one-month follow up.

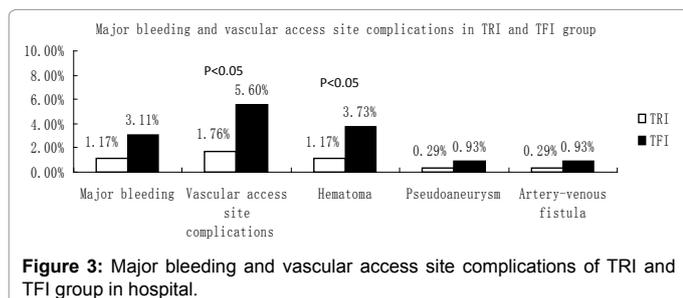


Figure 3: Major bleeding and vascular access site complications of TRI and TFI group in hospital.

Many studies have been published comparing TFI and TRI in patients with MI [16,19–21]. These studies have most often been conducted in small groups of patients. A meta-analysis (23 trials; >7,000 patients) by Jolly et al. [22] has been published which included randomised studies comparing diagnostic and PCI procedures in patients with and without MI performed via femoral approach against procedures performed via transradial approach. This review assessed the effects of vascular access site on the incidence of bleeding complications and ischemic events and concluded that TRI reduces the risk of periprocedural major bleeding and major adverse events in the STEMI setting. Recently, RIVAL (Radial Vs. femoral access for coronary intervention in patients with acute coronary syndrome study) released in ACC 2011 and RIFLE STEACS (Radial versus Femoral Randomized Investigation in ST Elevation Acute Coronary Syndrome) presented in TCT 2011 which were multiple-center, prospective, randomized and controlled trials confirmed that the transradial access for pPCI reduces mortality during primary PCI compared to transfemoral access. As experiences about TRI accumulated and evidences about TRI published, it has been proved that TRI has the same safety and efficiency during elective PCI and pPCI as TFI, specific advantages compared to TFI and maybe saves lives for its decreasing bleeding complications, which some ongoing trials are trying to confirm.

Similar to the studies mentioned above, the major finding of our single-center, retrospective and observational study is that, compared with a transfemoral approach, transradial approach for pPCI in STEMI patients is associated with less vascular access complications, cardiac mortality in a modern-day setting characterized by a high rate of stenting and GP IIb/IIIa inhibitor use, which is a real phenomenon of day-time pPCI work in China.

As mentioned before, bleeding events have been demonstrated to be associated with an increased risk of MACE including death and recurrent ischemic events in multiple studies. Although the exact relation between bleeding events and higher mortality is unclear, obviating bleeding seems equally important as recurrent ischemic events after PCI [23]. Possible mechanisms of worse outcome after a bleeding event might include bleeding-induced imbalance of the coagulant/

anticoagulant mechanisms (consumption of the anticoagulant proteins, higher platelet turnover), adverse effects induced by transfusion, and premature cessation of antithrombotic/anticoagulant therapy [22]. As a consequence of the combined and more potent anticoagulant and antiplatelet medications, bleeding is getting to be more frequent after acute intervention. Arterial puncture used for intervention is a predominant predilection site as the majority of bleeding originates from here. Reduction of the frequency of bleeding and mortality using the transradial approach has been recently demonstrated in a large registry study that included all-comers for PCI [24]. Similar reduction has been demonstrated in transradially treated cases in an observational study that included over a thousand non-ST segment elevation acute coronary syndrome patients [25]. Furthermore, two recent comprehensive meta-analyses of randomized comparisons of transradial and transfemoral accesses demonstrated that radial access reduces bleeding and access site complications. Neither of them found a significant link between the frequency of adverse events or mortality. It should be noted that these analyses included studies performed predominantly in elective settings and thus the benefit that the higher risk patients may have been concealed by the lower risk-cases that may have formed the majority. This study found decreased access site complications, including hematoma, pseudoaneurysm and artery-venous fistula in TRI group compared to TFI group which probable contributed to the mortality observed in our study at the same time.

Distrust supported by technical difficulties, higher failure rate, and increased radiation exposure still limits general acceptance of TRI. This uncertainty is graver in the setting of AMI, when the delay caused by unsuccessful arterial access may adversely affect the clinical outcome. Agostoni et al. [26] reported reduction of the entry-site complications at the expense of more frequent entry failure requiring crossover to a second entry site with significant heterogeneity among studies. They noted that this may have been due to an initial learning curve by cardiologists using the radial technique that was followed by a progressive equalization in technical skills for both the radial and femoral approaches through the years. In our study, the success rate and symptom to balloon time was the same in TRI and TFI groups. In addition, TRI had reduced vascular access site complications, hematoma and shorten the hospitalization time. Of course, access site crossover rate and radial arterial occlusion rate was higher in TRI group than TFI group.

Conclusions

The evolution of PCI practice has led to an emphasis on minimizing post-procedural vascular and bleeding complications while maintaining procedural success. Based on the results of this study, we can conclude that transradial approach for pPCI in STEMI patients is associated with less vascular access site complications, cardiac mortality and shorter hospitalization time than transfemoral approach. At the same time, transradial approach acquires the same success rate of pPCI as transfemoral approach.

Limitations

First, the number of study participants was limited. The statistical power thus might not be adequate for any negative data. Secondly, it was a single-center, retrospective, uncontrolled and observational study, which was not comparable to the RIVAL or RIFLE STEACS mentioned above. It just was considered as accumulated experiences, but implied the real-world practice. Furthermore, these findings warrant further investigation regarding the role of transradial approach for pPCI in

STEMI patients. Thirdly, technique of the operators in our study was difficult to control in both groups, which induced bias.

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