Comparative study on transradial versus transfemoral approach for primary percutaneous coronary intervention in Chinese patients with acute myocardial infarction

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ABSTRACT

الأهداف: مقارنة طريقة التدخل الجراحي للشريان التاجي عبر الزند (PCI) والطريقة الأخرى عبر الفخذ لدى المرضى الصينيين المصابين باحتشاء عضلي قلبي حاد (AMI).

الطريقة: من الفترة أغسطس 2005 حتى سبتمبر 2008 قمنا عشوائياً بتقسيم عدد 200 مريض مصاب باحتشاء في عضلة القلب (AMI) إلى مجموعة (TRI) التي أجري لها التدخل الجراحي عبر الزند والمجموعة الأخرى (TFI) التي أجري لها التدخل الجراحي عبر الفخذ. أجريت الدراسة قسم القلب – مستشفى السكان العاشر – جامعة تونغجي – شانغهاي – الصين. خلال العملية. تمت مراقبة نجاح عملية الثقب ونجاح الإجراء والدعامات المستخدمة ومقدار تيروفيبان المستخدم. كما تم تسجيل وقت الإجراء، وبعد الإجراء، تمت دراسة الأحداث القلبية الرئيسية العكسية (MACEs) والمضاعفات الوعائية. وتم تسجيل فترة البقاء في المستشفى أيضاً في هذه التجربة.

النتائج: كانت الصفات السريرية لقاعدة بيانات المرضى متشابهة لكلتا المجموعتين. لم يكن هنالك فروق إحصائية في الشريان الاحتشائي ذو العلاقة (IRA) وأمراض الوعاء الثلاثي والتيار الأولي والنهائي ومعدل الدعامة وكمية التيروفيبان المستعمل ومعدل الإجراء (p>0.05). لم يكن هنالك فروقاً إحصائية في الوقت ووقت تركيب القناة ووقت التسريب ووقت الإجراء وتمت مراقبة وقت التنظير في كلتا المجموعتين (p>0.05). لم يكن هنالك فرقاً في حدوث (MACEs) بين المجموعتين (p>0.05). لم تكن المضاعفات الوعائية أقل في مجموعة TFI فقط (p<0.01) ولكن أيضاً كانت فترة البقاء في المستشفى أقل في مجموعة (TFI) من مجموعة TRI p<0.001.

خاتمة: أن طريقة (TRI) التي أجري لها التدخل الجراحي عبر الزند للمرضى الصينيين الذين يعانون من AMI طريقة علاج جراحية ناجحة ولديها مضاعفات أقل لموضع المخرج الوعائي مقارنة مع طريقة (TFI).

Objectives: To compare the transradial approach and transfemoral approach for primary percutaneous coronary intervention (PCI) in Chinese patients with acute myocardium infarction (AMI).

Method: From August 2005 to September 2008, we randomly divided 200 AMI patients into transradial intervention (TRI) group and transfemoral intervention (TFI) group. The study took place in the Department of Cardiology, The Tenth People's Hospital, Tongji University, Shanghai, China. During the procedure, the puncture success, procedure success, infarction related artery (IRA), coronary flow, percentage of 3 vessel disease, stent used, and tirofiban used were observed. The procedural time intervals were also recorded. After the procedure, the major adverse cardiac events (MACEs) and the vascular complications were studied. In this trial, the hospital stay was also recorded.

Results: The baseline clinical characteristics of the patients were similar in both groups. There were no statistical differences in IRA, 3 vessel disease, initial and final thrombolysis in myocardial infarction (TIMI) flow, rate of stent and tirofiban used, and procedure rate (p>0.05). No statistical differences were observed in the puncture time, cannulation time, reperfusion time, procedural time, and fluoroscopy time in both groups (p>0.05). There was no statistical difference in the incidence of MACEs between the 2 groups (p>0.05). Not only the vascular complications were lower in the TRI group (p<0.01), but also the total hospital stay was longer in the TFI group than in the TRI group (p<0.001).

Conclusion: Transradial intervention for Chinese patients with AMI yields comparable procedural success, and has fewer vascular access site complications compared with the TFI group.

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Since the transradial approach to coronary angiography was first reported in 1989,[1] the transradial access has been used for percutaneous coronary intervention (PCI) for approximately 20 years. Many studies have confirmed the advantages of the transradial approach over the traditional transfemoral approach including decreased incidence of access site complications, earlier ambulation, and improved patient comfort.[2-7] These benefits may be obvious in patients with acute myocardium infarction (AMI) receiving emergency PCI as those patients are more likely to receive aggressive anticoagulation and antiplatelet therapy, particularly with the use of glycoprotein IIb/IIIa receptor inhibitors.[8,9] However, published studies concerning transradial PCI for AMI has been mostly retrospective and non-randomized; thus, making the studies prone to several sources of bias. In contrast to the Western population, Asians have a relatively small radial artery vessel sizes.[10] Concerns that transradial access may delay reperfusion as it is more technically challenging still exist. We therefore carried out this prospective randomized trial to compare transradial approach and the transfemoral approach for primary PCI in Chinese patients with AMI.

Methods. From August 2005 to September 2008 we randomly divided 200 AMI patients into the transradial intervention (TRI) group and transfemoral intervention (TFI) group. The study took place in the Department of Cardiology, The Tenth People's Hospital, Tongji University, Shanghai, China. The study was approved by the Ethics Committee of The Tenth People's Hospital, Tongji University, Shanghai, China. After the written informed consent was signed, the patients were randomly divided into transradial intervention (TRI) group and transfemoral intervention (TFI) group. Exclusion criteria were clinical indications to femoral approach due to cardiogenic shock, history of coronary bypass graft, negative Allen test, and non-palpable radial artery. Once the diagnosis of AMI was confirmed, all patients received aspirin (300 mg) and clopidogrel (300 mg). Fragmin 5000U or FraxiParine 4100U was also injected subcutaneously in all cases. The PCI procedures were performed by 3 senior interventional cardiologists who had performed over 200 cases of TRI. In case of the TRI, the wrist was fixed on the table for appropriate extension of the arm. After the skin overlying the radial artery was anesthetized by local infiltration using 1% lidocaine, the artery was punctured with a 21-gauge needle (Cordis), and the 0.53 mm straight tip guidewire (Cordis) was advanced through the needle carefully. After removal of the puncture needle, a 6-Fr sheath (Cordis) was inserted into the artery. Thereafter, 10 cc of a nitroglycerin cocktail (mixture of normal saline, 100 µg nitroglycerin, and 2 cc 1% lidocaine) was injected into the sheath to prevent arterial spasm and a bolus of heparin (5000 IU) was administered through the sheath. In case of transfemoral PCI, the femoral artery was punctured with an 18-gauge needle (Cordis) after local anesthesia with 1% lidocaine and a 0.965 mm guidewire was inserted into the needle cautiously. After removal of the puncture needle, a 6-Fr sheath (Cordis) was inserted into the artery. The choice of catheters, stents, and whether to use GPIIb or GPIIIa antagonists was the decision of the physicians. The sheath was removed immediately after the PCI procedure, and a radial compression device (TR-BAND, Terumo Medical Corp., Somerset, New Jersey) was used to achieve homeostasis in the TRI group. It would be removed after 6 hours if no bleeding event happened. In the TFI group, the sheath was removed 6 hours later and homeostasis was achieved by manual compression of at least 15 minutes followed by a pressure of 24 hours bandage. Endpoints were recorded from the start of the procedure to one month follow-up. Cannulation time was defined as the time from patient arrival at the catheterization laboratory to the effective placement of the arterial sheath. Reperfusion time was defined as the time from the cannulation to balloon inflation. Procedure time was defined as the time from the first attempt to puncture the artery to the end of the angioplasty. The procedure success was defined as residual diameter stenosis <30% with grade 3 coronary flow according to the classification of the thrombolysis in myocardial infarction trial. Access site bleeding was defined as major if associated with hemoglobin loss of at least 2 mmol/l, administration of blood transfusions, and needing vascular repair. Minor access site bleeding was defined as hematoma formation not requiring specific therapy. The major adverse cardiac events (MACEs) were defined as death, recurrent myocardial infarction, or target vessel revascularization (TVR).[11]

Statistical analysis was performed using the SPSS Version 13.0 statistical program (SPSS Inc., Chicago, USA). Continuous variables were expressed as mean±SD and compared with Student's t test. The differences between categorical variables were examined by the Chi-square test. $P<0.05$ was considered statistically significant.

Results. The baseline clinical characteristics of the patients were summarized in **Table 1**. Mean age, gender, and risk factors were similar in both groups. There were no statistical differences in cardiac function Killips classification between the 2 groups ($p>0.05$). Angiographic and procedural characteristics are shown in **Table 2**. There was no puncture failure in both groups. Four patients in the TRI group required a crossover to femoral access because of severe subclavian

artery tortuosity in 2 cases and spasm with radial artery tortuosity in 2 cases. There were no statistical differences in infarct related artery (IRA), 3 vessel disease, initial and final thrombolysis in myocardial infarction (TIMI) flow, rate of stent and tirofiban used, and success rate of procedure (p>0.05). Three patients in the TRI group and 5 patients in the TFI group did not receive stent implantation because they had lesions of <50% and TIMI-3 flow in the IRA. **Table 3** summarizes the procedural time intervals observed in the present study. There were no statistical differences in the puncture time, cannulation time, reperfusion time, procedural time, and fluoroscopy time in both groups (p>0.05).

Clinical and vascular outcomes at one-month follow up are shown in **Table 4**. One month follow-up was complete in all patients. Four patients in the TRI group died during the follow up (3 died of cardiac arrest and one due to ventricular fibrillation). Five patients in the TFI group died during the follow up. Two cases were due to cardiac arrest while other cases were due to ventricular fibrillation. No re-infarction or TVR occurred in either group. Taken together, there was no statistical difference

Table 1 - Baseline clinical characteristics.

Variables	Transradial intervention (n=100)	Trans-femoral intervention (n=100)	*P*-value
Age (years)			
Mean ± SD	64.9 ± 8.4	66.2 ± 7.7	0.23
95% Confidence intervals	63.2 - 66.5	64.7 - 67.7	
Male n (%)	72 (72)	69 (69)	0.64
Hypertension n (%)	42 (42)	50 (50)	0.25
Diabetes n (%)	22 (22)	15 (15)	0.20
Smoker n (%)	50 (50)	42 (42)	0.27
Obesity n (%)	23 (23)	30 (30)	0.26
Hypercholesterolemia (%)	35 (35)	40 (40)	0.47
Killip class			0.89
Class I n (%)	60 (60)	58 (58)	
Class II n (%)	30 (30)	33 (33)	
Class III n (%)	10 (10)	9 (9)	

Table 2 - Angiographic and procedural characteristics.

Variables	Trans-radial intervention (n=100)	Transfemoral intervention (n=100)	*P*-value
Puncture success	100	100	
Cross over	4	0	0.13
Infarct related artery			0.40
Left anterior descending	48	50	
Left circumflex	8	13	
Right coronary artery	44	37	
Three vessel disease	22	18	0.48
Initial TIMI			0.40
Flow 0-1	72	68	
Flow 2	20	18	
Flow 3	8	14	
Final TIMI			0.60
Flow 0-1	2	1	
Flow 2	2	4	
Flow 3	96	95	
Stent used	97	95	0.72
Tirofiban used	28	20	0.19
Procedure success	96	95	1.00

TIMI - thrombolysis in myocardial infarction

Table 3 - Procedural time intervals.

Variables	TRI (n=100)	TFI (n=100)	*P*-value
Puncture time (min)			0.24
Mean ± SD	2.3 ± 0.6	2.2 ± 0.6	
95% Confidence intervals	2.2 - 2.4	2.1 - 2.3	
Cannulation time (min)			0.24
Mean ± SD	2.5 ± 0.6	2.4 ± 0.6	
95% Confidence intervals	2.3 - 2.6	2.2 - 2.5	
Reperfusion time (min)			0.42
Mean ± SD	16.4 ± 1.7	16.2 ± 1.8	
95% Confidence intervals	16 - 16.7	15.8 - 16.6	
Procedural time (min)			0.17
Mean ± SD	37.2 ± 7.1	35.7 ± 8.1	
95% Confidence intervals	35.8 - 38.6	34 - 34.3	
Fluoroscopy time (min)			0.14
Mean ± SD	11.8 ± 2.0	11.4 ± 1.8	
95% Confidence intervals	11.4 - 12.2	11.1 - 11.8	

TRI - transradial intervention, TFI - transfemoral intervention
min - minutes

Table 4 - Clinical and vascular outcomes at one-month follow up.

Variables	TRI (n=100)	TFI (n=100)	*P*-value
MACEs	4	5	1.00
Death	4	5	1.00
TVR	0	0	
Reinfarction	0	0	
Vascular complications	3	11	<0.01
Major bleeding	0	3	0.24
Local hematoma	2	6	0.28
Pseudoaneurysm	0	2	0.16
Artery occlusion without ischemia	1	0	
Hospital stay (day)			<0.001
Mean ± SD	8.6 ± 1.8	12.7 ± 3.0	
95% Confidence interval	8.3 - 9.0	12.1 - 13.3	

TRI - transradial intervention, TFI - transfemoral intervention, MACE's - major adverse cardiac events, TVR - target vessel revascularization

in the incidence of MACEs between the 2 groups (p>0.05). In the TFI group, 3 patients suffered major bleeding with hemoglobin loss of at least 2 mmol/l due to large hematoma formation in the groin region. Six had local hematoma with diameters from 2-4 cm, 2 experienced pseudoaneurysm, which disappeared after constant manual compression. In the TRI group, only 2 patients suffered local hematoma, which dispersed a few days later. One had artery occlusion without ischemia. No patients experienced major bleeding and pseudoaneurysm. There was a statistical difference in the vascular complications between the 2 groups (p<0.01). The total hospital stay was longer in the TFI group than in the TRI group (p<0.001).

Discussion. Difficulty in learning the technique and the smaller size of the radial artery compared to the femoral artery is generally considered as the major limitations of TRI. With recent advances in instruments and techniques, many studies performed in the West have indicated that most PCI could be performed safely and timely through a transradial approach. However, since Chinese patients have smaller radial artery size than Europeans,[10] many cardiologists in China are still reluctant to perform transradial PCI, especially in patients with AMI. The present study has shown that emergency PCI in Chinese patients with AMI can be performed with a high procedural success rate by either radial or femoral access. There were no cases of puncture failure in both groups. But, we should emphasize since radial arterial access requires a learning period to achieve competence,[12] all the procedures in our study were performed by 3 experienced operators who had finished at least 200 TRIs.

In our previous study, we observed that the learning curve had a great impact; in the first 100 patients, the percentage of successes was only 90%. However, in the later cases the percentage of successful procedures improved up to 95%. There was no significant difference in the percentage of successful procedures between 3 operators in our center. It has been argued that TRI maybe more time-consuming than TFI. Many interventional cardiologists are worried that the reperfusion time would be prolonged in TRI. If this was true, the TRI would be limited to elective angioplasty only since several studies have shown that mortality is increased with delays in reperfusion.[13-15] In this study, however, we found that there was no statistical difference in the procedural time intervals including reperfusion time mentioned above. There was no statistical difference in the incidence of MACEs between the 2 groups (p>0.05). The results were consistent with those of previous published studies on the primary PCI of AMI via radial access.[16,17] Aggressive antithrombotic therapy is very important in the primary PCI of AMI, limiting the risk of reinfarction and the extent of myocardial damage, finally decreasing mortality.[18] Unfortunately, intensive antithrombotic therapy is associated with an increased risk of access site complications in TFI.[9,19-21] Despite improvement of access site management, vascular access site complications remain a challenge. In this study, we found that the vascular complications were lower in the TRI group than in the TFI group (p<0.01). There were 48 patients (28 in the TRI group and 20 in the TFI group) that received tirofiban therapy and patients suffered major bleeding were all from TFI group (20 patients). Although the difference was not statistically significant, we think that the result indicates that TRI has a trend to reduce the risk of major bleeding complications in patients receiving aggressive antithrombotic therapy. We also observed the significantly prolonged length of stay in the TFI group. This result was exclusively due to major complications requiring further therapy or minor access site complications requiring prolonged bed-time.

One limitation of this study is that TIMI flow grade was estimated by the operators' visual impression and is subject to some bias. Another limitation is that the type of guide catheter used in the procedure was not assessed, which may in some extent affect the procedural time intervals.

In summary, the present study suggests that TRI for patients with AMI is as safe and as feasible as TFI, and has fewer vascular access site complications compared to the TFI when performed by experienced operators. Future studies must consider a large multi-center random trial to confirm this conclusion.

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