Safety and Efficacy of Transradial versus Transfemoral Approach in Primary Coronary Angioplasty for Acute ST Elevation Myocardial Infarction

Mohamed Hegab, Ahmed Ramzy, Mohamed Hamouda and Heba Abd Mansour

Department of cardiology, Benha faculty of medicine, Benha University, and National heart institute*, Egypt
Corresponding author: Mohamed Hegab, Department of cardiology, National heart institute
Tel : 002-01063861106, e-mail: mohamedyehyaheg@gmail.com

Abstract

Background: Several randomized trials performed showed increase safety and efficacy of Transradial approach in primary PCI when compared with Transfemoral approach. **Method:** this study included 75 patients presenting to the National Heart Institute for the first time with acute ST segment elevation myocardial infarction divided into two groups ; Group A included 25 patients who were treated by primary PCI by the trans radial approach technique. Group B included 50 patients who were treated by primary PCI by the trans femoral approach technique. **Results:** this study showed significant difference regarding the puncture site complications 8% in transradial versus 40% in transfemoral approach with no significant difference in other complications . There was a significant difference in time from sheath to cocrnary cannulation, 2.36 minutes in transradial versus 2.42 minutes in transfemoral and there was no significant difference between both groups in final echo and hospital stay. **Conclusion:** the results of the current study suggests the transradial approach as a safe and effective procedure with high success rate

Key Words: transradial, transfemoral,1ry PCI

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Introduction

Although the traditional transfemoral arterial approach (TFA) for catheter-based coronary or carotid intervenetion is still popular**,** it has disadvantages, including the need for bed rest, puncture site compression after the procedure, and vascular complications of hematoma and arteriovenous fistula, as well as difficult access because of the tortuous aorta or if there is occlusion of the femoral-iliac-aortic route .The transradial arterial approach (TRA), which is a fairly simple route of access for catheter-based coronary intervention, has been developed for more than 15 years.

studies has further indicated that TRA is safe for elective coronary angiographic studies of outpatients**,**elective left main coronary intervention**,** cerebral angiographic studies or vertebral or carotid stenting.The safety and efficacy of the TFA approach for acute myocardial infarction (AMI) patients undergoing primary PCI have been extensively discussed, relevant issues for using the TRA for primary PCI have not been fully investigated**.**

Patients and methods

This prospective , controlled non randomized study enrolled 75 patients presenting to the National Heart Institute for the first time with acute ST segment elevation myocardial infarction according to the third universal definition of myocardial infarction which requires the presence of: Detection of rise and/or fall of cardiac biomarkers values (preferably troponin) with at least one value above the 99th percentile of the upper reference limit and with at least one of the following:Symptoms of ischemia.,New or presumably new significant ST-T changes or new LBBB,Imaging evidence of new loss of viable myocardium, or new regional wall motion abnormality &Identification of intra coronary thrombus by angiography. The patients were divided into two groups Group A: included 25 patients who were treated by primary PCI by the trans radial approach technique Group B: included 50 patients who were treated by primary PCI by the trans femoral approach technique. A written informed consent will be obtained from the patient or family member(s) before the primary PCI.

All patients in the two groups received:1- 300mg chewable aspirin. 2- A.D.P receptor blocker in the form of 600 mg Clopidogril 3- An injectable anti coagulant in the form of unfractionated 4- Glyco protein IIb/IIIa inhibitors in the form of heparin sulphate in a dose 70 I.U/kg. tirofiban or eptifeptide were considered if there was angiographic evidence of massive

thrombus, thrombotic complication, slow, or no-reflow.5- Angiographic coronary thrombus burden was scored based on TIMI thrombus grades. After wiring and/or small balloon dilation, patients with grades 4 and 5 (high thrombus burden) received thrombus aspiration with Glyco protein IIb/IIIa inhibitors injected intra coronary and then intra venous maintenance dose for 24 hours. Patients in group (A) Patients in group A had ulnar artery dominance by modified Allen′s test. The transradial approach was performed via the right or left radial artery

To prepare for the procedure, the patients' arm was abducted and his wrists were hyper extended. A local subcutaneous infiltration with 2% lidocaine, radial artery puncture was be performed with a 20-gauge angiocatheter needle and a 6 French radial sheath with a dilator will be introduced over a wire.

After sheath insertion, 10 cc of a nitroglycerin cocktail (mixture of normal saline, 50 µg of isosorbide dinitrate, and 5 mg of verapamil) and a bolus of heparin intravenous (5000 IU for coronary angiography or 10,000 IU for intervention) were given to the patient .

Coronary angiograms were performed using 4 French catheters and PCIs were performed with 6 French guide catheters. After the procedure, the arterial sheath was removed immediately and a compression dressing with gauze was applied for approximately 6 hours or more, without the interruption of anticoagulants or antiplatelets. Patients in group (B)

The transfemoral approach was performed via the right or left common femoral artery.

The common femoral artery was punctured with an 18-gauge arterial needle after local anesthesia with 2% lidocaine and a 6 or 7 French arterial sheath was introduced with a dilator over a wire.

The sheath was flushed by saline 0.9% then and a bolus of heparin (5000 IU for coronary angiography or 10,000 IU for intervention) was given.

Coronary angiograms were performed using 5 French catheters and PCIs were performed by 6 French guide catheters. Haemostasis was achieved by manual compression and the arterial access sheaths were removed 4 to 6 hours after the procedure without the use of closure devices. Patients were allowed to ambulate in their rooms 16-24 hours after femoral sheath removal.

After the coronary angiograms are performed for both groups, primary PCIs were done with the standard technique for the infarct related artery.Patients in both groups were been stenting by bare metal stents.

Exclusion criteria

1- Patients with cardiogenic shock. 2- Patients with bleeding disorders 3-Patients with end stage organ diseases

All patients were subjected to

1- Full history taking : focusing on the major risk factors of the CAD such as DM , HTN , Smoking & FH of CAD) 2- Clinical examination. 3- Twelve lead surface ECG 4-Laboraory investigations for a- Cardiac enzymes b- Renal function tests c- Random blood glucose d- Complete blood picture e- P.T, PTT, I.N.R 5-Echocardiograpy was done to all patients during the hospital stay 6- Comparison between the two groups in the following : Total procedures time,Fluoroscopy time in both groups, In hospital major adverse cardiac events including death, target vessel revascularization, re infarction and acute stent thrombosis, Bleeding at puncture site**:** major vascular bleeding was defined as bleeding related to the procedure with a fall in hemoglobin >3 g/dl requiring a blood transfusion, Any vascular events: Hematoma, A-V Fistula, Pseudo aneurysm, Retro peritoneal hemorrhage, dissection & Duration of hospital stay in both groups.

Statistical analysis

Data were analyzed using Statistical Program for Social Science (SPSS) version 18.0. Quantitative data were expressed as mean± standard deviation (SD). Qualitative data were expressed as frequency and percentage**.** The following tests were done Independent-samples t-test of significance was used when comparing between two means. Chi-square (X^2) test of significance was used in order to compare proportions between two qualitative parameters.

Results

This study included 75 patients presenting to the National Heart Institute for the 1st time with ST segment elevation MI from the period from November 2014 till September 2015.

Table (1) Comparison between group (A) and group (B) as regard demographic data

Demographic Data	Group (A)		Group (B)		x2/t*	p-value
	No.	%	No.	%		
Sex						
Male	22	88.0	45	90.0	0.102	0.749
Female	3	12.0	5	10.0		
Age						
Range	43-76		35-78		1.398*	0.241
Mean	56.72		53.94			

This table shows 25 cases in group A - 22 males and 3 females while in group B there 50 cases including 45 males and 5 females
the mean age of group A is 56.72 plus or minus 9.46 while the group B mean age was 53.94 plus or minus 9.74
the p value between the two groups shows no significance as it is 0.749 regarding sex and is 0.241 regarding the age .

Table (2): Comparison between group (A) and group (B) as regard risk factors

Risk factors	Group (A)		Group (B)		x2	p-value
	No.	%	No.	%		
DM	15	60.0	19	38.0	4.842	**0.028**
HTN	13	52.0	14	28.0	6.000	**0.014**
Smoker	18	72.0	40	80.0	0.877	0.349
F.H.	7	28.0	17	34.0	0.421	0.517

This table shows 15 cases of the group A had diabetes mellitus as risk factor (60%)versus 19 cases in group B (38%) the group B shows 19 cases. Thirteen cases in group A were hypertensive (52%) versus Fourteen cases in group B (28%)
Eighteen cases in group A (72%) were smokers versus 40 cases in group B (80%) Seven cases in group A (28%) had positive family history versus 17 cases in group B (34%)
Finally, This table shows statistically signficant difference between both groups as regard DM and HTN While the difference between both groups for smoking and family history was statistically insignificant.

Table (3): Comparison between group (A) and group (B) as regard timing

Timing	Group (A)		Group (B)		t-test	p-value
	Mean	±SD	Mean	±SD		
Time to presentation (min)	175.2	93.6	163.2	77.5	0.698	0.487
Time to puncture (min)	240	94.6	231.2	74.7	0.516	0.607
Time to 1st ballon inflation (min)	251.6	94.2	245.3	76.2	0.368	0.714
Time of puncture till sheath insertion (min)	9.28	15.4	9.35	15.4	-0.023	0.982
Time from sheath till coronary canulation (min)	2.36	0.8	2.01	0.6	2.420	**0.017**

This table shows statistically significant difference between both groups as regard time from sheath till coronary canulation (min) the femoral approach is much more rapid than the radial of the cannualtion to coronaries , other durations show insignificant differences between both groups

Table (4): Comparison between group (A) and group (B) as regard complications

Complications	Group (A)		Group (B)		x2	p-value
	No.	%	No.	%		
EARLY CPK	24	96.0	48	96.0	1.333	0.513
MACE	4	16.0	6	12.0	0.332	0.564
TYPE						
CABG	2	8.0	0	0.0	4.303	0.231
Death	1	4.0	2	4.0		
Reinfarction	1	4.0	3	6.0		
Other Complic.						
CVS	0	0.0	2	4.0	2.041	0.153
Puncture Site	2	8.0	20	40.0	17.045	**<0.001**

16% of the group A cases showed MACE versus 12% of the group B showed MACE

One case in group A died (4%) versus two cases died (4%)

In group A only one case showed reinfarction versus 3 cases in group B
no CVS complication in group A versus 3 cases in group B.

This table shows highly statistically significant difference between groups as regard puncture site. Two cases only had a complication in group A versus 20 cases in group B had complications in the puncture site which represent 40% of the cases

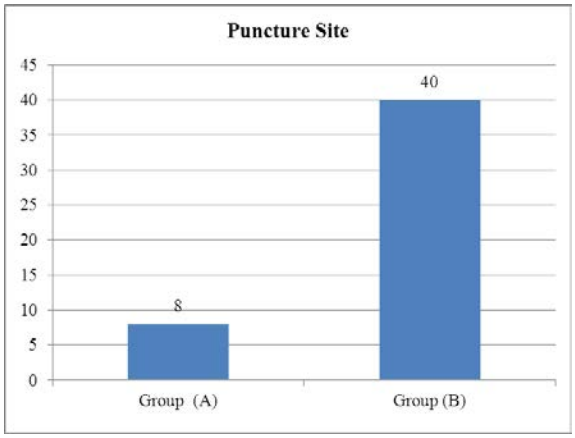

Figure 1 : Complication of puncture site in both groups

Table (5): Comparison between group (A) and group (B) as regard type of puncture site complication

Type	Group (A)		Group (B)		x2	p-value
	No.	%	No.	%		
Big hematoma	0	0.0	6	12.0	20.968	**0.004**
Big hematoma & pseudoaneurysm	0	0.0	1	2.0		
Bleeding	0	0.0	2	4.0		
Femoral artery dissection	0	0.0	2	4.0		
pseudoaneurysm	0	0.0	1	2.0		
Small hematoma	1	4.0	8	16.0		
Weak pulsations	1	4.0	0	0.0		

This table shows highly statistically significant difference between groups as regard type of complications. Six cases i.e 12% of the group B showed big hematoma versus 8(16%) of the same group showed small one …on the other hand no big hematoma in Radial while only one small hematoma in radial group representing 4% of the cases

2 cases of femoral group showed bleeding and one showed pseudo aneurysm while in radial group there was neither bleeding nor pseudoanuerysm

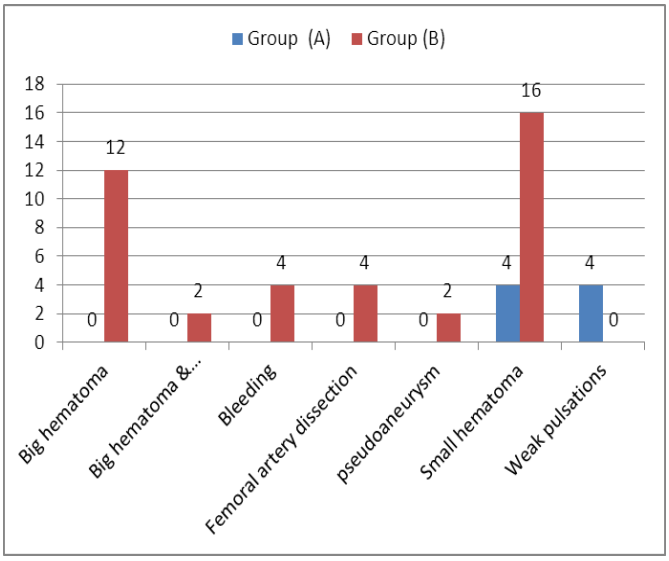

Figure 2: Puncture site complications % in both groups

Table (6): Comparison between group (A) and group (B) as regard Hosp. stay.

Groups	Hosp Stay/Day		t-test	
	Mean	☐SD	t	p-value
Group (A)	4.83	3.80	-0.225	0.823
Group (B)	5.00	3.46		

This table shows no statistically significant difference between groups as regard hospital stay the radial group showed fewer days than the femoral group but the difference is non significant

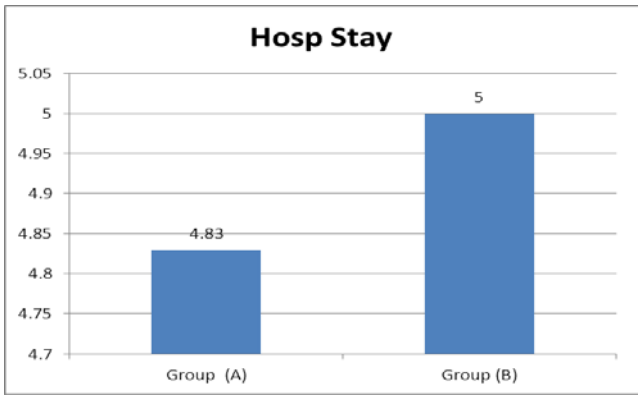

Figure 3 : Hospital stay per day in Both groups

Discussion

Coronary angioplasty and stenting is performed via the transfemoral approach in the majority of centers. The contemporary management of acute coronary syndromes involves aggressive anticoagulation which may include thrombolytic therapy or platelet glycoprotein IIb/IIIa receptor inhibitor in addition to heparin, aspirin and clopidogrel. Coronary stenting from the transfemoral approach in these patients is associated with an increased incidence of access site complications. The bleeding vascular complications are an important cause of increased patient morbidity , longer in hospital stays and higher hospital costs. Thus the transradial approach has the potential to significantly reduce the incidence of access site bleeding complications and may be beneficial in patients with acute coronary syndromes.The aim of this study was to compare the safety, feasibility and efficacy of primary PCI in patients presenting with acute ST myocardial infarction using transradial and transfemoral approaches.Number of the patient was 75 cases classified into 25 radial cases and 50 femoral cases . In this study there was no statistically significant difference between both groups as regard age , sex , smoking and Positive family history but the results were statistically significant for Diabetes Mellitus and Hypertension . The results of the present study were in agreement with the result reported by (Pancholy et al, 2010) where 283 consecutive patients underwent primary PCI , 177 by transradial approach and 106 by

transfemoral approach. In that study the demographic data and the procedural characteristics were statistically non-significant.Access site complications were more likely to occur when PCI wa performed under conditions of aggressive anticoagulation and antiplatelet treatment, especially with use of platelet glycoprotein IIb/IIIa receptor inhibitor (Willis , 2009). The present study demonstrated that the procedural success of transradial coronary intervention was the same as in transfemoral approach. The results of the present study are in agreement with the results of *Yves et al* 2000 where 1224 cases were registered for primary PCI using either transradial or transfemoral access. They concluded that angioplasty was successful in 95% of both radial and femoral access patients. Total procedural time didn`t differ between both groups; severe access site related complications were observed in femoral group only. As regards the procedural time in this study, there was significant difference between the two approaches as regards the time taken from sheath insertion till coronary cannulation. In the radial group, the time from sheath insertion to coronary cannulation was 2.36±0.8 minutes, and in the femoral group it was 2.01±0.6 minutes. (Table 8 – Figure 25)

The results of the present study were also in agreement with those reported by Hammon et al 2002. A series of 119 patients presenting with acute coronary syndromes were reported, including 39 patients who underwent primary or rescue PCI. TIMI grade 3 flow was obtained immediately after direct stent implantation in 93% of patients and after adjunctive pharmacological therapy with abciximab for no-reflow in the remaining 7% of patients. All patients were given verapamil (5mg via the radial sheath) and no significant radial spasm requiring alterative access site or bleeding complications. The procedural time did not differ from that required for a femoral approach in their institution. *Louvard et al, 2002* reported the results of a non-randomized comparison of the radial and femoral approaches for primary PCI. The study included 1214 patients treated in two European centers; 22% (n=267) of patients were treated via a transradial approach; 947 patients were treated via a transfemoral approach with the use of a vascular closure system (Per close) in 889 patients and manual compression in the remaining 58 patients. Overall procedural time, procedural outcome, and the rate of TIMII III flow (88-91%) did not differ between the transradial and transfemoral approach. These results were not consistent with the results of *Louvard et al, 2002 and Hammon et al, 2002* where the overall procedural time, procedural outcome, and the rate of TIMI3 flow (88-91%) did not differ between the transradial and transfemoral approach. In this study, although there were limited

number of patients, one patient from the radial group crossed over to the femoral group as he had severe subclavian artery tortuosity which made coronary artery cannulation impossible through transradial approach. Non of the patients from radial approach changed to the femoral approach due to radial artery puncture failure. Non of the patients from the femoral group changed to radial group for any cause.

Major Adverse Cardiac Events (MACE):

In current study, as regards MACE , the transradial and transfemoral approaches yielded approximately similar results. Three patients died in this study , one from radial group and two from femoral group . Four patients in this study suffered from re-infarction , one from the transradial group (4%) and three patients from the transfemoral group (6%) and all of them were successfully managed by undergoing another PCI. Two patients from the femoral group (4%) suffered from cerebrovascular insult most probably from the massive anticoagulation and antiplatelet therapy and was managed conservatively in-hospital. two patients from the transradial group transferred to undergo emergency CABG. Those patients suffered from complete heart block and temporary pacemaker was inserted. In the angiography of those patients LAD was the culprit and also another critical lesions in the left main coronary artery and right coronary artery . Successful PTCA was done to the infarct related artery and the patients ended up with TIMI 2 flow so the patient was transferred to emergency CABG. These results were in agreement with those reported by TEMPURA trial , they reported that the transradial approach does not increase MACE. follow up results of survivors in both groups (six months follow up) and the composite MACE-free survival showed no statistically significant differences in both groups. (Saito et al,2003). Also Philippe et al, 2004 , compared transradial versus transfemoral approaches in treatment of acute STEMI with primary PCI and anticoagulation and the results showed that uncomplicated clinical course occurred in 62 (97%) of patients in the radial group and 49 (89%) of patients in the femoral group were free of MACE (P=0.04). These results were statistically significant.

Access site complications: As regards the local vascular complications in this study, it showed that only two patients (8%) from the radial group suffered from puncture site complication which was (minor bleeding-small hematoma and weak pulsations). In comparison, 10 patients (20%) from the femoral group suffered from minor bleeding and small hematoma. Also 7 patients (14%) suffered from major bleeding and big hematoma and two of those patients needed

blood transfusion. one patients (2%) from the femoral group suffered from pseudo-aneurysm. The patients suffered from big hematoma and pseudo-aneurysm which was confirmed by Duplex and this patient spent twenty one days in the CCU and this complication was managed in-hospital with surgical debridement by general surgery intervention. Two patients (4%) from the femoral group suffered from femoral artery dissection. These results were statistically signficant and consistent with the results of other trials proving the lower incidence of local vascular complications through the transradial approach especially where aggressive anticoagulation and antiplatelet therapy is required as in cases of acute coronary syndromes especially acute STEMI.

The result of the present study are also in agreement with those reported by Philippe et al, 2004 compared transradial versus transfemoral approach in the treatment of patients with acute myocardial infarction with primary PCI and abciximab. They reported that the transradial access is more effective with fewer major access site complications than the transfemoral access. Transradial approach produces a shorter length of in-hospital stay as compared to the transfemoral approach. There were no major access site bleeding complications in the radial group, as opposed to three patients (5.5%) in the femoral group (p=0.03), all required blood transfusions, surgical repair was necessary in two of them.

In-hospital stay In this study, the mean hospital stay after transradial PCI was 4.83±3.8 days in the radial group compared to 5±3.46 day in the femoral group. These results were statistically non-significant (Table 21 – Figure 38). In the *TEMPURA Trial*, the length of hospital stay was 5.7±4.9 day in the radial group in comparison to 7.4±9.5 in the femoral group. (p=0.204) success in day 3 discharge was 58.9% in the radial group versus 48.5% in the femoral group (p=0.218)

Results of the AGGRASTENT Trial which addresses if early discharge is feasible following primary PCI with stent implantation via the radial artery under glycoprotein IIb/IIIa blockade for STEMI or not. One-hundred patients with STEMI eligible for PCI were included, of these 100 patients, 62% received treatment according to the protocol, e.g., transradial approach, successful PCI with stent implantation, full dose GP IIb/IIIa receptor blocker infusion and early discharge. The PCI was successful in 95%. Early discharge was achieved in 75 patients of the total study population. Major adverse cardiac and cerebral events (MACE) did not occur in the early discharge group, with a year event free survival rate of 91%. The combined MACE rates in the total study population at 1,6, and 12 months were 8%, 15% and 20%, respectively. However a larger study is needed to prove the efficacy of this strategy.(Dirksen et al., 2005).

Conclusion

It is a safe & effective as the transfemoral approach with a high procedural success rate and almost done in the same time needed as the transfemoral approach.It is done with almost no risk for bleeding vascular complications and other access site complications as pseudo-aneurysm especially for patients presenting with acute coronary syndromes where aggressive antiplatelet and anticoagulation therapy is needed, or patients who are expected to suffer from access site complications as hypertensive or obese patients.Major additional advantages as increased patient comfort and reduced post procedural work load associated with the achievement of hemostasis and all these advantages are really achieved with the transradial approach.It is an alternative route for coronary intervention in patients whom the transfemoral approach is impossible as in cases of bilateral peripheral vascular disease.

Recommendations

It is advisable for all interventional cardiologists to apply and master the technique of transradial approach in primary PCI because of the previously mentioned advantages (safe, effective , same time and duration as transfemoral approach in addition to less bleeding and other puncture site complications).It is an alternative approach to be used in patients in which aggressive antiplatelet and anticoagulation therapy is needed and expected bleeding complications as in patients presenting with acute coronary syndromes especially STEMI.Also this technique is very useful as it can be used as outpatient treatment in cases of elective Coronary Angiography and PCI where hospital stays and costs will be reduced.

Study limitation

1-Differences in the sector of ages between patients
2-Race and life style differences
3-The small number of cases and the short time of follow up.

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