TRANSRADIAL ACCESS FOR PCI: A NOVEL APPROACH / CHANGING TRENDS OF VASCULAR ACCESS

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ABSTRACT

Objective: Vascular complications associated with femoral artery access for interventional cardiological procedures may increase morbidity especially in patients receiving anticoagulants, aspirin, clopidogrel and platelet glycoprotein IIb/ IIIa receptor inhibitors. The use of radial arterial access reduces the incidence of access site bleeding complications. The purpose of the present study was to assess the feasibility, success, and safety of the transradial approach (TRA) for PCI.

Design: Single-centre, Prospective observational study.

Place and Duration of Study: The study was carried out in Armed Forces Institute of Cardiology – National Institute of Heart Diseases (AFIC-NIHD) over a period of six months from july 2009 to december 2009.

Patients and Methods: We collected data of 100 consecutive patients who underwent PCI by the transradial approach. Transradial access was performed only if the Allen's test was normal (positive), suggesting the presence of an adequate collateral circulation from the ulnar artery. Patients with previous CABG with LIMA grafting, ACS with cardiogenic shock or requiring TPM placement were excluded from this study. Study endpoints included procedure success rate, vascular complications at access site, and major adverse cardiac and cerebrovascular events during hospitalization.

Results: Mean age of the patients was 53 years (range 31-79 yrs). Procedural success was achieved in 100% cases. Right TR approach was used in 99% cases. Number of target lesions treated was 239 with multivessel PCI done in 61% cases. DES was used in 72%cases and BMS was used in 28% cases. Maximum no of target lesions treated included LAD 114(47.6%), followed by RCA 50 (20.9%),LCX 41(17.1%),OM branch 25(10.4%),Diagonal branch 9(10.4%). No case of vascular complications such as major access site bleeding, vascular perforation, radial artery occlusion, forearm ischemia or compartment syndrome was observed. There were no procedural myocardial infarctions or deaths, and no patient was referred for emergency bypass surgery.

Conclusions: We conclude that the transradial access for PCI is a safe and effective alternative to transfemoral access. It adds to patients comfort and convenience and offers coronary intervention with the potential of less vascular complications.

Keywords: Transradial angioplasty, Allen's test, coronary angiography, transradial intervention.

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INTRODUCTION

The transradial approach (TRA) for performing coronary angiography was initially proposed by Dr. Lucien Campeau in 1989,[2] and in 1993, Dr. Ferdinand Kiemeneij reported his experience with coronary angioplasty through the radial route.[3] The transfemoral approach provides an easier vascular access, but it is associated with a small and potentially serious incidence of vascular complications at the puncture site that may result in significant groin haematomas, blood transfusion or require surgical repair. Transradial access which involves a minimal vascular complication rate, eliminates the necessity for prolonged compression, and allows for earlier ambulation for the patient, rendering the radial approach more comfortable for the patient and one that decreases hospital costs and length of stay when compared to transfemoral access.[3] A meta-analysis that collected twelve randomized trials (n = 3224) has shown that the transradial approach for coronary procedures is a highly safe and effective technique for both transcatheter diagnostic and therapeutic procedures.[4] Procedural morbidity is less, and patients overwhelmingly prefer the transradial over the femoral approach.[5] The contemporary management of acute coronary syndromes involves intensive anticoagulation which may include thrombolytic therapy or platelet glycoprotein IIb/IIIa receptor inhibition in addition to heparin and aspirin. Coronary stenting from the femoral approach in these patients is associated with an increased incidence of access site complications[6-8]. These bleeding vascular complications are an important cause of increased patient morbidity, longer hospital stays, and higher hospital costs.[9-10] Thus, the transradial approach may be particularly beneficial in patients with acute coronary syndromes.

PATIENTS AND METHODS

An observational study with prospective data collection was carried out in Armed Forces Institute of Cardiology – National Institute of Heart Diseases (AFIC-NIHD) spanning over a period of six months from july 2009 to december 2009 involving 100 consecutive patients. Patients referred for coronary PCI who had a normal radial pulse and a good collateral flow via the palmar arch as indicated by a normal Allen test, were considered for transradial catheterization. Exclusion criteria included Patients with previous CABG with LIMA grafting, ACS with cardiogenic shock or requiring TPM placement. Our preference was to use the right radial artery whenever possible as it was nearest to where the operator stood while facing the cardiac monitors. Before the procedure, all patients were treated with aspirin 300 mg and loading dose of clopidogrel 600 mg and received an adjunctive bolus of heparin according to body weight (70 IU/kg). Activated clotting time (ACT) was measured at 30 minutes interval during the procedure and was maintained greater than 300s with additional heparin as necessary. Glycoprotein IIb/IIIa inhibitors (weight-adjusted intracoronary or intravenous dose) were administered as clinically indicated during the procedure. Radial artery was punctured with a 21 gauge needle and was cannulated with a 45 cm, 0.019 inch straight wire.A 6 Fr radial sheath (11 cm) was then inserted into the artery using the Seldinger technique. A 260 cm long guidewire was used in catheter exchange to facilitate the procedure and minimize catheter manipulation into the aortic arch and ascending aorta. Diagnostic angiography was performed by using 6 Fr judkins catheter or Tiger catheter.Coronary intervention (PCI) was performed using 6 Fr guiding catheters including Judkins, Amplatz, XB or EBU guiding catheters. At the completion of the procedure, pressure was applied over the puncture site with a gauze roll and crape bandage dressing for approximately six hours to achieve haemostasis. The pressure dressing and sheath were removed after 6 hours and the patient was allowed to ambulate and to be discharged the next day unless their clinical status dictated otherwise. The success of the transradial procedure was defined as success in performing PCI. Procedural and in-hospital complications were defined as those that may be related to the transradial approach. Vascular complications such as forearm hematoma, radial artery occlusion, forearm ischemia and compartment syndrome were noted. Access site bleeding was defined as major if associated with haemoglobin loss of at least 2 gm/dl, administration of blood transfusions, vascular repair or prolonged hospitalization and minor if bleeding at vascular access site only resulted in haematoma formation which did not require specific therapy. Any significant in-hospital major adverse cardiac events (MACE) were also noted. Major adverse cardiac events

(MACE) included cardiac death, urgent target lesion revascularization (TLR) and nonfatal myocardial infarction (MI) during hospitalization. MI was defined as an elevation of cardiac biomarkers (creatine kinase-MB >3 times the upper limit of normal) and/or electrocardiographic documentation of ST-segment elevation. TLR was defined as repeat PCI or coronary artery bypass grafting (CABG) of the target lesion due to recurrent ischemia.

DATA ANALYSIS:

Data collected was analyzed where necessary with a SPSS statistical analysis programme.

RESULTS

The baseline demographic and clinical characteristics of the patients are detailed in Table I. Mean age of the

Table-I: Baseline Clinical Characteristics
n= 100

AGE (Yrs)	53 +- 16.8
GENDER	
MALE	64 (64 %)
FEMALE	36 (36 %)
HYPERTENSION	73 (73 %)
DIABETES MELLITUS	39 (39 %)
DYSLIPIDEMIA	78 (78 %)
EF > 50%	61(61%)
RENAL DYSFUNCTION (S.Creat> 1.1 mg/dl)	33 (33%)
SMOKING HISTORY	41 (41 %)
PREVIOUS PCI	19 (19 %)
CLINICAL PRESENTATION	
STABLE ANGINA	65 (65%)
NSTE- ACS	35 (35%)

PTCA = Percutaneous transluminal coronary angioplasty ;
EF= Ejection fraction

patients was 53 years (range 31-79 yrs) and 64% (n= 64) were men and 36% (n=36) were females. CV risk profile revealed hypertension 72%, diabetes mellitus 39%, dyslipidemia 78% and smoking in 53% cases. Serum creatinine levels above 1.1 mg/dl were seen in 30 patients (30%).Majority of the patients (65%) had stable angina, where as 35% had ACS on presentation. Procedural success was achieved in 100% cases with no cross over to transfemoral access. Right TR approach was used in 99% cases and a 6F sheath was

Table-II: Procedural Characteristics
n= 100

Procedural Success 100 (100 %)	
Types of guiding catheters used	
EBU/ XB	75 (75%)
Judkins	22 (22%)
Amplatz	2 (2%)
Multipurpose	1 (1%)
Site of attempted TR access	
Right radial artery	99 (99%)
Left radial artery	1 (1%)
No of lesions treated	239
Multivessel PCI	146 (61%)
Multistents in SVCAD	93 (39%)
Location of target lesion	
Left anterior descending artery	114 (47.6%)
Left circumflex artery	41 (17.1%)
Right coronary artery	50 (20.9 %)
Diagonal branch	9 (3.7 %)
Obtuse marginal branch	25 (10.4 %)
LMS	0 (0 %)
Type of stents used	
Drug eluting (DES)	171 (72%)
Bare metal (BMS)	68 (28%)
Tempo of case	
Elective	98 (98%)
Emergent	2 (2%)

LMS= Left main stem

used in all cases (100%). The vast majority of cases (98 %) were elective. The procedural characteristics are shown in Table II. Number of target lesions treated was 239 with multivessel PCI done in 61% cases. DES was used in 72% and BMS was used in 28% cases. No of target lesions treated included LAD 114 (47.6%), RCA 50 (20.9%), LCX 41 (17.1%), OM branch 25 (10.4%) and Diagonal branch 9 (10.4%). Guiding catheters included EBU/XB (75%), Judkins right and left (22 %), Amplatz (2%) and Multipurpose (1%) cases. Specific details regarding transradial angioplasty are shown in Table II.

The most common complications seen after the TRA were minor forearm haematomas bruising and ache

(17 %) as shown in Table III. There were 15 cases of minor forearm bruising and 09 cases of minor forearm haematomas that occurred just after the completion of the procedure and settled with arm elevation and pressure bandage. Radial artery spasm(relieved spontaneously or with vasodilators) occurred in 20 patients (20%).There were no Major vascular complications such as major access site bleeding, vascular perforation , forearm haematomas (requiring blood transfusion or surgical repair) radial artery occlusion, forearm ischemia or compartment syndrome peri- or post-procedurally related to transradial access. It was also reassuring to see that there were no major adverse events (MACE) such as stroke, especially as we are manipulating the guide wire and catheter in close proximity to the right common carotid artery. All patients had a palpable radial artery post procedure and no patient had symptoms or physical signs of hand ischemia.

Table-III: Procedural complications during hospitalization n=100

None 83(83%)	
Major arm haematoma (requiring blood transfusion/ surgical repair)	0 (0%)
Compartment syndrome	0 (0%)
Fore arm ischemia	0 (0%)
Minor bruising or Haematoma	17 (17 %)
MACE	
Death	0(0%)
MI	0(0%)
Stroke/TIA	0(0%)
TLR	0(0%)

MACE= major adverse cardiac events
MI= myocardial infarction
TLR=target lesion revascularization
TIA=transient ischemic attack

DISCUSSION

The femoral artery has traditionally been the preferred access site for coronary procedures, but this approach has several limitations. The rate of complications at the femoral access site (haematoma, pseudoaneurysm, arteriovenous fistula, or need for blood transfusion or surgical arterial repair) is 2-8% after transfemoral PCI.[11-12] A period of post-procedure recumbency is needed to avoid disruption of the arterial puncture site. This may be poorly tolerated by patients with left ventricular dys-function, lung disease, or back and hip pain. In addition, transfemoral approach may also be unsuitable in some patients for a variety of reasons; these include severe aortoileofemoral obstructive disease, abdominal aortic aneurysm, gross obesity or groin infection. Large series involving the transfemoral approach have reported a significant rate of vascular complications (2.9–12.8%), including retroperitoneal bleeding (0.1–2.6%), need for transfusion (0.8–2.6%), and surgical repair (0.2–2.6%).[13-16] These morbidities are usually not life-threatening, but they affect patient's satisfaction, increase morbidity, length of hospital stay and costs and have driven the development of alternative vascular access for coronary procedures. Transradial access is an excellent alternative to femoral puncture. This artery has a superficial course, and there are no nerves or veins of significant size near the usual site of puncture. The incidence of complications at the radial access site is negligible in the presence of a satisfactory ulnar collateral circulation, even in patients treated with aggressive antithrombotic regimens. For transradial access, the right radial approach is often preferred over the left due to its more comfortable proximity to the operator. In our study right trans-radial approach was utilized in 99 patients(99%).Procedural success rate was 100 % in our study which closely matches 94-97% success rates achieved in some other studies.[17-18] Radial approach failure occurs in 1-9% of cases; the main causes include failed radial puncture, radial artery spasm, subclavian tortuosity or or aortic root dilatation.[19-20] The radial artery is smaller than the femoral artery, so guide catheter size is usually restricted to 6 French ,although operators have used 7 or 8 Fr on occasions. In our study a 6F sheath and a 6F guiding catheter was used in all cases (100%). Vascular complication rates with transradial access are extremely low. In our study there were no major vascular complications (major access site bleeding, vascular perforation , forearm haematomas requiring blood transfusion or surgical repair, radial artery occlusion, forearm ischemia or compartment syndrome) or MACE. There were 15 cases of minor forearm bruising and 09 cases of minor forearm haematomas that occurred just after the completion of the procedure and settled with arm elevation and pressure bandage. These findings are similar to published data by Kiemeneij et al.[13] In his study comparing percutaneous transluminal coronary angioplasty (PTCA) from various routes, he found a 2% incidence of major access site bleeding complications with the femoral approach and a 2.3% incidence with brachial access, whereas there was none encountered in the radial group. Aggressive antithrombotic therapy is a cornerstone of contemporary percutaneous coronary angioplasty in order to limit the occurrence of thrombotic complications during and after the procedure.[21]

Nevertheless, during transfemoral coronary intervention, intensive antithrombotic therapy is associated with an increased risk of access site complications.[22-23] TRI can be advantageous in patients with acute coronary syndrome (ACS) where aggressive antithrombotic and antiplatelet therapy is often instituted. Major bleeding is an independent predictive factor of adverse acute and 1-year outcomes, regardless of the access site. Mann et al compared the use of radial and femoral access sites for PCI in patients with ACS, and found identical 96% primary success rate in both groups. However, there was no access site bleeding complication in the radial group, as compared to the femoral group (4%).[24] Choussat et al examined outcomes among 150 (3.5%) patients who received the platelet glycoprotein IIb/IIIa receptor inhibitor abciximab out of 4231 PCI procedures at a single centre during a 28 month period.[25] He found no major access site complications (resulting in haemoglobin loss ≥2 g/dl, blood transfusion, vascular repair, or prolonged hospitalisation) in the radial group as compared with a rate of 7.5% in the femoral group.[25] Access site complication rates of zero have also been described in case series of transradial PCI for acute myocardial infarction that used glycoprotein IIb/IIIa inhibitors.[26] Other advantages of radial access over the femoral route is rapid mobilisation of the patient and earlier discharge from hospital. The reduction in bed occupancy might be expected to reduce expenditure per patient and increase turnover of patients. Among 200 stable patients randomised to PCI by either the radial or femoral approach, day one and week one measures of bodily pain, back pain, and walking ability all favoured the radial group ($P<0.01$).[27] Furthermore, those patients who had angioplasty by both approaches expressed a strong preference for the radial approach, with 80% preferring the radial approach and only 2% preferring the femoral approach ($P < 0.0001$).[27]

CONCLUSION

The radial artery is an excellent access site for coronary interventions and a safe alternative to femoral catheterization. The transradial approach virtually eliminates access site complications after PCI, even with the concomitant use of aggressive anticoagulant regimens or antiplatelet agents. Time to mobilization, length of hospital stay, and costs all are reduced after transradial percutaneous coronary intervention .The virtual absence of major access site complications combined with rapid mobilisation makes transradial PCI ideal for day case PCI and post-procedure recovery in the future is likely to be in a cardiac day case ward furnished with armchairs rather than beds.

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