

Transradial Coronary Angioplasty and Stenting - Immediate Results and 3-Month Clinical Follow-Up in the First 50 Patients Performed at the National Heart Institute

D Pillay, MRCP, K H Lam, MRCP, M N Muda, MRCP, Z Hamid, MRCP, Department of Cardiology, National Heart Institute, 145, Jalan Tun Razak, 50400 Kuala Lumpur

Summary

Aim: To explore the safety and feasibility of coronary angioplasty and stenting via the radial artery in a heterogenous group of patients and to report the immediate and 3-month clinical follow-up.

Background: The use of the transradial approach for coronary angiography was first described by Lucien Campeau in 1989. Based on the favourable initial results, this technique has gained widespread acceptance worldwide. Ferdinand Kiemeneij's work in transradial angioplasty and stenting has taken invasive cardiology into the exciting new era of "minimally invasive coronary intervention".

Methods and Results: Fifty consecutive patients underwent Transradial Percutaneous Transluminal Coronary Angioplasty (PTCA) with or without stenting from mid March 98 - December 98. The right radial approach was utilised in 41 patients (80%) while the left in 9 patients. Ninety percent of the procedures was done on an adhoc basis. Diabetes mellitus was present in 38% of patients. Eighty percent of patients had unstable angina pectoris and 60% had a prior history of acute myocardial infarction. The commonest vessel involved was the LAD (51%) and type B lesions predominated (54%). PTCA was successful in 96%. One patient had a total LAD occlusion, which could not be wired, and another developed severe spasm during catheter manipulation. The latter had successful PTCA via the right femoral route. Stents were utilised in 57% of patients. The commonest indication for stenting was suboptimal PTCA results (89%) and dissection (14%). There was no stent embolisation and all stents were successfully deployed (100%). One patient developed acute stent thrombosis necessitating repeat PTCA and another patient sustained an acute anteroseptal myocardial infarction 5 days post procedure as a result of subacute stent thrombosis and died. Two patients had successful primary PTCA. There was no bleeding or vascular complications. 60% of patients were treated on an outpatient basis. At 3-months follow up, 1 patient required CABG's for disease progression. Three patients had absent radial pulses without adverse consequence. No patient required repeat PTCA at follow up.

Conclusion: In summary, adhoc PTCA and stenting is safe and feasible in our patient population. A study on the cost effectiveness of the procedure compared to conventional femoral PTCA is warranted.

Key Words: Transradial, Angioplasty, Stenting

Table I
Guiding Catheters Commonly Used

Left Coronary Artery	Right Coronary Artery
Jean-Fajadet Radial Left (Cordis)	Jean-Fajadet Radia Right (Cordis)
Extra back-up (EBU)	Multipurpose 'Hockey Stick'
Judkins Left 3.5/4	Judkins Right 3.5
Cyber radial XT	Amplatz Right 2

Table II
Patient Demographics

No. of Patients	50
Males	94%
Mean Age (yrs)	53.7±3.9
Race	
Malay	33%
Indian	44%
Chinese	15%
Others	8%
Risk Factors	
Diabetes Mellitus	38%
Smoking	42%
Hypertension	36%
Positive Family History	27%
Hypercholesterolaemia	60%

Table III
Clinical Characteristics

Unstable Angina	80%
Prior history of AMI	60%
Acute AMI	4%
Prior CABG	4%
LVEF (mean)%	56.7+/-9.4

Introduction

Previous reports¹⁻⁷ have suggested that transradial angioplasty and stenting is feasible and safe in a selected group of patients and allows immediate mobilisation.

The safety of transradial coronary cannulation is determined by the following factors:

- * The superficial course of the radial artery enables easy haemostasis.
- * There are no major nerves or veins close to the artery and, therefore, no chance of neurovascular trauma.
- * There is dual blood supply to the hand and, therefore, no ischaemia, should there be occlusion of the radial artery in patients with a normal Allen test.

With present day miniaturised equipment, 6 French guiding catheters are normally utilised. The advantages of 6 French guiding catheters are:

- * Smaller puncture holes.
- * Ability for deep intubation with maintenance of adequate contrast delivery.
- * Wide range of 6 French compatible tools including stents.

The aim of this prospective study was to explore the safety and feasibility of coronary angioplasty and stenting via the radial artery in a heterogenous group of patients and to report the immediate and 3-month clinical follow-up.

Materials and Methods

Study Population

From mid March 1998 - December 1998 a total of 50 patients underwent transradial coronary angioplasty and stenting at the National Heart Institute. Forty-five patients (90%) underwent adhoc angioplasty and stenting while the remainder 5 patients (10%) had an elective procedure.

Patient Selection

In the initial phase of this study, 'ideal' patients were chosen i.e. male patients with stable angina. However, in the later stages, with improved operator experience, the inclusion criteria were extended to patients with unstable angina, complex coronary anatomy and acute myocardial infarction.

Table IV
Angiographic Characteristics

Single Vessel	80%
Double Vessel	16%
Triple Vessel	4%
Vessels Involved	
LAD	51%
LCx	11%
RCA	38%
Lesion Type (AHA Classification)	
Type A	36%
Type B	54%
Type C	10%

Table V
Complications within 24 hours

Death	Nil
AMI	Nil
Emergency CABG	Nil
Stroke	Nil
Acute stent Thrombosis & successful re-PTCA	1
Bleeding	Nil
Radial Artery Occlusion	3; no ischaemia
* Outpatients	30 (60%)

Patient exclusion criteria included concomitant need for right heart catheterisation, internal mammary artery angiography and patients with chronic renal failure on regular haemodialysis with a functioning arterio-venous fistula.

Patient Preparation and Procedure

All patients were premedicated with intramuscular diphenhydramine (phenergan) 25 - 50mg when called to the catheterisation laboratory. Topical EMLA cream was applied to the wrist 2 hours before the procedure. The right wrist was selected in 41 patients (80%) and the left wrist in (20%) as per operator preference. The

arm was abducted and hyperextended at the wrist. The wrist and bilateral femoral entry sites were disinfected and prepared for possible access. After local skin infiltration with 2% xylocaine, the radial artery was punctured with a 22G Cook needle. The artery was cannulated with an 0.025" straight non-teflonised guide wire. A 6 French Cordis Avanti sheath (Cordis) was then inserted. The long 23cm sheath is routinely used to minimise risk of radial artery spasm during catheter manipulation.

After sheath introduction, a spasmolytic cocktail consisting of 2mg Verapamil and 200mcg of nitroglycerine was given intraarterially. Coronary angiography was performed with a 6Fr Castillo II diagnostic catheter (Cordis). If an artery was judged to have a significant stenosis (>50% by visual estimation), the diagnostic catheter was exchanged for a 6Fr guiding catheter and adhoc PTCA was attempted.

Heparin sulphate 5,000-10,000 units was then injected through the side arm of the sheath. No quantitative angiography was performed pre or post-procedure. Table I show the common guiding catheters used.

Once the procedure was completed, the arterial sheath was immediately removed under full heparinisation and haemostasis was achieved with a Strepty P haemostasis device (Nichiban Corporation) over which a tourniquet was applied. The tourniquet was removed after 45 minutes while the Strepty P was kept in situ for 3 hours. Radial artery patency and local vascular complications were assessed at discharge. Post-stent treatment consisted of Aspirin 150 - 300mg for life and Ticlopidine 250mg twice daily for 1 month. No patients required low-molecular weight heparin or coumadin post-stenting.

Results

Demographic and clinical data are illustrated in Tables II and III. Table IV describes the angiographic characteristics of the vessels involved. Ninety Four percent of patients were males with a mean age of 53.7 ±8.9 years and the Indian community predominated (44%). Thirty-eight percent of patients had diabetes mellitus. Hypercholesterolaemia (defined as total serum

Table VI
Complications at 3 month follow up

Recurrence of angina	Nil
Repeat of PTCA	1
CABG	1
Stroke	Nil
Subacute stent thrombosis & Death (5 days post-disch.)	1
*Acute MI	1

*Occurred 5 days after PTCA

cholesterol ≥ 5.2 mmol/L) was present in 60%. 80% of patients had unstable angina, 60% had a prior history of an acute myocardial infarction. Two patients (4%) had primary angioplasty for acute myocardial infarction and two patients had prior coronary bypass surgery. The mean left ventricular ejection fraction was $56.7 \pm 9.4\%$. Single vessel disease was present in 80% of cases and the left anterior descending coronary artery was the commonest vessel involved (51%).

According to the ACC/AHA classification of lesion type, 36% were type A lesions, 54% were type B lesions and 10% were type C lesions.

Thirty-one stents were deployed in 56 lesions with an average of 1.6 stents/patient. The commonest indication for stenting was suboptimal PTCA results in 89% and dissection in 11%. A wide variety of stents were used. The AVEGFX stent was the commonest one deployed. All stents were premounted and there were no bare stents utilised in this initial series. After stent deployment, high pressure post-dilatation (12 - 18 Atm) was performed. Intravenous Abciximab (ReoPro, Eli-Lilly) was infused in 4 patients (8%). One patient required a temporary pacemaker insertion during PTCA to a large dominant right coronary artery. No patients required intra-aortic balloon pumping. Patients were discharged the same day whenever possible.

Results

Procedural Success

Successful cannulation of the coronary ostia was achieved in 100% of patients. Balloon angioplasty was successful

in 48 patients (96%) with 2 failures. In the failure group, 1 patient developed severe spasm during catheter manipulation. The other patient had a total occlusion of the left anterior descending coronary artery, which could not be wired. The former had the procedure completed via the femoral route. All stents were successfully deployed (100%) and there was no stent embolisation.

Clinical Outcomes

Tables V and VI illustrate the major complications within 24 hours and at 3 months.

There was no death, acute myocardial infarction or strokes within the first 24 hours and no patient required emergency coronary bypass surgery. One patient who had unstable angina developed acute stent thrombosis within an AVE GFX stent deployed in the left anterior descending artery. This patient underwent successful repeat PTCA with abciximab infusion. There were no major bleeding complications necessitating blood transfusion. Three patients developed radial artery occlusion post-procedure without any evidence of hand ischaemia. Outpatient angioplasty and stenting was performed in thirty patients (60%).

In the following 3 months, 46 patients were available for review. Out of this number, 40 underwent non-invasive evaluation for ischaemia in the form of a treadmill exercise test or stress echocardiogram. No patients required repeat PTCA and there was no recurrence of angina. One patient required coronary artery bypass surgery for disease progression in his vessels. One patient developed sub-acute stent thrombosis within a 2.5mm AVE GFX stent in the left anterior descending coronary artery 5 days post-procedure and had a Q-wave myocardial infarction and died.

No patient had any paraesthesia or limitation of hand movement at 3-month follow-up.

Discussion

This study demonstrates that transradial angioplasty and stenting is safe and feasible with an accepted complication rate in our patient population. Although the number of patients is small in this cohort studied,

nevertheless immediate and 3-month follow-up results are encouraging. Furthermore, radial artery occlusion is well tolerated in patients with a normal palmar arch^{8,9}. Two patients underwent primary angioplasty with excellent post-procedural results and were ambulant after 24 hours. Due to effective, stable and safe haemostasis, bleeding complications are minimised, despite immediate ambulation, which is appreciated by most patients. This opens the way to cost saving and to outpatient coronary angioplasty and stenting¹⁰. The presence of well developed collaterals with the ulnar artery is a pre-requisite for safe transradial PTCA and stenting as the incidence of early post-procedural radial artery occlusion is between 5-10%^{11,12}.

Radial artery spasm and local hematoma formation may prohibit arterial access especially after an unsuccessful attempt at puncture. However, with adequate precautions such as effective premedication, the use of an appropriate arterial access kit, long introducer sheaths and adequate guiding catheter selection, radial artery spasm and discomfort can be minimised^{11,12}.

6F sheaths and guiding catheters, which are 0.064 inches in diameter, do not allow the use of atherectomy

devices and some stents greater than 3.5 mm in diameter require larger lumen guiding catheters^{13,14}. However, with the development of larger bore 0.067 inch guiding catheters, stent delivery can be facilitated. The use of 7F sheaths in selected patients will need further evaluation in the future.

Conclusion

In conclusion, transradial coronary angioplasty has definite clinical benefits in our patient population. Access site complications are virtually eliminated and early ambulation may result in a shortened hospital stay and lower hospital costs. With proper patient selection, the procedure is safe and effective. Our experience provides evidence that the transradial approach is safe for the management of atherosclerotic coronary artery disease and that it can be successfully performed as a routine approach.

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