

## Early and late results of Percutaneous Transluminal Coronary Angioplasty in Ischaemic Heart Disease: Our Experience

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*The results of 130 consecutive percutaneous transluminal coronary angioplasty (PTCA) procedures carried out in 112 patients are reported. The follow up period ranged from 1 month to 24 months. Eighty-four patients (75%) had a single vessel disease, and 28 (25%) had multivessel disease. Two vessel dilatation was done in 23 patients. The primary success rate was 92%. In successful cases, the diameter of stenosis was changed on average from an initial 85% to 23%. Acute occlusion of the vessel occurred on 9 occasions (6.8%). Emergency coronary bypass surgery (CABG) was done in 3 (2.7%), 2 patients (1.8%) were subjected to immediate re-dilatation. One patient who underwent CABG died (case fatality 0.8%). Occlusion of dilated vessel did not occur after the patients were discharged from hospital. Follow-up data revealed that long-term clinical success (class I) was seen in 78 patients who had a successful primary dilatation. Of the 25 patients who were studied by a repeat coronary arteriography, 7 had developed restenosis. Five of these patients have been successfully redilated.*

*It is concluded that PTCA is an effective and safe method of treatment in selected patients with coronary artery disease, both single and multivessel disease.*

### Introduction

Percutaneous transluminal coronary angioplasty (PTCA) has become a well established method of non-surgical revascularisation of obstructed coronary arteries. The technique first introduced by Guentzig et al<sup>1</sup> in 1977 has rapidly evolved into a widely accepted therapeutic modality in selected patients of single and multivessel coronary disease<sup>2,3</sup>. Though a large number of patients have undergone this method of treatment in Europe, America and Australia, this method has been introduced only recently on a regular basis in India.

In this communication, we report our experience with PTCA carried out during the period November 1986 to October 1988.

### Material & Methods

During the period Nov 1986 to Oct 1988, 130 attempts at PTCA were carried out in 112

patients (93 males) at the Cardiothoracic Centre of All India Institute of Medical Sciences, New Delhi. Age of the patients ranged from 36-65 years (mean 44 years). The clinical status before PTCA comprised of chronic stable angina (Canadian Heart Association Class II & III) in 59 (53%), unstable angina (Crescendo angina) in 29 (26%) and angina following thrombolytic treatment for acute myocardial infarction (AMI) in 24 (21%) patients.

Single vessel disease was present in 84 patients, two vessel disease in 27 and three vessel disease in 1 patient (Table 1). Of the patients with multivessel disease, dilatation of 2 vessels was done in 23 patients and in the remaining only dilatation of the 'culprit' artery was attempted. Only symptomatic patients showing angiographic coronary artery stenosis measuring 70% or more in reduction of luminal diameter were taken up for PTCA. Patients underwent treadmill exercise stress testing according to the Bruce protocol and radionuclide gated blood pool scintigraphy with exercise wherever this was clinically possible before and after dilatation. A 12 lead ECG was taken before and immediately after PTCA.

**Protocol :** Patients were admitted to hospital one day before the procedure. Baseline ECG, Chest X-ray, blood grouping and cross matching and preparation as for CABG were done. Cardiothoracic surgery team and operation theatre was always available as a standby.

Oral medication included Isosorbide Dinitrate 10 mgs 6 hourly (-1 to + 3 days), Nifedipine 10 mg 8 hourly (-1 day to + 3 months), Aspirin 300 mg per day (- 1 day to continue) and Dipyridamole 100 mg 8 hourly (- 1 day + 3 months).

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Parenteral medicines were Dextran 40% Infusion (100 ml/hour) (-1 to + 12 hours), Nitroglycerine infusion ( 25-150 microgram/minute ) to maintain systolic pressure around 100 mm Hg (- 6 to + 24 hours )

Heparin was given 10,000 units I.V after introducing guiding catheter and 5000 units I.V. 6 hourly thereafter for 24 hours.

Technique : The procedure was done through transfemoral approach using an arterial valved sheath. Pacing lead was placed in right ventricular apex in patients taken for RCA or CIRC dilatation and pacemaker connected on a demand mode. Left or right (USCI) Judkin's guiding catheteres were used to selectively enter the appropriate coronary ostium and baseline



Fig. 1a : Stenosis of LAD.

angiograms were obtained in multiple views to delineate the lesion and assess its continued

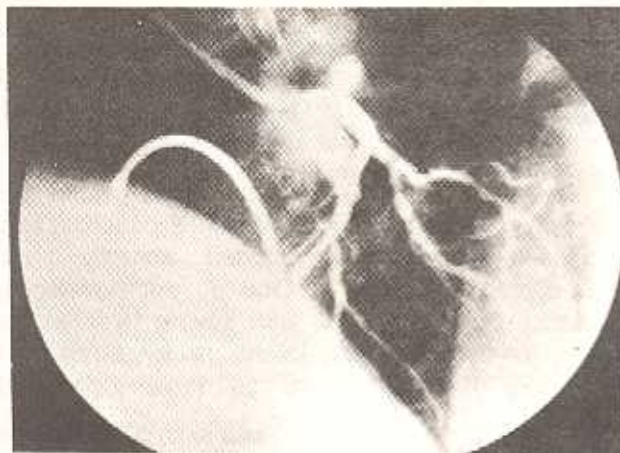


Fig. 1b : Successfully dilated.



Fig. 1la : Stenosis of circumflex.

suitability for PTCA. A steerable guidewire and appropriate sized balloon was advanced through



Fig. 1lb : Successfully dilated.

the guiding catheter to straddle the lesion. The balloons used were LPS-I, LPS-II, profile plus, probe (USCI) and micro-Hartzler and Hartzler balloon catheters (ACS). Resting transluminal pressure gradients were obtained in initial 55 patients and later with the use of newer lower profile balloons this was omitted altogether. After confirming the position, balloon was inflated at 5-10 atmosphere pressure (75-150 PSI) for 30-60 seconds and repeated if required till the balloon waist disappeared and vessel was dilated. Finally a low pressure prolonged dilatation (3-4 atmospheres for 60-75 seconds) was done as a "dressing" manoeuvre at the site of controlled injury. Post-PTCA angiography was done in multiple views to assess the change in luminal diameter. The indices of success were taken as (i) disappearance of the balloon waist; (ii)

decrease/abolition of translesional gradient (in initial 55 cases only); and (iii) angiographic evidence of success which was defined as reduction of stenosis by 20% or more with final stenosis being less than 50% without AMI, emergency CABG or death. Figure 1 and 2 shows pre and post PTCA angiogram showing effective dilatation of left anterior descending and left circumflex coronary artery respectively. There is adequate dilatation of vessel without residual lesion.

**Follow up :** Following PTCA the patients were observed in coronary care unit for 24 hours, ambulated next day and discharged on 3rd day with maintenance treatment as summarised under protocol and advised regarding risk factor modification. Repeat exercise test was planned within two weeks of PTCA for objective assessment of improvement in functional class experienced by the patient. Further outpatient follow up included clinical evaluation, ECG and treadmill exercise test at three and six months. Repeat coronary arteriography was done at 3-6 months period in patients who consented and in those who had recurrence of symptoms with objective evidence of ischaemia suggesting restenosis. The length of follow up was 6 weeks to two years.

Patients of AMI who received thrombolytic therapy were subjected to angiography and PTCA after 10 days to 4 months (average 33 days) of onset of MI and subsequent follow up was as per the protocol.

### Results

We attempted 130 PTCA in 112 patients. The arteries involved and success rates are shown in Table I. The primary success rate was 92% in single vessel disease (SVD), in multivessel disease (MVD) and overall success was 91% (119/130 lesions). Lesions of left anterior descending artery (LAD) had consistently higher success rate in both SVD and MVD but in right coronary artery (RCA) and left circumflex (Cx) artery the success rate was marginally lower, both in SVD and MVD group.

In successful cases the average stenosis of coronary artery reduced from 85% to 23% after

PTCA. The average translesional gradient measured in first 55 cases reduced from 62.5 mm of Hg to 10.5 mm of Hg (Table II).

**Table - I. Vessels dilated and details of Primary Success & Failures**

Coronary artery	SVD		MVD		Total	
	T	S	T	S	S	F
LAD	44	40(91%)	16	15(94%)	55	5
Intermediate	3	3	-	-	3	-
RCA	22	21(95%)	19	17(89%)	38	3
Cx	15	13(86%)	11	10(91%)	23	3
Total(%)	84	77(92%)	46	42(91%)	119(91%)	11

SVD = Single Vessel Disease  
MVD = Multi Vessel Disease  
T = Total S = Successful F = Failure  
LAD = Left anterior descending  
RCA = Right coronary artery  
Cx = Circumflex

PTCA was unsuccessful in 9 patients with 11 (8%) stenotic lesions, seven in SVD and two in MVD group. Details of failure and complications were as follows :

In 4 cases there was abrupt closure of dilated artery leading to AMI. Dissection of dilated coronary artery led to AMI in 2 patients. Side branch occlusion occurred in 2 patients. One patient restudied 3 month later however showed a patent side branch. Both were managed conservatively as the area at risk was small.

In one patient, perforation of right atrium related to pacing lead led to tamponade. This patient also had developed abrupt closure of a dilated artery.

Arrhythmias developed in two cases : atrial fibrillation in one and ventricular fibrillation (VF) in one. The patient with VF was resuscitated promptly and the procedure continued.

Failure to cross the lesion occurred in 3 patients, LAD (1) and Cx (2). The lesions were very tight and placed at angulation.

Emergency CABG was done within 1-4 hours of development of AMI in 3 patients. Two vessels which got occluded abruptly were re-dilated successfully. One patient developing abrupt closure of LAD with severe hypotension and bradycardia was taken up for CABG. At surgery he was found to have developed

tamponde secondary to a perforation of right atrium related to the pacing lead. This patient could not be weaned off the cardiopulmonary bypass and died.

Follow Up Data : Of 103 patients in whom PTCA was successful, follow up clinical status showed that 80 patients were asymptomatic, 13 Class II, 9 Class III and one had class IV symptoms (Table III). None of the patients presented with acute occlusion of the dilated vessel after being discharged from the hospital.

**Table - II Diameter of Coronary Lesions and Pressure Gradients in Patients with Successful PTCA**

	Before PTCA	After PTCA	ATRESTUDY (3-6 months after PTCA) Patency	Restenosed
Average diameter of stenosis	85%(105)	23%(105)	16% (18)	87% (7)
Average transluminal mean pressure gradient mm Hg.	62.5 (55)	10.5(55)	Not measured	

Figures in parenthesis indicate the number of patients

**Table - III Clinical Outcome After PTCA**

Clinical status	Pre-PTCA	Post-PTCA	Followup 6 months to two years
Class IV*	12	-	1
Class III	64	2	9
Class II	29	12	13
Class I	3	79	80

\*As per Canadian Cardiovascular Society Grading of Angina of effort.

Repeat treadmill test done in 90 patients (within one week of PTCA) was negative in 80 and positive in 10 patients. A follow up TMT was done in 35 patients (4-18 months). It was negative in 25 patients and positive in 10 patients (Details in Table IV).

**Table - IV Data of Treadmill Exercise Testing Before, After and During Follow up (Selzer's criteria)**

	Before PTCA	Within 1 week of successful PTCA	After 3** month of PTCA (n = 35)
Negative	4*	80	25
Mildly +ve	2	6	3
Moderately +ve	36	4	5
Strongly +ve	48		2

\* all have ischemia at exercise radionuclide ventriculography  
\*\* Follow up period (4 months - 18 months)

Radionuclide ventriculography was done in 22 patients within 3 months of a successful PTCA. The mean change in Left Ventricular Ejection Fraction (LVEF) before PTCA was  $-1.0 \pm 0.7\%$ , which significantly increased to  $+6.71 \pm 1.2\%$ . Likewise the post exercise regional wall motion abnormalities present before PTCA disappeared in all patients following PTCA (Table V).

**TABLE - V Data of Radionuclide Ventriculography Before and After Successful PTCA (N=22)**

	Before PTCA	within 6 weeks of PTCA
LEFT % (Mean Change)	$-1.0 \pm 0.7$	$+6.71 \pm 1.2$
RWM abnormality	$+1.6 \pm 0.1$	$-6 \pm 0.4$

LVEF - Left Ventricular ejection fraction  
RWM - Regional wall motion

Repeat Coronary Arteriography : In 25 patients repeat angiography was done at 3-6 months after PTCA. 18 patients had maintained patency of the dilated segment with average luminal diameter reduction of 16% only. Seven patients had developed restenosis (average luminal diameter reduction being 87%). Five of them were successfully redilated (3 LAD and 2 RCA). One asymptomatic patient had total occlusion of the dilated segment but distal vessel was filling through collaterals and hence no intervention was done. One patient with class III symptoms & strongly positive exercise test had 90% stenosis of LAD but patient was not willing to undergo repeat PTCA.

## Discussion

Our experience shows that PTCA is an effective alternative to CABG in patients with SVD and can be attempted in patients with multivessel disease having suitably placed lesions with gratifying primary success. Advent of new generation of balloons and accrued experiences of operators have made it possible to attempt more difficult lesions<sup>2</sup> and multivessel lesions<sup>3</sup> with higher success rate<sup>3,4</sup>. The lesion with 70% or more luminal diameter reduction should only be attempted<sup>2</sup> for revascularisation (complete or incomplete) to justify the risk of more severe recurrence<sup>5,6</sup>. Need for surgical back up in the centre undertaking PTCA has been well

emphasised because of a risk howsoever small, of acute problems necessitating emergency CABG<sup>2</sup>.

Acceptability of PTCA depends on three major factors. These are success rate, incidence of complication and restenosis.

Success Rate depends upon experience, equipment and case selection. We have achieved primary success rate of 92% for both single and multivessel disease group. This is marginally higher than the reported success rate by new National Heart Lung and Blood Institute (NHLBI) registry of 84% for single vessel disease (SVD), 75% for Double Vessel Disease (DVD) and 71% for TVD but correlates well with success rate of 91-92 reported by others<sup>7-11</sup>. Our better success rate is attributed to a careful case selection, newer dilatation equipments and straightening out of the learning curve because one of the operators had done the procedures elsewhere under supervision of an experienced team.

Prolonged chest pain following PTCA is caused by spasm, dissection or thrombosis. Spasm was prevented by continuous nitroglycerine infusion and intermittent intracoronary injection of Nitroglycerin 200 microgram. Dissection and thrombosis are sometimes difficult to differentiate; these generally occur within 30 minutes of PTCA<sup>5</sup> and AMI can be prevented if emergency CABG or redilatation is performed within one hour and hence the need of surgical standby.

Of the 9 patients who had complications, 3 underwent emergency CABG with one mortality. This patient had in addition developed perforation of right atrium related to pacing catheter resulting in additional problem of tamponade which was diagnosed at thoracotomy. This was the only fatality (0.9%), which is no different than 1% reported by old and new NHLBI Registry<sup>3,12</sup> and 0.85 to 0.9% reported by others<sup>5,8</sup>.

Nonfatal AMI occurred in 4 cases (3.5%) and this rate is comparatively less than overall 4.3% reported by NHLBI Registry<sup>3,12</sup>. Failure to cross the lesion was faced in 3 patients (2.7%) which is much less than the new NHLBI Registry

data of 7% in SVD and 9% in MVD. This is due to our strict case selection criteria. Emergency CABG was required in 3 patients (2.7%) which is comparatively less than the overall 3.4% in NHLBI Registry<sup>3</sup> and compares favourably by 2.1% reported by Hartzler<sup>8</sup>.

The incidence of restenosis following PTCA varies from 20-30%<sup>2,5,8,12</sup> at 6-8 months follow up. Angiographic restenosis may be slightly higher than the clinical restenosis as some patients harbour clinically silent restenosis<sup>2,5</sup>. Some incriminating factor for restenosis<sup>2</sup> include failure to control coronary risk factors following PTCA, bifurcational lesions, initial translesional gradient more than 40 mm Hg, presence of thrombus and recent onset angina. Restenosis is amenable to redilatation with excellent success rate<sup>2</sup>.

In the present series we have restudied only 25 patients at 3-6 months of follow up, 7 of them have showed restenosis (28%) and 5 of them have been successfully redilated. However till we have angiographic data on a larger number of patients and a longer follow up, the exact rate of restenosis in our material cannot be commented upon. Given the follow up profile so far, we do not expect restenosis figures to be materially different than what is reported by others<sup>2,5,8,11,12</sup>.

Coronary artery disease is a progressive disorder and many patients may eventually develop disease of other vessels. PTCA of suitable and culprit lesions may obviate the need of premature surgery and thus PTCA complements the Surgery in management of coronary artery disease. The results of currently ongoing trials comparing PTCA and surgery in various subsets of patients will clarify the present debate of PTCA or surgery for a given set of patients of coronary artery disease especially in the multiple vessel subgroup.

Based upon our findings we conclude that PTCA is an effective and safe method of treatment in selected patients of coronary artery disease in our setting. The relief of angina and objective evidence of ischaemia is both prompt and gratifying, though restenosis is emerging as a significant problem.

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