

Transradial Percutaneous Coronary Intervention without On-Site Cardiac Surgery for Stable Coronary Disease and Myocardial Infarction: Preliminary Report and Initial Experience in 174 Patients

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ABSTRACT: **Background:** On-site cardiac surgery is not widely available in developing countries despite a high prevalence of coronary artery disease.

Objectives: To analyze the safety, feasibility and cost-effectiveness of transradial percutaneous coronary intervention without on-site cardiac surgery in a community hospital in a developing country.

Methods: Of the 174 patients who underwent PCI for the first time in our center, we analyzed two groups: stable coronary disease and acute myocardial infarction. The primary endpoint was the rate of complications during the first 24 hours after PCI. We also analyzed the length of hospital stay and the rate of hospital readmission in the first week after PCI, and compared costs between the radial and femoral approaches.

Results: The study group comprised 131 patients with stable coronary disease and 43 with acute MI. Among the patients with stable coronary disease 8 (6.1%) had pulse loss, 12 (9.16%) had on-site hematoma, and 3 (2.29%) had bleeding at the site of the puncture. Among the patients with acute MI, 3 (6.98%) had pulse loss and 5 (11.63%) had bleeding at the site of the puncture. There were no cases of atriovenous fistula or nerve damage. In the stable coronary disease group, 130 patients (99%) were discharged on the same day (2.4 ± 2 hours). In the acute MI group, the length of stay was 6.6 ± 2.5 days with at least 24 hours in the intensive care unit. There were no hospital readmissions in the first week after the procedure. The total cost, which includes equipment related to the specific approach and recovery room stay, was significantly lower with the radial approach compared to the femoral approach (US\$ 500 saving per intervention).

Conclusions: The transradial approach was safe and feasible in a community hospital in a developing country without on-site cardiac surgery backup. The radial artery approach is

clearly more cost-effective than the femoral approach.

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KEY WORDS: angiography, catheterization, cardiovascular intervention, transradial, stent, percutaneous coronary intervention

The transradial approach to coronary artery disease has been performed successfully over the last decade, with the first report coming from Campeau in 1989 [1] regarding a case of diagnostic catheterization. Kiemeneij and Laarman [2] were the first to describe successful coronary artery stent implantation via the transradial approach. Despite several relative contraindications to transradial catheterization (abnormal Allen's test, small arterial size, significant upper extremity vascular disease), this approach has been helpful in treating patients with contraindications to femoral vascular access and/or requirements for uninterrupted anticoagulation or early ambulation [3].

Over time, improved technology and operator experience have led to increased use of percutaneous transluminal coronary angioplasty and stent placement versus in-hospital thrombolysis [4]. A limited number of studies have reported favorable outcomes for percutaneous coronary intervention programs in hospitals without on-site cardiac surgery [5,6], and the choice between PCI and thrombolysis in this type of center is still controversial.

PCI = percutaneous coronary intervention
MI = myocardial infarction

Compared with femoral arterial access, the transradial approach for PCI is associated with fewer access site complications, and the reduced recovery cost is a major factor in cost-effectiveness since the patient is immediately mobile post-catheterization and hemostasis can be obtained promptly. To our knowledge, no published reports have analyzed the use of the transradial approach for stable coronary disease or myocardial infarction in hospitals without on-site cardiac surgery. This study analyzes our experience performing PTCA and stent placement via the transradial approach in patients with stable coronary disease or acute MI in our facility without on-site cardiac surgery in a community hospital in a developing country.

PATIENTS AND METHODS

Between November 2004 and November 2007, 174 patients underwent PTCA and stent placement for the first time in our center (Cardiovascular Disease Unit, Hospital General de Puebla, Puebla, México) as the first choice for coronary artery disease (stable coronary disease and MI). Our center is the largest hospital in the south of Puebla City and handles most medical and surgical emergencies in the area. It has inpatient Surgery, Internal Medicine, Pediatrics and Obstetrics/Gynecology wards. Most patients are low income uninsured urban Hispanics. In 2004 we initiated a program for the transradial approach for PTCA and stent placement to reduce costs, which are usually shared by the hospital and patients.

STABLE CORONARY DISEASE

Our study group included 131 patients with stable coronary artery disease, including clinically stable angina pectoris with known coronary disease, positive stress test or echocardiogram suggestive of ischemia, and patients with worsening of symptoms despite optimal medical management. All were evaluated to assess the real need for PCI.

All patients had either type A or B lesions (National Heart Lung and Blood Institute criteria) in one or two vessels. All were > 80 years of age and had creatinine levels > 1.6 mg/dl and a normal Allen test.

Excluded were patients with type C lesions, complex lesions such as on bifurcations, three or more involved vessels, left main coronary disease and ulcerated plaques, who lived more than 2 hours from the hospital, or had a history of coronary bypass surgery (hospital policy dictates a femoral approach).

ACUTE CORONARY SYNDROME

This group comprised 43 patients complaining of typical chest pain with evidence of myocardial injury by measurement of cardiac biomarkers with ST-elevation, high risk patients with non-ST elevation MI such as those with ST-depressions in con-

secutive leads, and high risk patients with unstable angina such as those with prior MI or those with ST-depressions. Excluded were patients with three or more vessels involved, lesions on the left main coronary artery, previous coronary bypass surgery, and lesions that may preclude intraaortic balloon pump device placement for which a femoral approach is necessary.

Patients in both groups requiring surgical revascularization were sent to a nearby hospital with on-site cardiac surgery (about 2 miles away) and an immediate surgery transport protocol, which included a designated fully equipped ambulance for urgent patient transport and intraaortic balloon pump management for hemodynamic support.

PROCEDURE

Following enrollment, patients were scheduled for PCI. After cleaning forearms and wrists we administered 3 ml of simple xylocaine with an insulin syringe. The right radial artery was our first choice. The radial artery was punctured with a 20-gauge arrow needle (Radial Boston introductory kit™, USA). After a small skin incision with a #5 surgical blade the arterial introducer of 6 Fr was inserted until a fine flow from the artery was obtained. We then administered a cocktail of 5 mg verapamil and 5000 IU heparin in 20 ml of normal saline to prevent arterial spasm; if spasm occurred we administered more verapamil and intraarterial nitroglycerine.

Once the artery was accessed, we inserted a wired guide through the radial, humeral and aorta arteries until the valvular aortic area was reached. The correct catheter for each case was inserted over the wired guide followed by angiography and stent placement. Patients receiving a stent were treated with clopidogrel and aspirin. Stable coronary disease patients were treated with 300 mg clopidogrel prior to the procedure, and patients with acute coronary syndrome with both clopidogrel 300 mg and aspirin 325 mg. Glycoprotein IIb/IIIa thrombocyte receptor blocker (abciximab) was used when indicated (i.e., when thrombi were present). After PTCA and stent placement, the inserter was withdrawn and the site of puncture compressed with sterile gauze for a few minutes followed by application of a tensoplast-based bandage.

Stable coronary disease patients were sent to the general hospital for overnight monitoring and early ambulation, although most patients were discharged on the day of the procedure as part of the ambulatory transradial angioplasty program. Acute coronary syndrome patients were sent to the intensive care unit for monitoring; the length of stay varied.

ENDPOINT ANALYSIS

The primary endpoint was feasibility of the procedure according to the rate of complications (bleeding, nerve damage, femoral crossover, artery spasm, and hospital readmission during the first week). The secondary endpoint was length of hospital stay and hospital readmission in the first week after the pro-

PTCA = percutaneous transluminal coronary angioplasty

cedure. The third endpoint was a comparative cost analysis of the radial and femoral approaches, which involved analysis of direct and indirect costs. Direct costs included the material used during cardiac catheterization, the use of operating and hemodynamic rooms, recovery room stay in the hemodynamics unit, and intensive care unit stay in the hemodynamics unit of our Cardiovascular Disease Unit. Indirect costs included the monthly income of the nurse, radiology technician and the cardiologist performing the PTCA (information from the Administrative Department, Hospital General de Puebla).

STATISTICAL ANALYSIS

A conventional unpaired *t*-test was used to analyze differences between means in the two groups. Fisher's exact test was used to analyze qualitative differences between groups. A level of $P < 0.05$ was taken to indicate statistical significance. Results of the analysis of continuous variables are indicated as mean \pm standard deviation. The statistical analysis was performed using the SPSS statistical software for Windows.

RESULTS

PATIENT ANALYSIS [TABLE 1]

• Stable coronary disease

Of the 131 patients, 62 underwent stress testing and all 62 had a positive pharmacologic nuclear thallium stress test. A stress test was not performed in the remaining patients since the diagnosis was established earlier in the disease course by previous catheterization or stress test.

The indication for PCI was stable angina not responding to optimal medical therapy in 99 patients (75.57%), part of the preoperative workup to decrease the cardiovascular risk of non-cardiac surgery in 17 (12.98%), echocardiographic evidence suggestive of ischemia in 14 (10.69%), and due to chest pain on minimal activity (unstable angina) in 1 (0.76%). On echocardiogram the ejection fraction was $< 50\%$ in 3 patients (2.29%) and $> 50\%$ in 128 (97.71%).

• Acute coronary syndrome

Of the 43 patients with acute coronary syndromes, 40 (93%) were STEMI and 3 (7%) were NSTEMI with high risk electrocardiographic features (ST-depressions and chest pain not relieved by sublingual nitroglycerin and morphine). Patients were treated with standard therapy with unfractionated intravenous heparin, intravenous beta-blocker to a goal heart rate of 50–60 beats/minute, clopidogrel load of 300 mg and aspirin 325 mg as a single dose. All patients were triaged by the emergency medicine department and moved to the catheterization laboratory as soon as possible, activating the

Table 1. Comparison of groups

	Stable coronary disease	Acute coronary syndromes	P value
Age (yrs)	59.86 \pm 9.04	60.67 \pm 8.5	0.6
Women	46	13	0.7
Men	85	30	0.7
One-vessel disease	114	29	0.7
Two-vessel disease	17	14	0.5

door-to-balloon protocol. Thirty-seven patients presented with Killip I (no symptoms of heart failure) and 6 with Killip II (some pulmonary vascular congestion with shortness of breath but no pulmonary edema). There were no patients with Killip III or IV. Door-to-balloon time was 30–110 minutes (mean 49 \pm 23 min). The time from chest pain onset to emergency department triage area was 4.1 \pm 1.6 hours.

PROCEDURAL RESULTS

• Stable coronary artery disease

The distribution of lesions on diagnostic angiography was as follows: 114 patients (87.02%) had single vessel disease: namely, left anterior coronary artery in 48 (36.6%), left circumflex artery in 25 (19.08%), and right coronary artery in 41 (31.3%). Seventeen patients (13%) had double vessel disease: LAD + LCx in 3 (2.29%), LAD + RCA in 4 (3.05%), LCx + RCA in 5 (3.82%), LAD + diagonal 1 in 3 (2.29%), and D1 + LCx in 2 (1.53%).

Overall, 131 patients received bare metal stents and 18 drug-eluting stents. This was due to socioeconomic considerations, such as the cost of the device and the recommended length of clopidogrel administration.

• Acute coronary syndromes

The distribution of lesions on diagnostic angiography was as follows: 29 patients (66.44%) had one vessel stented: namely, 12 (27.91%) with anterior wall STEMI and the LAD stented, 4 (9.3%) with lateral wall STEMI and LCx stented, and 13 (30.23%) with inferior wall STEMI and RCA stented. Fourteen patients (32.56%) had two vessels stented: 12 (27.91%) with anterior-lateral STEMI and an LAD + LCx stent, and 2 (4.65%) with inferior-lateral STEMI and an RCA + LCx stent. All patients received a drug-eluting stent.

ENDPOINT RESULTS

• Stable coronary disease

The rate of complications was as follows: pulse loss in 8 patients (6.1%), on-site hematoma in 12 (9.16%), and bleed-

STEMI = ST segment elevation MI
NSTEMI = non-ST elevation MI

LAD = left anterior coronary artery
LCx = left circumflex artery
RCA = right coronary artery
D1 = diagonal 1

ing at the site of the puncture in 3 (2.29%). There were no cases of atriovenous fistula or nerve damage.

All patients were discharged within the first 48 hours, 130 (99%) on the same day and one the next day. None were readmitted to the hospital in the first week after the procedure. The mean time from the end of the procedure to hospital discharge was 2.4 ± 2 hours: 110 (83.96%) patients stayed 2 hours, 13 (9.92%) stayed 3 hours, 6 (4.58%) 4 hours, 1 (0.76%) 6 hours and 1 (0.76%) 24 hours (due to need for femoral crossover).

• **Acute coronary syndromes**

Pulse loss occurred in 3 patients (6.98%) and bleeding at the site of the puncture in 5 (11.63%). There were no cases of hematoma, atriovenous fistula or nerve damage.

The length of hospital stay was 6.6 ± 2.5 days, with a minimum 24 hour stay in the ICU after the intervention to monitor for acute MI complications such as ventricular arrhythmias. No patient was readmitted to hospital in the first week after the procedure.

COST ANALYSIS

The costs of radial and femoral approaches are shown in Table 2. Comparison of the radial and femoral approaches showed that transradial access for percutaneous cardiac procedures was associated with fewer access site complications and earlier ambulation. This meant a reduced need for diagnostic vascular imaging, additional laboratory tests, blood transfusions, vascular repair procedures, and longer hospital stay due to complications. The cost of the intervention was clearly higher for the femoral approach, both for direct (longer hospital stay, ICU care) and indirect (fixed overhead, increased nursing care, and greater use of support staff).

DISCUSSION

This study analyzed the short-term efficacy, safety and feasibility of PCI in a community hospital without on-site cardiac surgery in a developing country.

There is considerable disagreement as to whether hospitals with cardiac catheterization laboratories without cardiac surgery backup should offer and perform PCI [7-9]. In developing countries, such as Mexico, the availability of surgical backup is limited. Given the fact that PCI has become a safe and effective procedure and has been proven to be superior to thrombolysis for reperfusion [10], we started a program of PCI without on-site cardiac surgery backup for MI and stable coronary disease not responding to optimal standard medical therapy.

Several recent reports have studied PCI without on-site cardiac surgery in community hospitals [6,11,12]. Ting and

Table 2. Comparison of costs of radial and femoral approaches

Cost	Radial	Femoral
Direct	Materials used during cardiac catheterization* US\$ 1230	Materials used during cardiac catheterization* US\$ 1230
	Catheterization lab US\$ 500	Catheterization lab US\$ 500
Indirect	Nursing care** US\$ 190	Nursing care** US\$ 190
	Radiology technician** US\$ 190	Radiology technician** US\$ 190
	Interventional cardiologist** US\$ 340	Interventional cardiologist ** US\$ 340
	Recovery room stay per bed/day US\$ 186	Recovery room stay in ICU per bed/day US\$ 300
Length of hospital stay (mean)	2.4 hr US\$ 55	24-48 hr US\$ 450
Total	US\$ 2501	US\$ 3010

* Information reported according to the list of package for catheterization of the Cardiovascular Disease Unit, Hospital General de Puebla

** Cost/average based on studies per month during the study period and monthly salary per month.

colleagues [6] studied 1007 patients who underwent elective and primary PCI and reported a success rate of 97% vs. 95% when comparing on-site vs. off-site cardiac surgery, showing that similar clinical outcomes were achieved at a community hospital without cardiac surgery backup and at a tertiary center with on-site cardiac surgery.

In our elective procedures (stable coronary disease cases) there were complications in 23/114 patients but all were non-fatal and did not affect the length of stay. Likewise, in our primary PCI patients (acute coronary syndrome) there were complications in 8/43 patients: all were non-fatal, were not associated with higher morbidity, and did not require surgical intervention.

Primary PCI is the preferred treatment for acute MI, although whether it is preferable to thrombolysis in community hospitals without cardiac surgery backup is still controversial. Peels et al. [11] analyzed whether PCI for patients with STEMI could be performed more rapidly and with comparable outcomes in a community hospital versus a tertiary center with cardiac surgery backup and found that none of the 439 study patients required emergency surgery for failed primary PCI. They concluded that the time to treatment with primary PCI can be significantly shortened when treating patients in a community hospital setting with off-cardiac surgery backup compared with transport to a referral center with on-site cardiac surgery.

Our study confirms the feasibility of PCI by transradial access without on-site cardiac surgery. Saito and co-researchers [13] studied the feasibility of transradial stenting in acute STEMI in a large tertiary care center in the TEMPURA

ICU = intensive care unit

trial. The success rate of reperfusion and the incidence of in-hospital major cardiovascular events were similar in the transradial and transfemoral groups. They concluded that in selected patients with acute MI, primary stent implantation by the transradial approach is feasible as compared to the conventional transfemoral approach. Our study confirms that unselected patients with fewer than three vessels involved can be safely revascularized via transradial access without on-site cardiac surgery backup. There was no major cardiovascular event in our series.

The transradial approach has become increasingly popular in Europe. A meta-analysis of 12 randomized trials [14] found that the risk of major adverse cardiovascular events was similar for the radial and femoral approaches (odds ratio 0.92, 95% confidence interval 0.57–1.48; $P = 0.7$). Radial access was associated with a significantly lower rate of entry site complications (OR 0.20, 95% CI 0.09–0.42; $P < 0.0001$), even at the cost of a higher rate of procedural failure (OR 3.30, 95% CI 1.63–6.71; $P < 0.001$) mainly because radial access requires greater technical skills, thus yielding an overall lower success rate. In their recent study of 644 patients undergoing outpatient coronary angioplasty and randomized equally to transradial or transfemoral PCTA, Slagboom and team [15] found that PCTA was successful in 97% and 96% of cases, respectively, and there were no differences in the number of treated vessels or lesions. They concluded that PCTA on an outpatient same-day discharge basis can be safely performed in the majority of patients with stable and unstable angina pectoris and with single- and multivessel percutaneous interventions. We found that 99% of our patients with stable coronary disease were discharged the same day and there were no readmissions to the hospital in the first week for any cause. Our results suggest that this procedure is safe in a hospital without onsite cardiac surgery in a community setting in a developing country where reducing costs is essential.

With respect to the economic benefits of the radial approach, we found a reduced incidence of complications and, as reported, the avoidance of vascular complications associated with transradial access provides the greatest cost-benefit of this approach [16]. Several studies have demonstrated that compared with femoral access the transradial approach is associated with a significant reduction in bleeding complications at the vascular access site [16–18].

Our results also show important savings as a result of less involvement of medical and nursing staff in patient management, as well as fewer diagnostic costs (laboratory, ultrasound, angiography, CT, etc.) and treatment costs (extra devices, surgery and transfusions) and a more rapid return to productivity for working patients with same-day PCI. It is apparent that

shorter hospital time can be achieved by immediate mobilization of the patient. Recently, Roussanov et al. [19] showed that the radial artery approach to diagnostic cardiac catheterization is clearly more cost-effective than the femoral approach, with or without the use of a femoral closure device in 70, 62 and 49 consecutive cases; a comparative cost analysis between the radial or femoral approaches, where the total variable procedural cost, which included approach-appropriate equipment and recovery room stay, was significantly lower in the radial group than in the two femoral groups (US\$ 369.5 ± 74.6 vs. US\$ 446.9 dollars ± 60.2 and US\$ 553.4 ± 81.0; $P < 0.001$).

In conclusion, the transradial approach can be safely performed in a community hospital without on-site cardiac surgery in a developing country with limited access to cardiac surgery backup. The economic benefits obtained were primarily due to a lower incidence of access site complications and earlier ambulation. The results of our study will be the starting point in the development of a detailed program that should further reduce costs and improve the efficacy of PCI using the radial approach in acute MI for unselected patients, along with the development of an effective transport system in the event that cardiac surgical intervention is required.

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OR = odds ratio
CI = confidence interval

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