

Efficacy of the Radial Approach for the Performance of Primary PCI for STEMI

Carlos Cafri, MD, Doron Zahger, MD, Miriam Merkin, MD, Jean Marc Weinstein, FRCP, Sergio Kobal, MD, Reuven Ilia, MD

ABSTRACT: Background. Primary percutaneous coronary intervention (PPCI) for ST-elevation myocardial infarction (STEMI) is associated with increased bleeding complications, impacting clinical outcome. Transradial PPCI could decrease the risk of bleeding, but concerns about technical difficulties and longer reperfusion times limit its adoption. **Aim and Methods.** This was a retrospective comparison of reperfusion times and bleeding complications in a large cohort of STEMI patients treated by PPCI through the transradial (TR; n = 244) or transfemoral approach (TF; n = 364) from January 2005 to December 2009. Endpoints were door-to-balloon time, access-site and non-access site bleeding, as well 1-month and 1-year mortality rates. **Results.** Patients treated with TR-PPCI were younger than those having TF-PPCI, (57 ± 13 years vs 62 ± 13 years, respectively; $P < .01$), more frequently males (84% vs 73%, respectively; $P < .01$), and had less renal failure (9% vs 16%, respectively; $P < .01$) or hemodynamic compromise, ie, pulmonary edema or cardiogenic shock (1% vs 4%, respectively; $P = .01$). Angiographic and angioplasty characteristics, including the angiographic success rate, were similar, with the exception of a higher use of aspiration devices in the TR-PPCI group (31% vs 15%, respectively; $P < .01$). The door-to-balloon time was similar in both groups (76 ± 40 minutes vs 74 ± 41 minutes; $P = \text{NS}$). Significant lower rates of overall bleeding (6% vs 31%; $P < .01$), access-site bleeding (4% vs 27%; $P < .01$), non-access site bleeding (1% vs 3%; $P = .01$) and need for blood transfusion (0% vs 3%; $P = .01$) were observed in the TR-PPCI group. One-month (3% vs 7%; $P < .05$) and 1-year mortality rates (4% vs 11%; $P < .05$) were lower in the TR-PPCI group. Radial PCI was an independent predictor of 1-year mortality. **Conclusion.** TR-PPCI is feasible in STEMI patients and can be performed efficiently within the time limits recommended. This approach provides advantages in terms of reduction of bleeding that could translate into an improved clinical outcome.

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Key words: transradial primary PCI, transfemoral primary PCI, primary percutaneous coronary intervention

Primary percutaneous coronary intervention (PPCI) is the best existing reperfusion strategy for patients with ST elevation myocardial infarction (STEMI).^{1,2} Bleeding

complications are frequent in the setting of PPCI due to the intensive antithrombotic treatment used in this group of patients. Recently, bleeding after coronary interventions has been associated with an increased mortality rate in multiple trials. Therefore, strategies to reduce the risk of bleeding are needed.^{3,4} Access-site bleeding is the most frequent bleeding complication of transfemoral (TF) PPCI.^{5,6} In contrast, transradial percutaneous coronary intervention (TR-PPCI) has been demonstrated in multiple trials to be safer than the femoral approach due to the lower risk of significant bleeding. Implementation of the TR approach for PPCI (TR-PPCI) might lead to improved outcomes through reduced bleeding, but concerns remain regarding potential prolongation of reperfusion times with this more challenging technique. Our aim was to assess the efficacy and safety of the transradial approach in an unselected group of patients who had PPCI for STEMI.

Methods

Study populations. All consecutive patients admitted to Soroka University Medical Center with STEMI between October 2004 to October 2008 and treated with PPCI who belonged to Clalit Health Services were retrospectively identified from our computerized database. Patients were compared according to the access site used during the procedure. Seven operators were involved in the performance of PPCI (6 of them with a high degree of expertise in the use of the TR approach). The choice of arterial access was at the discretion of the operating physician. Patients' data were prospectively recorded in a computerized database and included demographic and clinical variables, risk factors, hemodynamic status and left ventricular function during admission, door-to-balloon time, angiographic and procedural characteristics, bleeding complication at the access site and other sites, as well as mortality up to 1 year of follow-up.

Vascular access. In patients selected for TR-PCI, Allen's test was performed. A delay of more than 10 seconds before the return of color to the blanched hand was considered abnormal and a contraindication to the use of the radial approach. Diagnostic angiography was performed using 6 Fr left and right Judkins catheters and the intervention was performed in 97% of cases with 6 Fr Extra back-up 3 or 3.5 (for left coronary interventions) or right Judkins guiding catheters (for right coronary interventions).

In patients selected for the femoral approach, diagnostic and interventional angiography were performed with conventional 6 Fr diagnostic or guiding catheters.

From the Cardiology Department, Soroka Medical Center and Ben Gurion University, Beer Sheva, Israel.

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Address for correspondence: Dr Carlos Cafri, MD, Ben Gurion University, Cardiology, Reger Av, Beer Sheva, 151, Israel. Email: drcarloscafri@gmail.com

Anticoagulation and antiplatelet regimen. All patients were pretreated before arrival at the catheterization laboratory with 300 to 600 mg of clopidogrel and 5000 units of heparin intravenously. Immediately prior to performing PCI, activated clotting time (ACT) was measured and additional heparin was administered, if necessary, to maintain an ACT >300 seconds. The use of glycoprotein IIb/IIIa antagonists was left to the operator's discretion.

Definitions. *Procedural success* was defined as a residual stenosis in the culprit lesion of <30% with Thrombolysis In Myocardial Infarction (TIMI) grade 3 flow. *Door-to-balloon* time was calculated as the time from the patient's arrival in the emergency room or the coronary care unit (in patients admitted directly to the coronary care unit) to the moment of first balloon inflation or first aspiration with a manual aspiration device. *Major hematoma* was determined by a minimal diameter of 6 cm.

Endpoints. Efficacy endpoints were procedural success, door-to-balloon time, fluoroscopy time, and contrast volume administered during the procedure. Safety endpoints were the rate of access-site and non-access site bleeding complications after the procedure as well as the need for blood transfusion. One-year mortality was obtained from the Interior Ministry of the State of Israel.

Statistical analysis. Continuous variables are expressed as mean $\pm$ standard deviation and are compared using the unpaired t-test. Categorical variables are expressed as absolute or relative frequencies and are compared using chi-square analysis. To examine the independent association between TR-PPCI and the 1-year survival, a multivariate analysis was performed using a logistic regression model. Probability values of <.05 were considered statistically significant. The adjusted risk of mortality is expressed as odds ratios (ORs) and their 95% confidence intervals (CIs).

Results

Baseline characteristics. A total of 608 patients with STEMI treated with PPCI were included in the study. TR-PPCI was performed in 244 patients (40%) and TF-PPCI was performed in 364 patients. The baseline characteristics are summarized in Table 1.

In the TR-PPCI group, patients were younger and more often males and smokers. The frequency of peripheral vascular disease was similar in both groups. The frequency of pulmonary edema or cardiogenic shock on admission was higher in the TF-PPCI group (8% vs 3%; $P<.01$), as was the frequency of moderate-to-severe left ventricular dysfunction (59% vs 50%; $P<.01$).

Angiographic and procedural characteristics. Angiographic and procedural characteristics are summarized in Table 2. No differences were observed in the number of vessels with significant disease, the culprit artery, or the complexity of the lesions. The use of intraortic balloon counterpulsation was most frequent in the TF-PPCI group (14% vs 5%; $P<.01$). The PCI technique applied was similar in both groups, with the exception of a higher frequency of direct stenting in the TR-PPCI group (48% vs 36%; $P<.05$). Importantly, angiographic success was similar in both groups.

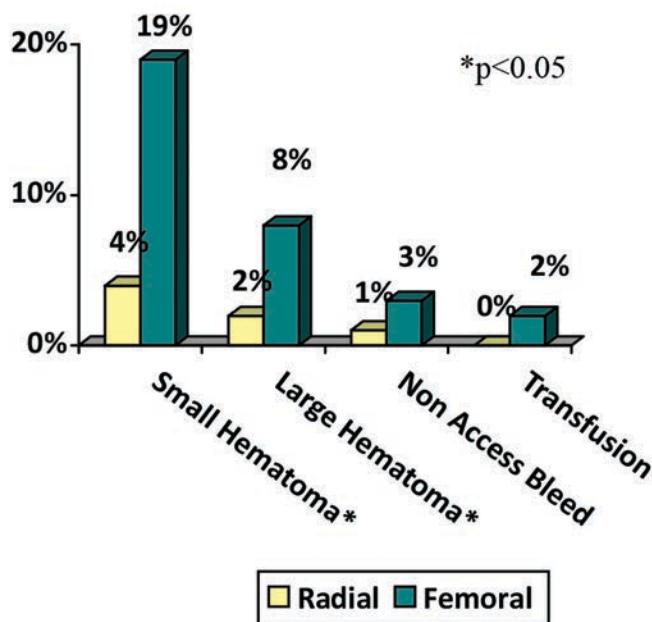


Figure 1. Bleeding complications.

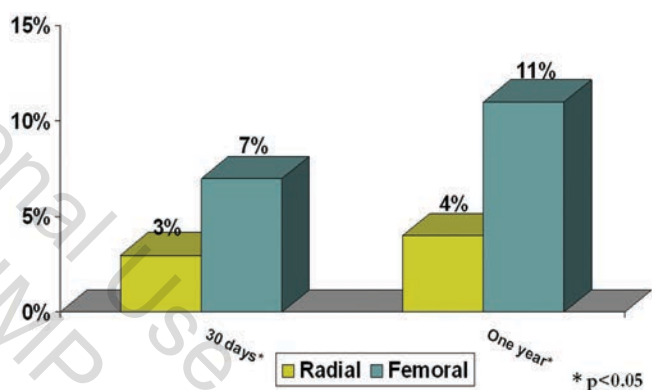


Figure 2. 30-day and 1-year mortality rate.

The door-to-balloon time (76 ± 40 minutes vs 75 ± 41 minutes; $P=.1$), fluoroscopy time (11 ± 7 minutes vs 13 ± 11 minutes; $P=.1$), and the amount of contrast used (146 ± 70 cc vs 149 ± 67 cc; $P=.1$) were similar in both groups.

Bleeding. Bleeding complications are displayed in Figure 1. A higher frequency of access-site small hematomas (19% vs 4%; $P<.01$), access-site large hematomas (8% vs 2%; $P<.01$), and bleeding complications (31% vs 6%; $P<.01$) was observed in the TF-PPCI group. No differences were observed in the frequency of non-access site bleeding.

Survival. The 1-month and 1-year cumulative survival rates are presented in Figure 2. Better survival was observed up to 1 month (97% vs 93%; $P<.05$) as well as at 1 year (96% vs 89%; $P<.05$) in the radial group.

Multivariate analysis showed that the femoral approach was associated with an increased 1-year mortality (OR, 1.9; 95% CI, 1.2-3.3). In addition, 1-year survival was influenced by age, Killip class, the presence of three-vessel

Table 1. Baseline clinical characteristics.

	Transradial (n = 244)	Transfemoral (n = 364)	P-Value
Age (years)	57 ± 13	62 ± 13	<.01
Male	84%	73%	<.01
Hypertension	54%	46%	NS
Diabetes mellitus	27%	27%	NS
Dyslipidemia	55%	45%	NS
Smoker	59%	41%	.05
Body mass index	27 ± 4	27 ± 4	NS
Anterior MI	46%	49%	<.01
Shock	0.3%	4.4%	<.01
BP <90 mm Hg	11%	17%	<.01
Severe LV dysfunction	18%	30%	<.01

MI = myocardial infarction; BP = blood pressure; LV = left ventricular.

Table 2. Angiography and procedural characteristics.

	Transradial (n = 244)	Transfemoral (n = 364)	P-Value
Bifurcation	42%	41%	NS
RVD (mm)	3 ± 0.5	3 ± 0.5	NS
Diameter stenosis (%)	98 ± 4	99 ± 5	NS
Aspiration	31%	15%	NS
Direct stenting	48%	36%	<.05
Stents (n)	1.2 ± 0.5	1.2 ± 0.4	NS
Stent diameter (mm)	3.1 ± 0.4	3.1 ± 0.4	NS
DES	9%	11%	NS
Dye volume (cc)	146 ± 70	149 ± 67	NS
Fluoroscopy time (minutes)	11 ± 7	13 ± 11	NS
Residual diameter stenosis (%)	3 ± 10	3 ± 12	NS
Final TIMI flow III	94%	92%	NS
Final blush III	63%	52%	.04
Success rate	87%	88%	NS
Pain-to-door time (minutes)	146 ± 70	149 ± 67	NS
Door-to-balloon time (minutes)	76 ± 40	75 ± 41	NS

Table 3. Multivariate analysis: 1-year mortality.

	95% CI	OR	P-Value
Gender (male)	1.2-6.8	2.9	<.01
Age (years)	1.01-1.07	1.04	<.01
3-vessel disease	1.4-6	2.9	<.01
Killip III/IV	2.4-13	5.7	<.01
Moderate/severe LV dysfunction	1.03-5.6	2.4	<.05
Femoral access	1.2-6.8	1.9	<.05

disease, and moderate-to-severe left ventricular dysfunction (Table 3).

Discussion

In this observational study, we demonstrated that PPCI can be performed safely and effectively, with reperfusion times and procedural success rates that parallel those obtained via the femoral approach. The radial approach was safer than the femoral approach due to a significant reduction of access-site bleeding and was associated with a reduction in the 1-year mortality rate.

PPCI has become the standard of care for STEMI patients, providing high rates of reperfusion and improving clinical outcomes in comparison with alternative therapies.¹ The benefit of PPCI depends heavily on reperfusion delays, which reflect the efficiency of prehospital and hospital triage, as well as that of the interventional team. Traditionally, the delay between hospital admission and reperfusion should not exceed 90 minutes.⁷⁻⁹ The superiority of PPCI for STEMI as well as the guidelines for its implementation are based on data of patients catheterized through the femoral artery.

The performance of PPCI through the radial artery is a strategy introduced recently in an attempt to improve safety and outcomes through a reduction in the rate of bleeding complications. Concerns about prolongation of reperfusion times have limited the wider application of this strategy. These concerns stem from the technical complexity and longer learning curve that characterize the radial approach, the anatomical variability of the arm arterial system, the occasional difficulties in coronary cannulation and inadequate catheter support during the intervention. Supporting those concerns, a crossover rate of 2%-10% from the radial to the femoral approach has been described during transradial PPCI.¹⁰⁻¹²

Despite these potential limitations, we found similar and adequate door-to-reperfusion times in both the femoral and radial groups. Moreover, indirect measurements of technical complexity and difficulties, such as the fluoroscopy time or amount of dye utilized, were also similar. This observation has been reported by previous authors in observational trials.^{13,14}

Bleeding after PCI has been recognized during the last decade as an independent predictor of adverse clinical outcomes including mortality.^{3,4} Radial PCI is considered safer than femoral PCI due to a significant reduction in the rate of bleeding complications and some trials have reported an improved clinical outcome associated with these findings.¹⁰ PPCI is associated with the simultaneous administration of multiple antiplatelet and antithrombotic drugs, generating a significant propensity for bleeding. Multiple pharmacological strategies have been investigated in this patient population, aiming for a reduction in the hemorrhagic rate while preserving the anti-ischemic properties of the drugs. TR-PPCI is a mechanistic strategy that in our trial was associated with a huge reduction in the rate of all types of bleeding,

including non-access site bleeding, access-site bleeding, small and large hematomas, as well as the need for blood product transfusions. This observation is not new and has been consistently reported in all the clinical trials that analyzed the radial approach during the performance of PPCI. Naturally, the major impact of the radial approach is the reduction in the rate of access-site bleeding — a factor that has been described previously as an independent predictor of clinical outcome.^{10,11}

The unadjusted 30-day and 1-year mortality rates were significantly lower in the patients that were treated through the radial artery. After multivariate analysis, the selection of the radial approach during the acute episode was an independent predictor of survival. This long-term benefit could be explained by the reduction in bleeding complications. Bleeding after PCI translates into adverse outcomes via multiple mechanisms, including hemodynamic instability, hypercoagulability state, and more importantly, causing modification or interruption of the antiplatelet treatment.

Study limitations. Although overall reperfusion time was similar in both groups, the time from arterial puncture to the moment of reperfusion was not measured and this may be a more accurate assessment of the technical aspects of each approach. Another limitation of this trial is the absence of data about the crossover rate to the alternative approach (from radial to femoral or femoral to radial). Although no differences in the length of reperfusion time were observed between the groups, this factor is important as it expresses the technical feasibility of each approach.

This is an observational retrospective trial, where sicker patients were more frequently selected for the femoral approach. Although multivariate analysis was performed to address this difference, it is likely that adjustments could not be made for all baseline differences.

Conclusions

TR-PPCI is technically feasible for patients with STEMI and can be performed efficiently within the time limits recommended by current guidelines. This approach provides a clear advantage in terms of reduction of bleeding complications, which could translate into an improved clinical outcome for these patients.

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