Journal of the American College of Cardiology
© 2014 by the American College of Cardiology Foundation
Published by Elsevier Inc.

Vol. 63, No. 10, 2014
ISSN 0735-1097/$36.00
http://dx.doi.org/10.1016/j.jacc.2013.08.1651

ST-Segment Elevation Myocardial Infarction Treated by Radial or Femoral Approach in a Multicenter Randomized Clinical Trial

The STEMI-RADIAL Trial

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Objectives This study sought to compare radial and femoral approaches in patients presenting with ST-segment elevation myocardial infarction (STEMI) and undergoing primary percutaneous coronary intervention (PCI) by high-volume operators experienced in both access sites.

Background The exact clinical benefit of the radial compared to the femoral approach remains controversial.

Methods STEMI-RADIAL (ST Elevation Myocardial Infarction treated by RADIAL or femoral approach) was a randomized, multicenter trial. A total of 707 patients referred for STEMI <12 h of symptom onset were randomized in 4 high-volume radial centers. The primary endpoint was the cumulative incidence of major bleeding and vascular access site complications at 30 days. The rate of net adverse clinical events (NACE) was defined as a composite of death, myocardial infarction, stroke, and major bleeding/vascular complications. Access site crossover, contrast volume, duration of intensive care stay, and death at 6 months were secondary endpoints.

Results The primary endpoint occurred in 1.4% of the radial group (n = 348) and 7.2% of the femoral group (n = 359; p = 0.0001). The NACE rate was 4.6% versus 11.0% (p = 0.0028), respectively. Crossover from radial to femoral approach was 3.7%. Intensive care stay (2.5 ± 1.7 days vs. 3.0 ± 2.9 days, p = 0.0038) as well as contrast utilization (170 ± 71 ml vs. 182 ± 60 ml, p = 0.01) were significantly reduced in the radial group. Mortality in the radial and femoral groups was 2.3% versus 3.1% (p = 0.64) at 30 days and 2.3% versus 3.6% (p = 0.31) at 6 months, respectively.

Conclusions In patients with STEMI undergoing primary PCI by operators experienced in both access sites, the radial approach was associated with significantly lower incidence of major bleeding and access site complications and superior net clinical benefit. These findings support the use of the radial approach in primary PCI as first choice after proper training. (Trial Comparing Radial and Femoral Approach in Primary Percutaneous Coronary Intervention [PCI] [STEMI-RADIAL]; NCT01136187) (J Am Coll Cardiol 2014;63:964–72) © 2014 by the American College of Cardiology Foundation

There is compelling evidence of better clinical outcomes with primary percutaneous coronary intervention (PCI) compared with thrombolysis in patients presenting with acute ST-segment elevation myocardial infarction (STEMI). However, major bleeding following primary PCI was initially worse than after intravenous thrombolysis (1). Although periprocedural bleeding has been somewhat reduced

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Manuscript received April 8, 2013; revised manuscript received August 1, 2013, accepted August 6, 2013.

with the emergence of smaller vascular sheaths and catheters and less intensive antithrombotic regimens, it remains a major clinical burden. Major bleeding has been identified as an independent predictor of mortality in a number of observational and randomized studies.

The radial approach has been associated with >50% relative reduction in bleeding and access site complications compared with the standard femoral approach in various clinical scenarios (2–4). In 2 recent large randomized clinical trials, the radial approach showed better clinical benefit (and a significant reduction in 30-day mortality) than the femoral approach in patients with acute coronary syndromes (5,6). However, these studies had several limitations. In the STEMI population of the RIVAL (RadIal Vs. femorAL) trial, only 74% of patients underwent primary PCI (7). In the RIFLE-STEACS (RadIal versus FemoraL randomizEd investigation in ST-Elevation Acute Coronary Syndrome) trial, patients with cardiogenic shock were included. In both studies, investigators also included a number of patients after thrombolysis and with symptom duration up to 24 h. Furthermore, the experience of operators with the radial approach was highly variable and the crossover rate from radial to femoral approach varied from 5.3% to 9.6%. Not all patients involved in both studies met class of recommendation criteria for primary PCI and Level of Evidence: IA according to current North American and European guidelines for STEMI (8,9).

Our study was designed to compare the clinical outcomes between the radial and femoral approach in patients presenting with acute STEMI, within 12 h of symptom onset, in high-volume experienced centers proficient in both access sites.

Methods

Study design and endpoints. The STEMI-RADIAL (ST Elevation Myocardial Infarction treated by RADIAL or femoral approach) trial was a randomized, national, multicenter, parallel group trial. Patients that were admitted with an acute STEMI, within 12 h of symptom onset, and referred for an invasive approach with the ability to use both access sites were eligible for inclusion. Written informed consent was obtained in the catheterization laboratory immediately prior to the invasive procedure. The operators performed randomization with personal password through computerized web system.

The primary endpoint was the cumulative incidence of major bleeding and vascular access site complications requiring intervention at 30 days. The net adverse clinical events (NACEs) were defined as a composite of death, myocardial infarction (MI), stroke, and major bleeding/vascular complications. Secondary endpoints included major adverse cardiovascular events (defined as a composite of death, MI, and stroke), technical success, access site failure, procedural and fluoroscopy times, contrast utilization, intensive care unit stay, and all-cause mortality at 6 months.

Abbreviations and Acronyms

MI = myocardial infarction

NACE = net adverse clinical event(s)

PCI = percutaneous coronary intervention

STEMI = ST-segment elevation myocardial infarction

Local ethics committees of each participating center approved this study. Exclusion criteria were cardiogenic shock or inability to obtain written informed consent, prior aortobifemoral bypass, absence of bilateral radial or femoral artery pulses, participation in another ongoing clinical trial, negative Allen's test or Barbeau test type D curve (10), and treatment with oral anticoagulants. The study was registered as a clinical trial (NCT1136187). Following 50% patient enrollment, an independent data safety monitoring board reviewed the blinded data and recommended trial completion.

Population and procedures. All randomized eligible patients undergoing invasive procedure at 4 high-volume, 24/7 PCI centers were pre-treated during the first medical contact with acetylsalicylic acid, a 600-mg loading dose of clopidogrel, and a bolus of unfractionated heparin 70 IU/kg or 5,000 IU. Additional unfractionated heparin was added during the procedure according to activated clotting time with the aim to achieve an activated clotting time ≥250 s. The use of glycoprotein IIb/IIIa inhibitors, thromboaspiration, and the individual PCI strategy (i.e., pre-dilation, direct stenting, and post-dilation) was left to operators' discretion. Anticoagulants were stopped at the end of the procedure, whereas dual antiplatelet treatment was recommended for 12 months after the index event. In the case of radial approach, the vascular sheath was removed at the end of the procedure and hemostasis was achieved with a compressive device TR Band (Terumo, Tokyo, Japan), as previously reported (11). In the case of femoral approach, the use of arterial closure device or manual compression was applied according to local practice.

Definitions and data collection. STEMI patients were defined as having chest pain for at least 20 min with the following electrocardiography changes: ST-segment elevation ≥2 mm in 2 continuous precordial leads or ≥1 mm in 2 limb leads, new left bundle branch block, or electrocardiography changes compatible with true posterior MI. The major bleeding definition was based on the HORIZONS-AMI (Harmonizing Outcomes With Revascularization and Stents in Acute Myocardial Infarction Trial) criteria (12). Due to the fact that small hematomas do not significantly affect mortality, only hematomas >15 cm were recorded (13). Based on the EASY (EArly Discharge After Transradial Stenting of CoronarY Arteries) classification for transradial PCI, this size corresponds to a grade >2 (14). Moreover, these hematomas generally lead to unplanned diagnostic examination and prolonged hospitalization, and could be associated with the risk of antiplatelet discontinuation and the need for additional treatments (6). Access site complications were defined as pseudoaneurysms requiring closure, periprocedural access site bleeding requiring anticoagulation