

obviates the need for additional stent implantation, this new treatment should be the default strategy for patients who have limus-eluting stent ISR. The European guidelines currently recommend DEB therapy for use only with bare-metal stents.

Trial Results Confirm the Benefit of Radial Access for PCI in Patients with STEMI

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The Trial Comparing Radial and Femoral Approach in Primary Percutaneous Coronary Intervention (PCI) [STEMI-RADIAL; NCT01136187] is the most recent randomized trial to show the benefit of radial access for PCI compared with femoral access for patients with ST-segment-elevation myocardial infarction (STEMI). Radial access was associated with lower rates of bleeding and access-site complications and an increase in net clinical benefit.

Ivo Bernat, MD, PhD, University Hospital, Pilsen, Czech Republic, reported on the trial, saying that physician experience with the radial approach has been variable in previous trials. The 4 sites enrolling patients in STEMI-RADIAL were all very high-volume radial centers, with the radial approach used in more than 80% of procedures.

The trial enrolled 707 patients with STEMI who were randomly assigned to PCI with radial access (n=348) or femoral access (n=359) within 12 hours after symptoms onset. Baseline characteristics were similar for the 2 groups except that more patients in the radial access group had hypertension. All patients received aspirin, clopidogrel, and heparin, and 45% of patients in both treatment groups received glycoprotein IIb/IIIa inhibitors.

The primary endpoint was the 30-day rate of bleeding, defined by the Harmonizing Outcomes with Revascularization and Stents in Acute Myocardial Infarction [HORIZONS-AMI] bleeding criteria, and access-site complications, defined as a hematoma of >15 cm. Several secondary endpoints, such as length of stay in the intensive care unit (ICU), use of contrast material, major adverse cardiac events (MACE), and mortality were also evaluated.

Prof. Bernat reported that the radial access was associated with a significantly lower rate of the primary endpoint (1.4% vs 7.2%; p=0.0001). In addition, the radial access was associated with a significantly shorter stay in the ICU (2.5 vs 3 days; p=0.0016) and use of significantly less contrast material (170 vs 182 mL; p=0.01; Table 1).

Table 1. Secondary Outcomes in STEMI-RADIAL.

Outcome	PCI Access Group		p Value
	Radial	Femoral	
Intensive care unit stay (days)	2.5	3	0.0016
Use of contrast dye (mL)	170	182	0.01
Bleeding driven by occurrence of hematomas ≥15 cm (%)	0.6	5.3	
Hemoglobin drop >3 g/dL with clinically overt signs (%)	0.9	2.8	
Hemoglobin drop ≥4 g/dL without clinically overt signs (%)	0.3	0.3	
MACE* (%)	3.5	4.2	0.7
Net adverse clinical events (bleeding + MACE; %)	4.6	11.0	0.0028

MACE=major adverse cardiovascular events; PCI=percutaneous coronary intervention.

*MACE included death, myocardial infarction, and stroke.

The 30-day net adverse clinical event rate, which included MACE plus major bleeding, was significantly lower in the radial access group (4.6% vs 11.0%; p=0.0028). There was no significant difference in the MACE rate alone (3.5% vs 4.2%; p=0.7) or in overall mortality rate (2.3% vs 3.1%; p=0.64). Prof. Bernat noted that the study was underpowered for death.

When STEMI-RADIAL was initiated in 2009, no other data comparing the 2 access routes had been published. However, since then 2 published studies have demonstrated benefits of radial access compared to femoral access: RIVAL [Jolly SS et al. *Lancet* 2011] and RIFLE-STEACS [Romagnoli E et al. *J Am Coll Cardiol* 2012]. Similar to the current STEMI-RADIAL trial, both previous studies demonstrated benefits with the radial approach. In the RIVAL trial, which included 7021 patients (1958 with STEMI), radial access was associated with a significantly lower rate of large hematomas at 30 days (p<0.0001). Among the 1001 patients with STEMI in RIFLE-STEACS, the rate of net adverse clinical events (a composite of cardiac death, stroke, MI, target lesion revascularization, and bleeding) was significantly lower for radial access than for femoral access (13.6% vs 21%; p=0.003).

Prof. Bernat and his coinvestigators concluded that radial access is the preferred approach for PCI for patients with STEMI. However, radial access is a challenge in many facilities because of the lack of experienced operators.