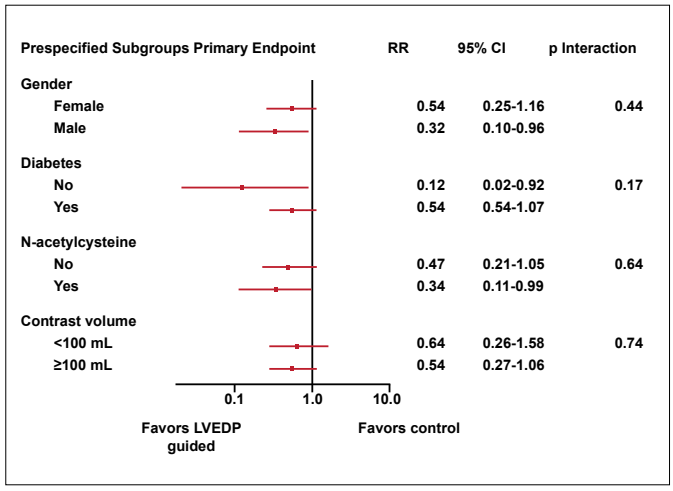
Figure 2. Outcomes of Subgroup Analyses.



LVEDP=left ventricular end diastolic pressure.

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Drug-Eluting Balloon Angioplasty Is Effective for Restenosis of Stented Vessel

Written by ***Lori Alexander***

Angioplasty with a paclitaxel-eluting balloon (PEB) was as effective as implantation of another drug-eluting stent (DES) for patients who have in-stent restenosis (ISR) in the presence of a "limus"-eluting stent. Both procedures were significantly better than plain old balloon angioplasty (POBA), according to the results of the Intracoronary Stenting and Angiographic Results: Drug Eluting Stents for In-Stent Restenosis: 3 Treatment Approaches [ISAR-DESIRE 3; NCT00987324] trial.

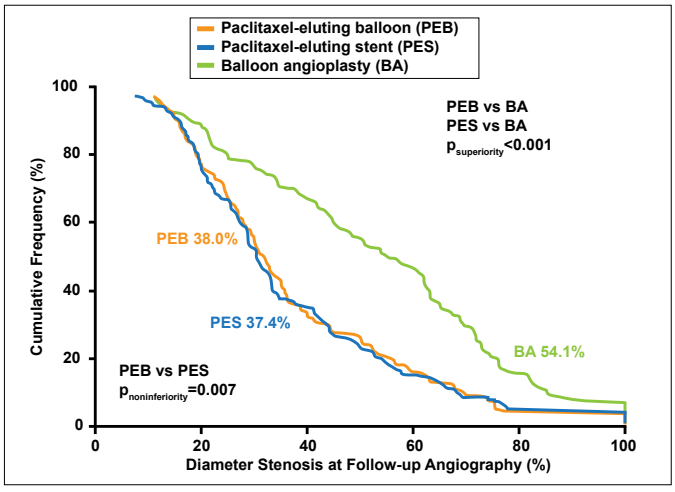
DES have been used for more than a decade, but the optimal treatment for ISR is unknown, said Robert A. Byrne, MBBCh, PhD, Deutsches Herzzentrum, Technische Universität, Munich, Germany, who reported on the study. He said that drug-eluting balloon (DEB) angioplasty has the advantage of avoiding additional stent layers, and small studies have shown promise for the treatment in patients who have ISR with a bare-metal stent. However, the role of this therapy for ISR in the presence of a DES is poorly defined. ISAR-DESIRE 3 was designed to compare the antirestenotic efficacy of 3 treatments of limus-eluting ISR: angioplasty with a PEB, implantation of a paclitaxel-eluting stent (PES), and traditional balloon angioplasty.

The trial enrolled 402 patients at 3 centers in Germany. All patients had ISR of more than 50% in a limus-eluting stent in the presence of symptoms/signs of ischemia. Patients with left main stem disease, acute ST-elevation myocardial infarction (MI), or cardiogenic shock were excluded. The patterns of restenosis at baseline were well balanced across the groups, with a focal pattern in two-thirds of patients and a nonfocal pattern in one-third.

The patients were randomly assigned in a 1:1:1 manner to the 3 treatment groups. The primary endpoint was percentage diameter restenosis on follow-up angiography at 6 to 8 months. Secondary efficacy endpoints were binary restenosis and target lesion revascularization (TLR). Safety endpoints were target lesion thrombosis and a composite of death and MI.

On follow-up angiography, the percentage restenosis was noninferior between the PEB and PES groups (38.0% vs 37.4%, respectively (p for noninferiority=0.007; Figure 1). Both the PEB and PES groups had significantly lower percentage of restenosis when compared with the POBA group (54.1%; p<0.001). The results for the secondary efficacy endpoints followed a similar pattern. Binary restenosis (percentage of patients with restenosis >50%) was found in 26.5% of the patients in the PEB group and 24.0% of the patients in the PES group (p=0.61) compared with 56.7% of the patients in the POBA group (p<0.001). The rates (TLR) were 22.1% for the PEB group, 13.5% for the PES group (p=0.09), and 43.5% for the POBA group (p<0.001).

Figure 1. Primary Endpoint.



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In the safety analysis, the rates of death/MI and target lesion thrombosis were low and similar among all 3 groups.

Prof. Byrne noted that the results of the study are limited to limus-eluting stent ISR and cannot be extrapolated to PES ISR. However, he added that there is no compelling reason to believe that the findings would differ substantially.

The researchers concluded that because DEB angioplasty

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

Written by ***Lori Alexander***

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.

	PCI Access Group		
Outcome	Radial	Femoral	p Value
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.