Dr. Stone reported clinical events at 30 days and acknowledged that the trial was underpowered for these events. The rate of major adverse cardiovascular events was similar for the MGuard stent and standard stent(1.8% vs 2.3%; p=0.75). Similarly, no significant difference in mortality was observed between the MGuard group (n=0) versus the standard group (n=4; p=0.06), but mortality trended in favor of the MGuard consistent with the STR findings.

Long-term clinical and angiographic follow-up of the patients in the trial is ongoing. A larger randomized trial is needed to determine whether the use of an embolic protection stent results in reduced infarct size and improved clinical outcomes.

POSEIDON: Cutting the Risk of Contrast Nephropathy

Written by ***Rita Buckley***

Procedures using intravascular iodinated contrast media are being widely applied for both diagnostic and therapeutic purposes but represent one of the main causes of contrast-induced nephropathy (CIN) and hospital-acquired renal failure. In selected subsets of patients with major risk factors (eg, advanced chronic kidney disease, diabetes, or impending percutaneous coronary interventions [PCIs]), CIN risk can run as high as 50% [Marenzi G et al. *Intern Emerg Med* 2012]. Somjot S. Brar, MD, MPH, Kaiser Permanente, Los Angeles, California, USA, presented findings on the Prevention of Contrast Renal Injury with Different Hydration Strategies [POSEIDON; NCT01218828] trial.

Several studies have shown that CIN is associated with increased morbidity and mortality, extended length of hospital stay, and increased costs [Gallagher S, Knight C. *BMJ* 2011]. CIN has no effective treatment [Marenzi G. et al. *Intern Emerg Med* 2012]. The hallmark of therapy is prevention, yet preventive strategies remain limited, said Dr. Brar.

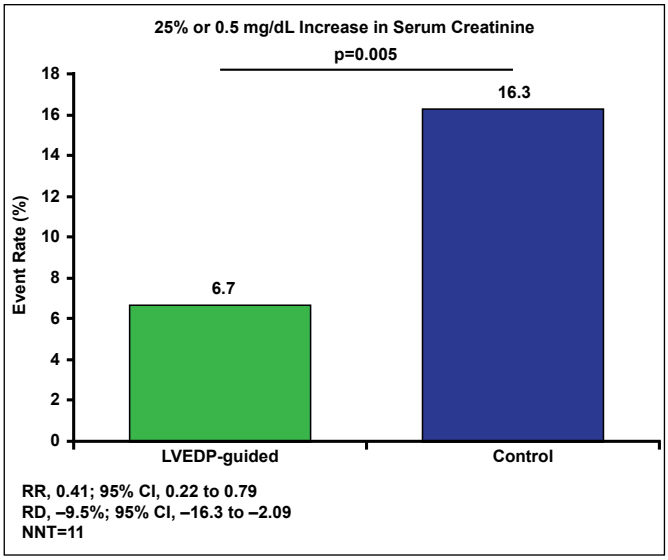
The Phase 3, randomized POSEIDON trial compared standard intravenous (IV) hydration (0.9% saline) with left ventricular end diastolic pressure (LVEDP)-based hydration therapy. Questions surrounding standard IV hydration therapy include its rate and duration, and whether it can be optimized to the patient's needs. The trial's hypothesis was that LVEDP-guided hydration would reduce the incidence of CIN. LVEDP is an intravascular, hemodynamic parameter routinely measured in the cardiac catheterization laboratory, representing a patient's preload or volume status.

The single-blinded POSEIDON trial was carried out between November 2010 and July 2012 in patients undergoing angiography or PCI (inpatient and outpatient) at a high-volume tertiary care center. Inclusion criteria included estimated glomerular filtration rate <60 mL/min/1.73 m^2 (by Modification of Diet in Renal Disease equation) and at least one of the following: diabetes mellitus, age >75 years, hypertension (>140/90 mm Hg or treatment), or history of congestive heart failure. The primary endpoint was a 25% or 0.5 mg/dL increase in serum creatinine on two measurements between Days 1 and 4.

In the trial, 396 patients were randomized (1:1) to either LVEDP-guided hydration (n=196) or standard hydration (n=200). Prior to the procedure, all subjects received 0.9% saline IV at a rate of 3 mL/kg for 1 hour. Standard hydration patients then received 1.5 mL/kg/hr for 4 hours post-procedure. Those with LVEDP hydration received 5, 3, or 1.5 mL/kg/hr for 4 hours based on LVEDP of <13 mm Hg, 13 to 18 mm Hg, or >18 mm Hg, respectively.

The LVEDP-guided approach significantly reduced the primary endpoint by 59% compared with conventional hydration (RR, 0.41; 95% CI, 0.22 to 0.79; p=0.005). Treating 11 patients with an LVEDP-guided hydration approach would prevent 1 case of contrast nephropathy (Figure 1).

Figure 1. POSEIDON Primary Endpoint.



LVEDP=left ventricular end diastolic pressure; NNT=number needed to treat.
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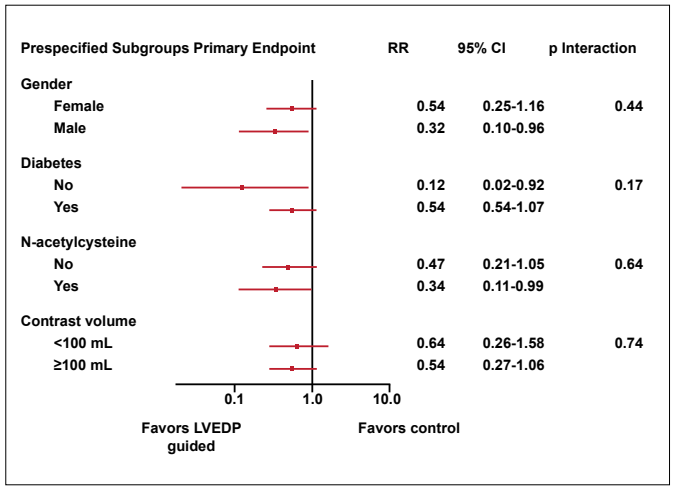
Dr. Brar pointed out that this was the first trial to test the hypothesis of an LVEDP-guided hydration strategy for prevention of CIN. In subgroup analyses, the treatment effect was also consistently in favor of LVEDP-guided hydration (Figure 2).

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.

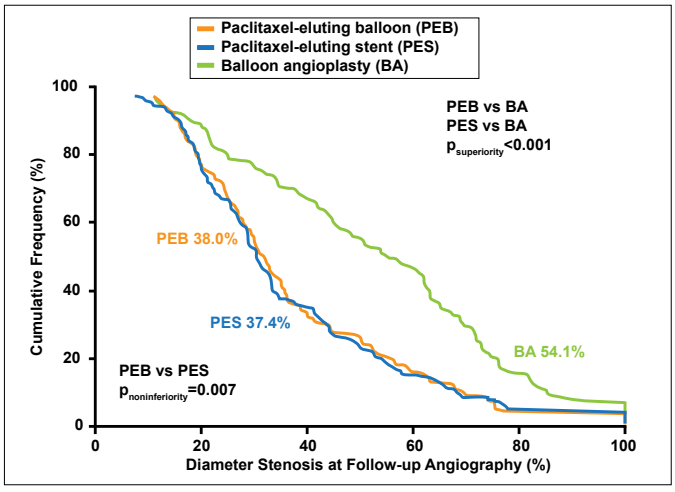
DES have been used for more than a decade, but the optimal treatment for ISR is unknown, said Robert A. Byrne, MBBCh, PhD, Deutsches Herzzentrum, Technische Universität, Munich, Germany, who reported on the study. He said that drug-eluting balloon (DEB) angioplasty has the advantage of avoiding additional 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