Novel Mesh-Covered Stent Improves Rates of Complete ST-Segment Resolution

Written by ***Rita Buckley***

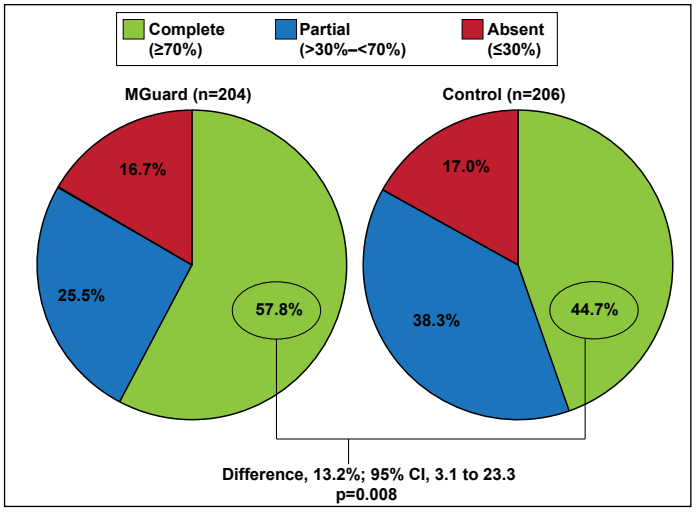
A novel, thin-strut, metal stent with a mesh covering significantly improved the achievement of complete ST-segment resolution (STR) compared with standard stents after percutaneous coronary intervention (PCI) in patients with acute ST-segment elevation myocardial infarction (STEMI). Gregg W. Stone, MD, Cardiovascular Research Foundation, New York, New York, USA, reported the findings of the Safety and Efficacy Study of MGuard Stent after a Heart Attack [MASTER] trial, which were also published simultaneously in the *Journal of the American College of Cardiology* [Stone GW et al. 2012].

Dr. Stone described the stent used in the study as an embolic protection stent. The MGuard™ stent has a polyethylene terephthalate micronet sleeve covering that is designed to trap thrombi and friable atheromatous debris, thereby preventing distal embolization during PCI. PCI-induced distal embolization is thought to contribute to suboptimal myocardial perfusion after PCI, which is common and results in increased infarct size and mortality.

The MASTER trial enrolled 433 patients at 50 sites in 9 countries. All patients had acute STEMI, were seen within 12 hours of symptom onset, and were treated with emergent PCI. The patients were randomly assigned to treatment with the mesh-covered MGuard stent (n=217) or with a commercially available bare-metal or drug-eluting stent (n=216). The primary endpoint was the rate of complete STR, defined as a ≥70% reduction in the summed 12-lead extent of ST-segment elevation from the baseline electrocardiogram (ECG) to ECG done 60 to 90 minutes after PCI. Dr. Stone said complete STR is a strong surrogate for subsequent survival.

The trial met its endpoint with a significantly higher rate of complete STR for the MGuard stent compared with the standard stents (57.8% vs 44.7%; p=0.008; Figure 1). The MGuard stent was also associated with a significantly higher rate of TIMI-3 epicardial coronary flow compared with the standard stents (91.7% vs 82.9%; p=0.006). The rates of grade 2 or 3 myocardial blush were similar for the 2 groups (83.9% vs 84.7%; p=0.81).

Figure 1. Primary Endpoint: Complete ST-Segment Resolution.



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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.

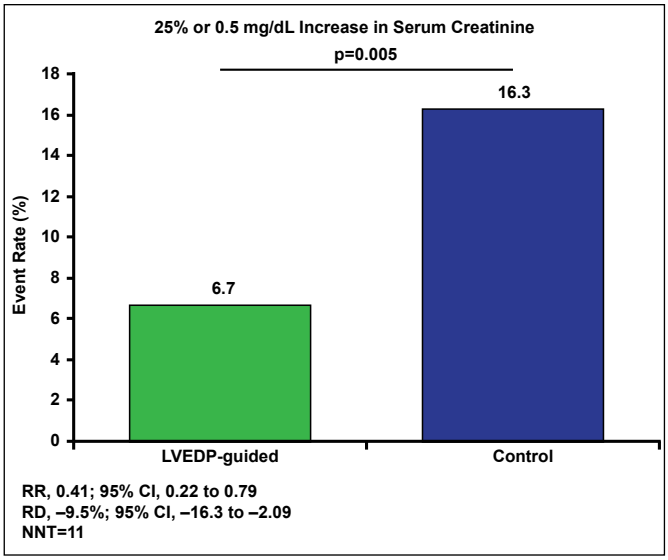
The Phase 3, randomized POSEIDON trial compared standard intravenous (IV) hydration (0.9% saline) with left ventricular end diastolic pressure (LVEDP)-based hydration therapy. Questions surrounding standard IV hydration therapy include its rate and duration, and whether it can be optimized to the patient's 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).