

TCT: Stent with Mesh Cover Helps in Acute MI *On the Scene*

By Crystal Phend, Senior Staff Writer, MedPage Today [Download Complimentary Source PDF](#)

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Reviewed by Zalman S. Agus, MD; Emeritus Professor, Perelman School of Medicine at the University of Pennsylvania and Dorothy Caputo, MA, BSN, RN, Nurse Planner

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MIAMI -- When restoring blood flow in acute MI, a stent covered in mesh for embolic protection appears to resolve ischemia better than conventional stents, a trial showed.

Complete resolution of the ST-segment of the myocardial infarction indicating ischemia occurred within 60 to 90 minutes in 58% of patients who got the MGuard stent compared with 45% getting standard stents ($P=0.008$),

Sigmund Silber, MD, PhD, of the Heart Center at the ISAR in Munich, Germany, reported here at the Transcatheter Cardiovascular Therapeutics meeting.

The novel mesh-covered bare-metal stent also restored full perfusion to the heart in a significantly higher proportion of patients in the MASTER (Safety and Efficacy Study of MGuard Stent After a Heart Attack) trial, which was published simultaneously in the *Journal of the American College of Cardiology*.

These proof-of-concept results may be expected to help prevent heart failure and reduce the risk of death based on prior studies, although the clinical impact needs to be studied prospectively in a properly powered trial, Silber told *MedPage Today*.

Covered stents have been tried for embolic protection before but they used a tightly woven material that ended up squeezing friable material out like toothpaste rather than trapping it.

The MGuard stent uses a loosely-interlaced mesh instead to imprison material that would be prone to plug up small vessels downstream, Silber explained.

With conventional stents, "you get a great result on the occlusion, now it's open, beautiful, but the whole thing went downstream," he said in an interview. "Once the whole thrombus debris goes distally, you're lost. There's no drug, nothing you can do."

That debris slows down blood flow in the artery and can actually make the infarct larger, explained Chris Cannon, MD, of Yale, who called the results "very promising." It's especially a problem in ST segment elevation MI (STEMI), with lesions that are highly thrombotic compared with stable disease, Silber pointed out at a press conference for late-breaking clinical trials.

The international trial included 433 patients who presented within 12 hours of symptom onset. They were randomized to get the MGuard stent or the clinician's choice of commercially-available bare-metal or drug-eluting stents.

For the primary endpoint, the mesh-covered stent boosted the rate of complete -- defined as at least 70% -- resolution of the ST-segment on electrocardiogram at 60 to 90 minutes after implantation by 13 percentage points over that of the standard stent group (95% confidence interval 3 to 23).

The difference was consistent across subgroups, including whether thrombus was aspirated before



Action Points

PCI-induced distal embolization of thrombus and/or friable atheromatous debris is believed to contribute to impaired myocardial perfusion and adverse clinical outcomes. The MGuard is a bare-metal stent with a polyethylene micronet mesh covering designed to trap and exclude embolism-prone.

In this study of patients with acute STEMI undergoing emergent PCI, the MGuard stent compared with conventional metal stents resulted in superior rates of epicardial coronary flow and complete ST-segment resolution.

stent placement or not.

Restoration of Thrombolysis In Myocardial Infarction (TIMI) grade 3 flow occurred in significantly more patients with the novel stent, at 92% versus 83% ($P=0.006$). Myocardial blush grade 2 or 3 was similarly likely between groups (84% versus 85%, $P=0.81$).

Thus, the rate of angiographic success was higher with the mesh covering, although the procedural success rate was lower.

The device couldn't reach or cross the lesion for nine patients in the MGuard stent group, all using an earlier less flexible version of the device, for an overall rate of 4%.

In two cases, the mesh-covered stent dislodged, both while being withdrawn after an unsuccessful attempt to pass through the blocked vessel. One embolized peripherally without clinical complications, the other landed in a nearby vessel.

Clinical outcomes appeared to be at least equivalent between the novel stent and its conventional competitors.

The MGuard stent was associated with a trend, albeit nonsignificant, for fewer deaths from any cause (0% versus 1.9%, $P=0.06$).

That finding would tend to fit with ST resolution being a good marker for improved mortality as shown in the [HORIZONS-AMI](#) trial, Roxana Mehran, MD, of Mount Sinai School of Medicine in New York City, noted at the press briefing she moderated.

However, Bernard Gersh, MBChB, DPhil, of the Mayo Clinic in Rochester, Minn., questioned whether the difference shown in the trial was substantial enough to really translate into a mortality benefit for patients with smaller infarcts.

All discussants at the press conference agreed, though, that proof is needed.

"This is a small study, it's a pilot study, it's a proof-of-principle study," David P. Faxon, MD, of Brigham and Women's Hospital in Boston, pointed out.

Silber also acknowledged that further, larger trials would be needed to adequately assess hard clinical outcomes with the mesh-covered stent.

Reinfarction and stent thrombosis rates were both nearly identical between groups, while the ischemia-driven target vessel revascularization rate was numerically higher with the novel mesh-covered stent but not significantly so (3% versus less than 1%, $P=0.12$).

The researchers cautioned that the trial wasn't powered to draw definitive conclusions about infarct size or clinical events and needs longer-term follow-up to determine late restenosis.

They pointed out that further iterations of the device are expected. **Silber pointed out that a drug eluting version may be the next step.**

Nevertheless, "for the patient who has a heart attack, in the acute phase his problem is not restenosis down 9 months. His problem is to save the myocardium right now" Silber said. "So it is better to prevent the thrombus going downstream with a bare stent than putting in a drug-eluting stent with less restenosis but the thrombus already has damaged the myocardium."

Silber reported receiving research grants from and/or consulting for InspireMD.

Primary source: Journal of the American College of Cardiology

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Stone GW, et al "Prospective, randomized, multicenter evaluation of a polyethylene terephthalate micronet mesh-covered stent (MGuard) in ST-segment elevation myocardial infarction: The MASTER trial" *J Am Coll Cardiol* 2012.

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