ACC: Elective PCI Affirmed Safe Without Surgeon On Hand

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Elective percutaneous coronary intervention (PCI) can be done safely without on-site surgical backup, the MASS COMM trial affirmed.

Safety came out equal between community hospitals without cardiac surgery backup as at those with on-site cardiac surgery, with 9.5% versus 9.4% rates of the composite of death, myocardial infarction, repeat revascularization, and stroke at 30 days ($P<0.001$ for noninferiority, Alice Jacobs, MD, of Boston Medical Center, and colleagues found.

Efficacy in terms of those major adverse event rates at 12 months were likewise similar at 17.3% and 17.8%, respectively, again meeting non-inferiority criteria, they reported here at the American College of Cardiology meeting.

Having a rapid transfer agreement instead of cardiac surgery available 24/7 appears to be an "acceptable option," Jacobs told attendees at the late-breaking clinical trial session.

"These data now add to the growing body of evidence from single-center experience, registry data, and the randomized CPORT-E trial [1], all of which showed favorable outcomes among patients undergoing elective or nonemergency PCI at hospitals without on-site cardiac surgery," her group concluded in a simultaneous publication online in the *New England Journal of Medicine*.

However, cardiologists here were quick to note that these good results wouldn't apply to just any community hospital.

The 'Ifs'

Safety depends on the preparation for disasters in performing PCI without a surgeon on hand, explained Neal S. Kleiman, MD, from the Methodist DeBakey Heart and Vascular Center in Houston.

"The critical thing is this was not a haphazard decision to order some catheters, some stents, and guidewires then say 'Let's do it,'" he noted at a press conference. "This was a very rigorously designed program with a long training period and very clearly defined pathways to manage the pathways."

Hospitals in MASS COMM had to have a formal PCI development program, a collaboration agreement with a center that could provide 24-hour surgical backup with transfer within 60 minutes, and a volume of at least 300 diagnostic cardiac catheterizations and 36 primary PCIs per year.

Operators had to perform at least 75 PCIs per year and be board certified interventional cardiologists.

In CPORT-E, participating centers had to offer around-the-clock PCI and to be capable of doing at least 200 cases a year.

Both trials excluded patients with significant left main coronary artery stenosis, an ejection fraction under 20%, and other higher-risk scenarios.

It's an "if" story, commented Thoralf M. Sundt, MD, chief of cardiac surgery at the Massachusetts General Hospital and co-director of its Institute for Heart, Vascular, and Stroke Care in Boston.

"If you pick the anatomy right, which they did, and you do the procedure right, which they did, you get good outcomes, which they did," he said in an interview. "They had a very, very low incidence of complications, and if you have a low incidence of complications, you don't need onsite cardiac surgery."

The Trial

The Randomized Trial to Compare Percutaneous Coronary Intervention between Massachusetts Hospitals with Cardiac Surgery On-Site and Community Hospitals without Cardiac Surgery On-Site (MASS COMM) was done to provide state public health officials evidence to support a change in regulations.

It included 3,691 patients who presented for elective PCI at a hospital without on-site cardiac surgery capabilities and were randomized to get PCI there at one of the 10 participating community centers or to be transferred to one of seven partner hospitals with on-site cardiac surgery backup.

None of the secondary endpoints showed any significant difference between groups at 30 days or 1 year:

- Death from any cause
- Repeat revascularization
- Stroke
- Ischemia-driven target-vessel revascularization
- Target-lesion revascularization
- Definite or probable stent thrombosis
- Emergency coronary artery bypass
- Emergency or urgent PCI
- Major vascular complications

The only outcome trend of even borderline significance was for fewer stent thrombosis events in the on-site surgical backup hospitals (1.1% versus 2.1%, P =0.07).

The results were the same after adjusting for variance between hospitals.

Seven patients needed emergency surgery. All were transferred within 50 minutes; none died.

A random 10% of the patients checked angiographically to see how well their procedure had been done showed no difference between the two types of hospitals in procedural success, or proportion with complete revascularization.

Nor did sites without a cardiac program treat differently in terms of meeting guidelines for anatomical indications for PCI.

Limitations were lack of 12-month follow-up in 13% of patients, lack of generalizability to excluded patient groups, and lack of power for comparisons in individual components of the primary composite endpoint.

The Concerns

Even though safety has been answered, there are still plenty of questions as programs like these roll out, Jacobs and others pointed out here.

"The fact that we can do it doesn't mean we should do it, so we need to think about how it's going to work," Harlan Krumholtz, MD, of Yale, told *MedPage Today*.

"The bigger question is how many sites do you need and to what degree is this improving the health of the population. I've seen sites grow where it seems to be part of a business model rather than someone taking a larger perspective of what the population needs."

It's possible that the strategy could bring down overall healthcare costs, Sundt suggested.

Eliminating the requirement for on-site surgical backup would mean PCI programs don't have to support the economics of small but expensive cardiac surgery programs, he explained.

On the other hand, this has to be balanced against overproliferation of PCI programs, Sundt added. "Every hospital on every corner shouldn't be doing it because they won't have high enough volume."

Another concern is how to provide truly informed consent and offer patients the option of surgery or PCI when seen at a center without an onsite cardiac surgery program, Sundt noted.

"How do you have a heart team approach at Our Lady of the Highways Hospital that doesn't have on-site cardiac surgery?" he posited. "You've got to adhere to appropriate use guidelines, you've got to have teleconferences."

Also, how will fellows get trained, Jacobs noted.

"The things we worry about are really not easy to study," she told *MedPage Today*. "We have to put our heads together."

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