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MED-MAL MATTERS

Last November, researchers revealed at the American Heart Association's annual meeting in Philadelphia a set of blockbuster findings regarding treatment of ischemic heart disease.

Over the last several decades, untold millions of patients have undergone invasive procedures – coronary artery bypass grafting and angioplasty – to treat clogged coronary arteries. At the AHA meeting, however, researchers revealed the results of a large study called ISCHEMIA.

These commonly performed invasive procedures do not provide any benefit over medical therapy and lifestyle changes for patients with stable ischemic heart disease and moderate to severe ischemia on noninvasive stress tests. In other words, millions of potentially useless elective cardiac procedures, with their attendant potentially deadly complications, have been performed and billed over the last several decades.

At first glance, these results may appear to simply reflect the advance of scientific knowledge: We just didn't know before this study. But the evolution of the invasive treatment of ischemic heart disease offers another possible explanation.

Angioplasty, now known as percutaneous coronary intervention, or PCI, has been around since the late 1970s. It involves the insertion of a catheter through the skin (percutaneous) and into the femoral artery, or increasingly, the radial artery. In PCI, a cardiologist advances a catheter through a distal artery into the heart, then injects dye to highlight blockage in the coronary arteries. An additional catheter is then advanced over a guide-wire to inflate a balloon to open a blocked artery or to place a stent to keep the artery open.

Cardiologists distinguish between primary and elective PCI. Primary PCI is performed for a particular type of heart attack, characterized by ST-segment elevations on EKG and known as ST-segment myocardial infarction, or STEMI. Nonprimary, or elective, PCIs are those performed for all other indications, including ischemia on noninvasive stress test and stable coronary artery disease.

PCI presents certain risks to the patient, not the least of which is a perforation of the heart or an artery that requires emergency open-heart surgery to repair. The potential for this devastating complication prompted a committee from the American College of Cardiology (ACC), the Society for Cardiovascular Angiography and Interventions and the AHA to publish guidelines in 2005 recommending that elective PCIs not be performed at institutions that do not provide on-site cardiovascular surgery. In other words, if you per-



CHANGES VS. SURGERY

Study shows major heart procedures not a cure-all

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form a procedure that, even when done perfect, is known to cause a complication requiring emergent cardiac surgery, you better have the ability to perform that surgery.

By 2007, however, the Society for Cardiovascular Angiography and Interventions, a professional organization for clinicians who perform PCI, released a "consensus document" on PCI at facilities without on-site surgical backup. The document notes that centers in 28 states were performing both primary and elective PCI without on-site surgery and that the number of centers performing PCI without surgical backup grew from 3% to 16%, notwithstanding the 2005 guidelines.

Instead of reinforcing the 2005 standard, however, the society published a list of recommendations to try and make a potentially unsafe practice a little safer. Dr. Gregory Dehmer, lead author of the document, argued that the society was not "encouraging" PCI without on-site surgery, but acknowledging that this potentially unsafe practice was going on "very widely." By 2011, the society, the ACC and AHA had essentially thrown in the towel. These organizations published another expert consensus document on PCI without on-site surgery, this time embracing elective and primary PCI, with some exceptions, at facilities with no ability to fix a known, emergent complication.

In a section titled "Financial Considerations for Facilities Providing PCI Without On-site Surgery,"

a 2014 update to the PCI recommendations by the same organizations provides some insight into one of the possible reasons that facilities without surgical backup want to perform PCIs and the dilution of patient safety guidelines over time to allow them to do so. In a word, money.

Exclusion from providing STEMI care and "loss of downstream revenue" from more testing in patients suspected of having an acute coronary syndrome are also key financial drivers. This includes testing to exclude coronary artery disease and testing for the noncardiac causes of chest pain.

In the new standard, Dehmer states that the informed consent process should include the fact that the procedure is being performed without on-site surgical backup. That's true as far as it goes, but shouldn't that discussion take place before the patient ever shows up for a procedure? What reasonable patient, if truly fully informed, would choose to have an elective PCI in an institution that cannot save her life if she needs emergent cardiac surgery?

When it comes to PCI, money talks and patient safety walks. **CL**

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