The results of the International Study of Comparative Health Effectiveness With Medical And Invasive Approaches (ISCHEMIA) were presented at the American Heart Association meeting this weekend. Their take-home finding that stents and surgery are no better than optimal medical management in treating cardiac disease is being pushed by the mainstream media. And while that finding is "true," the results and their real-world implications are, as always, more complex and nuanced.

"All of the experts who spoke with TCTMD said they were not particularly surprised by the results, but all of them had caveats."

The study

This is an international study of approximately 5,200 patients with stable coronary artery disease – that is a key phrase. These are patients who are not having a heart attack, are asymptomatic for chest pain (angina). They are patients who have been identified as having coronary artery disease based on testing that shows abnormal blood flow in the arteries serving their hearts. Additional patients were excluded that had disease of their left main coronary artery, that were at such additional risk that ignoring interventional management was unethical – they call it a "widow-maker" lesion for a reason.

All patients received optimal medical therapy, aspirin and statins, and treatment of their co-morbidities; they were then randomized, half being offered interventions, e.g., stents and surgery.
For the study's two initial endpoints (and again initial is a keyword), a subsequent heart attack or death there were no significant differences in the two groups — optimal medical therapy alone, without the need for surgery or stents ($$$), produced the same results. Several secondary endpoints were added during the study, "hospitalization for unstable angina, hospitalization for heart failure, or resuscitation due to cardiac arrest." Again, for these endpoints, there was no difference. But because additional endpoints were added, you can expect that some interventionalists (cardiologists placing stents and surgeons doing bypass surgery) to cry foul, "you moved the goalposts." This is true, but the survival benefit, a primary endpoint, shows no difference.

The median follow-up of these patients is 3.3 years, but the trajectory of these two groups differed. At six months post-randomization, the group having interventions had a slightly higher incidence of heart attacks, 5.3%, compared to those treated solely with medications, 3.4%. But over time, those results flipped with those undergoing intervention having fewer cardiovascular events, 11.7%, then those receiving medications, 13.9%. This speaks to a more significant issue that "results" in chronic disease change over time and that survival advantage and disease-free intervals might look different if the study had been carried out for a more extended period. That is one of the reasons there is a push to continue funding the research and again move those goalposts.

There was some joy amongst the interventionalist though, in looking at the quality of life data. Specifically, 50% of those in the intervention group were chest-pain free as compared to 20% in the optimal medical management group. None of this is a surprise, surgery and stents are designed to relieve angina.

ISCHEMIA is a follow-on study to COURAGE, Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation (you have to love the acronyms), which demonstrated the same findings several years ago — results that were questioned leading to ISCHEMIA. Among the questions and concerns were diagnostic criteria, study endpoints, and my personal favorite, "we used older stent technology, we are better now." The same interventional cardiologists, invested in interventional care, are touting the quality of life benefit.

"Feeling better or living longer are "what patients want," Stone [an author of ISCHEMIA] continued. "What we've shown in this trial, with a high precision, is that we're not going to make you live longer by undergoing an invasive strategy, but we will most likely make you feel better."

What should I advise the patient sitting in front of me to do?
That is the million-dollar question or in this case, $1 billion question (open-heart surgery, $116 million [2], drug-eluting stents $917 million [3]). This tightly controlled study at a range of international centers will not translate directly into the real world. First, and most importantly, medical management needs to be optimal, and that requires appropriate prescribing by physicians and compliance by patients – two qualities showing significant variability. And let us just say that we somehow mandated optimal medical management by physicians, who makes the patients comply? In the real world, many people, given a choice, would choose medicine over exercise and stents over swallowing several pills a day. That is just how people act.

Second, how do I manage the "worrisome" images? There are any numbers of studies showing that interventionalists, and I include myself in that group, respond to the troubling images of disease with the treatments we have to offer, surgery, and stents. It is tough to see a blockage that might result in amputation (for my patients) or death for the cardiologists' patients and sit on our hands. It is not about the money, although it does play some role, it is about breaking up that "see - do" response of our training and experience, and the amount of risk that our patient and we can tolerate.

The real take-home from the study is better information for the discussion between physicians and patients. We can again say, that for this limited group of patients, (remember they have a stable chronic disease that is minimally symptomatic), intervention is no better than optimal risk management in your survival or risk of a heart attack. It will reduce your anginal symptoms.

Then the discussion shifts as to how much the patient wishes to risk and do. Unfortunately, we know from a variety of other sources that eating nutritious foods and exercising on a nearly daily basis, is not what people choose. Many of our fellow citizens would rather than a few pills, and when pushed further, would be happy to undergo a stent placement if they could continue on their way, eating and living as they wish. That is a bottom-line truth, and it is why this study will not move the treatment needle as much as it should. I know this because I ride that Peloton every day, just before I have my donut. Not everyone does what is good for us, even when we have a new shiny study to give us guidance.