ASCERT: Better survival for CABG vs PCI in some high-risk patients

JAN 30, 2012 Reed Miller

STS

Ft Lauderdale, FL – ASCERT, a large comparative-effectiveness study derived from **Medicare** and professional society databases, found that CABG surgery provides better four-year survival odds than PCI in high-risk stable patients with two- or three-vessel disease [1].

Dr Fred Edwards
[Source: ASCERT]

"We still don't have the answer to the question of how patients with stable coronary artery disease should be treated if they don't respond to medical therapy," ASCERT primary investigator **Dr Fred Edwards** (University of Florida, Jacksonville) told heartwire. So the **Society of Thoracic Surgeons** (STS), the **American College of Cardiology** (ACC), and the **Centers for Medicare & Medicaid Services** (CMS) collaborated to develop ASCERT, a comparative-effectiveness study of surgery vs PCI in stable coronary atherosclerosis patients.

The ASCERT high-risk subset results, presented here at the Society of Thoracic Surgeons 2012 Annual Meeting, show a long-term survival benefit for surgery over percutaneous intervention. "This confirms, in current real-world practice, the results of other studies, from the New York state data to the randomized trials like SYNTAX," STS president **Dr Michael Mack** (Baylor Health Care System, Plano, TX) told **heart*wire***. "That's what we're finding in the real world under current medical therapy. This is encouraging information, in that the results of previous trials are still relevant to current populations.

Dr Michael Mack

"The whole reason that the ACC and STS formed their databases to begin with is that administrative data are not able to adjust for risk . . . but one of the shortcomings of that was that we could capture only 30-day outcomes and couldn't get long-term follow-up," Mack said. "So linking this to CMS data is huge in terms of all of this research long term. It has the best of both worlds. It's risk-adjusted and has long-term outcomes."

The study combines PCI data from **National Cardiovascular Data Registry** (NCDR), bypass surgery data from the STS

Survival rates favored percutaneous intervention within one year—about 1% vs 2% mortality for percutaneous intervention vs surgery, respectively. But after one year, bypass surgery was associated with progressively better survival than percutaneous intervention. For high risk patients—75 or older, diabetic, ejection fraction <50%, and glomerular filtration rate <60 mL/min/1.73m^2—bypass surgery was associated with lower four-year mortality thar (risk ratio=0.72).

"The results should improve the quality of care for patients with coronary disease and should clarify the indications the subgroups [analyzed in the study]," Edwards said.

The complete ASCERT results will be presented at the **American College of Cardiology 2012 Scientific Sessions** i Chicago in March.

The authors also conducted multiple propensity analyses to root out any selection bias or unmeasured confounders The statistical analysis found that if there is an unknown confounder, it would have to have an effect as big as diab or end-stage renal failure to produce the difference between survival curves seen in this trial, Edwards said.

"Now the key is for referring physicians, cardiologists, and surgeons to avail themselves of this new information ab long-term survival and make sure that that's discussed with the patients and all of the care providers of the patient decide what the optimal course of therapy is," Edwards said.

Is this a comparison or just a description?

Dr Christopher Whit

President of the **Society for Cardiovascular Angiography and Interventions** (SCAI), **Dr Christopher White** (Ochsr Medical Center, New Orleans, LA), told **heart*wire*** that although SCAI supports ASCERT, the study should not be interpreted as a direct comparison between the two therapies.

"This is not a comparison. This was never comparison of patients. This is a description in a database of what happe when patients are treated one way or another," he said. "What this report really says is that we are really good at pi out which patients do better with surgery and which patients do better with stenting. They are not the same patient getting those treatments. So it's crazy for someone to say that surgery is better than stenting. That's not what this about. When see a patient in my clinic and I think they have problems that warrant surgery, I refer them there and t get surgery, but when I see someone who needs stenting, I do that," he said.

"There's a whole number of patients who are too ill and too high risk to get surgery, so those patients are offered [and often the reasons for not doing surgery is that the patients have comorbidities . . . which also kill them," he sai "There's no way to risk-adjust that kind of information because the outcomes are too divergent.

"If you really want to know whether surgery is better than stenting, you have to do the randomized trial, and those out there. That's what SYNTAX is, [for example]," he said.

The first fruit of an important collaboration

ASCERT represents over 10 times as many patients as the total enrollment of the randomized trials comparing bypa surgery and PCI in this population, and this is only now available because the STS, ACC, and CMS were able to work

Mack added: "The fact that there are two databases married to CMS data is hugely [important]. This is the first toe i the water of being able to do honest-to-goodness robust comparative-effectiveness research, and it's not only just first information that comes out of it but what it is going to lead to down the line." Mack pointed out that the TVT Registry of transcatheter valves is a "son or daughter of ASCERT" because it evolved out of this ACC/STS/CMS collaboration. Edwards is also leading that registry.

In addition to the long-term survival comparison, Edwards's group plans to look at stroke rates, hospital-readmissi rates, and cost effectiveness to create efficiency measures. "Survival is only one part of the picture," Edwards said during the presentation of these results at the STS meeting. "We shouldn't say 'Well, you got better survival with thi intervention or the other, and therefore everybody should have the one with better survival.' Quality of life clearly n to be taken into account."

They are also going to compare coronary bypass surgery and percutaneous intervention SYNTAX score strata and tl therapies in patients with single-vessel disease. But White said he doubts that analysis will reveal anything beyond confirming the original SYNTAX results. "The patients who get stents are more likely to die regardless of what you d them within two years than the people you give surgery. I'm not sure anything will be able to balance that as a risk adjustment," he said. "The SYNTAX trial was already done in randomized people, where you really do get a compari

Edwards said they're also considering conducting a similar study in patients with left main disease, but the small numbers and selectivity of those patients may preclude that study.

Edwards is a consultant for Humana. Mack has a nonremunerative position of interest on the executive committee the PARTNER trial for Edwards Lifesciences. White is on the advisory boards of St Jude, Neovasc, and Baxter Cellula Therapy.

Source

1. Edwards F, Peterson E, Weintraub W, et al. Survival analysis of clinical subsets from the ASCERT study (ACCF-STS database collaboration on the comparative effectiveness of revascularization strategies): CABG compared to percutaneous stent placement in 189 793 patients with multivessel coronary disease. Society o Thoracic Surgeons 2012 Annual Meeting; January 30, 2012; Ft Lauderdale, FL.

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