Table 1. Mortality and Stroke Outcomes at 30 Days

Outcome	S3i Group, % of Patients	S3HR Group, % of Patients
All-cause mortality	1.1	2.2
CV mortality	0.9	1.4
All stroke	2.6	1.5
Disabling stroke	1.0	0.9

CV, cardiovascular; S3HR, high-risk or inoperable patients who received the SAPIEN 3 valve; S3i, intermediate-risk, operable patients who received the SAPIEN 3 valve.

the S3 THV system for use in inoperable, high-risk, and intermediate-risk patients.

Susheel Kodali, MD, Columbia University Medical Center, New York, New York, USA, presented an as-treated analysis of 30-day data from the PARTNER II trial, which consisted of 2 single-arm, nonrandomized, historical-controlled studies, and enrolled a combined 1659 patients with symptomatic severe AS: 1076 intermediate-risk operable (S3i), and 583 high-risk operable or inoperable (S3HR). All patients received the S3 THV. Exclusion criteria were stroke or transient ischemic attack within 6 months, myocardial infarction within 1 month, untreated significant coronary artery disease, upper gastrointestinal bleed within 3 months, renal failure, prior prosthetic valve, left ventricular ejection fraction < 20%, and estimated life expectancy < 24 months. S3HR patients were enrolled at 29 sites across the United States, and S3i patients were enrolled at 51 US sites.

In both patient groups, 99.5% of patients completed follow-up visits 30 days after receiving the S3 THV. Baseline characteristics reflect the high-risk nature of both groups; the average ages were > 80 years, with average Society of Thoracic Surgeons (STS) surgery risk scores at 5.3% for S3i patients and 8.6% for S3HR patients. Between-group differences in baseline characteristics and comorbidities also reflected the risk status of each group.

Thirty-day results for the as-treated S3i and S3HR patients are summarized in Table 1. The STS risk scores were 5.3% for the S3i group and 8.6% for the S3HR group.

AEs were low for these populations, and the procedure was considered well tolerated.

Compared to previous studies, at 30-day follow-up, the S3 THV resulted in the lowest rates of all-cause mortality, stroke, and paravalvular leak of all available balloon-expandable THVs. Dr Kodali went over the excellent clinical outcomes seen in both the intermediate-risk and high-risk/inoperable groups, and cited these results as evidence that the S3 THV is an attractive alternative to surgery for all patients with AS.

BEST Trial: PCI Fails to Match CABG in Patients With Multivessel CAD

Written by Francesca Coltrera

Long-term data from the prospective open-label BEST trial found percutaneous coronary intervention (PCI) with a second-generation drug-eluting stent to be inferior to coronary artery bypass graft (CABG) surgery in patients with multivessel coronary artery disease (CAD), according to Seung-Jung Park, MD, PhD, Asan Medical Center, Seoul, Korea [Park SJ et al. *N Engl J Med*. 2015].

Recent studies have found that CABG surgery is associated with lower rates of adverse outcomes in patients with multivessel CAD when compared with PCI. The BEST trial was designed as a randomized noninferiority trial that compared optimal revascularization with PCI using everolimus-eluting stents to CABG in patients with multivessel CAD.

A total of 880 patients from 4 countries in East Asia with angina and/or objective evidence of a myocardial ischemia and multivessel CAD confirmed by angiography were enrolled in the trial. The study was terminated early because of slow enrollment.

Patients were randomly assigned to PCI (n = 438) or CABG (n = 442), although crossovers and other treatment changes occurred. The primary end point was the composite of major adverse cardiac events (all-cause death, myocardial infarction [MI], and target vessel revascularization) at 2 years. Key secondary end points included stroke, new lesion revascularization, and TIMI major bleeding.

Follow-up was performed with either a clinic visit or phone interview at 30 days; 6, 9, and 12 months; and then annually. Medications for secondary prevention (aspirin, statins) were strongly recommended, and routine angiography in the absence of ischemia was discouraged.

The composite primary end point occurred in 11.0% of PCI patients and 7.9% of CABG patients at 2 years with an absolute risk difference of 3.1 percentage points (95% CI, –0.8 to 6.9; $P_{\text{Noninferiority}} = .32$). The incidence of the primary outcome was significantly higher in the PCI group vs the CABG group at 5 years (Table 1). CABG performed better for the primary end point in all of the prespecified subgroups. As shown in Table 1, some secondary outcomes were increased at 5 years in the PCI group vs the CABG group, while TIMI major bleeding was significantly lower.

In conclusion, the BEST trial found that PCI with the second-generation everolimus-eluting stent was inferior to CABG for the primary end point of all-cause death, MI, or target vessel revascularization at 2 years. Patients randomized to PCI had an increased risk of all-cause death, MI, and target vessel revascularization that remained present at 5 years.

Table 1. Incidence of Primary and Secondary Outcomes at 5 Years*

End Point	PCI (n = 438)	CABG (n = 442)	Hazard Ratio (95% CI)†	*P* Value‡
	No. (percent)			
Primary end point: death, myocardial infarction, or target-vessel revascularization	67 (15.3)	47 (10.6)	1.47 (1.01 to 2.13)	.04
Secondary end points				
Death				
Any cause	29 (6.6)	22 (5.0)	1.34 (0.77 to 2.34)	.30
Cardiac cause	18 (4.1)	16 (3.6)	1.15 (0.58 to 2.25)	.69
Noncardiac cause	11 (2.5)	6 (1.4)	1.87 (0.69 to 5.05)	.21
Myocardial infarction				
Any	21 (4.8)	12 (2.7)	1.76 (0.87 to 3.58)	.11
Fatal	4 (0.9)	0	NA	NA
Spontaneous	19 (4.3)	7 (1.6)	2.75 (1.16 to 6.54)	.02
Spontaneous Q wave	4 (0.9)	2 (0.5)	2.03 (0.37 to 11.1)	.40
Death or myocardial infarction	43 (9.8)	34 (7.7)	1.28 (0.82 to 2.01)	.28
Stroke				
Any	11 (2.5)	13 (2.9)	0.86 (0.39 to 1.93)	.72
Ischemic stroke	9 (2.1)	12 (2.7)	0.77 (0.32 to 1.82)	.54
Hemorrhagic stroke	2 (0.5)	1 (0.2)	2.03 (0.18 to 22.4)	.55
Death, myocardial infarction, or stroke	52 (11.9)	42 (9.5)	1.26 (0.84 to 1.89)	.26
Death from cardiac cause, myocardial infarction, or stroke	42 (9.6)	37 (8.4)	1.16 (0.74 to 1.80)	.52
Repeat revascularization				
Any	48 (11.0)	24 (5.4)	2.09 (1.28 to 3.41)	.003
Target vessel	31 (7.1)	17 (3.8)	1.88 (1.04 to 3.40)	.03
Target lesion	25 (5.7)	17 (3.8)	1.51 (0.82 to 2.80)	.19
New lesion	24 (5.5)	10 (2.3)	2.47 (1.18 to 5.17)	.01
Death, myocardial infarction, stroke, or any repeat revascularization	87 (19.9)	59 (13.3)	1.54 (1.11 to 2.14)	.01
Death from cardiac cause, myocardial infarction, stroke, or any repeat revascularization	78 (17.8)	54 (12.2)	1.51 (1.06 to 2.13)	.02
Bleeding				
TIMI major bleeding§	30 (6.8)	132 (29.9)	0.20 (0.14 to 0.30)	< .001
Fatal bleeding	3 (0.7)	7 (1.6)	0.44 (0.11 to 1.68)	.21

* Percentages are crude rates and are from the intention-to-treat analysis. NA denotes not applicable.

† Hazard ratios and 95% confidence intervals were assessed for events on the basis of all available follow-up data.

‡ P values were calculated with the use of the log-rank test on the basis of all available follow-up data.

§ Thrombolysis in Myocardial Infarction (TIMI) major bleeding refers to events that were adjudicated on the basis of TIMI criteria.

CABG, coronary artery bypass graft; MACE, major adverse cardiovascular events; MI, myocardial infarction; PCI, percutaneous coronary intervention; RR, repeat revascularization.