In the 36% of the patients who required rescue or urgent PCI the median time to PCI following bolus tenecteplase was 2.2 hours. In the remaining 64% a nonurgent angiography was performed after a median of 17 hours

Patients assigned to early fibrinolysis were more likely to have Thrombolysis in Myocardial Infarction (TIMI)-3 blood flow prior to PCI compared with the primary PCI group (58.5% vs 20.7%; p<0.001) but there was no significant difference in TIMI-3 blood flow after PCI (91.1 % vs 92.3%; p=0.41). Coronary artery bypass graft surgery was performed about twice as often in the early fibrinolysis versus the primary PCI group (4.7% vs 2.1%; p=0.002).

STREAM suggests that a strategy involving early fibrinolysis in appropriate patients on a background of contemporary antithrombotic therapy may be beneficial in patients with STEMI who present within 3 hours of symptom onset and who cannot undergo primary PCI within 1 hour of first medical contact. An important implication of STREAM is the key role of prehospital systems capable of early diagnosis, therapy, and triage at the first point of care. In addition, STREAM underscores the importance of efforts to improve the availability of primary PCI for patients presenting with STEMI.

Science Advisor's note: As specified in the methods the statistical testing was considered exploratory and therefore these findings should be considered hypothesis-generating.

New SAPIEN XT System Is Noninferior to and Safer Than Old SAPIEN System

Written by Phil Vinall

Results from the Placement of Aortic Transcatheter Valves 2 trial [PARTNER 2; NCT01314313] indicated that the new SAPIEN XT transcatheter heart valve (THV) system is noninferior to the old SAPIEN system when used in an inoperable cohort of patients. The new slimmer version was associated with improved procedural outcomes and reduced vascular complications, including major vascular bleeding. Martin B. Leon, MD, Columbia University Medical Center and New York-Presbyterian Hospital, New York, New York, USA, presented the results of PARTNER 2.

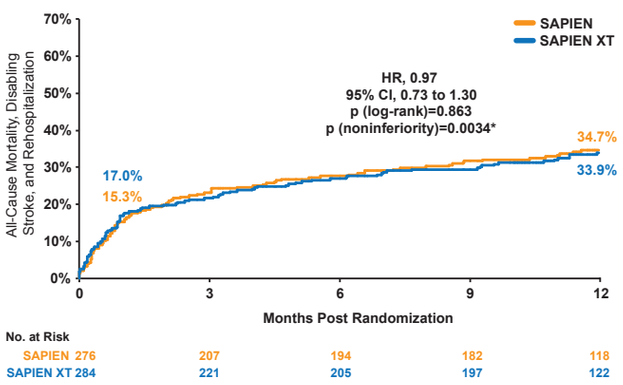
The objective of PARTNER 2 was to compare the safety and effectiveness of the new balloon-expandable SAPIEN XT with the old SAPIEN system in a randomized controlled trial of patients with symptomatic severe aortic stenosis who could not have surgery. The longer-profile SAPIEN XT incorporates important enhancements to the valve support frame, the valve leaflet geometry, the delivery system, and a significant reduction in sheath size designed to improve clinical outcomes.

This noninferiority trial included patients with severe aortic stenosis, NYHA Class ≥II and ≥50% risk of death or of serious irreversible morbidity as assessed by a cardiologist and 2 surgeons. After being assessed for inoperability and transfemoral access, patients (n=560) were randomly assigned 1:1 to THV replacement with either the SAPIEN XT or SAPIEN system. The primary study endpoint was a composite of all-cause mortality, disabling stroke, and rehospitalization for symptoms of aortic stenosis and/or complications of the valve procedure at 1 year.

Randomized patients (n=560) were 50% female, a mean age of 84 years, and had a mean Society of Thoracic Surgeons (STS) score of 10.3. More than half (59%) were deemed inoperable due to frailty.

At 12 months, SAPIEN XT was noninferior for the primary endpoint compared with SAPIEN (33.9% vs 34.7%; HR, 0.97; 95% CI, 0.73 to 1.30; p for noninferiority= 0.0034; p for superiority=0.863; Figure 1). There was no significant difference in all-cause mortality at 12 months between the SAPIEN XT and SAPIEN groups (22.5% vs 23.7%; HR, 0.93; 95% CI, 0.66 to 1.33; p=0.706; Figure 2). There were also no significant differences between the 2 groups in the number of disabling strokes or rehospitalization events.

Figure 1. All-Cause Mortality, Disabling Stroke, and Rehospitalization



*Preliminary based upon 100% CEC adjudication at 30 days and 89% CEC adjudication at 1 year.

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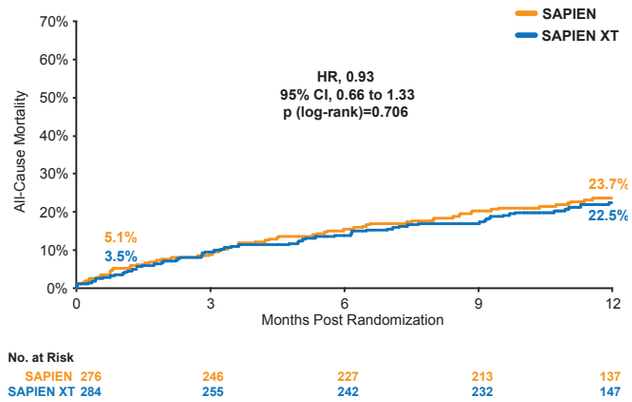
There were no significant differences between the SAPIEN XT and SAPIEN groups at 30 days for the primary endpoint (17.0% vs 15.3%; p=0.60), all-cause mortality (3.5% vs 5.1%; p=0.36), or disabling stroke (3.2% vs 3.0%; p=0.85).

There were lower rates of major vascular complications with SAPIEN XT (9.6% vs 15.5%;

p=0.04). Disabling bleeding was also numerically lower but not statistically significantly lower with SAPIEN XT (7.8% vs 12.6%; p=0.06).

Figure 2. All-Cause Mortality



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SAPIEN XT was associated with numeric reductions in anesthesia time (197.6 vs 212.0 minutes; p=0.02), need for multiple (≥2) valve implants (3 vs 10; p=0.05), aborted procedures (2 vs 8; p=0.06), and need for intra-aortic balloon pump support during the procedure (1 vs 6; p=0.06) compared with SAPIEN.

By 1 year, >80% of patients were categorized as NYHA Class I or II heart failure after either intervention. Increases in echocardiographic value area, and reductions in mean and peak gradients based on as-treated analyses were similar for both devices at 30 days and persisted to 1 year. Values for total aortic regurgitation were also similar.

Dr. Leon said that the SAPIEN XT system represents a worthwhile advance with incremental clinical value and is now considered the preferred balloon-expandable THV system.

MASS COM Trial: Nonemergency PCI Safe Without On-Site Surgery Capability

Written by **Wayne Kuznar**

Nonemergency percutaneous coronary intervention (PCI) performed at hospitals without on-site cardiac surgery capability, but with sufficient procedural volume was as safe and effective as PCI performed at hospitals with cardiac surgery services.

Alice Jacobs, MD, Boston University, Boston, Massachusetts, USA, presented results from a Randomized Trial to Compare Percutaneous Coronary Intervention Between Massachusetts Hospitals With Cardiac Surgery-On-Site and Community Hospitals Without Cardiac Surgery-On-Site [MASS COM; Jacobs AK et al. *N Engl J Med* 2013] which compares the outcomes of nonemergency PCI at 10 hospitals in Massachusetts without on-site cardiac surgery services and 7 hospitals with on-site cardiac surgery services.

Since emergency coronary artery bypass graft surgery is rare following PCI, it raises the question of whether on-site cardiac surgery is still necessary for the performance of safe and effective PCI, said Dr. Jacobs. The need for patients with ST-elevation myocardial infarction to have timely access to PCI has justified expansion of emergency (primary) PCI to hospitals without on-site cardiac surgery. Further expansion to the nonemergency setting has been controversial because of an uncertain risk:benefit ratio.

In MASS COM, short-term safety and 12-month outcomes were assessed in 3691 patients who were randomly assigned in a 3:1 ratio to undergo PCI at hospitals without on-site cardiac surgery (n=2774) or at hospitals with surgical back-up (n=917). The primary safety endpoint was death, myocardial infarction (MI), stroke, or repeat revascularization at 30 days while efficacy for the same endpoint was assessed at 12 months. The study was designed to test for noninferiority (using noninferiority margins of 1.5 for safety and 1.3 for effectiveness) on an intent-to-treat basis. A random sample of 376 of enrolled subjects was selected to monitor clinical practice patterns of the hospitals.

Hospital and operator requirements for participation included a minimum of 75 PCI procedures performed annually. Hospitals without on-site cardiac surgery were required to have a signed collaboration agreement with an on-site surgery hospital for backup and to perform a minimum of 300 diagnostic procedures in each of the previous 2 years and a minimum of 36 primary PCI procedures per year.

Baseline characteristics were similar between the 2 groups, but more patients randomized to hospitals without on-site surgery had a prior history of MI compared with those randomized to hospitals with on-site surgery (24.1% vs 20.2%; p=0.015).

There were no significant differences between the 2 treatment groups with respect to procedural success rates, completeness of revascularization, or the proportion of lesions that met indication criteria for PCI. However, patients treated at hospitals without on-site surgery received drug-eluting stents less often than those treated at hospitals with on-site surgery (63.7% vs 69.3%; p<0.001).

The 30-day primary safety endpoint—a composite of death, MI, stroke, or repeat revascularization—occurred in 9.5% of patients treated at sites without on-site cardiac surgery compared with 9.4% in those treated at sites with surgical services (p<0.001 for noninferiority; Figure 1).