

# PROM Score Accurate for Long-Term Survival

BY MARK S. LESNEY

FROM THE ANNUAL MEETING OF THE SOCIETY OF THORACIC SURGEONS

SAN DIEGO – The Society of Thoracic Surgeons Predicted Risk of Mortality score is a well-validated predictor of mortality during the first 30 days after cardiac surgery.

The PROM score's role in predicting longer-term survival, however, has not

been investigated, according to Dr. John D. Puskas.

To fill this void, Dr. Puskas and his colleagues from Emory University, Atlanta, undertook a study to statistically validate PROM at 1, 3, 5, and 10 years after cardiac surgery. He presented the study's results at the meeting.

The investigators found that the STS PROM algorithm accurately predicted mortality both at 30 days and during 12

years of follow-up with almost equally strong discriminatory power.

"This may have profound implications for informed consent as well as for longitudinal comparative effectiveness studies," Dr. Puskas said in an interview.

"The STS Predicted Risk of Mortality models are probably underutilized and underappreciated in their power to predict short- and long-term outcomes for

our patients. The STS provides this service free of charge, and it is available online 24/7. I am hopeful that this newfound ability to predict longer-term survival after cardiac surgery will find utility in comparative effectiveness research and ultimately in shaping health policy," he added.

Dr. Puskas and his colleagues evaluated the survival rates for 24,222 patients who underwent cardiac surgery at a sin-

Effient is indicated to reduce the rate of thrombotic CV events (including stent thrombosis) in UA/NSTEMI patients who are to be managed with PCI and in STEMI patients when managed with primary or delayed PCI.

## REDUCTIONS IN THROMBOTIC CV EVENTS IN TRITON-TIMI 38 INCLUDING HIGH-RISK PATIENTS SUCH AS THOSE WITH DIABETES<sup>\*†1,2</sup>

The reduction in the primary composite endpoint of CV death, nonfatal MI, or nonfatal stroke in patients with diabetes treated with Effient plus ASA compared with Plavix plus ASA was consistent with those observed in the overall UA/NSTEMI and STEMI populations



\*As measured by reduction in the primary composite endpoint of CV death, nonfatal MI, or nonfatal stroke. †The LD of Effient was 60 mg followed by a 10-mg daily dose (plus ASA) and the loading dose of Plavix was 300 mg followed by a 75-mg daily dose (plus ASA). ‡Relative risk reduction. §Absolute risk reduction.

- Difference in treatments was primarily driven by a significant reduction in nonfatal MIs, with no significant difference in CV death or nonfatal stroke<sup>1</sup>
  - In the overall study population, approximately 40% of MIs occurred periprocedurally and were detected solely by changes in CK-MB
- In TRITON-TIMI 38, the LD of Plavix was delayed relative to the placebo-controlled trials that supported its approval for ACS
- TRITON-TIMI 38 was not designed or powered to demonstrate independent efficacy or safety in the diabetes subgroup

### SELECTED SAFETY, INCLUDING SIGNIFICANT BLEEDING RISK

Effient can cause significant, sometimes fatal, bleeding. In TRITON-TIMI 38, overall rates of non-CABG TIMI major or minor bleeding were significantly higher with Effient plus ASA (4.5%) compared with Plavix plus ASA (3.4%). In patients who underwent CABG (n=437), the rates of CABG-related TIMI major or minor bleeding were 14.1% with Effient plus ASA and 4.5% with Plavix plus ASA.

gle academic center during 1996-2009. Long-term all-cause mortality was determined by referencing the national Social Security Death Master File. Logistic and Cox survival regression analyses were used to evaluate the long-term predictive utility of PROM. The AUROC (area under the receiver operator character-



istic) curve measured the discrimination of PROM at 1, 3, 5, and 10 years. Kaplan-Meier curves were stratified by quartiles of PROM risk to compare long-term survival. All analyses were performed for both the whole sample and 30-day survivors. The investigators found an overall 30-day mortality rate of 2.78%.

**The models are 'underutilized and underappreciated in their power to predict short- and long-term outcomes.'**

**DR. PUSKAS**

Among all patients and 30-day survivors, AUROC values for PROM at 1, 3, 5, and 10 years were remarkably similar to the 30-day end point for which PROM is calibrated. Moreover, PROM was highly predictive of Kaplan-Meier survival, even when this analysis was restricted to patients surviving beyond 30 days, he added. Among 30-day survivors, each percent increase in PROM score was significantly associated with a 9.6% increase in instantaneous hazard of death (*P* less than .001).

VITALS

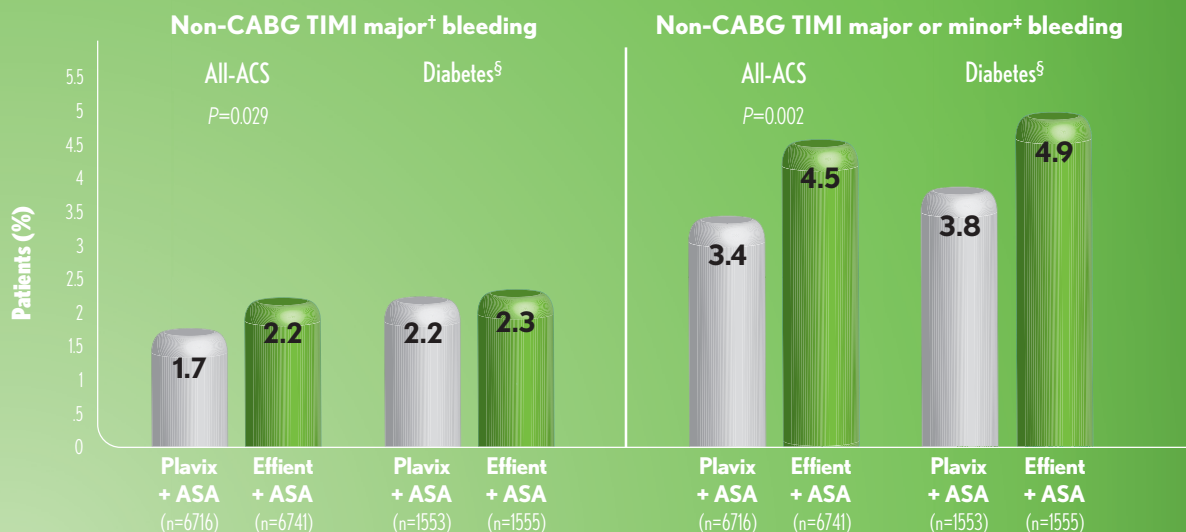
**Major Finding:** The STS PROM algorithm accurately predicted mortality both at 30 days and during 12 years of follow-up with almost equally strong discriminatory power.

**Data Source:** A retrospective analysis of 24,222 patients who underwent cardiac surgery at a single academic center between Jan. 1, 1996, and Dec. 31, 2009.

**Disclosures:** Dr. Puskas and his colleagues reported no relevant disclosures with regard to their study.



**NON-CABG-RELATED BLEEDING: TRITON-TIMI 38 ALL-ACS POPULATION, INCLUDING DIABETES SUBGROUP\*1,4**



\*Observed event rates. <sup>†</sup>Intracranial hemorrhage or clinically overt bleeding associated with a fall in hemoglobin  $\geq 5$  g/dL. <sup>‡</sup>Clinically overt bleeding associated with a fall in hemoglobin of  $\geq 3$  g/dL but  $< 5$  g/dL. <sup>§</sup>*P* value not provided because the trial was not designed to prospectively evaluate bleeding differences in subgroups.

- In TRITON-TIMI 38, overall rates of non-CABG TIMI major and non-CABG TIMI major or minor bleeding were significantly higher with Effient plus ASA compared with Plavix plus ASA<sup>1</sup>
- In patients who underwent CABG (n=437), the rates of CABG-related TIMI major or minor bleeding were 14.1% with Effient plus ASA and 4.5% with Plavix plus ASA. Do not start Effient in patients likely to undergo urgent CABG<sup>1</sup>
- Patients at highest risk for non-CABG TIMI major or minor bleeding were those  $\geq 75$  years of age and/or those  $< 60$  kg (132 lb)<sup>1</sup>
- Effient is contraindicated in patients with active pathological bleeding, such as from a peptic ulcer or intracranial hemorrhage (ICH), or a history of transient ischemic attack (TIA) or stroke, and in patients with hypersensitivity to prasugrel or any component of the product<sup>1</sup>
  - Patients who experience a stroke or TIA while on Effient generally should have therapy discontinued

Please see Important Safety Information, including Boxed Warning regarding bleeding risk, on previous page. See also Brief Summary of Prescribing Information on subsequent pages.