

Vit. D Deficiency Raises Heart Failure Death Risk

VITALS

Major Finding: Adults with vitamin D deficiency were 3.4 times more likely to die from heart failure, compared with those who had normal levels of vitamin D. They were also 1.45 times as likely to die prematurely, compared with those who had normal levels of vitamin D.

Data Source: A total of 13,131 men and women aged 35 and older enrolled in the prospective cohort of the NHANES III from 1988 to 1994.

Disclosures: The researchers had no relevant financial disclosures to make.

BY DOUG BRUNK

FROM THE ANNUAL MEETING
OF THE HEART FAILURE
SOCIETY OF AMERICA

SAN DIEGO — Adults with decreased levels of serum 25-hydroxyvitamin D are significantly more likely to die from heart failure or die prematurely, compared with adults who have normal

serum levels of vitamin D, results from a large analysis found.

“This may be additional justification for a study of vitamin D supplementation in appropriate patients to determine if there is causality and if this is a treatable condition,” Dr. Howard J. Eisen said at the meeting.

In a study led by his associate, Dr. Longjian Liu of the depart-

ment of epidemiology and biostatistics at Drexel University School of Public Health, Philadelphia, the researchers reviewed data from 13,131 individuals (6,130 men and 7,001 women) aged 35 and older who were enrolled in the prospective cohort of the Third National Health and Nutrition Examination Survey (NHANES III) from

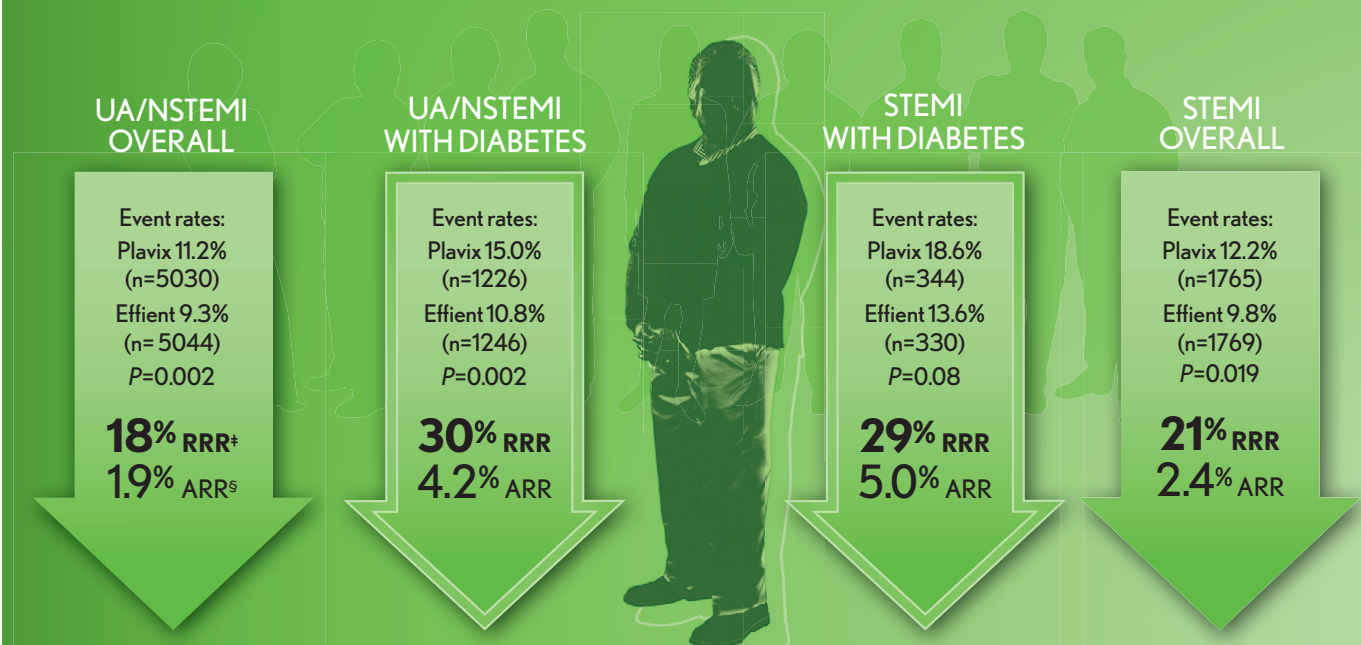
INDICATIONS AND USAGE

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: TRITON-TIMI 38 DIABETES SUBGROUPS**1,2

The greater reduction in the primary composite endpoint 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 loading dose 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.

- In the overall study, the benefit in each population was primarily driven by a significant reduction in nonfatal MIs, with no significant differences in CV death or nonfatal stroke¹
 - Approximately 40% of MIs occurred periprocedurally and were detected solely by changes in CK-MB
- In TRITON-TIMI 38, the loading dose of Plavix was delayed relative to the placebo-controlled trials that supported its approval for ACS
- TRITON-TIMI 38 was not prospectively designed or powered to determine if Effient would have greater efficacy over Plavix in the UA/NSTEMI or STEMI diabetes subgroups alone

SELECTED SAFETY, INCLUDING SIGNIFICANT BLEEDING RISK

Effient can cause significant, sometimes fatal, bleeding. With the dosing regimens used in TRITON-TIMI 38, major and minor bleeding events were more common with Effient plus ASA compared with Plavix plus ASA.

1988 to 1994 and followed for mortality through the year 2000. At baseline, a radioimmunoassay kit was used to measure the serum vitamin D level of each participant.

Vitamin D deficiency was defined as a serum level below 20 ng/mL, and vitamin D insufficiency was defined as a serum level of 20-29 ng/mL. Normal levels were defined as 30 ng/mL or greater, said Dr. Eisen of the department of medicine at Drexel University, Philadelphia.

Premature death was defined as death before the age of 75. The researchers

used Cox proportional hazards regression analysis to examine the association between serum levels of vitamin D and mortality risk.

Dr. Eisen reported that more than 60% of African American study participants were vitamin D deficient, compared with 20% of whites and about 40% of Hispanics. "This might be yet another explanation for the high prevalence of heart failure [among African Americans]," he said.

During an average follow-up period of 8 years, there were 3,266 deaths among the 13,131 participants (24.9%), including

101 heart failure deaths (0.8%). Of the total deaths, there were 1,066 premature deaths (33%). Death from cardiovascular disease accounted for as many as 34% of the total premature deaths.

The rate of vitamin D deficiency among heart failure deaths was 37%, compared with 26% among non-heart failure-related deaths, a difference that was statistically significant.

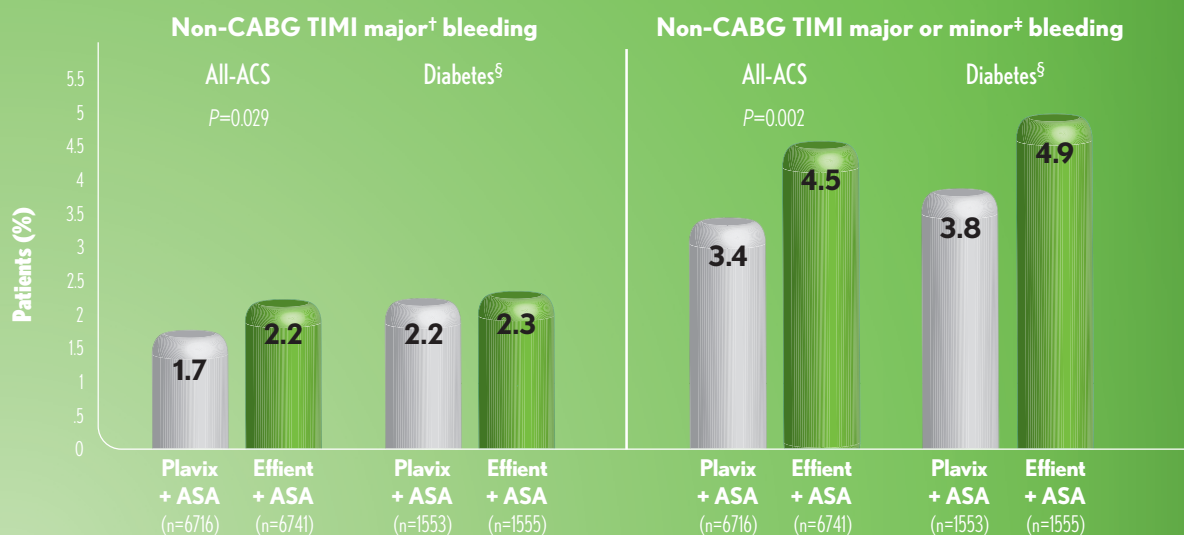
After the researchers adjusted for age, gender, race, and baseline medical conditions, study participants with vitamin D deficiency were 3.4 times more likely to die from heart failure, com-

pared with those who had normal vitamin D levels, while those with vitamin D insufficiency were 2 times more likely to die from heart failure, compared with those who had normal vitamin D levels.

In addition, study participants with vitamin D deficiency were 1.45 times more likely to die prematurely, compared with those who had normal vitamin D levels, while those with vitamin D insufficiency were 1.14 times more likely to die prematurely, compared with those who had normal vitamin D levels. ■

Effient
(prasugrel) tablets

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



*Observed event rates. [†]Intracranial hemorrhage or clinically overt bleeding associated with a fall in hemoglobin ≥ 5 g/dL. [‡]Clinically overt bleeding associated with a fall in hemoglobin of ≥ 3 g/dL but < 5 g/dL. [§]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 on Effient than on Plavix¹
- 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 CABG¹
- Patients at highest risk of bleeding were those ≥ 75 years of age and/or those < 60 kg (132 lb)¹
- Effient is contraindicated in patients with active pathological bleeding, such as from a peptic ulcer or ICH, or a history of TIA or stroke¹
 - Patients who experience a TIA or stroke 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 adjacent pages.