Barrett's Esophagus Does Not Affect Survival

BY SHERRY BOSCHERT

SAN DIEGO — Among 366 patients with Barrett's esophagus, 82% were alive 5 years after diagnosis, a rate that was essentially no different than the overall survival rate seen in a matched control group from the general population.

The retrospective study is one of the first on survival in a large cohort of patients with Barrett's esophagus in the United States, Dr. Ganapathy A. Prasad said at the annual meeting of the American College of Gastroenterology.

Among previous studies, some found decreased survival in patients with Barrett's esophagus, compared with matched controls, while others showed comparable overall survival rates. Those data came predominantly from Europe, said Dr. Prasad of the Mayo Clinic, Rochester, Minn.

Dr. Prasad and his associates identified 401 patients with Barrett's esophagus in the Rochester Epidemiology Project who were diagnosed between January 1976 and January 2007, and excluded 35 who had some evidence of cancer or who developed cancer within 6 months of diagnosis.

The 366 patients in the study were followed for a mean of 7.1 years. They had a mean age of 62 years at baseline, 70% were male, and more than 85% were Caucasian. The investigators compared the study cohort's survival rate with survival data from an age- and gendermatched cohort from the U.S. Census for the white population in Minnesota.

Dr. Prasad noted that survival rates at 10 and 15 years after diagnosis also did not appear to diverge significantly between groups; the overall survival rates were 68% at 10 years and 58% at 15

Barrett's esophagus was defined as a combination of endoscopically evident columnar mucosa at least 1 cm in size and histologic diagnosis of specialized intestinal metaplasia on biopsy.

At diagnosis, the mean segment length of the Barrett's esophagus was 4.8 cm, and 59% of patients had longsegment Barrett's esophagus. No dys-



plasia was apparent in 84% of patients, low-grade dysplasia was seen in 14%, and 2% had high-grade dysplasia at

The only predictors of death were older age and higher scores on the Charlson Comorbidity Index at the time of Barrett's esophagus diagnosis, a multivariate analysis showed. Neither male gender nor the presence of dysplasia affected survival significantly.

Among comorbidities at baseline, 24% of the Barrett's esophagus group had peptic ulcer, 18% had chronic pulmonary disease, 12% had diabetes, 11% had cerebrovascular disease, and 7% each had a history of MI, heart failure, peripheral vascular disease, or moderate to severe renal disease. Thirteen percent of the patients had cancers other than esophageal adenocarcinoma.

Only 5% of the 104 patients who died

during follow-up died of esophageal adenocarcinoma. Cardiovascular disease was the leading cause of death (with 28% dying of cardiac causes and 4% dying of cerebrovascular causes), followed by deaths from nonesophageal neoplasms in 21% (colorectal, lung, hematologic, renal, and other cancers).

Disclosures: Dr. Prasad reported that he had no relevant conflicts of interest.

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Indication
TWYNSTA is indicated for the treatment of hypertension, alone or with other antihypertensive agents. It may also be used as initial therapy in patients who are likely to need multiple drugs to achieve their blood pressure goals. Base the choice of TWYNSTA tablets as initial therapy for hypertension on an assessment of potential benefits and risks including whether the patient is likely to tolerate the starting dose of TWYNSTA tablets. Consider the patient's baseline blood pressure, the target goal, and the incremental likelihood of achieving goal with a combination compared with monotherapy when deciding whether to use TWYNSTA tablets as initial therapy. use TWYNSTA tablets as initial therapy.

Volume depletion and/or salt depletion should be corrected in patients before initiation of therapy or start treatment under close medical supervision with a reduced dose, otherwise symptomatic hypotension may occur. Observe patients with severe aortic stenosis closely for acute hypotension when administering amlodipine.

Hepatic Impairment In patients with impaired hepatic function, initiate telmisartan at low doses and titrate slowly, or initiate amlodipine at 2.5 mg. The lowest dose of TWYNSTA is 40/5 mg; therefore, initial therapy with TWYNSTA is not recommended in hepatically impaired patients.

Renal Impairment

Monitor carefully in patients with impaired renal function, especially in patients whose renal function may depend on the activity of the renin-angiotensin-aldosterone system (RAAS) (eg, patients with severe congestive heart failure or renal dysfunction); treatment of these patients with ACE inhibitors and ARBs has been associated with oliguria and/or progressive azotemia and, rarely, with acute renal failure and/or death. In patients with unilateral or bilateral renal artery stenosis, increases in serum creatinine or blood urea nitrogen may occur.

Dual RAAS BlockadeWhen adding an ACE inhibitor to an ARB, monitor renal function closely.
Use of telmisartan with ramipril is not recommended.

Uncommonly, increased frequency, duration, and/or severity of angina or acute myocardial infarction have developed in patients treated with calcium channel blockers, particularly patients with severe obstructive coronary artery disease. Closely monitor patients with heart failure.

TWYNSTA that were more frequent than with placebo were peripheral edema (4.8% vs 0%), dizziness (3.0% vs 2.2%), clinically meaningful orthostatic hypotension (6.3% vs 4.3%), and back pain (2.2% vs 0%).

Special Populations

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In clinical studies, the magnitude of blood pressure lowering with TWYNSTA in black patients approached that observed in non-black patients, but the number of black patients was limited. TWYNSTA is not recommended as initial therapy in patients who are 75 years or older, or who are hepatically impaired. In nursing mothers, nursing or TWYNSTA should be discontinued.

References: 1. Twynsta Pl. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; 2009. 2. Data on file, Study 1235.1, Boehringer Ingelheim Pharmaceuticals, Inc. 3. Chobanian AV, Bakris GL, Black HR, et al. The seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: the JNC 7 report. JAMA. 2003;289:2560-2572.

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