

Undiagnosed Diabetes Common in Acute MI

The prevalence of previously undiagnosed diabetes was significantly higher in women than in men.

BY MITCHEL L. ZOLER

FROM THE ANNUAL SCIENTIFIC SESSIONS OF THE AMERICAN HEART ASSOCIATION

ORLANDO – A fifth of women with an acute myocardial infarction have previously undiagnosed diabetes, according to results from a German registry that included 706 women.

The registry analysis also showed that the prevalence of previously undiagnosed diabetes in women with a recent acute myocardial infarction significantly exceeded the rate in men, Dr. Anselm K. Gitt said at the meeting. And the 3-year outcome of women with an acute myocardial infarction and newly diagnosed diabetes closely tracked the outcomes of women who survived an acute myocardial infarction and had previously diagnosed diabetes.

The 3-year mortality rate in both groups of women was about 30%, re-



'Our new data confirm the recommendation' for oral glucose tolerance tests in acute MI patients.

DR. GITT

ported Dr. Gitt, a cardiologist at the Heart Center in Ludwigshafen, Germany, and vice director of the Myocardial Infarction Research Institute in Ludwigshafen.

Guidelines issued in 2007 by the European Society of Cardiology and the European Association for the Study of Diabetes recommended that physicians routinely perform an oral glucose tolerance test on all patients following an acute myocardial infarction who had not previously been diagnosed with diabetes mellitus (*Eur. Heart J.* 2007;28:88-136).

"We started this study to see whether the recommendation had value in clinical practice. I think our new data confirm the recommendation," Dr. Gitt said.

However, because of results from the Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial (*N. Engl. J. Med.* 2008;358:2545-59) and the Action in Diabetes and Vascular Disease: Preterax and Diamicron MR Controlled Evaluation (ADVANCE) trial (*N. Engl. J. Med.* 2008;358:2560-72), simply focusing on intensive glycemic control in post-MI patients with newly diagnosed diabetes is probably not an ideal management approach, Dr. Gitt acknowledged.

Although study results have not clearly established an optimal strategy, he suggested "good glycemic control with attention to avoiding hypoglycemia, along with aggressively treating cardio-

vascular risk factors such as lipids and hypertension."

Dr. Gitt and his associates tallied the prevalence of diabetes in acute MI patients with data collected in the SWEET-HEART registry, which enrolled 2,767 patients within 24 hours of either an ST-

elevation MI or non ST-elevation MI at 30 German centers, and then followed the patients for 3 years. The group included 706 women (26%), with an average age of 71 years, compared with an average age of 64 among the 2,061 enrolled men. The prevalence of previously diagnosed diabetes was 30% among the women, and 23% among the men.

All patients without a prior diagnosis

of diabetes underwent assessment with an oral glucose tolerance test, following the recommendation made by the ESC and EASD in 2007. This identified an additional 20% of the women and 15% of the men with diabetes (a blood glucose level greater than 200 mg/dL 2 hours following the oral glucose challenge), as well as 18% of the women and 23% of the men with impaired glucose tolerance.

For adult patients with type 2 diabetes in addition to diet and exercise

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- Onglyza is widely accessible,¹ with most commercially-insured eligible patients paying only \$10 per month†

Indication and Important Limitations of Use for ONGLYZA™ (saxagliptin)

ONGLYZA is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus in multiple clinical settings.

ONGLYZA should not be used for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.

Important Safety Information for ONGLYZA

Warnings and Precautions

- **Use with Medications Known to Cause Hypoglycemia:** Insulin secretagogues, such as sulfonylureas, cause hypoglycemia. Therefore, a lower dose of the insulin secretagogue may be required to reduce the risk of hypoglycemia when used in combination with ONGLYZA
- **Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with ONGLYZA or any other antidiabetic drug

Most Common Adverse Reactions

- Most common adverse reactions (regardless of investigator assessment of causality) reported in ≥5% of patients treated with ONGLYZA and more commonly than in patients treated with control were upper respiratory tract infection (7.7%, 7.6%), headache (7.5%, 5.2%), nasopharyngitis (6.9%, 4.0%) and urinary tract infection (6.8%, 6.1%).
- When used as add-on combination therapy with a thiazolidinedione, the incidence of peripheral edema for ONGLYZA 2.5 mg, 5 mg, and placebo was 3.1%, 8.1% and 4.3%, respectively.

Laboratory Tests

There was a dose-related mean decrease in absolute lymphocyte count observed with ONGLYZA.

Drug Interactions

Because ketoconazole, a strong CYP3A4/5 inhibitor, increased saxagliptin exposure, the dose of ONGLYZA should be limited to 2.5 mg when coadministered with a strong CYP3A4/5 inhibitor (e.g., atazanavir, clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, ritonavir, saquinavir, and telithromycin).

VITALS

Major Finding: Following an acute myocardial infarction, the prevalence of previously undiagnosed diabetes was 20% in women, 15% in men.

Data Source: Review of 706 women and 2,061 men with an acute myocardial infarction enrolled into the SWEETHEART registry at 30 centers in Germany.

Disclosures: Dr. Gitt has received research grants from, and has been a consultant to or served on the speakers bureau for, AstraZeneca, Bristol Myers Squibb, Essex, GlaxoSmithKline, Merck, MSD, Pfizer, Roche, Eli Lilly, Sanofi-Aventis, Schering Plough, and Servier. He said that he has received research grants from Abbott and Hexal, and that he has been a consultant to or served on a speakers bureau for Amgen, Daiichi Sankyo, Iroko, and Novo Nordisk.

The total 50% prevalence of both newly and previously diagnosed diabetes among the women who entered

the study was significantly higher than the combined 38% prevalence rate among the men, Dr. Gitt said.

During hospitalization for the index acute MI, the mortality rate among both the women and men newly diagnosed with diabetes was about 3%, similar to the rate among those with previously diagnosed diabetes.

Mortality among the women and men with newly identified impaired glucose tolerance ran 0.8% and 0.4%, respectively, while mortality among those with no diabetes or glucose impairment was 1.2% among women and 1.3% among men.

During the 3-year follow-up, mortality in the newly diagnosed women was

31%, and it was 22% among the men. This finding is "important," because it shows that once physicians diagnose diabetes in a recent MI patient "their risk is very high," Dr. Gitt said.

In women with a prior diabetes diagnosis, the 3-year mortality rate was 30%, while in men with previously identified diabetes the mortality rate was 35%.

Men and women with either impaired glucose tolerance or no identified glucose metabolism disorder had substantially lower 3-year mortality rates that ranged from 11% to 13%, Dr. Gitt added. ■



Use in Specific Populations

- **Patients with Renal Impairment:** The dose of ONGLYZA is 2.5 mg once daily for patients with moderate or severe renal impairment, or with end-stage renal disease requiring hemodialysis (creatinine clearance [CrCl] \leq 50 mL/min). ONGLYZA should be administered following hemodialysis. ONGLYZA has not been studied in patients undergoing peritoneal dialysis. Assessment of renal function is recommended prior to initiation of ONGLYZA and periodically thereafter.
- **Pregnant and Nursing Women:** There are no adequate and well-controlled studies in pregnant women. ONGLYZA, like other antidiabetic medications, should be used during pregnancy only if clearly needed. It is not known whether saxagliptin is secreted in human milk. Because many drugs are secreted in human milk, caution should be exercised when ONGLYZA is administered to a nursing woman.
- **Pediatric Patients:** Safety and effectiveness of ONGLYZA in pediatric patients have not been established.

For more information about Onglyza, visit www.onglyza.com/three.

Please read the adjacent Brief Summary of the Product Information.

*Pioglitazone or rosiglitazone

†Based on Tier 2 coverage and the Onglyza Value Card Program.

See Onglyza Value Card Program details at www.onglyza.com/hcp/value-card.aspx.

Reference: 1. Fingertip Formulary® data as of March 18, 2011. Data on File, March 2011.



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