

NPs Match Physicians in Weight Loss Counseling

BY MARY ANN MOON

FROM THE ARCHIVES OF INTERNAL MEDICINE

Lifestyle counseling from specially trained nurse practitioners in a primary-care setting was no better at preventing weight gain than was usual care delivered by the primary-care physician, in a 3-year study of more than 400 men and women.

Researchers in the Groningen Overweight and Lifestyle (GOAL) study compared the effects of two different approaches to preventing weight gain in the primary-care setting: structured lifestyle counseling provided by nurse practitioners (NPs) versus usual care.

The study subjects were 457 men and women aged 40-70 years who attended 11 primary-care practices in the Netherlands. They had a body mass index between 25 kg/m² and 40 kg/m² and concomitant hypertension or dyslipidemia, said Nancy C.W. ter Bogt of University Medical Center Groningen, The Netherlands, and her associates.

These subjects were randomly as-

VITALS

Major Finding: Behavioral counseling by a nurse practitioner was no better than usual care by a primary physician in helping overweight patients prevent further weight gain.

Data Source: A randomized, controlled trial involving 457 overweight patients attending 11 primary-care practices in The Netherlands who were followed for 3 years.

Disclosures: This study was supported by The Netherlands Organization for Health Research and Development and Foundation Fund de Gavere. No conflicts of interest were reported.

signed to usual care with the primary physician (232 patients) or to an intervention in which NPs counseled them in four in-person 30-minute individual sessions and one telephone "feedback" session during the first year, followed by one individual and two feedback sessions during the next 2 years.

The NP sessions incorporated several elements of behavioral counseling such as individual goal-setting, keeping food diaries, using pedometers to track physical activity, and addressing barriers to lifestyle change.

The primary aim of the intervention was to prevent

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

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Indication and Important Limitations of Use

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

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

ONGLYZA has not been studied in combination with insulin.

Important Safety Information

- **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** (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).

Primary Care Provider Is Key

In an accompanying editorial, Debra Haire-Joshu, Ph.D., and Dr. Samuel Klein noted that while this study did not demonstrate that using a nurse practitioner to provide limited lifestyle counseling within a general medical practice results in meaningful long-term weight loss, substantial data suggest "that intensive interventions achieve weight loss that improves health outcomes. ..."

"The primary care provider is a critical entry point to the health care setting for the obese population. The high prevalence rate of obesity and its association with medical complications ensures that obese patients are commonly encountered in primary care practice. Patients usually make three health care visits annually, mostly to their primary care physician. Therefore, the primary care provider is uniquely positioned to consistently monitor weight, health indicators, and risk and to counsel or refer for weight management" (Arch. Intern. Med. 2011;171:313-4).

DR. HAIRE-JOSHU is director of the Obesity Prevention and Policy Research Center and DR. KLEIN is director of the Center for Human Nutrition, both at Washington University, St. Louis. They reported no conflicts of interest.

weight gain and, in those patients who were motivated to do so, to promote the loss of 5%-10% of body weight.

After 1 year, 80% of the subjects in the NP group had not gained any weight, compared with only 64% in the physician group.

However, in this follow-up at 3 years, that difference had disappeared. An equal proportion of both groups – approximately 60% – had maintained or lost weight. Ms. ter Bogt and her colleagues said (Arch. Intern. Med. 2011;171:306-13).

Subjects counseled by NPs showed a slight advantage in fasting glucose level at 3 years, and there were no differences between the two groups in serum lipid levels or blood pressure levels.

The researchers hypothesized that two visits with the NP after the first year of the intervention may not have been sufficient to help patients sustain weight loss.

However, analysis showed that maintaining weight was not related to the number of visits in either study group.

Analysis of data in subgroups of patients showed that those who had attempted to lose weight four or more times in the years preceding the study had less success in preventing weight gain than did those who had not.

“This means that our intervention is not suitable for experienced dieters,” Ms. ter Bogt and her associates wrote. ■

VERBATIM

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Aghaegbuna ‘Ike’ Odelugo, who pled guilty to fraudulently billing Medicare, page 50



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] ≤ 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.

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*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 April 9, 2010. Data on File, April 2010.



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