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A recent study in the *American Journal of Epidemiology* Vol. 155, No. 5 : 387-393 indicated that snoring was an independent risk factor in the eventual diagnosis of diabetes. **GlucoFree SnoreQuell** is proven to decrease or eliminate snoring without raising blood glucose levels. Click here to participate in the **SnoreQuell** survey.

DIABETES IN CONTROL.com NEWSLETTER
The Newsletter for Professionals in Diabetes Care

June 26 2002, Issue 110

From the Editors Desk:

Be sure to check out my story about the BOD POD, nothing more humbling than wearing speedos in front of 10,000 ADA members. [Click here to learn more.](#)

We are opening up the SnoreQuell study this week. After spending 7 days in the room next to Steve Freed, our publisher, and not hearing him snore all night, I am convinced this works. If your patients, you or anyone you live with snores, **sign up for this study.**

We had some exclusive interviews at the ADA and ENDO conferences and will have those for you starting next week.

Dr Rosen brings us "Looking For Lipid In All The Wrong Places". Learn how lipids end up in all the wrong places

Check out 2 new studies that have just opened: Patient Passouts and SnoreQuell.

Dave Joffe
Editor-in-Chief

News Update: Metrika receives NGSP Certification for their A1cNow instant A1c test. Now less than 10 dollars for the first and only A1c test that is instant and disposable. For more info on how you can now use it in your office practice [click HERE!](#)

"Tools" for Your Practice:

The Pritchett & Hull Patient Handout Medical Professional Experience Survey:

Pritchett and Hull has been producing high quality patient education materials for over 28 years, and they would like your feedback on three of their diabetes tear sheets.

We have arranged for **Prichard and Hull** to provide you with the following handouts at no charge

Carbohydrate Counting Tearpad, Diabetes Exercise Plan Tearpad, and Foot Care Tearpad,

All you have to do is give them your feedback. [Click here for more info](#)

Dr. Rosen's Feature

"Looking For Lipid In All The Wrong Places" Learn how lipids end up in all the wrong places and what new drugs might suppress enzymes that promote lipid deposition where they are not supposed to be.



News Flash - News Flash

Medicare Prescription Program Dead for this year. [Click Here](#)

New Product Information:

The "BOD POD" as seen at ADA. (That is our Editor inside the Bod Pod)

It's a system for measuring body fat and lean muscle mass using patented air displacement technology. It is based on the principle of under water weighing, but uses the displacement of air pressure rather than a complete body dunk. [Click here to see more of our editor Dave Joffe in the Bod Pod.](#)

Dr. Richard Bernstein's Corner:

Check out Dr. Bernsteins Corner for Insights for Controlling Blood Sugars
<http://www.diabetesincontrol.com/bernsteinarchive.htm>

Dr. Bernsteins Feature: Foot Care

The following guidelines are essential for all diabetics, to prevent foot injury and the potentially grave consequences that may ensue. Print the 19 steps to prevent amputations. **Click HERE!**

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This newsletter is the condensed version. If you would like to see the full newsletter go to
<http://www.diabetesincontrol.com/Issue110index.htm>

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OPEN STUDIES:

The Pritchett & Hull Patient Handout Medical Professional Experience Survey—receive high quality patient handouts at no charge, and give the company your feedback. **Click Here**

SnoreQuell Patient Experience Survey: will evaluate the effectiveness of this product in decreasing or eliminating snoring. This will be determined by comparing before and after questionnaires to be completed by each participant. This survey is open to educators, diabetes patients and their partners.
Click Here

Gym Study II: Gymnemosupium II, a combination of the extracts of Gymnema sylvestre, Pterocarpus marsupium, Diachrome and Vanadium. **Click Here**

RELAXATION – WarmFeet® study Version II Open For Registration (less labor intensive version) Learn More:
Click here

SOON TO OPEN STUDIES for your participation

1. **A new feedback study for you and your patients- Using a medical/nutritional assessment survey**
2. **The S.T.E.P. study, 10,000 Steps To Enhanced Prevention**

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This Weeks Items:

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ITEMS For The Week:

Item #1

ADA: Post-Prandial Glucose Directly Correlated to Cardiovascular Outcomes

Effective treatment of elevated post-prandial glucose levels in hyperglycemic patients may reduce cardiovascular disease and mortality associated with type 2 diabetes.

Hyperglycemia has been shown in prior research to add significantly to adverse outcomes associated with type 2 diabetes. Recent studies have indicated that higher than normal post-prandial glucose may be an independent factor associated with morbidity and mortality.

The investigators undertook a review of published data to evaluate the association of elevated post-prandial glucose levels with cardiovascular outcomes and all-cause mortality in type 2 diabetes and to establish the strength of this association in comparison to fasting blood glucose (FPG) levels.

They conducted a MEDLINE search of English-language articles published from 1980-2001, supplemented by a search of bibliographies and references supplied by content experts. They used specific criteria to find articles addressing the association of post-prandial glucose and cardiovascular morbidity/mortality and/or all-cause mortality.

They found 4,242 pertinent references in the literature. They finally accepted 14 studies for the review, 12 prospective and 2 cross-sectional.

Twelve of the studies (85 percent) documented a positive association between elevated PCG and cardiovascular morbidity/mortality and/or all-cause mortality in type 2 diabetes.

Seven studies provided direct comparison data on FPG and post-prandial glucose levels. Five studies (71 percent) indicate that post-prandial glucose is a better predictor of cardiovascular morbidity/mortality and/or all-cause mortality than FPG. The other 2 studies indicated no association between either FPG or post-prandial glucose and morbidity or mortality.

"Fasting plasma glucose is an important screening tool in diabetes," said investigator Myriam Bernal, research associate at ZYNX Health in Los Angeles. "We also found that there is powerful evidence in the wider medical literature to support the belief that post-prandial glucose, if it's higher, is directly correlated with cardiovascular outcomes. It should be targeted by physicians." *The study was supported by a grant from Novartis Pharmaceuticals. American Diabetes Association's 62nd Annual Scientific Sessions*

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If your patients are having a problem paying for their medications go to www.diabetesmeds.org and download the application that will allow them to get all of their medications for 10 dollars or less for a 90 day supply.

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Item #2

ADA: Thiazolidinediones May Pose Heart Failure Risk

Physicians should thus remain vigilant to CHF symptoms in patients taking these drugs

Although thiazolidinediones (TZDs) have a broad spectrum of anti-diabetic and potential vasculoprotective properties, they may increase the risk of congestive heart failure (CHF), researchers reported at the 62nd Scientific Sessions of the American Diabetes Association (ADA).

Thomas E. Delea, MBA, with Policy Analysis, Inc. in Brookline, Massachusetts, United States, and his team used a health insurance claims database with information on roughly 17 million patients annually to examine the risk of CHF in patients treated with TZD. They selected all patients with at least one diagnosis for type 2 diabetes and at least one prescription for an oral anti-diabetic drug during a recent six -year period.

Patients with at least one claim for a TZD were designated "exposed". The date of the first TZD claim for each such patient was designated the "index date". Five unexposed controls were randomly selected for each TZD patient and assigned the same index date. The trial excluded all patients who were not continuously enrolled, those who had a diagnosis of CHF, or those who had a prescription for digoxin or a diuretic in the year before the index date.

A total of 5,445 patients were considered exposed to TZD and had a mean age of 57 years, while the 28,137 controls had a mean age of 59 years.

Those on TZD were more likely to have the following characteristics: coronary artery disease/stroke/transient ischemic attack; diabetes complications; a recent prescription for an angiotensin-converting enzyme inhibitor or a beta blocker or insulin; and higher pre-index medical costs.

The primary outcome measure was the incidence of CHF, as defined by the occurrence of at least one claim with a primary or secondary diagnosis of CHF.

Results showed that TZDs were independently associated with an increased risk of CHF after controlling for differences in baseline clinical characteristics (hazard ratio 1.7, p<0.001). Adjusted Kaplan-Meier estimates of CHF risk at 36 months were 8.2 percent for patients on TZD compared to 5.3 percent for controls.

Delea cautioned that interpretation of the results may be limited by the fact that treatment was not based on random assignment, suggesting that the observed difference in risk may be due to differences in unobserved factors such as hemoglobin A1c levels and body mass index. Also, clinicians were not blinded to treatment. Thus, the observed difference in risk may be due to heightened vigilance to signs and symptoms of heart failure in patients taking a TZD, he said.

The investigators concluded that the results suggest use of TZDs is associated with an increased risk of CHF, and physicians should thus remain vigilant to CHF symptoms in patients taking these drugs. Alternate therapies should be considered in those who develop shortness of breath. *The study was sponsored by Novartis Pharmaceuticals. American Diabetes Association's 62nd Annual Scientific Sessions*

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Item #3 Item Revisited: **June 27, 2001 Issue #58 (ADA 2001)**

Lack Of Sleep Linked To Diabetes

Another new study this year shows even 2 hours deprivation of sleep can cause problems

New evidence that inadequate sleep may prompt development of insulin resistance, a well-known risk factor for diabetes, was reported Tuesday at the American Diabetes Association's 61st Annual Scientific Sessions.

"We have shown that failure to get the slightly more than eight hours sleep per night that clinical experts recommend may contribute to the rising incidence of diabetes," said Bryce A. Mander, a research assistant in the Endocrinology Section of the Department of Medicine at the University of Chicago.

The research was done in the laboratory of well-known sleep researcher Eve Van Cauter, Ph.D., a professor of medicine at the university.

"When you chronically get inadequate sleep, you are not merely developing a sleep debt but also disrupting other body functions," said Mander. "Such endemic sleep loss is widely seen in industrialized countries and has now been shown to decrease the body's sensitivity to its own insulin."

Approximately 16 million Americans have diabetes, a group of serious diseases characterized by high blood sugar levels that result from defects in the body's ability to produce and/or use insulin.

Another 20 to 30 million have impaired glucose tolerance, a potentially pre-diabetic condition that results from poor insulin sensitivity.

Diabetes can lead to severely debilitating or fatal complications, such as blindness, kidney disease, heart disease and amputations. It is the sixth leading cause of death by disease in the U.S.

The sleep research was undertaken to explore the hypothesis that one of the many functions of sleep is to help assure normal metabolism of sugar. This is a special concern as people in industrialized societies drive themselves for high work performance, progressively curtailing their sleep duration.

The sleep researchers studied 27 healthy, non-obese adults, aged 23 to 42 years; 14 were "normal" sleepers, whose average weekday sleep duration was 7.5 to 8.5 hours, while 13 were chronic "short" sleepers, whose average weekday sleep duration was under 6.5 hours. Their sleep patterns had been stable for at least six months.

The two groups were matched for gender and ethnic distribution, exercise habits, and diabetic family history. The participants wore a wrist activity monitor for eight consecutive nights and, on the last two, recorded their sleep at home using an ambulatory recording system.

Over the course of the study, the short sleepers averaged five hours and 16 minutes per night, while the normal sleepers averaged three minutes under eight hours of sleep per night.

On the final day of the study, the participants were admitted to the Clinical Research Center and, after an overnight fast, underwent an intravenous glucose tolerance test.

"Insulin sensitivity in the short sleepers was almost 40 percent lower than in the normal sleepers," said Mander. "Our research demonstrates that chronic sleep curtailment in otherwise healthy, young adults impairs the ability of insulin to do its job properly."

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FACT:

Studies show that up to 92 percent of people with type 2 diabetes are insulin resistant.

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Item #4

ADA: Treatment with a Sustained Release Formulation of GLP-1

Induces Weight Loss in Patients with Type 2 Diabetes.

The human incretin hormone GLP-1 has several antidiabetic actions which have been demonstrated in patients with type 2 diabetes: Strictly glucose-dependant stimulation of insulin secretion, suppression of glucagon levels, delay of gastric emptying, and weight loss.

Since native GLP-1 is rapidly degraded by the peptidase DPP IV, a sustained release formulation of a DPP IV resistant analogue, LY307161SR, was developed for single daily administration.

In this study, 24 patients with Type 2 diabetes (age: 58+/-1.5 y; weight: 90.9+/-2.1 kg; BMI: 30.2 +/-0.6 kg/m²; HbA1c: 7.3+/-0.1 %; on diet (16), metformin (7), or metformin plus sulfonyleurea participated in a single blind dose-escalation study. Patients received LY307161 SR treatment as a single injection prior to breakfast with either 2.5 mg or 3.5 mg for 6 days. In a third group a dose of 4.5 mg was given for 21 days.

Treatment with LY307161 SR was well tolerated.. Once daily administration of LY307161 SR resulted in sustained drug concentrations for the duration of the 24 hour dosing interval. LY307161 plasma concentrations after once daily dosing for 6 days were approximately 3-fold higher than single dose values. Mean average LY307161 concentrations ranged from 370 to 620 pg/mL across the entire dose range.

Fasting glucose was lowered by 19, 24, and 15% and 2 hour post prandial glucose peaks were reduced by 26, 37, and 27% in the 2.5, 3.5, and 4.5 mg dosing groups, respectively, compared to pre-treatment values. No hypoglycemia was observed. Body weight was lowered at all doses. Six day treatment with 2.5 and 3.5 mg/d resulted in 1.1+/-0.7kg (1.2%) and 1+/-0.7 kg (1%) weight loss respectively. Following 4.5 mg/d for 21 days patients had lost 2.1+/-0.5 kg (2.3%) body weight, indicating a continuous weight reducing effect..

LY307161 SR may offer a unique new treatment for patients with type 2 diabetes that combines the benefits of weight loss with improved glycemic control. *American Diabetes Association's 62nd Annual Scientific Sessions*

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Advertorial

Snoring increases diabetes risk. A recent study in the *American Journal of Epidemiology* Vol. 155, No. 5 : 387-393 indicated that snoring was an independent risk factor in the eventual diagnosis of diabetes. In addition irregular sleep patterns have been associated with hormonal imbalance, possibly affecting fasting glucose values. If you have diabetes and live with a snorer, your interrupted sleep patterns can affect your glucose as well.

Traditional products often have side effects and are not highly successful in reducing or eliminating snoring. The ingredients in GlucoFree SnoreQuell are proven to decrease or eliminate snoring without raising blood glucose levels. [Learn More here.](#)

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Item #5

ADA: Oralin as a Meal Insulin in Treatment of Type-2 Diabetes

RapidMist, a novel buccal diabetes rapid insulin delivery device.

The painful nature of injections is a major problem for Type-2 diabetics failing on oral agents and most patients are reluctant to go on injections. The alternative to this is the RapidMist, a novel Diabetes Management System based on a unique liquid aerosol formulation of oral insulin (Oralin). It allows a precise insulin dose delivery as fine aerosolized droplets directed in the mouth and rapidly absorbed through the buccal and oropharynx mucosae. In the present study we evaluated the efficacy of the Oralin versus s.c. injection (0.11u/kg) in controlling post-prandial glucose in 11 Type-2 diabetic patients after a standard meal challenge. In a single blind, randomized, crossover study, 11 Type-2 diabetic patients received Oralin (15 puffs) via the RapidMist device or s.c. injection (0.11u/kg) followed by a 360 cal Ensure meal, 10 mins after the dose. The table below shows serum glucose, insulin and C-peptide changes from the baseline.

Time, min	Injection Oral Glucose mg/dl	Injection Oral Glucose mg/dl	Injection Oral Insulin uU/ml	Injection Oral Insulin uU/ml	Injection Oral C-peptide ng/ml	Injection Oral C-peptide ng/ml
0	163	183	47	32	0.52	0.47
15	168	180	67	88	0.55	0.46
60	227	213	74	50	1.01	0.76
120	262	254	71	47	1.44	1.05
240	199	204	70	29	0.92	0.77

We conclude that the oral insulin absorption and elimination was much faster when compared to s.c injection (Tmax=88, at 15 min) and outperformed s.c. injection in terms of glucose and C-peptide lowering capacity as well as rise in the insulin levels. *American Diabetes Association's 62nd Annual Scientific Sessions*

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73% of graduating students have some type of guaranteed student loan. You can refinance those loans at a much lower rate. [Click here to get more info](#)

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Item #6

ADA: Effectiveness of a Diabetes Educator (DE) in Increasing Physician Compliance with Type II Diabetes Case Management

DHE presence in a private practice setting was effective at increasing diabetic patient testing compliance for HbA1c, lipids and ALB.

Private practice type II diabetes management includes providing care and testing according to established clinical guidelines. Previous studies have shown that increasing physician knowledge is an important step in better diabetes management.

Monitoring compliance with testing provides evidence that knowledge is manifested in better practice. This study examines if a Diabetes Health Educator (DE) working within a private practice can have the measurable effect on increasing patient testing.

A part time (24 hour per-week) DE instructed private practice physicians on current guidelines, standards and practices for diabetes case management to a private practice with 362 diabetics. Physician compliance with testing for hemoglobin (HbA1c), lipids and micro-albumin (m-ALB) were then followed at one year intervals for two years. Patients without direct DE involvement were treated as controls. Analysis methods included chi-square test's between patients followed by and DHE and those in the standard practice (controls).

The results showed compliance with testing was equivalent ($p>0.05$) for HbA1c, Lipids and m-ALB at baseline, demonstrating equality between groups. Overall compliance rates at baseline were 62% for HbA1c, 63% for Lipids and 35% for m-ALB. At one year physicians and patients with the DE education component ($n=258$) increased compliance to 77% for HbA1c versus 36% in the controls ($p<0.001$, $n=104$) at two years compliance increase to 88% in the DE group and 63% in the controls ($p<0.002$). Data for lipids demonstrated that DE education was 65% compliant at one year compared to 30% in controls ($p<0.001$). At two years compliance increased to 78% in DE education compared to 74% in controls ($p=0.556$). Results were similar for m-ALB, with 100% compliance in the first year ($p<0.001$) for DHE patients, and reduced to 48% compliance in the second year ($p=0.682$)

The study concluded that DE presence in a private practice setting was effective at increasing diabetic patient testing compliance for HbA1c, lipids and ALB. The lack of significance for the year two results could best be explained as Hawthorne effect, indicating that physicians have learned the diabetes management program and are implementing HbA1c, lipid and m-ALB testing in all diabetic patients in their practice without DE intervention. Further efforts are continuing in making testing 'routine' in the private practice setting. *American Diabetes Association's 62nd Annual Scientific Sessions*

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Did you know? Soy Supplements Help Blood Sugar

Women with type 2 diabetes may help to keep their blood sugar and cholesterol levels under control with soy supplements. That's the finding of a study presented at the annual scientific sessions of the American Diabetes Association. In the study, researchers looked at 32 postmenopausal women with type 2 diabetes. The women were given either a dietary supplement with soy or one without soy for 12 weeks, then given no supplements for two weeks, then switched to the other type of supplement for another 12 weeks. The researchers found that after 12 weeks the women taking supplements with soy had significantly better blood sugar control and lower levels of total cholesterol and low-density lipoprotein ("bad" cholesterol). This could be because soy contains substances called phytoestrogens, which act like estrogen does in the body, the IntelliHealth News Service reports. Some studies have suggested estrogen could help prevent heart disease, but results from other studies have been mixed. The researchers say more study is needed to see if the benefits of soy supplements last, and if they actually prevent heart disease.

Item #7

ADA: Use of a Continuous Glucose Monitoring System to Treat Hypoglycemia in Infants and Children *CGMS is a useful adjunct in the diagnosis and evaluation of hypoglycemia.*

The purpose of the study was to evaluate the use of a continuous glucose monitoring system (CGMS) in the evaluation and treatment of infants and children with hypoglycemic disorders.

Patients with hypoglycemic disorders were admitted to the Pediatric Clinical Research Center and wore the CGMS device during their evaluation and treatment. Glucometer values were obtained at least 3 times each day and entered into the device for calibration purposes. The monitor was downloaded to a computer where the CGMS signal was converted to glucose values. We compared readings from CGMS to those obtained via glucometer. We evaluated the number of hypoglycemic episodes below 60 mg/dl detected by CGMS compared to glucometer and characterized episodes by their duration and severity.

Five patients with hypoglycemic disorders were included in the study. There were a total of 13,369 sensor points, 343 paired sensor and glucometer data points, and 57 days included. A total of 180 episodes of hypoglycemia occurred in these 5 patients, with an average duration of 55 +/- 13 minutes. Forty-four percent of the episodes were 15-60 minutes and 25% were greater than 60 minutes in duration. Using a cut-off of 60 mg/dl for hypoglycemia, the sensor had a sensitivity of 65.4%, specificity of 90.6%, and false positive rate of 42.9%. The positive and negative predictive

values were 57.1% and 93.2%, respectively. In a Clarke Error Grid analysis, 96.2% of paired values were in the clinically acceptable range.

From the study it was concluded that CGMS is a useful adjunct in the diagnosis and evaluation of hypoglycemia, and for documentation of euglycemia in these patients following therapy. CGMS should be used in conjunction with frequent glucometer checks and careful clinical assessments. *American Diabetes Association's 62nd Annual Scientific Sessions*

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Advertisement

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Know your number TODAY! And prevent the complications from diabetes TOMORROW!

If you are not using an A1c test, which is now **NGSP certified**, that gives results while the patient is in front of you, you are missing a great opportunity to motivate. The A1cNow test is now available for shipping. You can now have your patients check their HbA1c when they come in for their appointments.

Learn how to purchase the A1cNow for less than 10 dollars for your office or clinic. go to www.A1cNow.net

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Item #8

ADA: Using the Diabetes Educator to Decreasing Physician Workload

A nurse practitioner and clinical pharmacist-directed diabetes center improved clinical measures and decreased physician workload.

As the prevalence of diabetes mellitus continues to increase to near epidemic levels in this country, the impact on the United States healthcare system is significant. Patients with new-onset and uncontrolled diabetes require considerable time requirement to understand the nature of the disease and develop self-management skills to prevent acute and chronic complications. Over 30 million physician office visits for diabetes are reported annually.

Harbor Medical Associates, a multi-specialty physician group in South Weymouth, MA and CVS Health Connection collaborated to implement the Center for Wellness and Education. The center integrates medical care with diabetes education and monitoring. The nurse practitioner and clinical pharmacist, both trained as diabetes educators, provide general wellness programs, comprehensive diabetes management services including initial and follow-up physical examination, laboratory test ordering, and medication adjustment and monitoring, working together with the group's physicians. The diabetes individual and group education program incorporates behavioral change to improve diabetes knowledge, self-monitoring skills and lifestyle modification to decrease diabetes and cardiovascular risk. Currently over 200 patients are managed with approximately 30 new referrals per month. At follow-up, participants with two or more results reported average decrease in HbA1c of 0.93% (p=0.001), decrease in systolic and diastolic blood pressure by 7.4 mm Hg (p<0.0001) and 4.2 mm Hg (p=0.001), respectively, and decrease in triglycerides by 51.7 mg/dL (p=0.04). The proportion of patients with HbA1c > 8.0% at baseline decreased at follow-up (p=0.001). Physician workload has decreased by referring patients to the center for routine diabetes follow-up.

In summary, implementation of a nurse practitioner and clinical pharmacist-directed diabetes center improved clinical measures and decreased diabetes and cardiovascular risk while reducing physician workload. *American Diabetes Association's 62nd Annual Scientific Sessions*

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Did You Know: Supersizing The Calories

For just a little more money, fast food restaurants will give you a lot more calories and saturated fat. A survey by the National Alliance for Nutrition and Activity finds that "bargain" super-sized portions of fast food pack on extra calories and saturated fats. The organization says these oversized portions contribute to rising rates of obesity in the United States, The Associated Press reports. The survey, which looked at fast food prices and calorie and fat content, was conducted in five U.S. cities. The survey found that while a large order of McDonald's fries cost 62 percent more than a small order, it had 157 percent more calories. A large Cinnabon cinnamon bun costs only about 25 percent more than a small cinnamon roll, but has twice as many calories and three times as much fat. The AP quotes restaurant industry representatives as saying that lack of exercise is the main culprit behind obesity in the United States.

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Item #9

ADA: The Effect of Orlistat on Glycemic Control Is Independent of Weight Loss

Blood glucose improvements independent of weight loss.

Orlistat (ORL) in conjunction with a mildly reduced-calorie diet is associated with improvements in glycemic control, lipid profile and blood pressure and significant weight loss in patients with type 2 diabetes (T2D).

The mean change from baseline in body weight was comparable in ORL- and PL-treated patients. However, compared to PL-treated patients, ORL-treated patients had a significantly greater decrease in both HbA_{1c} and FPG (LSM differences were -0.43% and -0.85 mmol/L respectively). A regression analysis demonstrated that the change in glycemic control in ORL-treated patients was significantly less correlated to weight loss than for PL-treated patients.

In conclusion, much of the glycemic improvements in ORL- compared to PL-treated patients are independent effects not related to weight loss. *American Diabetes Association's 62nd Annual Scientific Sessions*

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Item #10

ADA: INTERNATIONAL RESEARCH LINKS INFLAMMATION AND TYPE 2 DIABETES

So inflammation may be the common link for developing insulin resistance, diabetes, and heart disease. Insights Open New Pathways for Prevention and Treatment.

A series of international research reports have now linked inflammation to type 2 diabetes, opening new pathways for prevention and treatment of the disease and its complications, according to reports last week at the American Diabetes Association's 62nd Annual Scientific Sessions. "In the past year, about six studies have shown that markers of inflammation predict development of type 2 diabetes," reported Joshua Barzilay, M.D., of the division of endocrinology at Kaiser Permanente of Georgia, who spoke at a symposium on inflammation and diabetes. "One of the purposes of this meeting is to review recent findings and suggest new areas for investigation in this brand new field, including possible ways to reduce inflammation as a means of preventing or forestalling illness."

Inflammation is the way the body normally responds to injury – sending specialized blood cells to the area to destroy and clean up damaged cells – and can be seen on the skin, for example, as redness, swelling, and heat. But when the immune system malfunctions, such as in rheumatoid arthritis, the inflammatory process itself damages healthy tissue, such as joints. In recent years, researchers have discerned that inflammation may play a role in diseases not previously considered inflammatory, such as coronary heart disease. As a result, doctors theorize that the anti-inflammatory effects of aspirin – long recommended to heart patients for its anti-clotting ability – also may be yielding benefits.

See item 11 for more research. *American Diabetes Association's 62nd Annual Scientific Sessions*

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Item #11

ADA: Link Between Heart Disease and Inflammation

Doctors found higher levels of markers of inflammation in the blood of people with heart disease

The Link was made, in part, when doctors found higher levels of markers of inflammation in the blood of people with heart disease and then found that such markers also predicted risk for a heart attack. Higher levels of those same markers have now been found in people with diabetes and those at high risk for diabetes. One of those markers is CRP (C-reactive protein), which appears to be elevated in the presence of heart disease, diabetes, and obesity. "It's possible that if you have excessive fat, substances secreted from fat stimulate markers of inflammation," explained Vivian Fonseca, M.D., professor of medicine at Tulane University, New Orleans, who spoke at a symposium on diabetic dyslipidemia and inflammation. "So inflammation may be the common link for developing insulin resistance, diabetes, and heart disease, making it very attractive to monitor and treat high CRP levels."

In an ancillary study of the Atherosclerosis Risk in Communities (ARIC) project, an NIH funded research effort, more than 10,000 people who did not have diabetes were followed with blood sampling for nine years. The researchers found an association between developing diabetes and a series of inflammatory markers, especially sialic acid, according to Bruce Duncan, M.D., Ph.D., associate professor in the School of Medicine of the [Federal University of Rio Grande do Sul](#). "The quarter of the sample with the highest levels of these markers were at a 20% to 60% higher risk than the lowest quarter, clearly suggesting that something about the inflammatory response is related to diabetes." *American Diabetes Association's 62nd Annual Scientific Sessions* See item 12 for more research

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Item #12

ADA: Those with Higher CRP Values Greater Risk for Cardiovascular Disease

In Kuwait, research found that "the percentage of diabetic individuals who were in the highest 20% of CRP values were four times more likely to be suffering from cardiovascular disease compared to those who were in the lowest

20% of CRP," according to Nabila Abdella, MB, CHP, FRCP, Professor of Medicine at Kuwait University. Therefore she concludes that a high CRP value is indicative of a high risk for cardiovascular disease among those with diabetes and warrants more aggressive management, including tight control of blood sugar, blood pressure, and high cholesterol, as well as daily aspirin. In a Hong Kong study, a high CRP level was found to be an independent predictor for development of diabetic nephropathy.

ADA: Drugs Now Available to Treat Inflammation of CVD

Two classes of drugs statins and thiazolidinediones are available to treat inflammation.

Although some research is underway to explore the benefits of potent anti-inflammatory drugs, other studies have shown that several drugs already widely used by people with diabetes have anti-inflammatory benefits. Rosiglitazone (Avandia) is one of a class of drugs (thiazolidinediones) known to lower blood sugar and is widely prescribed for type 2 diabetes. In a recent study, standard doses were given to a group of people with diabetes and blood samples were taken at baseline and at 1, 2, 4, 6, and 12 weeks. A series of markers of inflammation, including CRP and NFkappaB, were measured.

"Not only did average blood glucose levels fall from 147 to 127 as expected, but all the indicators of inflammation fell by 20% to 40% by week 6, when the drug was discontinued," reports Paresh Dandona, M.D., Ph.D., Head of the Division of Endocrinology, Diabetes, and Metabolism at the State University of New York at Buffalo. "This leads us to speculate that patients treated with rosiglitazone might not develop atherosclerosis at the high rate usually seen in diabetes."

In addition, Dr. Dandona suggested that such anti-inflammatory treatment of those at risk for diabetes might help prevent the disease itself. A class of drugs used to reduce high cholesterol levels – the HMG-CoA reductase inhibitors, nicknamed "statins," – are also widely used by people with diabetes and have also been found to reduce inflammation. Now, a study has been made of Saskatchewan adults who were newly started on any of the oral hypoglycemic agents used to treat type 2 between the years of 1991 and 1996. Records were kept to determine who was also given a statin, to discern whether such treatment might increase the period of time to when these patients were prescribed insulin for their diabetes, a signal of worsening control. "We found that statin use was associated with an average 10-month delay before starting insulin treatment," reported Jeffrey A. Johnson, Ph.D., associate professor of Public Health Sciences at the University of Alberta, Canada. His group recommended that the potential of statins to delay onset of diabetes in high-risk individuals be evaluated. *American Diabetes Association's 62nd Annual Scientific Sessions*

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FACT

PHYSICIANS RANK DIABETES AS HIGHER RISK FACTOR FOR CARDIOVASCULAR DISEASE THAN SMOKING, NEW SURVEY FINDS

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Item #13

ADA: Xenical (Orlistat) Helpful For Type 2 Diabetics With High A1c Levels

Orlistat (Xenical) has a beneficial effect on HbA1c levels, fasting plasma glucose and waist circumference in patients with baseline hemoglobin A1c (HbA1c) levels of 8 percent or greater.

The findings were reported at the annual meeting of the American Diabetes Association (ADA). ADA guidelines recommend a target HbA1c level of 7 percent and suggest medical intervention at eight percent or higher.

Jaime Davidson, MD, associate professor of medicine at the University of Texas Southwestern Medical School, in Dallas, Texas, United States, presented data on a pooled analysis of seven multicentre, double-blind trials, evaluated to study the effect of adjunctive orlistat treatment on glycaemic control in overweight or obese patients (BMI 28-43 kg/m²) with Type 2 diabetes who also had a baseline HbA1c of 8 percent or greater.

The researchers in the seven studies randomized the subjects to treatment with orlistat 120 mg/day or placebo in addition to a mildly reduced-calorie diet (500-600 kcal/day deficit) and metformin, sulfonylurea and/or insulin treatment ongoing for no more than one year.

Mean baseline HbA1c level was approximately 9.3 percent. Intention-to-treat (ITT) analysis showed that at end point (24 or 52 weeks) there was a significantly ($p < 0.0001$) greater decrease in HbA1c levels in the 728 patients treated with orlistat (0.99 percent) than in the 699 treated with placebo (0.52 percent).

A significantly higher proportion ($p < 0.0001$) of orlistat-treated patients showed a decrease of at least 0.5 percent (63.9 percent) or at least 1 percent (49.0 percent) in HbA1c levels compared with placebo-treated patients (46.9 percent

and 33.5 percent, respectively).

In the orlistat-treated population, mean fasting plasma glucose (FPG) level at baseline was approximately 11.40 mmol/L. At end point, ITT analysis indicated a significantly greater decrease ($p < 0.0001$) in mean FPG levels with orlistat (1.83 mmol/L, $n = 769$) than with placebo (0.75 mmol/L, $n = 752$).

ITT analysis at end point also indicates a significantly greater decrease ($p < 0.0001$) in mean waist circumference, which was approximately 110 cm at baseline, in the orlistat group (4.00 cm, $n = 685$) than in the placebo group (2.02 cm, $n = 651$).

"Orlistat, in combination with diet, represents a clinically beneficial adjunct to anti-diabetic therapy for overweight or obese patients with Type 2 diabetes who have inadequate glycemic control," the authors concluded. *American Diabetes Association's 62nd Annual Scientific Sessions*

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Item #14

ADA: A "Breakthrough" for Diabetic Peripheral Neuropathy

LY333531, is the first drug to attack the cause of nerve-damaging diabetic peripheral neuropathy.

LY333531 inhibits PKC-beta, an enzyme involved in the process of microvascular damage. "Treating glucose variations and offering symptom relief has been about all we could for our patients up to this point," said Aaron Vinik, M.D., professor of internal medicine at Eastern Virginia Medical Center in Norfolk, United States. "We found that LY333531 gets to the root of the function of PKC-beta activity. With LY333531, we believe that we are getting at the bottom of the disease process, and we can begin to modify that process rather than just treat its destructive and painful symptoms."

Symptoms of peripheral neuropathy include numbness, prickling, aching pain, burning pain, and allodynia or lancing pain caused by ordinary skin-object contact. Over half of all diabetics develop diabetic peripheral neuropathy, according to the International Diabetes Federation. There is no FDA-approved treatment for the underlying process of microvascular damage causing diabetic peripheral neuropathy.

In a year-long, double-blind, placebo-controlled trial, Dr. Vinik and his research team randomized 205 Type 1 and Type 2 diabetics with peripheral neuropathy to receive LY333531 at 32mg/day, 64mg/day or to receive a placebo. At both dosages, LY333531 improved neurological examination scores, notably in the limbs and reflexes most affected by diabetic peripheral neuropathy. These positive findings were corroborated by a battery of other standardized tests.

"This is a potential breakthrough in diabetes treatment," said Anne Meyer, M.D., an endocrinologist and diabetes specialist practicing in San Francisco. "We can really begin for the first time to talk about stopping and healing nerve damage caused by this terrible disease."

Based upon results collected to date, the manufacturer of the compound, Eli Lilly and Company, will conduct three new global trials studying diabetic peripheral neuropathy. This will make six Phase 3 trials underway using LY333531. The three new trials will begin this year. Lilly plans to file with the FDA in 2004 for approval of LY333531 for the treatment of symptoms of diabetic peripheral neuropathy.

Lilly is also investigating the PKC-beta inhibitor as a treatment for diabetic retinopathy and diabetic macular edema, microvascular complications that can lead to blindness. *American Diabetes Association's 62nd Annual Scientific Sessions*

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Item #15

ADA: Nuts May Lower Risk of Diabetes

Nut consumption was inversely associated with risk of diabetes

New data presented at the 62nd Scientific Sessions of the American Diabetes Association suggest that eating nuts helps prevent the development of diabetes and that zinc supplementation in obese, insulin-resistant women improves insulin sensitivity, even in the absence of zinc deficiency.

"Major constituents of nuts (unsaturated fatty acids, magnesium and fiber) have been inversely associated with risk of type 2 diabetes; however, the overall effects of nut consumption on risk of type 2 diabetes are not available," write Rui Jiang and colleagues from Brigham and Women's Hospital in Boston. "Our results suggest that frequent nut consumption is associated with lower risk of type 2 diabetes in women."

In this offshoot of the Nurses' Health Study, the authors analyzed data from validated dietary questionnaires completed in 1980 by 83,818 women, aged 34 to 59 years, without a history of cardiovascular disease, cancer, or diabetes. During 16 years of follow-up, 3,206 women developed type 2 diabetes.

After adjustment for age, body mass index (BMI), smoking, physical activity, family history of diabetes, alcohol, and total energy intake, nut consumption was inversely associated with risk of diabetes. Compared with women who almost never ate nuts, multivariate relative risk (RR) among women who ate nuts less than once weekly was 0.93 (95% confidence interval [CI], 0.86-1.01). RR was 0.84 (95% CI, 0.76-0.93) among those who ate nuts one to four times weekly, and RR was 0.72 (95% CI, 0.60-0.88) among those who ate nuts more than five times weekly ($P < .0001$ for trend).

The protective effect of nuts did not vary after further controlling for dietary factors, including intake of vegetables, fruits, and whole grain, and a composite diet score composed of trans fat, cereal fiber, glycemic load, marine omega-3 fatty acids, folate, and polyunsaturated fat-to-saturated fat ratio.

"The inverse association persisted within strata defined by levels of family history of diabetes, body mass index, smoking, alcohol use, physical activity, and dietary variables," the authors write.

In a separate study by Dilina N. Marreiro and colleagues from Universidade de Sao Paulo-SP in Brazil, zinc supplementation enhanced insulin sensitivity in obese women who were not zinc-deficient.

In this prospective, double-blind, clinical interventional study, 56 obese women with normal glucose tolerance were randomized to treatment with zinc, 30 mg daily, or placebo for four weeks. At baseline, age was 25 to 45 years, mean BMI was 36.2 ± 2.3 kg/m², and both groups were similar in clinical and laboratory parameters.

Insulin resistance as measured by a homeostasis model assessment did not change in the placebo group, but it decreased from 5.8 ± 2.6 to 4.3 ± 1.7 ($P < .05$) in the zinc-supplemented group. Insulin decreased from 28.8 ± 14.1 to 21.2 ± 8.1 mU/mL ($P < .05$) in the zinc group but was unchanged in the placebo group.

"A short time of zinc supplementation improved insulin sensitivity in obese insulin [resistant] women without zinc deficiency," the authors write. "Although the mechanism concerning the effect of zinc supplementation is not completely understood, further studies are recommended to address the possible role of zinc therapy in insulin resistance states such as [diabetes]." *ADA Annual Meeting: Abstracts 1644-P, 569-P. June 16-17, 2002*

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Quote of the Week-----

-----Patience and time do more than strength or passion.

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