

DIABETES IN CONTROL.com Newsletter

The Newsletter for Professionals in Diabetes Care

November 29, 2006 Issue #340

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Top Diabetes Stories:

Fasting Glucose Predicts Heart Failure, Death Rate, MI and Stroke, Independent of Diabetes*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4354>

Multiple Births Increase Risk for Type 2 Diabetes*

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Study Links Job Stress to Doubling the Risk for Diabetes*

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Diabetes Linked to Lower Prostate Cancer Risk*

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Sitagliptin Role As Monotherapy, Adjunct*

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More Evidence Showing Breastfeeding Protects Against Type 2 Diabetes*

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High Sugar Intake Increases Risk for Pancreatic Cancer*

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Breakthrough in Tracking Islet Cells Will Help in Finding a Cure*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4343>

From the editor's desk

For an inside look at how ADA has built relationships with food and drug companies, join us in reviewing an article that **Marc Santora, writer, New York Times** wrote In Diabetes Fight, Raising Cash And Keeping Trust. This Week Part 1. Who's logo is it anyway?

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4355>

Now that your patients are over their fear of activity, **Sheri Colberg, Ph.D., FACSM** helps you Choose Planned Activities—Cardio Workouts for your patients, and how you can get your patients to do them. [Click here](#) to read this and all of **Dr. Colberg's** features.

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To ensure that you receive the **Diabetes in Control newsletter** arrives in your inbox, please add diabetes@topica.email-publisher.com to your Contact List, Safe List or Address Book.

December 4, 7PM ET on CNBC

Cardiologist Dr. Sheldon Gottlieb discusses how to minimize your risk factors for diabetes-related heart disease; *Parade* magazine editor Fran Carpentier talks frankly about juggling career and family with type 1 diabetes; and tips for eating out without losing control. Tune in to dLifeTV on CNBC at 7:00 PM ET, 6:00 PM CT, and 4:00 PM PT. Check your local listings for details.

We can make a difference!

This week's overview:

Item #4: Metabolic Syndrome Classification of Little Help in Diabetics

Item #8: Anemia Often Develops in Type 2 Diabetics: Study

Item #9: Cost Of Treating Diabetes Continues to Surge in US

Item#11: Vildagliptin (Galvus) Suppresses Postprandial Blood Glucose

Item#13: Use Folic Acid to Cut Heart Disease, Say Experts

Item#14: A Cup of Confusion: Is Coffee Healthy or Not?
Item#15: Nasal Insulin Spray Moving Forward with Phase 2 Trials

Check out this weeks "Test Your Knowledge" question.
<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4357>

Dave Joffe, *Editor-in-Chief*

NEW STUDY:

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NEWS FLASH:

Novo Nordisk is planning to sue the US Patent and Trademark Office after its inhaled insulin product has had its patent application knocked back for the second time. According to the Patent Office the patent application for Novo Nordisk's AERx device was rejected because it did not contribute anything new to the field.

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Tools for Your Practice:

The Pharmaceutical Research and Manufacturers of America have some great PDF's as part of their new multi-media national health education campaign on diabetes awareness. These are great to print for your patients:



http://www.phrma.org/files/Dol_Diabetes.pdf and
<http://www.phrma.org/files/FoP%20Diabetes.pdf>

New Product:



Zero-Click Software System for use with the AgaMatrix Wave 1 meter

enables users to effortlessly download data via a USB style connection by simply connecting a BGMS to a computer. No keyboard or mouse clicks are required for a user to be able to view or download data from their meter, much in the same way that a computer automatically detects and plays audio CDs. There is a home user mode optimized for ease-of-use for self-testers and a professional mode designed for more advanced users and multi-patient support by health care providers. More info...

<http://www.diabetesincontrol.com/issues/issue340/zeroclick.php>

This Week's Items:

1. Fasting Glucose Predicts Heart Failure, Death Rate, MI and Stroke, Independent of Diabetes*
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ITEMS For The Week:

Item 1

Fasting Glucose Predicts Heart Failure, Death Rate, MI and Stroke, Independent of Diabetes

An analysis based on the combined interim results from two prospective randomized trials, rates of HF hospitalization over more than two years rose in tandem with baseline fasting plasma glucose levels.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4354>

Two studies presented at last week's **American Heart Association 2006 Scientific Sessions** [1,2], suggested that, two common measures of insulin resistance are associated with poor outcomes in a "dose-response" fashion in nondiabetic patients with heart failure,

In one of them, an analysis based on the combined interim results from two prospective randomized trials, rates of HF hospitalization over more than two years rose in tandem with baseline fasting plasma glucose levels in a "high-risk" population of >30 000 diabetic and nondiabetic patients with vascular disease. The association was significant even after adjustment for medical therapies, diabetic status, and other components of the metabolic syndrome, reported Dr Claes Held (Karolinska University Hospital, Stockholm, Sweden).

Similarly, the two-year rate of cardiac death went up significantly and independently with baseline levels of glycated hemoglobin (HbA_{1c}) in a prospective study of several hundred patients with systolic HF. As reported by Dr Nicolas Lamblin (Centre Hospitalier Regional Universitaire de Lille, France), baseline HbA_{1c} levels also seemed to predict severity of HF and other morbidity measures.

"These studies provide further evidence that insulin resistance plays an important role in the risk of developing heart failure and the risk of mortality once heart failure develops." "These studies have important implications for how physicians recognize and manage patients with or at risk for heart failure, stated Dr Gregg C Fonarow (University of California, Los Angeles Medical Center)

Definitions of diabetes are based on degree of glycemia, but patients with glycemic indices below the arbitrary diagnostic thresholds can still be at increased risk for worsening heart failure, according to Held. "I look at glucose levels as I do cholesterol or blood pressure. It seems to be a continuous risk variable." "The lower the better, to a certain limit, of course."

No one is claiming, based on current evidence, that either fasting glucose or HbA_{1c} is a viable target for therapy of heart failure specifically; that would have to be established in prospective, randomized trials, all three researchers emphasized. But both new studies are consistent with research in other populations suggesting that insulin resistance is closely tied to HF progression. [3,4].

For example, both studies are consistent with an analysis from the randomized **Heart Outcomes Prevention Evaluation** (HOPE) trial in which the risks of CV events, HF, death, and clinically evident nephropathy were each independently associated with rising levels of HbA_{1c} among diabetic patients. In the same study, a mixed cohort of diabetics and nondiabetics showed similar relationships between fasting plasma glucose and the same set of outcomes. Observational studies have long suggested that diabetes is common among patients with HF and may contribute to the syndrome's progression.

Over a mean follow-up of 2.4 years, the hazard ratio for HF hospitalization climbed 5% (95% CI 1.02-1.08, p<0.001) for each 1-mmol/L increment in the baseline level of fasting plasma glucose, independent of diabetic status. When outcomes were analyzed by glucose quartiles, the risk went up significantly even at levels within the "normal" range and was more pronounced among patients with established diabetes compared with those with diabetes diagnosed at baseline.

The findings suggest that fasting plasma glucose independently predicts HF hospitalization and that "the degree of dysglycemia is the key determinant of this relationship, although they do not prove causality," Held said during his presentation.

Interviewed, Held said other data from the same patients suggest a similar link between baseline fasting plasma glucose levels and the composite rate of death, MI, or stroke. "So it's not just heart failure, but the strongest relationship is with heart failure."

Baseline levels of HbA_{1c} were inversely related to LV systolic function and rose with increasing ventricular dimensions and greater HF morbidity in a cohort of consecutive nondiabetic patients with heart failure and an LVEF <45%. The group's two-year rate of cardiac death also went up with increasing HbA_{1c} levels, Lamblin reported. In this analysis, cardiac death included urgent cardiac transplantation.

"Our study shows for the first time that HbA_{1c} levels are associated with the severity and prognosis of heart failure in nondiabetic persons," according to Lamblin.

Fonarow noted that the study's "minor elevations" in HbA_{1c} were "strongly linked to increased heart-failure severity. So whether this is merely another indicator of heart-failure severity or providing a truly independent mediator needs further study. Furthermore, knowing how best to lower this risk requires further studies, as trials of glycemic-control medications have generally excluded patients with preexisting heart failure."

1. Held C, Gerstein HC, Zhao F, et al. Fasting plasma glucose is an independent predictor of hospitalization for congestive heart failure in high-risk patients. *American Heart Association 2006 Scientific Sessions; November 13, 2006. Abstract 2562.*
2. Lamblin N, Bauters C. Hemoglobin A_{1c} levels are associated with severity and prognosis of systolic chronic heart failure in nondiabetic patients. *American Heart Association 2006 Scientific Sessions; November 13, 2006. Abstract 2372.*
3. Gerstein HC, Pogue J, Mann JF, et al. The relationship between dysglycemia and cardiovascular and renal risk in diabetic and non-diabetic participants in the HOPE study: A prospective epidemiological analysis. *Diabetologia 2005; 48:1749-1755.*
4. Barsheshet A, Garty M, Grossman E, et al. Admission blood glucose level and mortality among hospitalized nondiabetic patients with heart failure. *Arch Intern Med 2006; 166:1613-1619.*

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Item 2

Multiple Births Increase Risk for Type 2 Diabetes

Women with five or more live births are at increased risk of developing type 2 diabetes mellitus. This appears to be the case, even after adjusting for obesity and socioeconomic factors.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4353>

Dr. Wanda K. Nicholson and colleagues at the Johns Hopkins School of Medicine in Baltimore, Maryland, came to that conclusion after conducting a prospective, population-based study of more than 7000 Caucasian and African-American women.

The subjects were between 45 and 64 years of age, and mean follow-up was for nine years. They were grouped according to parity, defined as nulliparous (including stillbirths and other non-live births), one to two live births, three to four live births, or grandmultiparous, with five or more live births.

There were 754 incident cases of type 2 diabetes during follow-up. Type 2 diabetes incidence rates were highest among the grandmultiparous, at 23 cases/1,000 person-years and lowest among women with one to two live births, at 11 cases/1,000 person-years.

The researchers acknowledge that the bulk of diabetes risk was due to obesity and lower socioeconomic status. However, after adjusting for these recognized risk factors as well as clinical status, inflammatory markers and lifestyle factors, grandmultiparity remained a risk factor for type 2 diabetes.

Whether the link between high parity and diabetes is biological or due to lifestyle is unknown. The investigators conclude that the association may be better understood after prospective studies of "specific, pregnancy-related weight gain measures, lifestyle factors and changes in socioeconomic status."

Diabetes Care Nov 2006;29:2349-2354.

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DID YOU KNOW:

Working Long Hours Increases Risk Of Diabetes: A University of California study of nurses finds that working long hours increases the risk of diabetes in young and middle-aged women. The researchers, who used data from the Nurses Health Study and tracked nurses aged 29 to 46, found that those who worked 60 hours a week or more were more than twice as likely to develop Type 2 diabetes, the British newspaper, The Mirror, reported. Those who worked 40 to 60 hours were 50 percent as likely to get diabetes as those who worked 21 to 39 hours. "Results were consistent with an impact of job stress on diabetes outcome and hours worked per week may reflect the extent of exposure to stress," said Candyce Kroenke, who led the research team. Single women tended to drink and smoke more than married nurses and were also more likely to develop diabetes. Researchers believe that stress raises cortisol levels, leading to higher body fat and blood pressure. [Nurses Health Study](http://www.channing.harvard.edu/nhs/)
<http://www.channing.harvard.edu/nhs/>

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Item 3

Study Links Job Stress to Doubling the Risk for Diabetes

Workers suffering from job burnout are more prone to develop Type 2 diabetes, according to a new study
<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4352>

Researchers from Tel Aviv University in Israel suggest that job burnout could increase the risk of illness by a magnitude comparable to risk factors such as high body-mass index, smoking and lack of physical exercise.

The researchers, however, caution that the study does not definitively confirm a link between workplace stress and diabetes Samuel Melamed, an associate professor at Tel Aviv University and the article's main author, and his colleagues analyzed the experiences of 677 Israeli workers from 1998 to 2003. Nearly 77 percent of the workers were men, and their average age was about 43 years.

Of the 677 workers, 17 developed Type 2 diabetes during the study period

The researchers found that people who experienced job burnout were 1.84 times more likely to become diabetic, even when factors such as age, sex and obesity were taken into account

When researchers looked at a smaller sample of workers (507) and tried to statistically eliminate the possible effect of blood-pressure levels, they found that burned-out workers were then 4.32 times more likely to get Type 2 diabetes. According to Melamed, the ability of workers to cope with job stress also plays an important role in the possible link to Type 2 diabetes.

"It is possible that these people are prone to diabetes because they can't handle stress very well," Melamed said. "Their coping resources may have been depleted not only due to job stress but also life stresses, such as stressful life events and daily hassles."

Stress can disrupt the body's ability to process glucose, especially in people whose genetics make them vulnerable, said Richard Surwit, chief of the Division of Medical Psychology at Duke University Medical Center.

Surwit explained to *Occupationalhazards.com* that the study results should be replicated in a much larger group of subjects. He asserted that Melamed "needs to look at hundreds of thousands of people to see if he gets the same thing."

2006 November/December issue of the journal *Psychosomatic Medicine*.

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Item 4

Metabolic Syndrome Classification of Little Help in Diabetics

A diagnosis of metabolic syndrome does not appear to provide additional prognostic information in patients with type 2 diabetes.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4351>

Senior investigator Dr. Edoardo Mannucci stated, that in recent years many have "criticized the clinical value of metabolic syndrome, considering that the choice of parameters selected as diagnostic criteria, and the thresholds set for each of those components, are largely arbitrary."

To investigate the predictive utility of three or more metabolic syndrome components, Dr. Mannucci of the University of Florence and colleagues conducted an observational study involving about 4000 patients with type 2 diabetes.

They were divided into four categories. These consisted of hyperglycemia plus one other component of the metabolic syndrome, namely elevated blood pressure, hypertriglyceridemia, low HDL cholesterol and elevated waist circumference.

Within each category, there was no significant difference in mortality at a median follow-up of about 33 months in those with and without the metabolic syndrome at baseline.

For elevated blood pressure this was 7.9% versus 6.4% and for hypertriglyceridemia, 12.0% versus 10.7%. For low HDL cholesterol, corresponding values were 19.0% versus 14.0%, and for elevated waist circumference 11.9% versus 11.1%.

Even after adjustment, metabolic syndrome was not associated with increased mortality in any of the groups studied.

Give these findings, Dr. Mannucci added that the number of components needed to perform diagnosis of the metabolic syndrome -- conventionally three -- is also arbitrary.

"In diabetic patients with one or more components of metabolic syndrome other than hyperglycemia," he concluded, "the presence of further alterations does not modify long-term prognosis."

Diabetes Care Nov, 2006;29:2515-2917

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DID YOU KNOW:

Odds are that gamblers have more health problems, including diabetes: People who gamble at least five times a year have more health problems than people who gamble less frequently, a new study reveals. And people with a severe gambling addiction are the most likely to report serious health problems, such as increased heart rate, angina and liver disease when compared to people who have never had a gambling problem. "One of the questions that has never been answered is whether gambling is associated with health risks," said co-author Nancy Petry, Ph.D., an expert on gambling disorders from the University of Connecticut Health Center in Farmington. "Helping practitioners look at the broader issues — that gambling doesn't occur in isolation — is a potential outcome of this research."

Read and print the full news article at:

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4358>

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Item 5

Diabetes Linked to Lower Prostate Cancer Risk

Having type 2 diabetes may have one benefit, in that men with long-term diabetes may have a reduced risk of prostate cancer, according to the results of a study published in the American Journal of Epidemiology.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4350>

"Recent studies have suggested an association between type 2 diabetes mellitus and lower risk of prostate cancer," Dr. Mona Saraiya and colleagues from the Centers for Disease Control and Prevention, Atlanta, write. "It has been hypothesized that men with long-term diabetes have a lower risk of prostate cancer than nondiabetic men, and recently diagnosed men have a higher risk."

In the current study, the researchers used data from the National Health and Nutrition Examination Survey 2001 to 2002 to investigate the association between diabetes and prostate-specific antigen (PSA) levels, a biological marker for prostate cancer. Higher PSA levels indicate an increased risk of cancer.

The researchers adjusted the findings for the effect of known potential risk factors. For subjects without a diagnosis of diabetes, the researchers used fasting blood sugar measurements to determine the presence of undiagnosed diabetes.

The average PSA levels were 21.6 percent lower among men with a self-reported diagnosis of diabetes compared with men without diabetes.

This difference increased with years since the diabetes diagnosis was made. Men diagnosed more than 10 years ago had a 27.5 percent lower average PSA level. Overweight men who had been diagnosed with diabetes more than 10 years ago had a PSA level that was 40.8 percent lower than normal-weight men without diabetes.

"It is unclear whether the lowered PSA level in diabetic men accurately reflects a decreased risk of prostate cancer in the diabetic population or whether their lower PSA levels result in a reduced likelihood of receiving a diagnostic workup for detection of asymptomatic prostate cancers, as has been suggested for obese men," Saraiya and colleagues note.

"If the latter were true, diabetic men might well be diagnosed with later-stage tumors and have poorer treatment outcomes, and overweight diabetic men would have later-stage tumors than normal-weight diabetic men."

American Journal of Epidemiology, November 2006.

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Item 6

Sitagliptin Role As Monotherapy, Adjunct

The newly licensed glucose-lowering agent sitagliptin phosphate (Januvia) appears safe and somewhat effective. It could become a replacement for sulfonylurea, due to its ability to control blood sugars without weight gain and hypoglycemia.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4349>

Sitagliptin, manufactured by Merck & Co. under the name Januvia, is a once-daily oral agent that will cost \$4.86 per tablet. The first of the new class known as dipeptidyl peptidase-4 (DPP-IV) inhibitors, it was approved by the Food and Drug Administration in October as monotherapy or in combination with metformin or a thiazolidinedione.

The DPP-IV inhibitors work by blocking the enzyme that breaks down the two incretin hormones glucagonlike peptide-1 (GLP-1) and glucose-dependent insulinotropic peptide, which help regulate glucose metabolism via increased insulin release, suppressed glucagon release, and delayed gastric emptying.

“Despite the numerous therapies already available, many people are not adequately controlled in their blood sugar. So a new treatment option for type 2 diabetes, particularly one in a new class, is always a useful addition,” Dr. Robert Meyer, director of the FDA's Office of Drug Evaluation II, said in a telephone press briefing.

Another DPP-IV inhibitor, Novartis' vildagliptin (Galvus), was expected to be approved by the end of the year, but it now seems that it will be delayed.

Whether or not sitagliptin represents a distinct advantage over other available glucose-lowering agents is a matter of debate. Dr. Priscilla Hollander, who conducted clinical trials on sitagliptin for Merck, envisions use of the drug as a replacement for sulfonylureas in patients who don't achieve glucose targets with metformin or a thiazolidinedione (TZD) alone.

Metformin and TZDs address the insulin resistance component of type 2 diabetes, and sitagliptin's ability to promote β -cell insulin secretion without causing hypoglycemia or weight gain might make it an attractive substitute. “One place sitagliptin could probably play a very major role is where we currently use the sulfonylureas,” Dr. Hollander said in an interview.

It might also benefit elderly patients who need a “push” to their β cells but are sensitive to the hypoglycemia induced by sulfonylureas and perhaps are intolerant to the side effects of metformin or TZDs, she added.

Data from three phase III studies on sitagliptin were presented at the annual meeting of the European Association for the Study of Diabetes, in Copenhagen.

Dr. Pablo Aschner of the Colombian Diabetes Association, Bogota, presented data from a 24-week monotherapy trial in which 741 patients aged 18–75 years were randomized to daily placebo, 100 mg sitagliptin, or 200 mg sitagliptin. The study population began with a mean hemoglobin A1c of 8.0% and fasting plasma glucose of 9.6 mmol/L. At 24 weeks, the two sitagliptin doses produced significant, placebo-adjusted reductions in A1c of 0.79% with 100 mg and 0.94% with 200 mg, and in fasting plasma glucose of 1.0 mmol/L and 1.2 mmol/L, respectively.

Patients who started at an A1c of 9% or higher had a mean reduction of 1.52% with 100 mg sitagliptin and 1.5% with 200 mg, vs. 0.8% and 1.13%, respectively, among those with baseline A1c levels of 8.0%–8.9%, and 0.57% and 0.65% among those with baseline A1c of less than 8%. The proportion of patients achieving an A1c level of less than 7% were 41% with 100 mg sitagliptin and 45% with 200 mg, while 18% and 20%, respectively, reached an A1c below 6.5%.

Placebo-adjusted reductions in 2-hour postmeal glucose values were 47mg/dL (2.6 mmol/L) with 100 mg and 54mg/dl (3.0 mmol/L) with 200 mg sitagliptin. Improvements with sitagliptin relative to placebo also were seen in postmeal insulin and C-peptide concentrations, as well as in homeostasis model assessment-β and the ratios of insulin to glucose areas under the curve and proinsulin/insulin, suggesting improved β-cell function, Dr. Aschner said.

Neither hypoglycemia nor gastrointestinal events were increased with sitagliptin, compared with placebo. Small reductions in body weight were seen with sitagliptin (0.2 kg with 100 mg and 0.1 kg with 200 mg), but placebo subjects lost more weight (1.1 kg).

A second study, presented by Dr. Avraham Karasik, of Chaim Sheba Medical Centre, Tel Hashomer, Israel, randomized 701 type 2 diabetic patients who were inadequately controlled on 1,500 mg/day or more of metformin alone to receive placebo or 100 mg/day of sitagliptin for 24 weeks. Adjunctive sitagliptin led to significant mean placebo-subtracted reductions from baseline in hemoglobin A1c (0.65%), fasting glucose (25mg/dl [1.4 mmol/L]) and 2-hour postprandial glucose (50mg/dL [2.8 mmol/L]).

The proportions achieving a hemoglobin A1c value of less than 7% were 47% with sitagliptin plus metformin vs. 18% with metformin; 17% and 5%, respectively, reached an A1c level below 6.5%. Adding sitagliptin to metformin had no effect on body weight, nor did it increase the risk for hypoglycemia or gastrointestinal adverse events, compared with placebo, Dr. Karasik said.

Dr. Julio Rosenstock, of the Dallas Diabetes and Endocrine Center and the University of Texas Southwestern Medical Center, Dallas, reported on 353 patients who had hemoglobin A1c values between 7% and 10% while taking 30 mg or 45 mg/day of pioglitazone. At 24 weeks after randomization to receive the addition of placebo or 100 mg/day of sitagliptin, mean A1c was 7.2% with sitagliptin and 7.8% with placebo, a significant difference.

Nearly half those receiving sitagliptin achieved an A1c level of less than 7%, compared with 23% of those who received placebo. Also, 24% of the sitagliptin group and 5% of the placebo group reached the lower A1c target of 6.5%.

Internal Medicine: Volume 39, Issue 22, Page 1,4 (15 November 2006)

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Item 7

More Evidence Showing Breastfeeding Protects Against Type 2 Diabetes

Breastfeeding in infancy appears to be associated with a reduced risk of type 2 diabetes later in life, according to a quantitative analysis of published evidence.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4348>

Dr. Christopher G. Owen who led the study, stated that, "Whether this effect is attributed to a difference in the content of breast milk compared to formula milk, or whether the family environment and nurture of infants breast fed differs from those formula fed remains to be established."

In either case, breast milk is "the food of choice in infancy, based on numerous short- and long-term health benefits," added Owen, of St. George's, University of London.

Because evidence from individual studies that examined the relationship between breastfeeding and the risk of type 2 diabetes has been inconsistent, Owen's team conducted a systematic review and pooled analysis of relevant studies published in the medical literature on the topic.

In seven studies involving 76,744 subjects, those who were breastfed as infants had a 39-percent lower risk of developing type 2 diabetes in adulthood. The findings of these seven studies were "broadly consistent, despite widely differing nature of the populations," the authors note in the American Journal of Clinical Nutrition.

In six studies involving 4,800 subjects, levels of insulin -- the body's key blood sugar-regulating hormone -- were marginally lower in breastfed non-diabetic children and adults compared with formula-fed non-diabetic children and adults.

In these studies, fasting blood sugar concentrations were no different in breastfed and formula fed children and adults. However, in infancy, breastfeeding was consistently related to lower concentrations of blood sugar and insulin than was formula feeding. Chronically high levels of insulin raise the risk of heart disease and exacerbate the effect of diabetes.

"On the basis of the published evidence, breastfeeding may provide a degree of long-term protection against the development of type 2 diabetes, which could be of public health importance," Owen and colleagues conclude.

American Journal of Clinical Nutrition, November 2006.

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Dr. Bernstein will be doing another live teleconference call soon. If you would like to ask a question or just register for the free teleconference call, just go to <http://www.askdrbernstein.com> and register. There were over 600 people on the last call. More info at <http://www.diabetes911.net>

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Item 8

Anemia Often Develops in Type 2 Diabetics: Study

In patients with type 2 diabetes, a decrease in hemoglobin (Hb) is insidious and occurs predominantly in older people with chronic kidney disease and damaged large blood vessels, research suggests.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4347>

Dr. Merlin C. Thomas from the Baker Medical Research Institute in Melbourne, Australia stated that, "The early identification of anemia may be achieved by annual or biannual screening in these high-risk groups."

Anemia occurs when there is a drop in the blood's ability to carry oxygen, because of a deficiency in red blood cells or their oxygen-carrying component, hemoglobin. A lack of iron in the diet or blood loss, perhaps from internal bleeding or diseased blood vessels, are two potential causes of anemia.

"Anemia is now recognized as another problem in patients with diabetes, which develops earlier and is more severe in patients with diabetic kidney disease," Thomas said.

In a 5-year prospective study of roughly 500 type 2 diabetics, Thomas and colleagues found that 12 percent had anemia at baseline and an additional 13 percent developed anemia during follow-up.

Overall, Hb levels fell by -0.07 grams per deciliter per year. This suggests that anemia is "the endpoint of a process that begins more than 10 years previously, with the initiation of microvascular (small blood vessel) damage," Thomas and colleagues write in the American Journal of Kidney Diseases.

In patients with small blood vessel disease, decreasing Hb levels tracked with decreasing renal function. The rate of Hb decline was fastest in patients with established and progressive renal injury and large blood vessel or "macrovascular" disease at baseline.

"These data," Thomas concludes, "are important for developing a rational response to prevention and early management of anemia in individuals with diabetes."

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Proc Natl Acad Sci 2006;103:17438-17443.

<http://www.diabetesincontrol.com/studies/inset.php>

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FACT:

Stroke happens more often in those with impaired glucose tolerance: To determine whether impaired glucose tolerance is associated with an increased likelihood for ischemic stroke. Researchers carried out a prospective cohort study among a sample of 1,032 people. They measured the association between impaired glucose tolerance and diabetes. Patients were examined in the year 1990 and followed up for stroke occurrence until death or until the end of 2002. Mean follow-up time was 9.6 years. In total, 119 patients (11.5%) suffered a stroke during the follow-up. In logistic regression model, previous stroke, previous TIA, DM and atrial fibrillation were risk factors for stroke occurrence." The researchers concluded: "Stroke tended to happen more often in the impaired glucose tolerance group than in the normal group, but the difference was not statistically significant. Statistically significant risk factors for stroke in elderly people are previous TIA or stroke, DM and atrial fibrillation. *Age and Ageing* 2006 35(6):592-596; doi:10.1093/ageing/af1094. November 2006

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Item 9

Cost Of Treating Diabetes Continues to Surge in US

Drug costs double and triple due to the new medications that are available with out generic copies. Diabetes makes up over 33% of the Medicare Budget!

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4346>

The cost of caring for U.S. adults with diabetes rose sharply between 1996 and 2003, a period in which the number of patients soared from 9.9 million to 13.7 million and the average annual inflation-adjusted treatment costs rose from \$1,299 to \$1,714, according to reports released recently by HHS' Agency for Healthcare Research and Quality.

The rising costs of prescription drugs accounted for much of the cost increase. An adult diabetic's average annual spending for prescription medicines jumped nearly 86 percent during the time period, from \$476 to \$883. Patients aged 45 to 64, for whom drug costs doubled, were the age group most dramatically affected.

The federal report also found:

- ?? Overall, hospitals spent \$58 billion in 2004 on the 6 million stays of patients diagnosed with diabetes. That's 20 percent of the total amount spent by hospitals on the 38.6 million patient stays that year.
- ?? Diabetes patients tended to be hospitalized longer than other patients. Uninsured diabetes patients with less access to care were more likely to be admitted principally to have their diabetes treated than insured patients.
- ?? The number of foot or lower leg amputations per 1,000 hospital stays of diabetes patients was twice as high for the uninsured and more than two times higher for men than for women.
- ?? Overall care for patients with diabetes -- including treatment in all settings and for other illnesses such as congestive heart failure - averaged more than \$10,000 annually.

This AHRQ release is based on two data analyses: Proportion and Medical Expenditures of Adults Being Treated for Diabetes, 1996 and 2003, MEPS [Statistical Brief # 146](#), and Hospital Stays among Patients with Diabetes, 2004, HCUP [Statistical Brief # 17](#).

For further information please go to: [Agency for Healthcare Research and Quality](#)

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Item 10

High Sugar Intake Increases Risk for Pancreatic Cancer

Consumption of foods and drinks with high sugar content were associated with increased risk for pancreatic cancer, according to the results of a prospective, population-based cohort study of Swedish men and women.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4345>

"Emerging evidence indicates that hyperglycemia and hyperinsulinemia may be implicated in the development of pancreatic cancer," write Susanna C. Larsson, MD, of the Karolinska Institute in Stockholm, Sweden, and colleagues. "Frequent consumption of sugar and high-sugar foods may increase the risk of pancreatic cancer by inducing frequent postprandial hyperglycemia, increasing insulin demand, and decreasing insulin sensitivity."

In 1997, a total of 77,797 women and men aged 45 to 83 years with no previous diagnosis of cancer or history of diabetes completed a food frequency questionnaire. Follow-up continued through June 2005.

During a mean follow-up of 7.2 years, there were 131 incident cases of pancreatic cancer. Consumption of added sugar, soft drinks, and sweetened fruit soups or stewed fruit was positively associated with pancreatic cancer risk. For the highest compared with the lowest consumption categories, the multivariate hazard ratios were 1.69 for sugar (95% confidence interval [CI], 0.99 - 2.89; *P* for trend = .06), 1.93 for soft drinks (95% CI, 1.18 - 3.14; *P* for trend = .02), and 1.51 for sweetened fruit soups or stewed fruit (95% CI, 0.97 - 2.36; *P* for trend = .05).

"High consumption of sugar and high-sugar foods may be associated with a greater risk of pancreatic cancer," the authors write. "Given the practical implications of these findings and the poor prognosis of pancreatic cancer, further research on sugar and high-sugar foods in relation to pancreatic cancer risk is warranted."

Am J Clin Nutr. 2006;84:1171-1176.

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Item 11

Vildagliptin (Galvus) Suppresses Postprandial Blood Glucose

A single dose augmented insulin secretion and inhibited glucagon release. This single dose of vildagliptin had carryover throughout the evening and sleeping hours until the following morning.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4344>

A recent study has found that a single dose of the DPP-IV inhibitor vildagliptin caused a significant suppression of endogenous glucose production in patients with type 2 diabetes.

Previous research has indicated that the therapeutic effects of DPP-IV inhibitors are related mostly to their effect on glucagon-like peptide 1 and glucose-dependent insulinotropic peptide, and how this in turn effects insulin secretion. "However, there are a number of observations that suggest that factors other than change in insulin levels may be important," said Ralph A. DeFronzo, MD, chief of the diabetes division at the University of Texas Health Science Center at San Antonio. "We also know that the effects of these drugs can be seen in the absence of a meal. Clearly there is a lot more that we need to learn about how these drugs work."

DeFronzo and colleagues conducted a study testing the effects of an acute single dose of vildagliptin (Novartis) given before an evening meal in patients with type 2 diabetes. Research on chronic administration of the drug has shown that glucose levels drop over time, but the present study looked for acute effects independent of these chronic metabolic changes.

The study included 16 patients (mean age 48; 10 men) with type 2 diabetes, an average BMI of 34.4 and an average HbA1c of 9%. On two days separated by about two weeks, each patient received either 100 mg vildagliptin or placebo, followed 30 minutes later by a six-hour meal tolerance test.

“When the patients ingested vildagliptin, you could see within 15 minutes a marked inhibition of DPP-IV activity,” DeFronzo said. “This was at a maximum within 30 minutes and the inhibition persisted until 8 a.m. the following morning.”

Following vildagliptin, patients’ GLP-1 levels nearly doubled, an effect that also persisted until 8 a.m. the following morning. A similar effect was seen with GIP levels.

Also seen throughout the night was a glucose difference of about 15 mg/dL between vildagliptin and placebo patients. “Clearly this single dose of vildagliptin had carryover throughout the evening and sleeping hours until the following morning,” DeFronzo said.

Researchers also saw a significantly greater suppression of endogenous glucose production during the meal tolerance test with vildagliptin compared with placebo (1.02 mg/kg·min vs. 0.74 mg/kg·min; $P=0.004$); this difference was also evident from 6 p.m. through 8 a.m. the following morning (0.8 mg/kg·min vs. 0.5 mg/kg·min; $P<0.03$).

Insulin secretory rates also increased by 21% during the meal tolerance test with vildagliptin ($P=0.003$ vs. placebo). This occurred despite a reduction in mean plasma glucose with vildagliptin compared with placebo (213 mg/dL vs. 230 mg/dL; $P=0.006$).

Finally, suppression of mean plasma glucagon during the meal tolerance test was five times greater with vildagliptin than with placebo ($P<0.02$).

By including 3-³H-glucose and 1-¹⁴C-glucose intravenously along with the meal, the researchers were able to examine glucose appearance rates. “We failed to see any effect of vildagliptin on the rate of oral glucose appearance from the gastrointestinal tract,” DeFronzo said. “This means that there is not a delay in gastric emptying and there is no enhancement of glucose uptake by the gastrointestinal tract or the liver.”

DeFronzo said that this study shows that a single dose of vildagliptin results in a “nice improvement in beta-cell function tested in the insulin secretory rate, and nice reduction in endogenous glucose production.”

Dr. DeFronzo is on the advisory board for and has received a research grant from Novartis. Baig M, Balas B, Watson C, et al. Vildagliptin suppresses endogenous glucose production and increases beta cell function after single dose administration in type 2 diabetic patients. Presented at: 42nd European Association for the Study of Diabetes Annual Meeting 2006; Sept. 14-17; Copenhagen.

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DID YOU KNOW:

Diet or Exercise: Which One Works Better to Reduce Your Risk of Diabetes? According to a new study by researchers examining whether a calorie-restrictive diet can extend the human lifespan, both diet and exercise provide profound benefits to reduce the risk of diabetes. The researchers, who initially thought that exercise would produce greater benefits, examined 50 to 60 year olds whose body mass index was between 23 and 30 (at the high end of normal weight or overweight, but not obese). The study participants were divided into groups and treated with either an exercise regimen or a calorie-restricted diet. All participants had their insulin action and glucose tolerance evaluated at the beginning and end of the study. The ultimate goal of the diet group was to cut the number of calories they ate by 20 percent, while the exercise group was charged with burning 20 percent more of their calories. Glucose tolerance and insulin levels improved to roughly the same degree in both the dieters and exercisers. Both groups also lost weight. *American Journal of Clinical Nutrition* November 2006; 84(5): 1033-1042

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<http://www.cemedicus.com/diabetes>

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Item 12

Breakthrough in Tracking Islet Cells Will Help in Finding a Cure

Scientists in London have found a way to track insulin-producing islet cells after they have been transplanted, a breakthrough in the drive to find a cure for diabetes.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4343>

"It is getting us closer to a cure," Dr. Joo Ho Tai, a researcher at the Lawson Health Research Institute", said.

Tai and Robarts Research Institute scientists Dr. Paula Foster and Dr. David White are the first in Canada to image islet cells using the type of MRI scanner found in hospitals. Their work is published in the November issue of the journal Diabetes.

Islet cell transplantation, developed by scientists in Edmonton, has been heralded as a promising cure for diabetes, a disease that has hit more than two million Canadians. But there have been problems with the method.

The body's immune system views the transplanted cells as foreign invaders, wiping out as many as 80 per cent of them at the time of transplantation. And islet levels can continue to drop, leaving the individual dependent on insulin again and open to complications.

The ability to obtain MRI images of islet cells will allow physicians to know how well the transplant has worked and monitor the survival of the cells over time. That will make it possible to adjust medications or change treatments to protect the islet cells.

"Without an image of the islets, doctors won't have the right cure or treatment," said Tai. "Imaging is not a cure itself, but it is a great tool."

To track the islet cells, Robarts imaging scientists developed a technique to place non-harmful iron particles inside the cells so they can be detected by the MRI scanner. Without the ability to produce images of the cells inside the body, physicians currently rely mainly on blood tests to check on their survival. But by the time blood tests show the transplanted cells being rejected and attacked by the body's immune system, it's too late, Foster said. "By the time they detect anything, it is all over. There is no way you can go in and help.

"If the imaging can pick it up earlier, then you could decide do we need to put more islets in or do we need to give some different immunosuppressive along with it," she said.

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Item 13

Use Folic Acid to Cut Heart Disease, Say Experts

The scientific evidence is strong enough to justify using folic acid as a cheap and simple way of reducing heart disease and strokes, say researchers in this week's BMJ.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4342>

Debate continues over whether raised homocysteine levels in the blood (an amino acid implicated in the

development of arterial disease) causes heart disease and stroke, and whether folic acid, which lowers homocysteine, will help reduce the risk of these disorders.

So heart expert, Dr David Wald and colleagues set out to clarify the issue. They examined all the evidence from different studies to see whether raised homocysteine is a cause of cardiovascular disease.

Some studies looked at homocysteine and the occurrence of heart attacks and strokes in large numbers of people (cohort studies), some focused on people with a common genetic variant which increases homocysteine levels to a small extent (genetic studies), while others tested the effects of lowering homocysteine levels (randomised controlled trials).

The cohort studies and genetic studies yielded similar results, indicating a protective effect from lower homocysteine levels, even though they did not share the same sources of possible error. The randomised trials were too small to be conclusive although their results were consistent with the expected protective effects of folic acid.

The conclusion that homocysteine is a cause of cardiovascular disease explains the observations from all the different types of study, even if the results from one type of study are, on their own, insufficient to reach that conclusion, say the authors.

Since folic acid reduces homocysteine concentrations, it follows that increasing folic acid consumption will reduce the risk of heart attack and stroke.

They therefore take the view that the evidence is now sufficient to justify action on lowering homocysteine concentrations, although the position should be reviewed as evidence from ongoing clinical trials emerges.

BMJ Volume 333 pp 1114-7 Click here to view paper: <http://press.psprings.co.uk/bmj/november/ac1114.pdf>

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FACT:

Metformin Beneficial for Obese and Non-Obese Patients with Diabetes: *The diabetes drug metformin is at least as effective in normal and overweight patients as it is in obese patients, according to a report in the journal Diabetes Care. Although metformin is a first-line therapy for obese patients with type 2 diabetes, the authors point out, there is little information about the effectiveness of metformin in patients who are not obese. Researchers used a database to compare the long-term outcomes of metformin therapy in 644 type 2 diabetics who were normal weight, overweight or obese. Metformin provided comparable long-term control of blood sugar levels in obese and non-obese patients, the report indicates. Moreover, it was just as effective in both groups at preventing diabetes complications. Obese patients lost more weight than did nonobese patients on metformin, the researchers note, but patients who were not obese at the beginning of the study remained thinner throughout follow-up than those who started out obese. The patients who weren't obese were able to maintain their glucose levels without requiring other drugs for a longer duration than obese patients. "Metformin is at least as efficacious in the nonobese as it is in the obese," the authors conclude. "This study provides evidence-based data to support metformin use in nonobese individuals who have type 2 diabetes."* *Diabetes Care, November 2006.*

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Item 14

A Cup of Confusion: Is Coffee Healthy or Not?

New studies suggest java helps protect against major diseases, including diabetes.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4341>

Considering all the past concern about possible health risks from drinking coffee, newer reports of coffee's possible protective effects may leave many people confused.

Overall, recent studies suggest that coffee (regular and decaffeinated) may offer a variety of health benefits against diseases such as cancer and diabetes. However, coffee may not deserve a place in the same category with other healthful foods like vegetables, fruits and whole grains.

Laboratory studies suggest that the anti-inflammatory, antioxidant compounds in coffee could help reduce risk of cancer. Coffee also has a tendency to speed the passage of waste through the digestive tract. Potentially, this may lessen the time that cancer-causing compounds spend in contact with the intestinal tract, which could reduce

the risk of colon cancer. Population studies, however, tend to split between coffee intake having no effect on or reducing risk of breast and colon cancer.

Diabetes prevention- The case for coffee's ability to protect against diabetes is strengthened by several recent studies. In the Iowa Women's Health Study, more than 28,000 women were followed for 11 years. The women who drank four or more cups of coffee daily were about 20 percent less likely to develop diabetes. That became a 30 to 40 percent drop among those who drank decaf coffee.

A study in Finland linked consumption of three to six cups of coffee per day with a 25 percent lower risk of diabetes. In both studies, benefits were seen after adjusting for other diabetes risks, such as weight, diet, and activity level. Several studies now link moderate coffee consumption with lower risk of Type 2 diabetes. Researchers are working to understand the potential advantage of decaf versus regular coffee and how weight control is involved.

Potential increased risk of high blood pressure and heart disease has been one of the long-standing concerns about coffee. Recent studies confirm that caffeine can raise blood pressure, but this effect is observed with soft drinks, not coffee. Laboratory studies suggest that perhaps coffee's healthful compounds can counterbalance the blood-pressure raising effects of caffeine.

In the Iowa Women's Health Study noted above, four to five cups of coffee a day were linked with a 19 percent lower risk of heart-related death. Other studies have found no effect of coffee consumption on heart disease risk. But people should follow their doctor's advice.

Coffee does warrant some cautions, however. Both regular and decaf coffee relax the muscle that keeps stomach acids from rising into the throat, so those with heartburn or reflux disease (GERD) are encouraged to avoid or strictly limit coffee. People with trouble sleeping should limit or avoid caffeinated coffee.

Studies now suggest it is unnecessary for pregnant women to completely avoid caffeinated coffee. Until the impact of caffeine is more clearly understood, however, many experts suggest that pregnant women limit their daily caffeine from coffee, soft drinks and other sources to about 300 mg, the equivalent of three cups of regular coffee.

It's exciting that something as simple as drinking coffee might help lower our risk of cancer, diabetes and heart disease. However, while brewed coffee (not instant) is a concentrated source of antioxidants, it can't be a substitute for berries, legumes, nuts, and other fruits and vegetables that provide antioxidants along with a wide range of vitamins, protective compounds and dietary fiber.

Nutrition Notes is provided by the [American Institute for Cancer Research](#) in Washington, D.C.

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Item 15

Nasal Insulin Spray Moving Forward with Phase 2 Trials

Two earlier studies conducted in Ireland with normal subjects and Type I diabetic patients demonstrated rapid absorption from the nasal spray and the expected glucose response.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4340>

Bentley Pharmaceuticals, Inc., a specialty pharmaceutical company, announced that, following successful review of its Investigational New Drug (IND) application by the U.S. Food and Drug Administration, a phase II program is now in effect and under way evaluating Bentley's human recombinant Intranasal Insulin Spray for the treatment of postprandial hyperglycemia in diabetics.

Bentley's Chief Medical Officer Robert Stote said, "Bentley's intranasal method of insulin administration is designed to provide a quick and easy self-medication to improve patient compliance. In general, drugs entering

the nasal cavity are readily absorbed across the highly vascularized nasal mucosa directly into the circulatory system, avoiding first-pass metabolism in the liver. The rapid absorption affords a fast onset of action comparable to the very rapid-acting, injectable insulin formulations.

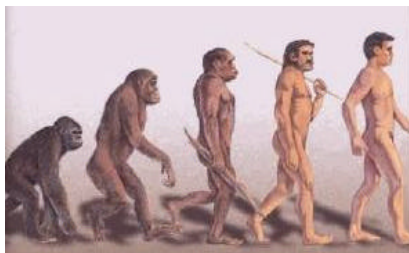
"Using Bentley's CPE-215 drug delivery platform, initial studies have indicated that our intranasal insulin spray passes quickly through the nasal mucosa, delivering a larger payload compared to other non-injectable delivery systems. Further, we believe that targeting the nasal mucosa can avoid concerns for lung deposition and potential impacts on respiratory function in chronic treatment."

The initial phase II studies have been planned and are being carried out in Texas at the Diabetes and Glandular Disease Clinic of San Antonio, P.A. under the direction of Sherwyn Schwartz as Principal Investigator. Schwartz stated, "Nasal insulin has the potential of helping a lot of people, particularly those who are afraid of needles or who have lung disease."

Over the next 12 months, Bentley expects to complete phase II clinical studies for both Type I and Type II diabetic patients. Two earlier studies conducted in Ireland with normal subjects and Type I diabetic patients demonstrated rapid absorption from the nasal spray and the expected glucose response. Peak insulin levels were generally attained in 15 to 20 minutes, remaining elevated for approximately 1 hour; the resultant impact on glucose peaked in 40 minutes and decreased 1.5 to 2 hours after dosing. Calculated relative bioavailability of insulin using Bentley's nasal spray formulation was in the range of 15-20% of subcutaneously injected insulin.

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Quote of the Week!



*“If God had wanted us to walk
He’d have given us two legs and made
us to stand erect.”*

..... Anonymous

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