

# DIABETES IN CONTROL.com Newsletter

The Newsletter for Professionals in Diabetes Care

December 17, 2008 Issue 447

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## Top Current Diabetes News:

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### Fibrate Drug Does Not Cut Heart Risks In Diabetics\*

<http://www.diabetesincontrol.com/results.php?storyarticle=6331>

### Type 2 Diabetes An Addiction?\*

<http://www.diabetesincontrol.com/results.php?storyarticle=6330>

### Diabetes Drugs 'Double Bone Risk' \*

<http://www.diabetesincontrol.com/results.php?storyarticle=6329>

### Body Clock Linked to Diabetes And High Blood Sugar\*

<http://www.diabetesincontrol.com/results.php?storyarticle=6327>

### Fructose Metabolism - What You Don't Know!\*

<http://www.diabetesincontrol.com/results.php?storyarticle=6325>

### New Genes Present Drug Targets For Managing Cholesterol And Glucose Levels\*

<http://www.diabetesincontrol.com/results.php?storyarticle=6324>

### Thiamine Reverses Early Diabetic Kidney Disease in 35% of Type 2 Patients\*

<http://www.diabetesincontrol.com/results.php?storyarticle=6323>

### Fast Heart Rate Warns of Obesity, Diabetes\*

<http://www.diabetesincontrol.com/results.php?storyarticle=6322>

### Low-Dose Terbutaline Can Prevent Nocturnal Hypoglycemia in Type 1's\*

<http://www.diabetesincontrol.com/results.php?storyarticle=6319>

### Benefit of Prior Intensive Diabetes Therapy on Retinopathy Risk Wanes Over Time\*

<http://www.diabetesincontrol.com/results.php?storyarticle=6317>

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## From the editor's desk:

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More and more of our patients using insulin are exercising and participating in sports. They often lower their basal rates or decrease their mealtime dose to try and compensate. This can lead to hyperglycemia or hypoglycemia after exercising. Why does that happen and what changes over time.

**Dr. Sheri Colberg, Ph.D., FACSM** explains how that happens and what your patients can do about it in

[Why How Much Insulin You Have "on Board" during Exercise Matters](#)

<http://www.diabetesincontrol.com/results.php?storyarticle=6332>

When your patients go into the hospital they often need complex therapies with a lot of different drugs and the possibilities for interactions and side effects are great. Last week I spent some time at the [American Society of Healthcare-System Pharmacists Midyear Clinical meetings](#). These are the pharmacists who make sure everything is done right for you and your patients

**David Kliff, Publisher, Diabetic Investor**, has been looking at the President-elect's recent appointments and keeps wondering who will be the new head the Food and Drug Administration. Whoever it is will have an interesting road ahead of them. To read what is going on and what Dave thinks, [click here](#)

<http://www.diabetesincontrol.com/results.php?storyarticle=6333>

## dLife TV, Dec. 21, 7PM ET on CNBC

Why kicking the smoking habit is harder when you have diabetes, and tips for quitting. Then, back from Iraq, a soldier returns home to his toddler's diabetes management. Also, the special issues of women with diabetes, and a Jim Turner flashback to his teen years. Enjoy another great episode of dLifeTV: on Sundays on CNBC at 6:00 PM ET, 5:00 PM CT, and 3:00 PM PT

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*We can make a difference!*

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## More Current News on Diabetes

Item #4: Effect of Cranberry Extracts On Lipid Profiles Of Type 2 Patients

Item #6: Sitagliptin Reduces Blood Glucose In Elderly Type 2's

Item #11: Weight Loss Drug Onexa Reduces Hemoglobin A1c By 1.6% & Wt By 9%

Item #12: Low-Glycemic Diet Better Than High-Fiber Diet for Type 2's

Item #14: SGLT2 Inhibitors a Promising New Therapy for Type II Diabetes

Check out this weeks **"Test Your DIABETES Knowledge"** question.

<http://www.diabetesincontrol.com/results.php?storyarticle=6334>

Dave Joffe, *Editor-in-chief*

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### NEWS FLASH:

Senator Edward Kennedy Honored With American Diabetes Association's Distinguished Service Achievement Award

<http://www.diabetesincontrol.com/results.php?storyarticle=6335>

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### This Week's Product Update:

#### MetControl™ Metformin Chewing Gum

2½ years ago, we brought you news of a new chewing gum for diabetes. Now Generex has announces positive results of trial that shows the company's metformin chewing gum is therapeutically equivalent to traditional metformin tablets. This gum appears to have less gastric side effects and overcomes the problems of bad taste and swallowing a big tablet.



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### This Week's Tool:



#### Pri-Med Patient Education Center

Many of us have attended a PriMed Medical Update or CME program but did you know that they have patient education handouts, written by Harvard Medical School. You can find them at <http://patientedu.org/asp/HealthELibrary/healthecat.aspx?helcategoryid=32>

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2. Type 2 Diabetes An Addiction?\*

<http://www.diabetesincontrol.com/results.php?storyarticle=6330>

**3. Diabetes Drugs 'Double Bone Risk' \***

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**4. Effect of Cranberry Extracts On Lipid Profiles Of Type 2 Patients**

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**7. Fructose Metabolism - What You Don't Know!\***

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**10. Fast Heart Rate Warns of Obesity, Diabetes\***

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**11. Weight Loss Drug Qnexa Reduces Hemoglobin A1c By 1.6% & Wt By 9%**

<http://www.diabetesincontrol.com/results.php?storyarticle=6321>

**12. Low-Glycemic Diet Better Than High-Fiber Diet for Type 2's**

<http://www.diabetesincontrol.com/results.php?storyarticle=6320>

**13. Low-Dose Terbutaline Can Prevent Nocturnal Hypoglycemia in Type 1's\***

<http://www.diabetesincontrol.com/results.php?storyarticle=6319>

**14. SGLT2 Inhibitors a Promising New Therapy for Type II Diabetes**

<http://www.diabetesincontrol.com/results.php?storyarticle=6318>

**15. Benefit of Prior Intensive Diabetes Therapy on Retinopathy Risk Wanes Over Time\***

<http://www.diabetesincontrol.com/results.php?storyarticle=6317>

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**Articles For The Week:**

Item 1

**Fibrate Drug Does Not Cut Heart Risks In Diabetics**

*Long-term treatment with fenofibrate, a type of fibrate drug often used to lower cholesterol, does not reduce coronary plaques or signs of "atherosclerosis" in patients with type 2 diabetes, according to a published report.*

<http://www.diabetesincontrol.com/results.php?storyarticle=6331>

Prior research has suggested that fibrate therapy can have beneficial cardiovascular effects. However, in the main analysis of the Fenofibrate Intervention and Event Lowering in Diabetes (FIELD) study, researchers found that treatment with fenofibrate did not reduce heart attacks in type 2 diabetics.

The focus of this FIELD substudy was to determine if fenofibrate therapy reduced atherosclerosis, a main risk factor for heart attacks, in patients with type 2 diabetes. Included were 170 patients randomly assigned to receive fenofibrate or inactive "placebo" for 5 years.

Dr. Anne Hiukka at the University of Helsinki, Finland, and colleagues report that during follow-up, atherosclerosis progressed to a similar extent in each group.

In a related editorial, Dr. Evan A. Stein, from the Metabolic and Atherosclerosis Research Center, Cincinnati, Ohio, comments that these substudy results, combined with main FIELD findings, suggest that fenofibrate treatment offers little heart benefits to diabetic patients.

*Journal of the American College of Cardiology, December 16/23rd issue, 2008.*

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Item 2

### **Type 2 Diabetes An Addiction?**

*Sugar as addictive as cocaine, heroin, studies suggest. Start your day with protein.*

<http://www.diabetesincontrol.com/results.php?storyarticle=6330>

It's one addiction that won't land you in court or an inpatient rehab. But sugar - as anyone who mainlines sweets can attest - can be just as habit-forming as cocaine.

Researchers at Princeton University studying bingeing and dependency in rats have found that when the animals ingest large amounts of sugar, their brains undergo changes similar to the changes in the brains of people who abuse illegal drugs like cocaine and heroin.

"Our evidence from an animal model suggests that bingeing on sugar can act in the brain in ways very similar to drugs of abuse," says lead researcher and Princeton psychology professor Bart Hoebel..

In the studies, he explains, animals that drank large amounts of sugar water when hungry experienced behavioral changes, too, along with signs of withdrawal and even long-lasting effects that resemble cravings.

Some people experience powerful cravings for sweets - internal messages telling them to eat sugar even though they know it's bad for them - says Dr. Louis Aronne, director of the Comprehensive Weight Control Center at N.Y. Presbyterian Hospital/Weill Cornell Medical Center. "These people get strong urges to consume sweets, and these cravings border on addiction," he says. "When they eat sugar, just like when someone ingests cocaine, some people get that feeling of well-being, a rush that makes them feel good for a period of time. When the sweets are taken away, the people just don't feel right."

In the animals studied at Princeton, bingeing released a surge of the neurotransmitter dopamine in the brain. "It's been known that drugs of abuse release or increase the levels of dopamine in that part of the brain," Hoebel said.

After the rats' sugar supply was withdrawn, they became anxious. Their teeth chattered and they grew unwilling to venture into the open arm of their maze. Instead, they stayed in the tunnel of the maze.

Deprived of their sugar, the rats displayed signs of withdrawal similar to the symptoms seen in people when they stop smoking, drinking alcohol, or using drugs.

Just as not everyone has the tendency to become an alcoholic or a drug addict, so not everyone is hard wired to be a sugar-holic, Aronne says. And there is certainly effective treatment for a sweet addiction, though it's not likely to go down easily among those who like their candy and cookies.

"If people eat starch and sugar in the morning, it's very difficult to get their behavior in control and they'll be craving sweets all day," Aronne says. "So we have people start out their day by eating protein and vegetables in the morning, like a broccoli omelet for breakfast.

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### **DID YOU KNOW:**

**Simple Change Could Reduce Obesity in U.S. by 20 Percent:** According to a new study, a ban on fast food advertisements in the United States could reduce the number of overweight children by as much as 18 percent. Should the U.S. pursue this path, they would be following Sweden, Norway and Finland, which are thus far the only countries to have banned commercial sponsorship of children's programs. Research indicates that there is an 80 percent chance an overweight adolescent will be an obese adult. Over 300,000 deaths can be attributed to obesity and weight in the United States every year. [Science Daily November 19, 2008](#)

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#### Item 3

### **Diabetes Drugs 'Double Bone Risk'**

*Long-term use of a class of drugs for type 2 diabetes doubles a woman's risk of breaking a bone, research suggests.*

<http://www.diabetesincontrol.com/results.php?storyarticle=6329>

Thiazolidinediones, including rosiglitazone and pioglitazone, had already been linked to a raised risk of fractures, as well as heart problems. UK and US researchers have quantified the risk, and showed that using the drugs for more than a year thins the bones significantly. It found no increased fracture risk among men.

Two million prescriptions were written for rosiglitazone and pioglitazone in the UK alone last year. The European Medicines Agency carried out a safety review of rosiglitazone and pioglitazone last year, and concluded their benefits outweighed their risks.

But the researchers argued the drugs had relatively modest therapeutic effects, and the regulators should think again.

Lead researcher Dr Yoon Loke, of the University of East Anglia, said: "Women with type 2 diabetes are already at an increased risk of fractures - with a near doubling in the risk of hip fractures - so any additional risk from thiazolidinedione therapy could have a considerable impact on public health."

Dr Loke said the underlying cause of the effect of thiazolidinediones was unclear, and required further research. One suggestion is that the drugs may cause fractures by replacing bone marrow with fat cells. However, he stressed women should not stop taking the drugs without first taking medical advice.

The latest study, also conducted by researchers at Wake Forest University in North Carolina, examined data from 10 previous trials, involving a total of 13,715 patients. It found that year-long thiazolidinedione use among elderly, postmenopausal women with type 2 diabetes resulted in one extra fracture per 21 women. Among younger women, aged around 56, the figure was one extra fracture per 55 women.

There is no clear evidence that other drugs used to treat type 2 diabetes, such as metformin and sulfonylurea, cause an increased risk of fractures.

Recent research into thiazolidinediones has focused on the drugs' adverse effects on the heart and cardiovascular system. One study found that they doubled the risk of congestive heart failure, while another found rosiglitazone was associated both with increased heart attacks and a doubling of heart failure.

Dr Victoria King, of the charity Diabetes UK, said: "We really do need further evidence through properly controlled trials before we can conclusively link thiazolidinediones to increased risk of various bone conditions in humans and determine which groups of people may be at greater risk."

In a statement, the Medicines and Healthcare products Regulatory Authority (MHRA) said fears that thiazolidinediones raised the risk of fractures in women had been raised before, and healthcare professionals notified.

The information leaflet providing with the drug to patients already contains a warning about fracture risk. GlaxoSmithKline, which markets rosiglitazone as Avandia, said the safety and effectiveness of the drug was backed by one of the largest clinical trial programs ever undertaken for any medicine, with 52,000 patients studied.

New findings out of Wake Forest University School of Medicine and the University of East Anglia show that long-term use of a popular class of oral diabetic drugs doubles the risk of fractures in women with type 2 diabetes.

"We knew going into this study that there was an association between thiazolidinediones and fracture risk, however the magnitude of risk had not been evaluated," said Sonal Singh, M.D., M.P.H., an assistant professor of internal medicine and a co-researcher for the study. "This study shows that these agents double the risk of fractures in women with type 2 diabetes, who are already at higher risk before taking the therapy."

In absolute terms, Singh said, if thiazolidinediones (TZDs) are used by elderly, postmenopausal women (around 70 years) with type 2 diabetes for one year, one additional fracture would occur among every 21 women. Among younger women (around 56 years), use of the drugs for one year or longer would result in one additional fracture for every 55 women.

For the study, researchers reviewed 10 previously completed trials that lasted at least one year. All of the studies included participants with impaired glucose tolerance and type 2 diabetes, and all compared the risk of fracture among patients with type 2 diabetes who were taking TZD therapy and patients not taking the therapy. Nearly 14,000 participants were included in the studies. Data was broken down by gender in five of the studies.

Overall, the results showed that use of TZDs significantly increased the risk of fractures among patients with type 2 diabetes and was associated with changes in bone mineral density at the lumbar spine and the hip.

Data from the studies that reported sex-specific results showed that TZDs significantly increased the risk of fractures among women. They were not, however, associated with the same increase of fracture risk in men. The studies also showed a consistent decline in bone mineral density in women exposed to TZD therapy.

"Women with type 2 diabetes are at an increased risk of nonvertebral fractures, with a near doubling in the risk of hip fractures," the researchers wrote in their findings. "Any additional risk from thiazolidinedione therapy could have considerable impact."

In 2006, there were nearly 4 million patients in the United States taking TZDs, half of whom were likely women, Singh said.

While the underlying cause for the sex-specific effect of TZDs needs further investigation, researchers suggest that the drugs may cause fractures by replacing bone marrow with fat cells.

*The findings appear online on the Web site for the Canadian Medical Association Journal and will appear in the January 6 issue.*

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Item 4

**Effect of Cranberry Extracts On Lipid Profiles Of Type 2 Patients**

*Cranberry supplements are effective in reducing atherosclerotic cholesterol profiles.*

<http://www.diabetesincontrol.com/results.php?storyarticle=6328>

To examine the effect of cranberry ingestion on lipid profiles in Type 2 diabetic patients taking oral glucose-lowering drugs, thirty type 2 diabetic subjects (16 males and 14 females; mean age 65 +/- 1 years) who were taking oral glucose-lowering medication regularly were enrolled in this randomized, placebo-controlled, double-blind study.

Changes in lipid profiles, oxidized low-density lipoprotein (ox-LDL), glycemic control, components of the metabolic syndrome, C-reactive protein (CRP) and urinary albumin excretion (UAE) were assessed after cranberry or placebo treatment for 12 weeks.

The results showed that low-density lipoprotein (LDL) cholesterol decreased significantly in the cranberry group (from 3.3 +/- 0.2 to 2.9 +/- 0.2 mmol/l, P = 0.005) and the decrease was significantly greater than that in the placebo group (-0.4 +/- 0.1 vs. 0.2 +/- 0.1 mmol/l, P < 0.001). Total cholesterol and total : high-density lipoprotein (HDL) cholesterol ratio also decreased significantly (P = 0.020 and 0.044, respectively) in the cranberry group and the reductions were significantly different from those in the placebo group (P < 0.001 and P = 0.032, respectively). However, ox-LDL levels did not change significantly in response to cranberry consumption. Neither fasting glucose nor glycated hemoglobin improved in either group. Changes in components of the metabolic syndrome, UAE and CRP were not significantly different between groups.

From the results it was concluded that, Cranberry supplements are effective in reducing atherosclerotic cholesterol profiles, including LDL cholesterol and total cholesterol levels, as well as total : HDL cholesterol ratio, and have a neutral effect on glycemic control in Type 2 diabetic subjects taking oral glucose-lowering agents.

[Diabet Med.](#) 2008 Dec;25(12):1473-7

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**FACT:**

**High heart rates linked to obesity, diabetes: study:** High resting heart rates may be linked to the development of obesity and diabetes, a Japanese study shows. In an article, researchers in Japan said people with resting heart rates of over 80 beats per minute had higher odds of developing insulin resistance, diabetes and cardiovascular problems. The project was one of the first studies to assess the impact of higher heart rates on the body's metabolism. It involved 614 participants who were followed over a period of 20 years. The researchers believe that excessive nerve activities may lead to obesity because they lower the amount of fat burn in the body. *American Journal of Hypertension, 2008.*

**See This Week's Item #10**

<http://www.diabetesincontrol.com/results.php?storyarticle=6322>

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## **Body Clock Linked to Diabetes And High Blood Sugar**

*Diabetes and high levels of blood sugar may be linked to abnormalities in a person's body clock and sleep patterns, according to a genome-wide association study*

<http://www.diabetesincontrol.com/results.php?storyarticle=6327>

The research suggests that diabetes and higher than normal blood sugar levels could partly be tackled by treating sleep problems, say the researchers, from Imperial College London, the French National Research Institute CNRS, Lille University, McGill University in Canada, Steno Diabetes Centre in Denmark and other international institutions.

People with high blood sugar levels and diabetes have a greatly increased risk of developing a range of conditions, including cardiovascular diseases.

The new study shows that a mutation called rs1387153, near a gene called MTNR1B, is associated with having an increased average blood sugar level and around a 20 percent elevated risk of developing type 2 diabetes.

MTNR1B forms part of a signalling pathway that controls the action of the hormone melatonin. This hormone regulates the body's circadian rhythm - the internal clock that controls sleeping and eating patterns – by responding to daylight and darkness.

The discovery of the rs1387153 mutation provides evidence that high blood sugar and diabetes could be directly linked to an impaired circadian rhythm.

Professor Philippe Froguel, the corresponding author of the research from the Department of Genomic Medicine at Imperial College London, said: "There is already some research to suggest there are links between sleep problems and conditions such as obesity and depression, both of which are associated with diabetes. For example, we know that obese children tend to sleep badly and that people become more obese if they are not having enough sleep. Our new study demonstrates that abnormalities in the circadian rhythm may partly be causing diabetes and high blood sugar levels. We hope it will ultimately provide new options for treating people."

In healthy people, blood sugar levels are kept under control by insulin, which the pancreas releases in varying amounts at different periods during a 24-hour natural cycle. The researchers suggest that when there is a genetic abnormality that affects melatonin levels and sleep patterns, this may also disturb the levels of insulin in the blood, preventing the body from maintaining control of blood sugar levels.

Insulin is normally secreted in peaks during the daytime, in order to allow blood sugar from meals to be processed properly, and at lower levels at night. In contrast, melatonin levels are low during the daytime and high at night.

The new study is part of a series of discoveries about the genetics of diabetes made by Professor Froguel and his colleagues. In May 2008 they identified a genetic mutation that can raise the amount of sugar in a person's blood to harmful levels and in February 2007 they identified the key genes associated with a risk of developing type-2 diabetes in the first study to map the genes of any disease in such detail.

The new study shows that identifying which people have high numbers of genetic mutations can reveal who is at most risk of developing high blood sugar levels. On average, the more genetic mutations associated with high blood sugar levels people had, the higher their blood sugar level.

For example, people with five genetic mutations had an average fasting blood sugar level of 98mg/dL., whereas people with one mutation had an average level of 92mg/dL.

Forty three percent of those carrying six or more mutations had levels of fasting blood glucose of 101mg/dL. (5.6 mmol/l) or more. This level is defined as being 'impaired' by the American Diabetes Association, meaning that such people have a very high risk of developing diabetes in the future.

Professor Froguel added: "We have been developing quite a clear picture of the key genes involved with high blood sugar and diabetes and this allows us to better understand them and suggest new avenues for treatment. We are also nearing the stage when we can develop tests that can identify the people at most risk of developing high blood sugar and diabetes later in their lives, so we can intervene to improve their health before they reach that point."

For the new study, the team analyzed the genetic makeup of 2,151 non-diabetic French people (comprising 715 lean adults, 614 lean children, 247 obese adults and 575 obese children) and identified the rs1387153 mutation as being associated with high blood sugar levels. They confirmed their findings by looking at the genetic makeup of more than 16,000 non-diabetic people from different groups in France, Denmark and Finland.

The team then determined that the presence of the rs1387153 increased the risk of type 2 diabetes by comparing the genetic makeup of 6,332 French and Danish diabetic subjects with that of a group of 9,132 French and Danish people with normal blood sugar levels. The researchers found the same links between rs1387153 and a risk of diabetes in all the European populations they studied.

*Journal nature Genetics, Dec. 7<sup>th</sup>, 2008*

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Item 6

### **Sitagliptin Reduces Blood Glucose In Elderly Type 2's**

*Elderly patients assigned to once-daily sitagliptin experienced significant reductions in blood glucose without the risk for hypoglycemia in a new study.*

<http://www.diabetesincontrol.com/results.php?storyarticle=6326>

The 24-week randomized, double-blind, placebo-controlled trial enrolled 206 patients aged 65 years to 95 years with baseline HbA1c levels of 7% to 10%. Researchers randomly assigned 102 patients to once-daily sitagliptin (Januvia, Merck) 100 mg (50 mg if estimated creatinine clearance was 30-50 mL per minute) and 104 patients to placebo.

"The elderly population presents challenges for the treatment of type 2 diabetes, as various factors can affect the ability to lower these patients' blood sugar to target levels," Nir Barzilai, MD, director of the Institute for Aging Research at Albert Einstein College of Medicine, said in a press release.

At 24 weeks, patients assigned to sitagliptin experienced a mean placebo-adjusted HbA1c reduction of 0.7% from baseline (-0.5% for sitagliptin vs. 0.2% for placebo;  $P < .001$ ). More than twice as many sitagliptin-treated patients achieved an HbA1c  $< 7\%$  compared with placebo-treated patients (35% vs. 15%;  $P < .05$ ).

Responses were similar among patients aged 75 years and older ( $n=30$ ) and patients younger than 75 years ( $n=71$ ) treated with sitagliptin. The mean reduction in HbA1c was 0.7% ( $P = .988$ ).

Sitagliptin was also associated with reductions in fasting plasma glucose (27 mg/dL) and two-hour postprandial glucose (61 mg/dL) from baseline to week 24 ( $P < .001$ ). Mean weight loss from baseline was 1.1 kg with sitagliptin ( $P = .079$ ) and 1.7 kg with placebo ( $P = .010$ ).

According to the researchers, sitagliptin monotherapy was efficacious and generally well-tolerated in elderly patients. The incidence of overall adverse events was 46% in the sitagliptin group compared with 53% in the placebo group and serious adverse events were observed in 7% of sitagliptin-treated patients compared with 13% of placebo-treated patients. Adverse events leading to discontinuation were low (sitagliptin, 5%; placebo, 3%). No hypoglycemia was reported in either group.

A subgroup analysis revealed that the greatest reductions were seen in patients with baseline HbA1c =9% (1.6% reduction) followed by HbA1c of 8% (0.9%) and HbA1c <8% (0.5%).

"Together, these data suggest that sitagliptin is safe in the elderly and associated with fewer adverse events," stated, Barzilai.

"Also, this study evaluated once-daily sitagliptin, and having to take just one antidiabetes drug in the morning is a major advantage for the elderly," he said.

*Barzilai N. LB-77. Presented at: Gerontological Society of America 61st Annual Meeting; Nov. 21-25, 2008; National Harbor, Md.*

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Item 7

### **Fructose Metabolism - What You Don't Know!**

*A new University of Illinois study suggests that we may pay a price for ingesting too much fructose. According to lead author Manabu Nakamura, dietary fructose affects a wide range of genes in the liver that had not previously been identified.*

<http://www.diabetesincontrol.com/results.php?storyarticle=6325>

Chances are you consume quite a bit of fructose. Most Americans do—in refined sugars such as sucrose or table sugar (which is half fructose) and in high-fructose corn syrup, used in products as diverse as soft drinks, protein bars, and fruit juice.

But many scientists believe that high dietary fructose contributes to the development of metabolic syndrome, a group of risk factors that predict heart disease and Type 2 diabetes.

"For this reason, it's important for scientists to understand exactly how consuming high amounts of fructose affects human health," said Nakamura, a U of I associate professor of food science and human nutrition.

Nakamura's lab is continuing to study the metabolism of fructose with an eye to making recommendations about its dietary use.

His study shows that the metabolism of fructose is more complex than the data had indicated. "Our gene-expression analysis showed that both insulin-responsive and insulin-repressive genes are induced during this process. Our bodies can do this, but it's complicated, and we may pay a price for it," he said.

According to the scientist, most carbohydrates are handled fairly simply by our bodies. They are converted quickly to glucose and used for energy or stored as fat. "When we are eating, blood sugar--and insulin production--goes up. When we sleep or fast, it goes down," he said.

The process is not so simple with fructose, he noted. "In order for fructose to be metabolized, the body has to create both fasted and fed conditions. The liver is really busy when you eat a lot of fructose."

Because, unlike glucose, fructose metabolism occurs mainly in the liver, Nakamura wanted to gain a complete picture of gene expression in the liver during fructose metabolism.

In Nakamura's study, 24 rats were fed either a 63 percent glucose or fructose diet four hours a day for two weeks; at the end of this period, half the animals fasted for 24 hours before the scientists performed a gene expression analysis; the other half were examined at the end of a four-hour feeding.

Fructose feeding not only induced a broader range of genes than had previously been identified, there were simultaneous increases in glycogen (stored glucose) and triglycerides in the liver.

"To our surprise, a key regulatory enzyme involved in the breakdown of glucose was about two times higher in the fructose-fed group than in the glucose-fed group," Nakamura said.

The study also suggests that a protein called carbohydrate response element binding protein is responsible for the fructose effect on certain genes that trigger the production of fat, he said.

"We're continuing to assess the risk of fructose insulin resistance and the consequent risk for development of diabetes," he said.

*Biochimica et Biophysica Acta*, are Hyun-Young Koo, Matthew A. Wallig, Takayuki Y. Nara, and B. H. Simon Cho of the University of Illinois and Byung Hong Chung of the University of Alabama at Birmingham.

University of Illinois at Urbana-Champaign (2008, December 11). Fructose Metabolism More Complicated Than Was Thought. *ScienceDaily*.

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Item 8

### **New Genes Present Drug Targets For Managing Cholesterol And Glucose Levels**

*Scientists have identified 12 new genes that link gallstones and blood cholesterol levels, others link melatonin and sleep patterns to small increases in glucose levels and larger jumps in the risk of diabetes.*

<http://www.diabetesincontrol.com/results.php?storyarticle=6324>

While these associations are surprising, all the genes are potential new drug targets and some of them could help explain conditions that have been a mystery. *Nature Genetics* will publish two papers explaining the findings online Dec 7, in advance of the January print edition.

The 12 new genes relate to cholesterol and glucose levels, but several point to somewhat surprising links between these traits and other conditions, said Goncalo Abecasis, associate professor of biostatistics at the University of Michigan School of Public Health who co-directed the cholesterol study.

Cholesterol is a strong predictor of heart disease and in a previous study, Abecasis, Boehnke, Willer and colleagues had shown that genetic variants that raise LDL cholesterol (low density lipoprotein or so-called bad cholesterol) levels also increase the risk of heart disease. The current study describes the most detailed assessment of the genetics of cholesterol to date, examining genetic variants and cholesterol levels in more than 40,000 individuals.

"An important finding is that several of these genes have multiple different changes that can affect cholesterol," Willer said. For example, in the PCSK9 gene there are common variants that affect about 40 percent of the population and increase LDL by about 3-6 milligrams per deciliter, a fairly small amount.

Another variant affects roughly 2 percent of individuals but increases LDL by about 15-30 milligrams per deciliter. Finally, there are extremely rare changes in the same gene that affect fewer than 1 in 1000 people but can increase LDL by well over 100 milligrams per deciliter.

"We think looking at this list of genes in individuals with extremely high cholesterol may clarify a lot of those unexplained cases," Abecasis said. In the cholesterol study, U-M scientists and collaborators at more than 10 institutions in the U.S. and Europe located 30 genetic variants associated with cholesterol levels, including 11 new ones. Notably, several of the newly implicated genetic variants were also related to the risk of gallstones and certain rare forms of diabetes.

"Each of these genes is a potentially interesting drug target," said Abecasis. Statins, a class of cholesterol lowering drugs used to reduce the risk of heart disease, target the HMGCR gene, one of the genes identified in the study. The other genes identified in the study could lead to entirely new and more effective therapies to manage cholesterol levels and reduce the risk of heart disease. In addition, the genetic changes they identify can also help predict whether each individual will develop high LDL or low HDL.

In the paper studying glucose levels, Abecasis and Boehnke collaborated with researchers across the globe to discover genetic changes strongly associated with a small increase in glucose levels in non-diabetic individuals. They also found the same changes increased the risk of developing diabetes by up to 20 percent.

"Observing an increased risk for diabetes was surprising because the changes in glucose levels were well within the normal range," said Boehnke, who has studied the genetics of diabetes for more than 15 years.

The gene, called the melatonin receptor, helps regulate the circadian clock, among other things. The finding strengthens the association between disrupted sleep patterns and diabetes, Boehnke said.

In the glucose study, scientists looked at the genomes of 36,000 individuals.

Source: University of Michigan

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### **DID YOU KNOW:**

**Diabetes drugs double women's fracture risk:** Long-term use of a popular class of oral diabetes drugs doubles the risk of bone fractures in women with type 2 diabetes, a study reports. [See This](#)

[Weeks' Item #3](#)

<http://www.diabetesincontrol.com/results.php?storyarticle=6329>

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Item 9

### **Thiamine Reverses Early Diabetic Kidney Disease in 35% of Type 2 Patients**

*Researchers have discovered high doses of thiamine - vitamin B1 - can reverse the onset of early diabetic kidney disease.*

<http://www.diabetesincontrol.com/results.php?storyarticle=6323>

Kidney disease, or diabetic nephropathy, develops progressively in patients with type 2 diabetes. Early development of kidney disease is assessed by a high excretion rate of the protein albumin from the body in the urine, known as microalbuminuria.

The research team led by Dr Naila Rabbani and Professor Paul J Thornalley at Warwick Medical School, has discovered taking high oral doses of thiamine can dramatically decrease the excretion of albumin and reverse early stage kidney disease in type 2 diabetes patients.

In a paper published online, the team show 300 mg of thiamine taken orally each day for three months reduced the rate of albumin excretion in type 2 diabetes patients. The albumin excretion rate was decreased by 41% from the value at the start of the study. The results also showed 35% of patients with microalbuminuria saw a return to normal urinary albumin excretion after being treated with thiamine.

Forty patients with type 2 diabetes aged between 35 and 65 years old took part in the trial. They were randomly assigned a placebo or 3 x 100mg tablets of thiamine a day for three months.

The Warwick research group has already conclusively proven that type 2 diabetes patients have a thiamine deficiency. In an earlier study led by Professor Paul Thornalley at Warwick Medical School, the research team showed that thiamine deficiency could be key to a range of vascular problems for diabetes patients.

Dr Rabbani said: "This study once again highlights the importance of Vitamin B1 and we need to increase awareness. Professor Thornalley and I are planning a foundation at the University of Warwick to further education and research in thiamine deficiency."

online in the journal *Diabetologia* Dec. 8, 2008

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Item 10

### **Fast Heart Rate Warns of Obesity, Diabetes**

*A too-fast heartbeat in early adulthood is a warning sign for increased risk of cardiovascular problems decades later on, a Japanese study suggests.*

<http://www.diabetesincontrol.com/results.php?storyarticle=6322>

The study of 614 residents of a rural farming community in southwestern Japan found that a heart rate greater than 80 beats a minute during a first examination in 1979 predicted the development of obesity and diabetes, which contribute to heart problems.

A fast heart rate is a signal from the sympathetic nervous system, a part of the autonomic nervous system, which is the body's automatic pilot that governs instinctive responses, explained Mercedes Carnethon, assistant professor of preventive medicine at Northwestern University's Feinberg School of Medicine. She found the same rapid heartbeat association in a group of Americans she studied.

"If someone has a consistently fast heart rate, it is because of increased input from the sympathetic part of the nervous system because the body is preparing to respond to stress," Carnethon said. "There is an increase in levels of blood glucose -- essentially because the body is storing energy to prepare for fight or flight, so that predisposes to diabetes."

Carnethon's study followed Chicago residents even longer than the Japanese researchers. "Over a 33-year follow-up, we showed that people with a higher heart rate were more likely to have Medicare claims for diabetes-related conditions," she said.

There's a possible clinical use for the findings, Carnethon said, since doctors routinely listen to the heart rate.

"It is a very simple measure, regularly taken in clinical practice, that could be potentially useful because it suggests where there might be a higher incidence of heart risk and mortality," she said. "It is a first stage to alert the clinician that there might be something worth investigating."

The similar findings in the two studies half a world apart are noteworthy, Carnethon said. "We are always happy to see findings replicated by different investigators in different settings," she said.

Meanwhile, researchers are reporting a different built-in mechanism that protects a lucky few individuals from heart disease -- a genetic mutation that seems to reduce blood levels of the fats called triglycerides.

The mutation was found in members of the Old Order Amish community in Pennsylvania, said the lead investigator, Toni I. Pollin, an assistant professor of medicine at the University of Maryland School of Medicine.

Pollin and her colleagues looked through the complete genetic complement of more than 800 members of the Amish community. "We looked at genes involved in the response to dietary fat," she said. "One region came up strong on chromosome 11. This genetic marker was not too far from a cluster of genes involved in lipid metabolism."

The researchers closed in on one gene, designated APOC-3, according to a report in the Dec. 12 issue of the journal *Science*. That gene makes a protein that inhibits the breakdown of triglycerides. About 5 percent of the Amish in the study had a mutated form of the gene that limited production of the protein, and so they had low blood lipid levels.

"It is an apparent cardioprotective mechanism," Pollin said. "It raises the hope that by decreasing production of APOC-3 it could potentially be therapeutic."

It's possible that a drug designed to target the gene could be used to reduce levels of blood fats and thus reduce coronary risk, Pollin said.

The mutation has not been found outside the Amish community, Pollin said. "We have looked at 200 healthy individuals and have not found it, she said.

*The findings, from Kurume University School of Medicine, were published online Dec. 11 in the American Journal of Hypertension.*

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Item 11

**Weight Loss Drug Qnexa Reduces Hemoglobin A1c By 1.6% & Wt By 9%**

*Significant weight loss achieved and maintained by diabetic subjects.*

<http://www.diabetesincontrol.com/results.php?storyarticle=6321>

Drug developer Vivus Inc last Thursday, announced prelim results for the first of three late-stage trials and found that obese patients treated with the highest dose of its experimental drug Qnexa on average lost 9.2 percent of their weight. Qnexa is a combination of phentermine -- half of the recalled fen-phen diet pill -- and the epilepsy drug Topamax, or topiramate.

Qnexa(TM), an investigational drug, for the glycemic management of obese type 2 diabetics. The DM-230 study met its primary endpoint of demonstrating glycemic control as measured by a reduction of hemoglobin A1c of 1.6% from 8.8% to 7.2% for subjects treated with Qnexa, as compared to 1.1% from 8.5% to 7.4% in the placebo group at 56 weeks. Subjects in the study were actively managed according to ADA standards of care with respect to diabetes medications and lifestyle. For subjects treated with placebo, significant increases in the number and doses of concurrent anti-diabetic medications were required to bring about the observed reduction in HbA1c. By contrast, concurrent anti-diabetic medications were actually reduced over the course of the trial in subjects treated with Qnexa.

The DM-230 study was designed as a continuation study to the OB-202 diabetes study. The OB-202 study was a 28-week, randomized, double-blind, placebo-controlled, efficacy and safety study of Qnexa in the glycemic management of 206 obese type 2 diabetics. The DM-230 study enrolled 130 subjects at 10 study sites completing OB-202 to continue, in a blinded fashion as previously randomized for an additional 28 weeks. The results of the DM-230 study include assessments from the start of the OB-202 study through the end of the DM-230 study in this population, for a total treatment period of 56 weeks.

Fasting plasma glucose levels were reduced in subjects treated with Qnexa from 176 mg/dL to 133 mg/dL, as compared to a decrease from 171 mg/dL to 145 mg/dL for the placebo group (p=0.02). Over 56 weeks subjects treated with Qnexa also lost 9.4% of their baseline body weight, or 20.5 pounds, as compared to 2.7%, or 6.1 pounds, for the placebo group (p<0.0001). Subjects treated with Qnexa had reductions in blood pressure, triglycerides and waist circumference. Both treatment groups had a study completion rate greater than 90%.

"The results from DM-230 confirm our belief that Qnexa may be an appropriate treatment for type 2 diabetes given the reduction in HbA1c of 1.6% combined with weight loss of 9.4% seen in the most recent study," commented Leland Wilson, president and chief executive officer of VIVUS. "Historically, diabetic patients have a difficult time losing weight. With Qnexa, patients were able to lose over 20 pounds and importantly keep it off throughout the 56 week study with no rebound."

"The improved glycemic control demonstrated by the Qnexa treatment group in OB-202 continued as expected for an additional 28 weeks. More importantly, Qnexa's safety profile was favorable as demonstrated by high completion rates," commented a principal investigator of the study, Dr. W. Timothy Garvey, Professor of Medicine and Chair of the Department of Nutrition Sciences at the University of Alabama at Birmingham. "I am particularly impressed by the fact that treatment with Qnexa has the greatest effect in those patients that are most in need of treatment. Patients with baseline HbA1c greater than 8% had an overall reduction in HbA1c of 2.1% in 56 weeks, combined with the level of weight loss that is unheard of with current oral treatments. This phase 2 study is encouraging and indicates that Qnexa has the potential to greatly add to our armament of drugs for the treatment of type 2 diabetes."

The most common drug-related adverse events reported over the year for the treatment and placebo groups, respectively, were paresthesia (19%, 0%), constipation (13%, 4%) and nausea (12%, 6%). These adverse events decreased in frequency during the last six months as compared to the first six months to: paresthesia 5%, constipation 5% and nausea 1% in the treatment group. Subjects were monitored for depression and suicidality using the PHQ-9 questionnaire, the FDA's preferred mental health assessment tool. Subjects treated with Qnexa demonstrated greater improvements in PHQ-9 scores from baseline to the end of the study than the placebo group, providing further assurance that Qnexa treatment does not produce significant adverse mood changes or suicidality.

Despite a mean baseline HbA1c level of 8.7%, 53% of the subjects treated with Qnexa were able to achieve the ADA recommended goal of 7.0% or lower, versus 40% of the subjects in the placebo arm (p<0.05). The incidence of hypoglycemia in the treatment and placebo arms were similar (12% and 9%, respectively). Qnexa was well-tolerated, with no treatment-related serious adverse events.

*Release: VIVUS R&D Day December 12, 2008*

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## **DID YOU KNOW:**

### **Thiamine Reverses Early Diabetic Kidney Disease in 35% of Type 2 Patients:**

Researchers have discovered high doses of thiamine - vitamin B1 - can reverse the onset of early diabetic kidney disease. The researchers showed that 300 mg of thiamine taken orally each day for three months reduced the rate of albumin excretion in type 2 diabetes patients. The albumin excretion rate was decreased by 41% from the value at the start of the study. The results also showed 35% of patients with microalbuminuria saw a return to normal urinary albumin excretion after being treated with thiamine.

[See This Weeks' Item #9](#)

<http://www.diabetesincontrol.com/results.php?storyarticle=6323>

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Item 12

### **Low-Glycemic Diet Better Than High-Fiber Diet for Type 2's**

Persons with type 2 diabetes who had a diet high in low-glycemic foods such as nuts, beans and lentils had greater improvement in glycemic control and risk factors for coronary heart disease than persons on a diet with an emphasis on high-cereal fiber.

<http://www.diabetesincontrol.com/results.php?storyarticle=6320>

One dietary strategy aimed at improving both diabetes control and cardiovascular risk factors is the use of low-glycemic index diets, but there is disagreement over their effectiveness, according to background information in the article.

David J. A. Jenkins, M.D., of St. Michael's Hospital and the University of Toronto, and colleagues assessed the effects of a low-glycemic index diet vs. a high-cereal fiber diet on glycemic control and cardiovascular risk factors for 210 patients with type 2 diabetes. The participants, who were treated with antihyperglycemic medications, were randomly assigned to receive 1 of the 2 diet treatments for 6 months.

In the low-glycemic index diet, the following foods were emphasized: beans, peas, lentils, nuts, pasta, rice boiled briefly and low-glycemic index breads (including pumpernickel, rye pita, and quinoa and flaxseed) and breakfast cereals (including large flake oatmeal and oat bran). In the high-cereal fiber diet, participants were advised to take the "brown" option (whole grain breads; whole grain breakfast cereals; brown rice; potatoes with skins; and whole wheat bread, crackers, and breakfast cereals). Three servings of fruit and five servings of vegetables were encouraged on both treatments.

The researchers found that hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>; a substance of red blood cells tested to measure the blood glucose level) decreased by -0.50 percent absolute HbA<sub>1c</sub> units in the low-glycemic index diet compared with -0.18 percent absolute HbA<sub>1c</sub> units in the high-cereal fiber diet. Significant treatment effects were observed for high-density lipoprotein cholesterol (HDL-C) and the low-density lipoprotein cholesterol (LDL-C):HDL-C ratio. HDL-C increased in the low-glycemic index diet group by 1.7 mg/dL and decreased by -0.2 mg/dL in the high-cereal fiber diet group. The LDL-C:HDL-C ratio showed a greater reduction in the low-glycemic index diet group compared with the high-cereal fiber diet group.

"Lowering the glycemic index of the diet improved glycemic control and risk factors for coronary heart disease (CHD). These data have important implications for the treatment of diabetes where the goal has been tight glycemic control to avoid complications. The reduction in HbA<sub>1c</sub> was modest, but we think it has clinical relevance," the authors write. "Low-glycemic index diets may be useful as part of the strategy to improve glycemic control in patients with type 2 diabetes taking antihyperglycemic medications."

"Pharmacological interventions to improve glycemic control in type 2 diabetes have often failed to show a significant reduction in cardiovascular events. In view of the 2- to 4-fold increase in CHD risk in participants with type 2 diabetes, the ability of a low-glycemic index diet to address both glycemic control and CHD risk factors increases the clinical relevance of this approach for patients with type 2 diabetes, such as those in this study, who are overweight and also taking statins for CHD risk reduction."

*JAMA. 2008;300[23]:2742-2753. Dec. 17, 2008*

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Item 13

### **Low-Dose Terbutaline Can Prevent Nocturnal Hypoglycemia in Type 1's**

*A 2.5-mg dose of terbutaline at bedtime appears to prevent hypoglycemia during the night in patients with aggressively treated type 1 diabetes, without causing hyperglycemia the following morning, results of a pilot study indicate.*

<http://www.diabetesincontrol.com/results.php?storyarticle=6319>

Dr. Philip E. Cryer and colleagues at Washington University School of Medicine in St. Louis previously reported that a 5-mg dose of the beta-2-adrenergic agonist prevented nocturnal hypoglycemia, but blood glucose levels were high the next morning.

For their current randomized, double-blind, crossover trial, 15 patients (mean age 29 years; mean HgA1c 7.1%) were given one of two doses of terbutaline (2.5 or 5.0 mg) or placebo on three separate evenings at 10:00 p.m.

Results published in the December issue of Diabetes Care showed that mean nadir nocturnal plasma glucose concentrations were 87, 100, and 122 mg/dL following placebo, 2.5 mg terbutaline, and 5 mg terbutaline treatment, respectively. Corresponding levels at 7:00 the next morning were 113, 127, and 183 mg/dL.

Five patients had nadir levels < 50 mg/dL after taking placebo, and two had levels that low after taking low-dose terbutaline. None of those taking the higher dose had nadir levels < 60 mg/dL.

Even though the trial was too small to show statistically significant differences between placebo and low-dose terbutaline, the authors note, "the key efficacy end points... were intermediate between those taking placebo at bedtime and those taking 5.0 mg terbutaline at bedtime."

Dr. Cryer's team concludes that "terbutaline may be shown to be effective and safe in the prevention of nocturnal hypoglycemia in type 1 diabetes in a suitably powered randomized controlled trial."

*Diabetes Care 2008;31:2271-2272.*

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**FACT:**

**Body Clock Linked to Diabetes And High Blood Sugar:** Diabetes and high levels of blood sugar may be linked to abnormalities in a person's body clock and sleep patterns, according to a genome-wide association study. The research suggests that diabetes and higher than normal blood sugar levels could partly be tackled by treating sleep problems, say the researchers.

[See This Weeks' Item #5](#)

<http://www.diabetesincontrol.com/results.php?storyarticle=6327>

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Item 14

**SGLT2 Inhibitors a Promising New Therapy for Type II Diabetes**

*A new drug class is poised to make a splash in the diabetes market, according to a new report, "Diabetes Market Forecast to 2013"*

<http://www.diabetesincontrol.com/results.php?storyarticle=6318>

SGLT2 Inhibitors, which block the reabsorption of glucose in the kidneys, have had positive clinical results and have attracted the attention of top pharmaceutical companies. While no SGLT2 inhibitor is currently FDA-approved, this class is expected to generate more than \$500 million in revenue by 2011.

The race for first-in-class status is currently being led by dapagliflozin, which is in multiple Phase III trials in combination with other therapies including metformin and glimepiride. This drug, which was discovered by Bristol-Myers Squibb but licensed to AstraZeneca in a deal worth up to \$1.35 billion, is projected to generate more than \$500 million in annual sales by 2014. AVE2268 and remogliflozin, two other SGLT2s, are both in Phase II trials. Analysts have recently pushed expected launch dates to late 2011 or 2012, but these drugs should also yield hundreds of millions of dollars in sales within their first few years on the market.

Despite an anticipated second- or third-in-class launch status, AVE2268 sales are likely to be strong. Sanofi-Aventis will leverage its strong field sales organization and commercialization experience to launch the product if and when it gains FDA approval.

"When three companies of this magnitude are all sponsoring late-stage studies for products in an unapproved drug class, you know the science is quite strong," said Jeremy Spivey, the report's lead

author. "By the end of the next decade, this class may be neck-and-neck with the more established DPP-IV and GLP-1 classes in diabetes treatment."

A complimentary report brochure is available for download at <http://www.cuttingedgeinfo.com/Diabetes/index.htm#body>.

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Item 15

**Benefit of Prior Intensive Diabetes Therapy on Retinopathy Risk Wanes Over Time**

*The persistent difference in retinopathy complications between former intensive and conventional therapy for type 1 diabetes continues for years, but begins to decline within a decade, according to new data from the Epidemiology of Diabetes Interventions and Complications (EDIC) study.*

<http://www.diabetesincontrol.com/results.php?storyarticle=6317>

Dr. David M. Nathan at Massachusetts General Hospital, Boston, and colleagues note in their report in the Archives of Ophthalmology for December that in the original Diabetes Control and Complications Trial (DCCT), "intensive therapy aimed at near-normal glycemia reduced the risk of microvascular complications of type 1 diabetes mellitus compared with conventional therapy."

At the end of the 6.5-year DCCT, mean HbA1c levels were 7.3% in the intensive therapy group and 9.0% in the conventional therapy group. At that point, patients returned to their usual health care providers and most were enrolled in the observational EDIC study.

By the end of the first year following the close of the DCCT, HbA1c values had begun to converge, and after 4 years they were no longer significantly different.

Nonetheless, among the 1211 subjects with complete follow-up, the adjusted odds of retinopathy progression were reduced by 74% at EDIC year 4; however, this fell to 57% at year 10.

The authors observed similar patterns for severe nonproliferative and proliferative diabetic retinopathy, and clinically significant macular edema.

According to the authors' calculations, "the likelihood of further progression of retinopathy in both groups was strongly associated with the mean HbA1c value during the DCCT and EDIC combined, with a stronger effect of the mean HbA1c value during the DCCT."

They stress that the persistence of benefit does not mean that intensive therapy need only be applied for a limited period. "Rather," they conclude, "the results support the implementation of intensive treatment as early in the course of the disease as possible." If aggressive glycemic control is not maintained, however, the advantages are likely to diminish.

*Arch Ophthalmol 2008;126:1707-1715.*

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***Quote of the Week***

*“People who are unable to motivate themselves must be content with mediocrity, no matter how impressive their other talents.”*

.....Andrew Carnegie

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