

# DIABETES IN CONTROL.com Newsletter

The Newsletter for Professionals in Diabetes Care

June 6, 2007 - Issue #367

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## Top Diabetes Stories:

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### Risk Factor Cluster Found in Parents of Diabetics\*

<http://www.diabetesincontrol.com/results.php?storyarticle=4865>

### Diabetic Cardiomyopathy Can Occur Soon After Diabetes Appears\*

<http://www.diabetesincontrol.com/results.php?storyarticle=4864>

### Prescriber's Letter Clarifies Avandia Heart Attack Warning With Algorithm\*

<http://www.diabetesincontrol.com/results.php?storyarticle=4862>

### Study Tests Oral Insulin to Prevent Type 1 Diabetes\*

<http://www.diabetesincontrol.com/results.php?storyarticle=4858>

### Predicting Severe Hypoglycemia\*

<http://www.diabetesincontrol.com/results.php?storyarticle=4857>

### High-Carbohydrate Diets Are Linked to Higher Blood Pressure\*

<http://www.diabetesincontrol.com/results.php?storyarticle=4855>

### Sleep Apnea Associated with Gestational diabetes and High Blood Pressure\*

<http://www.diabetesincontrol.com/results.php?storyarticle=4852>

### Just Ten Minutes of Physical Activity A Day Has a Major Impact\*

<http://www.diabetesincontrol.com/results.php?storyarticle=4851>

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## From the editor's desk

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It seems that every medical journal or newspaper you pick up has an article on the current controversy about Avandia and heart problems. Our own publisher has written articles about it and we have had many features on it. **Richard K. Bernstein, M.D., F.A.C.E., F.A.C.N., C.W.S.** brings us information on a much bigger cardiovascular concern. In his new book there is an overview of *Recent Developments Regarding Risk Factors For Heart Disease* that puts the Avandia controversy in perspective.

<http://www.diabetesincontrol.com/results.php?storyarticle=4866>

**Julio C. Voltarelli, MD, PhD**, from the University of Sao Paulo in Brazil has been working on using stem cells for reversing Type 1 diabetes. Recently his group had success with a small number of patients. To find the results and see what other experts say read *Stem Cell Treatment Study Yields Promising Results For Type 1 Diabetes*

<http://www.diabetesincontrol.com/results.php?storyarticle=4867>

Would you be interested in going on a diabetes cruise? We are planning a 7-9 day Diabetes Education Cruise with Dr. Richard K. Bernstein for next spring or fall. We will provide CME for medical professionals to learn Dr. Bernstein's treatment methods and education for patients with diabetes. If you might be interested, just send us an email with "Diabetes Cruise" in the subject line. Send to [publisher@diabetesincontrol.com](mailto:publisher@diabetesincontrol.com)

### June 10, 7PM ET on CNBC

Gastric bypass surgery – last resort or best hope? Also, a soldier's battle with diabetes in Iraq; and a restaurant where the menu is 100% diabetes-friendly. Tune in for another exciting episode of dLifeTV on: Sundays on CNBC at 7 PM ET, 6 PM CT, and 4 PM PT Check your local listings for details.

## We can make a difference!

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## This week's overview:

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Item #3: Telmisartan Preserves Renal Function in Patients With Hypertension and Diabetes

Item #5: Vitamin A Metabolite Decreases Insulin Sensitivity and Increases Obesity

Item #6: Beta-Cell Regeneration at DRI

- Item #7: How Tummy Surgery Cures Diabetes In A Matter of Days
- Item #10: Pear Cactus Helps to Control Blood Sugars
- Item #12: Postprandial Hyperglycemia Impairs Diurnal Blood Pressure Variation
- Item #13: Aerobic Activity ly Increases HDL Cholesterol Levels

Check out this weeks **“Test Your Knowledge”** question.  
<http://www.diabetesincontrol.com/results.php?storyarticle=4868>

Dave Joffe, *Editor-in-Chief*

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**NEWS FLASH:**

**FDA Approves Continuous 7-Day Glucose Monitoring System and new DM2 software**

The company said it expects to initiate a limited launch of SEVEN near the end of its second quarter and a more robust launch in the third quarter. The software, allows healthcare professionals and patients to download continuous glucose data from their receivers to their computers. DexCom anticipates launching the DM2 Data Manager in conjunction with the SEVEN

**Interim Analysis Shows No Increased Heart Risk With Avandia:** -- June 5, 2007 --

GlaxoSmithKline said today that findings from an interim analysis of RECORD (Rosiglitazone Evaluated for Cardiac Outcomes and Regulation of glycemia in Diabetes), a prospective clinical trial designed specifically to determine cardiovascular outcomes in more than 4,400 patients with type 2 diabetes, adds further evidence to the overall cardiovascular safety profile of Avandia(R)

The study results, authored by Philip D. Home and colleagues on the RECORD Steering Committee, were published Tuesday in the online edition of *The New England Journal of Medicine*.

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**Tools for your Practice:**

**Avandia Patient Handout**

A handout for your patients using Avandia

**Avandia Handout**

<http://www.prescribersletter.com/pl/detaildocuments/230622PatHandout.pdf>

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**New Product:**



**B Clear™ Diabetic Energy Drink** is an all natural diabetic safe effervescent vitamin supplement used for the prevention of fatigue and dehydration. It was specifically developed for diabetics and people who are on sugar and carbohydrate restricted diets. B clear™ Diabetic Energy Drink differs from the current energy drinks on the market because of its unique proprietary effervescent diabetic friendly formula

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**This Week's Items:**

1. Risk Factor Cluster Found in Parents of Diabetics\*  
<http://www.diabetesincontrol.com/results.php?storyarticle=4865>
2. Diabetic Cardiomyopathy Can Occur Soon After Diabetes Appears\*  
<http://www.diabetesincontrol.com/results.php?storyarticle=4864>

3. Telmisartan Preserves Renal Function in Patients With Hypertension and Diabetes  
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6. Beta-Cell Regeneration at DRI  
<http://www.diabetesincontrol.com/results.php?storyarticle=4860>
7. How Tummy Surgery Cures Diabetes In A Matter of Days  
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8. Study Tests Oral Insulin to Prevent Type 1 Diabetes\*  
<http://www.diabetesincontrol.com/results.php?storyarticle=4858>
9. Predicting Severe Hypoglycemia\*  
<http://www.diabetesincontrol.com/results.php?storyarticle=4857>
10. Pear Cactus Helps to Control Blood Sugars  
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11. High-Carbohydrate Diets Are Linked to Higher Blood Pressure\*  
<http://www.diabetesincontrol.com/results.php?storyarticle=4855>
12. Postprandial Hyperglycemia Impairs Diurnal Blood Pressure Variation  
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15. Just Ten Minutes of Physical Activity A Day Has a Major Impact\*  
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## **ITEMS For The Week:**

Item 1

### **Risk Factor Cluster Found in Parents of Diabetics**

*The results of a new study suggest an association between nephropathy in type 1 diabetes and a higher prevalence of parental hypertension, diabetes, and stroke and paternal mortality.* Sleep Apnea Increases  
<http://www.diabetesincontrol.com/results.php?storyarticle=4865>

"Diabetic nephropathy occurs in one third of patients with type 1 diabetes, with an incidence peak after 15 to 20 years of diabetes," Dr. Per-Henrik Groop, of the University of Helsinki, Finland, and colleagues write. "Diabetic nephropathy clusters in families and in specific ethnic groups, indicating a genetic predisposition," they note. "The genetic risk factors are, however, still largely unknown."

The researchers examined the association between a parental history of hypertension, CVD or diabetes, and diabetic nephropathy in 2355 offspring with diabetes type 1, and if clustering of these traits increased the likelihood of diabetic nephropathy. The team also examined whether total or CVD mortality was increased among the 4676 parents of the patients.

The team defined diabetic nephropathy as macroalbuminuria (urinary albumin excretion rate > 200 mcg/min or > 300 mg/24 h) or end-stage renal disease.

Seven hundred eighty diabetic patients had diabetic nephropathy. Compared with patients without diabetic nephropathy, those with nephropathy had a higher prevalence of parental hypertension (55% versus 62%, respectively), stroke (12% and 15%), and type 1 diabetes (2.9% vs. 4.3).

The odds of diabetic nephropathy were 56% higher in offspring with two parents with hypertension compared with no parents with hypertension.

"Parental mortality and paternal mortality were more prevalent in patients with than without diabetic nephropathy," the researchers report. "No difference was observed in maternal mortality or parental, maternal and paternal CVD mortality."

These findings confirm that familial factors influence the development of nephropathy in type 1 diabetics. Specifically, parental clustering of diabetes type 1, hypertension and diabetes is associated with nephropathy in diabetic offspring.

*Diabetes Care* 2007;30:1162-1167.

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Item 2

### **Diabetic Cardiomyopathy Can Occur Soon After Diabetes Appears**

*Dramatic" losses of a key biochemical substance in heart muscle tissue occur in the very earliest stages of diabetes, according to a new study.*

<http://www.diabetesincontrol.com/results.php?storyarticle=4864>

Xianlin Han and colleagues did the study as part of a broader medical effort to understand diabetic cardiomyopathy. Heart abnormalities are the relatively common complication of diabetes and account for much of the increased mortality from heart disease in patients with diabetes.

The researchers used a powerful new technology termed "shotgun lipidomics" to show that hearts of diabetic mice lose large amounts of cardiolipin (CL), fatty materials essential for the heart's production of the energy needed for normal contraction. The changes, which involved a loss of CL followed by changes in the remaining CL, occurred as early as 5 days after rats became diabetic through administration of a compound that impairs insulin-producing cells in the pancreas.

Researchers observed the changes in two models of diabetes commonly used to study the two types of human diabetes. The changes happen before the appearance of toxic fatty materials regarded as a hallmark of diabetic cardiomyopathy and might be used as very sensitive biomarkers for the condition, the report indicates.

*Article: "Alterations in Myocardial Cardiolipin Content and Composition Occur at the Very Earliest Stages of Diabetes: A Shotgun Lipidomics Study" ACS' Biochemistry, May 29, 2007.*

## **DID YOU KNOW:**

**Physical Activity in Postmenopausal Women:** The relationship between physical activity dose and fitness is poorly understood. In an examination of this relationship, Church and colleagues randomly assigned sedentary, overweight or obese postmenopausal women to 1 of 3 exercise groups with an energy expenditure of 50%, 100%, or 150% of the National Institutes of Health Consensus Development Panel recommended physical activity dose or to a no-exercise control group to measure any change in aerobic fitness during the 6-month intervention. The investigators found a graded dose-response improvement in fitness across the 3 levels of exercise training that was similar across subgroups based on age, weight, baseline fitness, and ethnicity/race. *JAMA. 2007;297:2053.*

Item 3

### **Telmisartan Preserves Renal Function in Patients With Hypertension and Diabetes**

*Patients with hypertension and type 2 diabetes, telmisartan and ramipril both may help preserve cardiovascular and renal function by increasing nitric oxide (NO) activity of the renal endothelium, according to the results of a randomized controlled trial.*

<http://www.diabetesincontrol.com/results.php?storyarticle=4863>

"One of the earliest signs of vascular change is endothelial dysfunction, which is also known to provoke albuminuria and to predict cardiovascular prognosis," write Roland E. Schmieder, MD, FACC, from the University of Erlangen-Nürnberg in Germany, and colleagues. "The aim of this study was to analyze the effects of renin-angiotensin system (RAS) blockade on renal endothelial function."

In this multicenter, prospective, double-blind, forced-titration study, 96 patients with type 2 diabetes, hypertension, glomerular filtration rate greater than 80 mL/minute, and normoalbuminuria or microalbuminuria were randomized to once daily treatment with 40/80 mg of telmisartan or 5/10 mg of ramipril for 9 weeks. Nitric oxide activity was estimated using the decline in renal plasma flow (RPF) in response to intravenous N<sup>o</sup>-monomethyl-L-arginine (L-NMMA).

The mean fall in RPF in response to L-NMMA increased with telmisartan from 71.9 ± 9.0 mL/minute before therapy to 105.2 ± 9.7 mL/minute at the end of treatment (*P* < .001). With ramipril, RPF response to L-NMMA increased from 60.1 ± 12.2 to 87.8 ± 9.2 mL/minute (*P* = .018; adjusted difference between treatments, -17.1 ± 13.7 mL/minute; *P* = .214).

Without L-NMMA, telmisartan increased RPF at rest from 652.0 ± 27.0 to 696.1 ± 31.0 mL/minute (*P* = .047). In contrast, ramipril produced no significant changes in RPF. The greater the improvement in basal NO activity, the greater was the vasodilatory effect on renal vasculature (*r* = 0.47; *P* < .001).

"In patients with type 2 diabetes, telmisartan and ramipril both increased NO activity of the renal endothelium significantly, which in turn may support the preservation of cardiovascular and renal function," the authors write.

Boehringer Ingelheim, Bayer AG, and GlaxoSmithKline sponsored this study. The costs of publication of the current study were defrayed in part by the payment of page charges, mandating its being marked "advertisement" solely to indicate this fact.

*Diabetes Care. 2007;30:1351-1356.*

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Item 4

**Prescriber's Letter Clarifies Avandia Heart Attack Warning With Algorithm**

Analysts at Prescriber's Letter say that crunching the study's numbers reveals only part of the story. Since this report is a meta-analysis, it is merely a study of prior study results. <http://www.diabetesincontrol.com/results.php?storyarticle=4862>

Prescribers and diabetes patients alike are wondering what to make of recent media reports of a New England Journal of Medicine study suggesting Avandia (rosiglitazone) increases heart attack risk by 43% in diabetes patients. Critics are jumping to liken these N Engl J Med study results to the early cardiovascular concerns seen with Vioxx that ultimately led to its removal from the market.

In order to draw conclusions that can be applied by health professionals and patients, one has to consider this study along with earlier data and knowledge of a particular patient.

Prescriber's Letter helps prescribers and patients put this new study into perspective. Experts are concluding that, as with many other diabetes medications, Avandia's only definite benefit is lowering blood glucose to help control diabetes. This new study reinforces that Avandia does not provide any long-term cardiovascular benefit in diabetes patients. In fact, it's well known that both available drugs in the "glitazone" class, Avandia and Actos (pioglitazone), cause fluid retention and should be avoided in patients with moderate to severe heart failure.

Prescriber's Letter also addresses another question raised by this study. People want to know if the heart attack risk is a "class-effect" that will be observed with Actos. This study does not answer this question since it did not look at Actos. Another highly debated study suggests that Actos (pioglitazone) may actually reduce heart attacks and strokes. But the jury is still very much out on whether all the drugs in this glitazone class lead to cardiovascular problems.

Even more important for prescribers and patients, though, is how to make treatment decisions based on the

results of the new Avandia study.

Prescriber's Letter experts say to follow the recommendations in its Stepwise Order of Treatments For Type 2 Diabetes. After diet and exercise, most patients should be started on metformin. If a glitazone drug is to be started, preference should be given to Actos over Avandia. But if a patient is already stable and doing well on Avandia the patient should not be switched to Actos at this time, based only on the results of this study.

Prescriber's Letter, an evidence-based subscription resource for prescribers, provides the facts about the quality and results of studies like this one, without any spin or sensationalism. A concise analysis of this study is available at [www.prescribersletter.com/newsroom/avandia](http://www.prescribersletter.com/newsroom/avandia). In the article, the editors tell prescribers what they need to know to translate this study into practice. The editors also attach their Detail-Document that explores the facts that shaped the Letter's recommendations. This added resource also provides the Stepwise Order of Treatment guidelines and a handout to help doctors counsel patients on the risks of Avandia and Actos. The editorial team at Prescriber's Letter has been publishing drug information recommendations since 1985 and carefully researches the most important topics and compiles the evidence into monthly Letters consisting of concise articles each linked to an in-depth Detail-Document.

For a patient handout on What Patients Should Do, see this weeks Tools for Your Practice.

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### Start your own walking program



**New StepTracker Available** at special prices. See the results of the Step Program Study. <http://www.diabetesincontrol.com/programs/steps/index.shtml>  
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### FACT:

#### **Type 2 diabetes costs the U.S. health system an extra \$23 billion a year in direct medical**

**costs:** A study released last month at the American Association of Clinical Endocrinologists' annual meeting in Seattle found that poorly managed type 2 diabetes costs the U.S. health system an extra \$23 billion a year in direct medical costs. Diabetic complications cost almost \$10,000 per patient each year, concluded the author of that study, Willard Manning, PhD, a University of Chicago health economist.

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Item 5

#### **Vitamin A Metabolite Decreases Insulin Sensitivity and Increases Obesity**

*Retinaldehyde (Rald), a metabolite of vitamin A, increases the generation of adipose tissue and decreases insulin sensitivity, work conducted in a Harvard University laboratory shows.*

<http://www.diabetesincontrol.com/results.php?storyarticle=4861>

Rald inhibitors, on the other hand, decrease fat tissue and diet-induced obesity, Drs. Jorge Plutzky and Ouliana Ziouzenkova and colleagues report in an advance online publication of Nature Medicine, released May 27, 2007.

"There is a growing realization that retinoids, as naturally occurring molecules derived from vitamin A, can play important and quite specific roles in controlling gene expression," said Dr. Plutzky. "Through this, retinoids can have key roles in controlling responses, such as energy balance, obesity and diabetes. Our work is an example of this trend."

The investigators' research showed that Rald is present in rodent fat, and that it binds to retinol-binding proteins, inhibits adipogenesis and suppresses peroxisome proliferators-activated receptor-gamma and retinoid X receptor (RXR) responses.

Investigators announced that, "Mice lacking the Rald-catabolizing enzyme retinaldehyde dehydrogenase 1 (Raldh1) resisted diet-induced obesity and insulin resistance and showed increased energy dissipation."

"Now that we know retinaldehyde may play an important role in other locations outside the eye, including in locations like fat tissue, those pathways that control retinaldehyde levels could become targets for drug therapy," Dr. Plutzky said. "Likewise, variations in genes that control retinaldehyde levels may be involved in determining factors such as body weight, obesity and diabetes.

He cautioned that the results do not suggest a need for excess vitamin A supplementation. "A balanced well-rounded diet is always a good idea. Unmonitored excessive intake of any vitamin can be associated with health issues," he warned.

*Nature Medicine May 27, 2007*

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Item 6

### **Beta-Cell Regeneration at DRI**

*Ongoing research in cell regeneration suggests that insulin-producing islets cells may have the ability to regenerate under certain conditions.*

<http://www.diabetesincontrol.com/results.php?storyarticle=4860>

Researchers have shown that islet regeneration can be induced in a variety of experimental settings, however pregnancy is the only normal state that results in natural development and growth of these cells. During pregnancy, the body accommodates the increased needs of the mother and the developing fetus by modifying a host of biological functions. This includes a temporary expansion in the number of pancreatic beta cells required for regulating the blood sugar levels of both mother and baby. Scientists at the DRI (Diabetes Research Institute) are now taking a closer look at this physiological phenomenon in order to determine methods to regenerate islets in people with type 1 diabetes.

A critical first step in this process was to analyze the molecular signals that drive the natural islet expansion. Dr. Ricardo Pastori, director of molecular biology, and his team studied the role of a group of key molecules, called micro-RNA (miRNA), that control fundamental cell processes, such as the growth of islet cells.

Micro-RNAs, which have unique properties and are master regulators of gene expression, have proven difficult to study due to their elusive nature. Until now, the methods that scientists have used to study miRNA have been unreliable. In a major advance, the DRI team has been able to correctly measure and analyze miRNA expression, which is not only relevant in diabetes research, but is a significant finding for the entire medical research field.

The study results were recently published in the journal Biochemical and Biophysical Research Communications, and the team presented their findings in March at a meeting hosted by the Cambridge Healthtech Institute in Boston.

Dr. Pastori and his colleagues will now use this information to correctly profile islets isolated during pregnancy in rodent models to identify the novel genes and pathways involved in islet growth. These studies may lead to the development of novel methods to regenerate islets in the clinical setting.

**>>View Video Comments from DRI Researcher Luca Inverardi, M.D.**

<http://www.diabetesresearch.org/Newsroom/Publications/LucaInverardi.htm>

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**For the diabetic patient, it's not the cholesterol that's the problem.** It's the number of LDL particles, especially small LDL particles. To see the real risk, use the NMR LipoProfile(r) test, the only test that directly measures the number of LDL particles and the number of small LDL particles - the particles shown to be more predictive of CHD events than LDL-C. Click here to learn more.

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Item 7

### **How Tummy Surgery Cures Diabetes In A Matter of Days**

*Scientists at Swansea University School of Medicine have been funded to investigate why weight-reducing surgery can lead to the almost immediate disappearance of diabetes in patients even before any weight loss.*

<http://www.diabetesincontrol.com/results.php?storyarticle=4859>

95% of morbidly obese people - those with a Body Mass Index of over 40 - have Type 2 diabetes, sometimes known as maturity-onset diabetes. However, nearly 80% of patients who undergo gastric bypass surgery to reduce the size of their stomachs and small intestines find that their diabetes disappears within two to three days - before any weight loss has occurred.

Senior Clinical Lecturer Dr Jeffrey Stephens is leading the research at the School of Medicine's Diabetes Research Group. He said: "Although patients with Type 2 diabetes do not always require insulin treatment, the average diabetic needs about 30 units of insulin a day to control blood sugar levels.

"For obese patients, this can rise to 200 units a day. To go from such a high level of insulin-dependency to not needing insulin in a matter of a few days is a dramatic result, and we need to understand the reasons why this happens."

The research team, which includes Professor Steve Bain and Professor Rhys Williams from Swansea University's School of Medicine, and Professor John Baxter, a bariatric surgeon with Swansea NHS Trust, are focusing attention on a protein known as Glucagon Like Peptide 1 (GLP-1), which is produced in the small intestine.

Dr Stephens said: "Overweight people who have Type 2 diabetes tend to have lower levels of GLP1 and we are investigating whether these levels return to normal after bariatric surgery. Basically, we want to know whether reducing the size of the small intestine and stomach restores production of GLP1, and why this should be the case."

"Bariatric surgery is not just effective in terms of controlling obesity. It clearly has other major health implications, with the potential to impact positively on Type 2 diabetes and other associated conditions. There is also the potential for the NHS to generate substantial savings in long term treatment costs," added Dr Stephens.

"Not only will this research improve our understanding of why overweight people develop Type 2 diabetes, it may also lead to an effective, non-surgical treatment for those with the condition.

*For more information on the BUPA Foundation visit [www.bupafoundation.co.uk](http://www.bupafoundation.co.uk),*

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**Dr. Philip A. Wood has written a book for healthcare professionals and students of medicine**, nursing, pharmacy, and graduate studies, as well lay people interested in understanding the influences of genetics, nutrition, activity level and drugs on diseases associated with excess fat such as obesity, insulin resistance, metabolic syndrome and type 2 diabetes. The book is composed of short, readable chapters with helpful figures to further explain the mechanisms discussed. For further information please click here.

[http://www.amazon.com/exec/obidos/tg/detail/-/0674019474/qid=1132176956/sr=8-1/ref=pd\\_bbs\\_1/002-7853569-1175265?v=glance&s=books&n=507846](http://www.amazon.com/exec/obidos/tg/detail/-/0674019474/qid=1132176956/sr=8-1/ref=pd_bbs_1/002-7853569-1175265?v=glance&s=books&n=507846)

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Item 8

### **Study Tests Oral Insulin to Prevent Type 1 Diabetes**

*A new oral insulin is being used to prevent Type 1 diabetes at the University of Florida.*

<http://www.diabetesincontrol.com/results.php?storyarticle=4858>

University of Florida researchers have begun a clinical study of oral insulin to prevent or delay type 1 diabetes in people at risk for the disease.

The UF Health Science Center and Shands at UF are among 14 centers in the United States working with affiliate sites and participating physicians in Type 1 Diabetes TrialNet, a research group dedicated to the understanding, prevention and early treatment of type 1 diabetes.

“This is a unique opportunity to attempt to prevent the disease in relatives at risk for type 1 diabetes,” said Desmond Schatz, M.D., medical director of UF’s Diabetes Center of Excellence. “The intervention may also offer hope for delaying the onset of the disease.”

An estimated 1 to 2 million people with the disease have type 1 diabetes, which occurs when white blood cells vital to the body’s defenses against infectious diseases attack insulin-producing beta cells in the pancreas. The insulin these cells produce regulates how the body uses and stores sugar and other food nutrients for energy.

Research has shown the pancreas is resilient and more than half its insulin-producing beta cells must be irreversibly destroyed before an individual develops symptoms of the disease, which can take months or even years to occur. That long period prior to the onset of symptoms provides an opportunity for interventions aimed at preventing the disease’s development, Schatz said.

In the study, University of Florida researchers are testing whether an insulin capsule taken by mouth once a day can prevent or delay type 1 diabetes in a specific group of people at risk for the disease.

An earlier trial suggested that oral insulin might delay type 1 diabetes for about four years in some people with islet cell autoantibodies in their blood. The presence of these autoantibodies alerts physicians to the destruction of insulin-producing cells up to 10 years before symptoms set in and indicates an individual is at greater risk of developing the disease. For a person with high-risk genes and all three autoantibodies, the risk of developing diabetes in the next five years is greater than 50 percent, Schatz said.

Animal studies have also suggested that insulin taken orally might even prevent type 1 diabetes. Some scientists think that introducing insulin via the digestive tract induces tolerance, a quieting of the immune system.

First- and second-degree relatives of people with type 1 diabetes who may be at risk are initially being screened through TrialNet’s natural history study, which is examining the immune and metabolic events that precede diabetes symptoms.

Another TrialNet study seeks to turn off the body’s attack on beta cells with rituximab, a monoclonal antibody that binds to and temporarily destroys a class of immune cells. The rituximab trial is recruiting patients with type 1 diabetes diagnosed within the previous three months. Also under way is a study testing whether a combination of two drugs approved by the FDA to prevent rejection after an organ transplant can slow or arrest the autoimmunity of type 1 diabetes.

Lastly, the Environmental Determinants of Diabetes in the Young, or TEDDY, study aims to discover the genes and environmental exposures that may cause type 1 diabetes through a newborn screening program. Babies found to be at a high risk of developing the disease may enroll in TEDDY II and will be tracked over time to examine environmental risk factors.

*The Type 1 Diabetes TrialNet studies are funded by the National Institutes of Health. The Juvenile Diabetes Research Foundation International and the American Diabetes Association also support the initiative*

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**FACT:**

**Takeda Shares Touch 3-Month High on Actos Diabetes Drug Sales:** Takeda Pharmaceutical Co. shares touched a three-month high after data showed an increased demand for the Japanese drugmaker's Actos diabetes medicine. Takeda's share of new oral diabetes prescriptions more than doubled after GlaxoSmithKline Plc's rival diabetes drug Avandia fell out of favor with some U.S. doctors following a report by Cleveland Clinic researchers that the pill raised heart attack risks. Avandia's share fell to about zero from 10 percent in the two days after the May 21 report in the New England Journal of Medicine.

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Item 9

**Predicting Severe Hypoglycemia**

Severe hypoglycemia often follows a specific blood glucose fluctuation pattern that is identifiable from SMBG. <http://www.diabetesincontrol.com/results.php?storyarticle=4857>

Prevention of severe hypoglycemia (SH) is premised partially on the ability to accurately anticipate its occurrence. This study prospectively tests methods for predicting SH using blood glucose meter readings.

One hundred adults with type 1 diabetes were followed for 6 months, and 79 insulin-using adults with type 2 diabetes were followed for 4 months. During this time, subjects' routine self-monitored blood glucose (SMBG) readings were stored on and retrieved from memory meters, and participants were queried biweekly about occurrence of SH. Respective demographics for the two groups were age 40.7 and 50.2 years, duration of diabetes 20.0 and 12.2 years, A1C 7.6 and 8.8%, and male sex 43 and 39%, respectively.

The results showed that Relative risk for SH, quantified by the ratio of an individual's low blood glucose index (LBGI) based on the previous 150 SMBG readings to the LBGI based on recent SMBG readings, increased significantly in the 24 h before SH episodes in individuals with type 1 and type 2 diabetes ( $t = 10.3$ ,  $P < 0.0001$ , and  $t = 4.2$ ,  $P < 0.001$ , respectively). A sliding algorithm detected 58% of imminent (within 24 h) SH episodes in the type 1 diabetic group and 60% of those in the type 2 diabetic group when three SMBG readings were available in the 24 h before an episode. Detection increased to 63 and 75%, respectively, if five SMBG readings were available in the 24 h before an episode.

From the results it was concluded that severe hypoglycemia often follows a specific blood glucose fluctuation pattern that is identifiable from SMBG. Thus, partial prediction of imminent SH is possible, providing a potential tool to trigger self-regulatory prevention of significant hypoglycemia.

*Diabetes Care* 30:1370-1373, 2007

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Item 10

### **Pear Cactus Helps to Control Blood Sugars**

*Eating nopales along with a traditional Mexican breakfast can help people with diabetes keep their blood sugar under control, a new study shows.*

<http://www.diabetesincontrol.com/results.php?storyarticle=4856>

Dr. Montserrat Bacardi-Gascon from the Universidad Autonoma de Baja California in Tijuana, Mexico states that, Nopales are prickly pear cactus pads, and are common fare among people living in southern and central Mexico, available at any food market.

They sought to determine whether eating nopales, which have a very low glycemic index and are high in fiber, would reduce the post-meal rise in blood sugar among people with diabetes eating typical Mexican breakfasts.

The glycemic index is a measure of how quickly blood sugar (glucose) rises after meals. In general, low-fiber foods containing simple starches, for example candy, have a higher glycemic index than foods rich in fiber and more complex carbohydrates, such as whole grains and vegetables.

After a 12-hour fast, 36 individuals with type 2 diabetes ate chilaquiles (a casserole of corn tortillas with cheese, beans and tomato sauce), scrambled egg and tomato burritos, or quesadillas with pinto beans and avocados, with or without 85 grams (about 3 ounces) of nopales.

For each of the breakfasts, the researchers found, adding nopales to the meal resulted in a significantly lower rise in blood sugar than when the meal was eaten without nopales.

The blood sugar response was 48 percent lower when nopales were eaten with quesadillas, while nopales cut the increase by 30 percent with chilaquiles and 20 percent with burritos.

"The promising results shown with these typical Mexican breakfasts provide Mexican patients with a broader and more culturally based choice for the management of diabetes," the researchers conclude.

*Diabetes Care, May 2007.*

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Item 11

**High-Carbohydrate Diets Are Linked to Higher Blood Pressure**

*Carbohydrate-rich diets are associated with slightly higher blood pressure than diets rich in cis-monounsaturated fat, according to recently published findings.*

<http://www.diabetesincontrol.com/results.php?storyarticle=4855>

However, the difference is not enough to justify making dietary recommendations to change the carbohydrate and cis-monounsaturated fat content of the diet in order to manage blood pressure, Dr. Meena Shah and colleagues from the University of Texas Southwestern Medical Center at Dallas, write.

The researchers conducted a meta-analysis of intervention studies that compared high-carbohydrate and high-cis-monounsaturated fat diets in order to better understand the effect on blood pressure of carbohydrate and cis-monounsaturated fat. Study diets had to be isoenergetic in order to be included in the analysis.

In addition, the patients' body weight had to remain stable. A total of 10 studies were included in the analysis, including six randomized crossover, one randomized parallel, and three nonrandomized.

Results of a random-effects model revealed that carbohydrate-rich diets led to significantly higher systolic blood pressure (difference: 2.6 mm Hg,  $p = 0.002$ ) and diastolic blood pressure (difference: 1.8 mm Hg,  $p = 0.05$ ) compared to diets rich in cis-monounsaturated fat. When the analysis was restricted to randomized crossover studies, systolic blood pressure (1.3 mm Hg,  $p = 0.11$ ) and diastolic blood pressure (0.9 mm Hg,  $p = 0.11$ ) were higher with carbohydrate-rich diets than with high cis-monounsaturated fat diets, but the difference was not significant.

"The slightly higher blood pressure of subjects following the high-carbohydrate diet may be due to accentuation of hyperinsulinemia," Dr. Shah's team suggests. "Hyperinsulinemia is suggested to enhance sympathetic nervous system activity, which increases heart rate, cardiac output, vascular resistance, and sodium retention and thus blood pressure."

*Am J Clin Nutr 2007;85:1251-1256.*

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## **DID YOU KNOW:**

**Nanoencapsulation is one of the newest technologies in the area of immunoisolation research.**

The scientific team at the Diabetes Research Institute is aggressively pursuing the development of nanoencapsulation technology, the newest area in immunoisolation research. The scientific team is applying the same layering technology that is currently used by the electronics, optics and sensor industries to surround the cells with a protective casing. By adapting this methodology to cell-based science, researchers are developing biocompatible coatings on the same scale as the cell membrane. These coatings can serve as a type of

“camouflage” for the implanted islets, allowing them to go unnoticed by the body and avoid inflammatory reactions or immune attack. Another major advantage of this type of encapsulation is minimizing the size of the capsule and virtually eliminating the problem of oxygen delivery created by the space inside traditional microcapsules. The very thin coating has relatively little effect on diffusion in and out of the cell. Researchers are evaluating how effective multiple layers could be in protecting islets.

[>> View Video Comments from DRI Researcher Cherie Stabler, Ph.D.](#)

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Item 12

### **Postprandial Hyperglycemia Impairs Diurnal Blood Pressure Variation**

*Postprandial hyperglycemia is more common than fasting hyperglycemia in type 2 diabetic patients who show nocturnal nondipping of blood pressure.*

<http://www.diabetesincontrol.com/results.php?storyarticle=4854>

Dr. Frank Pistrosch from University Hospital Dresden, Germany stated that, "At the present stage I would not recommend different antidiabetic treatment regimes for the restoration of a dipping pattern." "However, considering the importance of postprandial hyperglycemia for cardiovascular events, we should treat fasting as well as postprandial hyperglycemia of our diabetic patients."

Dr. Pistrosch and associates investigated the relationship between the diurnal postprandial and fasting hyperglycemia and the corresponding blood pressure variation in 107 patients with type 2 diabetes and hypertension.

Three-quarters of the patients showed nocturnal nondipping of blood pressure, the authors report, but their systolic blood pressure during the day did not differ from that of patients with nocturnal dipping, and the diastolic blood pressure of nondippers was even lower than that of dippers.

Patients with abnormal diurnal blood pressure variation (nondippers) were more likely to have diabetic retinopathy and a higher urinary albumin excretion, both signs of advanced microvascular end organ damage, the researchers note.

Postprandial glucose increases were significantly higher in nondippers than in dippers, the investigators say, but fasting hyperglycemia did not differ significantly between the groups.

A logistic regression model that included day/night ratio of heart rate and the degree of postprandial hyperglycemia correctly predicted 84% of dippers and nondippers. Other factors (age, gender, body-mass index, glomerular filtration rate, and type of antihypertensive therapy) did not contribute significantly to the model.

"The mechanistic linkage between abnormal nocturnal blood pressure dipping status and abnormal glucose metabolism remains unclear," writes Dr. Kazuomi Kario from Jichi Medical School, Tochigi, Japan in a related critique. "Autonomic dysfunction and endothelial-cell dysfunction may be a missing link between glucose abnormality and nondipping status in diabetes."

*Am J Hypertens 2007;20:541-545,546-547.*

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Item 13

### **Aerobic Activity Increases HDL Cholesterol Levels**

*Hitting the treadmill, the bike trails, or donning your rollerblades can modestly increase high-density lipoprotein (HDL) cholesterol levels, according to the results of a new study.*

<http://www.diabetesincontrol.com/results.php?storyarticle=4853>

While not entirely surprising, the finding that regular aerobic exercise increases HDL cholesterol levels emerges from a new meta-analysis, with investigators also showing that exercise duration per session is the most important element of an exercise program.

Publishing the results in the of the meta-analysis in the *Archives of Internal Medicine*, Dr Satoru Kodama (Ochanomizu University, Tokyo, Japan) showed the effect of aerobic training resulted in a 2.53-mg/dL increase in HDL cholesterol levels. With each 1-mg/dL increment in HDL cholesterol levels associated with a 2% to 3% decreased risk of cardiovascular disease, exercise, by rough estimates, could result in a 5.1% and 7.6% reduction in cardiovascular disease risk in men and women, respectively, say investigators.

The value of increasing HDL cholesterol levels to reduce risk is widely accepted, the Japanese researchers write, but also point out that the results of aerobic exercise studies vary, often depending on the duration, intensity, or frequency of the exercise program, and the characteristics of subjects at baseline.

In this meta-analysis of 25 articles from 35 randomized control trials published between 1966 and 2005, Kodama and colleagues evaluated the effects of aerobic exercise on HDL cholesterol levels in adults aged 20 years and older. The sample size of the included studies was small, ranging from 9 to 200 subjects, for a total of 1404 subjects. The mean intervention period was 27 weeks, with the minimum intervention 8 weeks. The prescribed exercise intervention included a mean of 3.7 sessions per week, with each session lasting approximately 40 minutes. The mean estimated energy expenditure was just over 1000 kcal/week.

Across the studies, HDL cholesterol levels increased an average of 2.53 mg/dL in those randomized to an exercise program. For 21 studies in which the weekly estimated energy expenditure exceeded 900 kcal/week, the pooled change in HDL cholesterol levels was significant, but not significant in studies where energy expenditures were less than 900 mg/dL. Additionally, for 25 trials in which subjects exercised for more than 120 minutes/week, the increase in HDL cholesterol levels was significant, but not significant for subjects who exercised less. Also, the effect of exercise was greater in those with total cholesterol levels > 220 mg/dL and those with a body mass index (BMI) < 28 kg/m<sup>2</sup>.

In univariate analysis, the investigators found that only exercise duration, and not frequency or intensity, was associated with increases in HDL cholesterol levels. When subjects exercised between 23 and 74 minutes per session, each 10-minute increase in duration was associated with a 1.4-mg/dL increase in HDL cholesterol.

Practice Pearls:

- ?? The current meta-analysis demonstrates that the duration of exercise appears to be the most significant exercise-related factor in increasing HDL cholesterol levels, and patients who are less obese and have higher total cholesterol levels are more likely to benefit from exercise in terms of their HDL cholesterol levels.

*Arch Intern Med.* 2007;167:999-1008.

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**FACT:**

**AtheroGenics to focus on diabetes:** AtheroGenics Inc. will soon test AGI-1067 as a diabetes treatment. The Alpharetta, Ga.-based pharmaceutical company's drug trial for AGI-1067 as a heart medicine **failed**. However, the trial did show improvement in combinations of heart attacks, stroke and several key diabetes parameters. So AtheroGenics will soon begin a clinical trial studying the effect of AGI-1067 in patients with diabetes. Patient enrollment is expected to begin in the third quarter. "In the ARISE study, AGI-1067 exhibited encouraging effects on the pre-specified endpoints of glycemic control and in reducing cardiovascular events in over 2,200 diabetes patients," said Dr. Russell M. Medford, president and CEO of AtheroGenics. "We believe there is a critical unmet medical need for a new diabetes agent that works toward getting patients' A1c levels to goal, while at the same time, provides cardiovascular benefits."

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Item 14

**Sleep Apnea Associated with Gestational diabetes and High Blood Pressure**

*Study found that when the women's weight was taken into account, sleep apnea was associated with a doubling of the incidence of gestational diabetes and a fourfold increase in the risk of pregnancy-induced hypertension.*

In obstructive sleep apnea, the upper airway narrows, or collapses, during sleep. Periods of apnea end with a brief partial arousal that may disrupt sleep hundreds of times a night. Obesity is a major risk factor for sleep apnea.

The most effective treatment for sleep apnea is a technique called nasal CPAP (continuous positive airway pressure), which delivers air through a mask while the patient sleeps, keeping the airway open.

The researchers analyzed data from all pregnancies associated with sleep apnea, gestational diabetes (women who developed diabetes during pregnancy) and pregnancy-induced high blood pressure nationwide in 2003. Out of almost 4 million deliveries, 452 had sleep apnea. Of the 167,227 women who had gestational diabetes, 67 had sleep apnea. Of the 200,902 pregnancies with pregnancy-induced high blood pressure, 166 had sleep apnea.

"The repetitive decrease in oxygen that occurs during the night in someone with sleep apnea heightens the body's 'fight or flight' state, which can raise blood pressure," explains researcher Hatim Youssef, D.O. of UMDNJ-Robert Wood Johnson Medical School. "The body also secretes more hormones such as cortisol and epinephrine, and the body responds by producing more glucose coupled with a decreased sensitivity to insulin, which can lead to diabetes."

Pregnancy can worsen sleep apnea, especially during the third trimester when a woman's weight is greatest, Dr. Youssef explains. "When a mother's oxygen level drops at night, it may also affect the oxygen level of the fetus, and we don't know what the long-term effects are. That's why it's important for a pregnant woman with sleep apnea to be treated with CPAP during her pregnancy."

It is not yet known whether CPAP treatment can reduce the risk of diabetes and hypertension during pregnancy, he says. "In the non-pregnant population, research has shown that treating sleep apnea will reduce the risk of diabetes and hypertension.

He recommended that pregnant women who are obese, hypertensive or diabetic be closely evaluated for the presence of sleep apnea. If sleep apnea is present, treatment in the form of nasal CPAP should be used and her blood pressure and blood sugar should be closely monitored, Dr. Youssef says.

*"Sleep Apnea is Associated with Gestational Diabetes Mellitus and Pregnancy-Induced Hypertension"(Session D108; Abstract # 4836; Poster Board # 511) May 22, 2007*

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Item 15

**Just Ten Minutes of Physical Activity A Day Has a Major Impact**

*Even small amounts of physical activity — approximately 75 minutes per week — can improve cardiorespiratory fitness levels of sedentary overweight individuals, a study shows.*

<http://www.diabetesincontrol.com/results.php?storyarticle=4851>

While this level of exercise is lower than that currently recommended to produce weight loss, the current findings may be used to encourage those people who do not exercise at present to start doing some form of physical activity, the authors advise.

The authors point out that improvements in fitness are associated with a reduction in the risk for cardiovascular disease, diabetes and death, and that, as physical activity is the main determinant of fitness in adults, continuing

to refine efficient, safe, and acceptable exercise regimens is of substantial public health importance. Whereas the National Institutes of Health (NIH) Consensus Development Panel recommends at least 30 minutes of moderate-intensity physical activity on most days of the week, the authors note that recent reports suggest that 60 minutes of exercise each day may be necessary to prevent weight gain. But they add that the effect of much lower amounts of exercise has not been well studied.

The team therefore conducted a trial in which 464 sedentary postmenopausal women who were overweight or obese and had raised blood pressure were randomized to 3 different durations of moderate exercise (cycling or walking) or to a nonexercise control group for 6 months. The 3 exercise levels were designed to achieve energy expenditure of 4 kcal/kg (400 calories), 8 kcal/kg (800 calories), or 12 kcal/kg (1200 calories) per week, which corresponded to 50%, 100%, and 150% of NIH-recommended exercise levels. Aerobic fitness was assessed on a cycle ergometer and quantified as peak absolute oxygen consumption. Results showed a graded increase in fitness levels with increased exercise levels.

Church and colleagues report that these improvements in fitness occurred at a modest training intensity and during a time of life when fitness is decreasing at 1% to 2% per year. They also point out that the adherence rate was high and dropout rate was low, suggesting that the exercise regimens followed in this study were realistic and achievable. In addition, they found that the physical activity–fitness dose response relation to be similar across age, race, weight, baseline fitness, and hormone therapy subgroups.

Although the changes in fitness shown in this study were not accompanied by a reduction in blood pressure, weight, or most other cardiovascular risk factors, those who exercised did show a decrease in waist circumference, which the authors say is important given the increased risk for insulin resistance, diabetes, metabolic syndrome, and mortality associated with excess abdominal fat.

"Perhaps the most striking finding of our study is that even activity at the 4-kcal/kg per week level (approximately 72 min/wk) was associated with a significant improvement in fitness compared with women in the nonexercise control group," the authors write.

They note that nearly everyone understands that there are health benefits associated with physical activity, yet still about 20% of US adults do not engage in any physical activity at all. "Data presented in our study show that even 72 minutes of moderate-intensity physical activity per week accumulated over about 3 days has a significant effect on fitness in previously sedentary postmenopausal women. This information can be used to support future recommendations and should be encouraging to sedentary adults who find it difficult to find the time for 150 minutes of activity per week, let alone 60 minutes per day," they add.

But Dr. Lee concludes, "Although current knowledge regarding the dose-response relation between physical activity and health remains incomplete, the study by Church et al does provide important information on the dose of physical activity to improve physical fitness, a strong predictor of chronic disease and premature mortality. This may be succinctly summarized for patients and clinicians as 'Even a little is good; more may be better!'"

JAMA. 2007;297:2053, 2081-2091.

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## **Quote of the Week!**

***"A good plan today is better than a great plan tomorrow."***

.....George S. Patton

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