

# DIABETES IN CONTROL.com Newsletter

The Newsletter for Professionals in Diabetes Care

April 5, 2006 Issue #306

Dr. Richard Bernstein will be doing another teleconference call next month. It will be focused on insulin requiring people with diabetes. Just go to <http://www.askdrbernstein.com> to sign up and get more info.

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## Top Diabetes Stories:

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New Product GLUFAST for the Treatment of Type II Diabetes

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3611>

Diabetes Reversed: FDA Authorizes Human Trials

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3610>

Better Initial Glycemic Control With Metformin Linked to Longer Effectiveness

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3606>

FDA's Approval of Continuous Glucose Sensor Accelerates Development of

Artificial Pancreas

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3604>

FDA Accepts New Drug Application for Diabetes Drug Galvus

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3602>

Low-Carb Diet Controls Diabetes Without Weight Loss Or Insulin Use

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3601>

Three-Week Diet/Exercise Study Shows 50% Reversal in Type 2 Diabetes

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3598>

Postprandial Glucose Regulation: New Implications

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3597>

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## From the editor's desk

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Do you know a patient that has had diabetes for 25 or more years? If they have set a standard that you wish others would follow then you may want to nominate them for the 2006 LillyforLife Awards. To nominate that special patient just visit <http://www.LillyforLife.com> or call 1-888-545-5115 for more details.



Have you ever thought about a special cartoon for your patient or company? **Theresa Garnero, APRN, BC-ADM, MSN, CDE**, is back with a new cartoon, and can make a custom cartoon for you.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3612>

More excitement this week for the 3 oral DPP-IV inhibitors from Novartis, Merck & Co., and BMS, which are competing to be "First in Class". At least 5 phase II and 6 phase I DPP-IV inhibitors are closely following and more than 10 more companies are in advanced R&D. To learn more about the latest data see Item 10 and which company has the first application accepted by the FDA.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3602>

Does Cinnamon really improve glucose control in diabetes? Are all the products coming on the market really effective? Check out the original research by **Khan, Safdar, Khattak and Anderson**, and then stay tuned for further data.

<http://www.diabetesincontrol.com/issues/issue306/cinnamondiabcare.pdf>

**A'ishah Khan, Doctor of Pharmacy Candidate, University of Florida College of Pharmacy,** just finished her rotation with me and I asked her to share some things she learned about food. [Click here](#) to check out her "dietary tidbits"

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3613>

#### **Dlife TV for April 9, 7PM ET on CNBC**

An up-close and personal look at how elite athletes manage their diabetes while performing at the top of their games. Featuring Detroit Tigers pitcher Jason Johnson, champion ultramarathoner Missy Foy, and Pittsburgh Steelers offensive lineman Kendall Simmons.

**We can make a difference!**

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#### **This week's overview:**

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Item #3: Exercise Helps Speed Wound Healing in Older Adults

Item #4: Depression Rate High Among Diabetics

Item #5: Morphine Plus Gabapentin Better for Neuropathic Pain Than Each Drug Alone

Item #7: Cardiac Medications Prolong Survival in Peripheral Artery Disease

Item #9: Ankle/brachial Index Helps Identify Peripheral Artery Disease in Diabetics

Item #12: Empire Study: Effects of Rosiglitazone + Submaximal Doses of Metformin Verses Increasing Doses of Metformin in Type 2 Diabetes

Item #13: Therapeutic Efficacy of Mitiglinide + Glargine Vs. Basal Bolus Therapy

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

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3614>

Dave Joffe, *Editor-in-Chief*

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#### **NEWS FLASH:**

Generex Biotechnology announces that it will begin production of its Oral-lyn, insulin buccal spray and begin to ship the product sometime in April in Ecuador where it has been approved for distribution.

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#### **New Product:**



**RxWise:** The RxWise device offers people with diabetes a safety check system to help avoid potentially dangerous adverse drug reactions. The user records his or her medical information with the software to create a history of specific drugs taken and known medical conditions, as well as any drug allergies. Once the information is entered into the device, potential risks about medications that might cause an adverse reaction are displayed immediately. If desired, the user can then forward the warnings and information to his or her physician or pharmacist. RxWise covers prescription, over-the-counter, and herbal medications. It is available as a USB Flash Drive or in an online version. [www.rxwise.com](http://www.rxwise.com)

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#### **Tools for Your Practice:**



## Insulin Starter Kits, CDs and Educational Booklets



Novo Nordisk has some great Free educational materials in English and Spanish. They also have an insulin starter kit, over 11 booklets and an interactive CDRom that you can order right on the site. You will have to register. [Educational Materials](#)

[http://www.novomedlink.com/\(ezkyxljg55tvbpu3caxawc55\)/login.aspx](http://www.novomedlink.com/(ezkyxljg55tvbpu3caxawc55)/login.aspx)

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### This Week's Items:

1. New Product GLUFAST for the Treatment of Type II Diabetes\*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3611>

2. Diabetes Reversed: FDA Authorizes Human Trials\*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3610>

3. Exercise Helps Speed Wound Healing in Older Adults

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3609>

4. Depression Rate High Among Diabetics

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3608>

5. Morphine Plus Gabapentin Better for Neuropathic Pain Than Each Drug Alone

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3607>

6. Better Initial Glycemic Control With Metformin Linked to Longer Effectiveness\*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3606>

7. Cardiac Medications Prolong Survival in Peripheral Artery Disease

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3605>

8. FDA's Approval of Continuous Glucose Sensor Accelerates Development of Artificial Pancreas\*

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9. Ankle/brachial Index Helps Identify Peripheral Artery Disease in Diabetics

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10. FDA Accepts New Drug Application for Diabetes Drug Galvus\*

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11. Low-Carb Diet Controls Diabetes Without Weight Loss Or Insulin Use\*

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12. Empire Study: Effects of Rosiglitazone + Submaximal Doses of Metformin

Verses Increasing Doses of Metformin in Type 2 Diabetes

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3600>

13. Therapeutic Efficacy of Mitiglinide + Glargine Vs. Basal Bolus Therapy

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14. Three-Week Diet/Exercise Study Shows 50% Reversal in Type 2 Diabetes\*

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15. Postprandial Glucose Regulation: New Implications\*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3597>

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### ITEMS For The Week:

Item 1

#### **New Product GLUFAST for the Treatment of Type II Diabetes**

*Glufast, which is close to market is an insulin secretagogue with a rapid onset and short duration of action, lowers post-meal glucose levels by improving the body's own ability to produce insulin.*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3611>

Mr. Mutsuo Kanzawa, President and Chief Executive Officer of Kissei Pharmaceutical, stated, "We are very pleased to have signed the Glufast agreement with Elixir Pharmaceuticals. Since its launch in Japan in May 2004, Glufast has steadily increased its domestic market share and attained an important position in the treatment regimen for patients with type II diabetes. In addition to Japan, the product is currently in development in China, South Korea and the Middle East as part of Kissei's program to address patient markets worldwide."

Type II diabetes is a serious and debilitating disease, affecting 14 million patients in the United States alone. While there has been significant progress in the treatment of type II diabetes, there is still an enormous unmet medical need worldwide.

Mr. Heiden added, "We believe that Glufast represents an important advance for physicians and their patients who are seeking optimal glucose control. The launch of Glufast in the United States will be carried out by an Elixir specialty sales force with a focus on metabolic disease, specifically targeting diabetologists and endocrinologists.

Glufast, an insulin secretagogue with a rapid onset and short duration of action, lowers post-meal glucose levels by improving the body's own ability to produce insulin. Clinical data have shown that reducing post-meal glucose surges with Glufast decreases HbA1c levels (a standard means of assessing chronic elevated blood glucose levels). Epidemiological studies have demonstrated that uncontrolled surges in post-meal glucose levels are directly associated with negative long-term health outcomes in diabetics.

Glufast is a member of the meglitinide class of compounds; two currently marketed products in this class are expected to generate over \$300 million in sales in the U.S. in 2006.

Glufast has been studied extensively in human clinical trials in the U.S., Europe, Australia and Asia. Clinical results from more than 1,500 treated patients, including several years of in-market use in Japan, support Glufast's safety and effectiveness and will be used in Elixir's registration efforts in its licensed territories.

Elixir is a biopharmaceutical company focused on the discovery, development and commercialization of new therapies to treat metabolic disease. The Company is building on its Optimal Aging scientific platform to discover, develop and market new drugs for the treatment and prevention of metabolic disorders, as well as the prevention of age-related diseases. More information about Elixir is available at <http://www.elixirpharm.com/>  
SOURCE: Elixir Pharmaceuticals, Inc.

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Item 2

### **Diabetes Reversed: FDA Authorizes Human Trials**

*After successfully demonstrating that a groundbreaking treatment strategy can reverse type 1 diabetes in animal studies, the FDA has given the go-ahead for researchers from the University of Pittsburgh Medical Center to begin a phase I trial evaluating the treatment in humans.*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3610>

The FDA approved the start of a clinical trial to evaluate the safety and feasibility of the treatment. The trial is expected to begin sometime this spring and will include at least 15 patients over the age of 18, with type 1 diabetes.

The treatment involves specific modification of dendritic cells. University of Pittsburgh researcher Dr Massimo Trucco and his team found that by removing dendritic cells from the blood during a two-to four-hour procedure, some 20 million dendritic cells can be harvested.

Dendritic cells are cells found in the bloodstream and normally function as one of nature's most efficient immune function cells. The cells identify foreign substances such as cancer cells, process these foreign substances, and then jumpstart the immune response by bringing these foreign substances to the attention of T cells.

Once harvested, researchers then combine the dendritic cells with specific blockers of molecules, known as CD40, CD80 and CD86, all of which can be synthesized in a laboratory. This treatment strategy was found to inhibit the interaction and destructive effect of T cells on the insulin-producing beta cells of the pancreas, a process that is known to be a critical part of how diabetes occurs.

Subcutaneous injection of dendritic cells into the abdominal/pelvic area near the pancreas and lymph nodes, blocks the T cells as they travel to the pancreas to destroy beta cells.

"We did this in mice, giving them six injections over the course of several weeks. The injections interrupted the T cell and beta cell interaction, allowing the beta cells in the pancreas to regenerate. This enabled the pancreas of the mice to begin producing insulin again," said Dr Trucco. "The injections proved capable of stopping this vicious cycle, and through this process curing type 1 diabetes in a mouse."

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## **DID YOU KNOW:**

**Dyslipidemia, a Major Metabolic Disorder, Affects approximately 300 million people in the United States, Japan, and Western Europe.** Thousands of metabolic diseases have been identified in humans, yet just a handful of these diseases account for the vast majority of the morbidity and mortality. The World Health Organization (WHO) estimates that type 2 diabetes affects 135 million people worldwide and that 300 million people meet the criteria for obesity. Dyslipidemia is another major metabolic disorder, affecting approximately 300 million people in the United States, Japan, and Western Europe. *Research and Markets Ltd.*

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Item 3

### **Exercise Helps Speed Wound Healing in Older Adults**

*The body's ability to heal even small skin wounds normally slows down as we age. But a new study in older adults finds that regular exercise may speed up the woundhealing process by as much as 25 percent.*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3609>

"This is the first time we've been able to document this kind of enhancement associated with exercise," said Charles Emery, a professor of psychology and the lead author of the Ohio State University study.

*The faster that a wound heals, the less chance it will become infected.*

The study included 28 healthy older adults ranging in age from 55 to 77 (average age was 61). The participants hadn't exercised regularly for at least six months prior to the study. For the research, about half (13) of them exercised three times a week for three months. The other 15 participants served as controls and were asked not to change their physical activity habits during the study period.

Each subject received a small puncture wound on the back of the upper arm. Adults in the exercise group started working out about a month before the wound procedure; this gave their bodies enough time to adapt to a regular exercise program.

The wounds were about 1/8-inch across and deep. The researchers photographed the wounds three times a week until the wounds were no longer visible (about six to seven weeks).

The exercise sessions began with 10 minutes of warm-up floor exercises and stretching followed by 30 minutes of pedaling on a stationary bike. After that, participants either jogged or walked briskly on a treadmill for 15 minutes, followed by about 15 minutes of strength training. All sessions ended with five minutes of cool-down exercises.

Each participant completed assessments of exercise endurance and stress at the beginning and end of the study. The exercise endurance test, completed on a treadmill, measured each subject's aerobic fitness level by measuring how much oxygen he or she consumed while working out.

The researchers also collected saliva samples from each participant in order to measure levels of cortisol, a primary stress hormone. High cortisol levels indicate that the body is under stress; prior studies have suggested that exercise is associated with lower levels cortisol.

At the end of the study, the researchers found that skin wounds healed an average of 10 days faster in the people who exercised (29 days in the exercise group vs. 39 days in the non-exercise group.)

Not surprisingly, exercise endurance increased in the group that worked out, but remained the same in the non-exercise group.

The researchers were somewhat surprised to find a sharp increase in cortisol levels in the exercise group. The hormone is typically boosted by stress, and other studies have suggested that exercise may lower levels of stress.

"The stress of exercise may enhance the regulation of cortisol," Emery said. "This increase in cortisol levels may represent a biological pathway by which exercise helps wounds heal."

The current study supports the results of a related study on wound healing conducted at Ohio State a few years ago. That work compared wound-healing rates between older adults caring for a loved one with Alzheimer's disease to rates of older adults who weren't caregivers.

The healing rates of those who weren't caregivers was similar to the healing rates of the non-exercisers in the current study - wounds in both groups healed in about 40 days. Wounds among older caregivers took about 20 percent longer to completely heal.

"The findings from both studies indicate that the effect of exercise we found in the current study truly represents an enhanced rate of wound healing in older adults," Emery said.

*Journal of Gerontology March 2006*

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#### Item 4

##### **Depression Rate High Among Diabetics**

*Investigators have found that about 25 percent of patients with diabetes have symptoms of depression, confirming the relationship between these two conditions.*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3608>

Rates of depression were similar across ethnic groups, but there were significant differences in the use of depression treatment across groups.

Dr. Mary de Groot, of Ohio University, Athens, and colleagues examined rates of depressive symptoms, depression treatment, and satisfaction with treatment in a multicultural sample of 221 patients with type 1 (insulin-dependent) or type 2 (non-insulin-dependent diabetes).

Seventy-five had type 2 diabetes, 60 percent were women, the average age was 54 years and 53 percent were white.

Conservatively, 25.3 percent of the subjects had clinically significant depression. There were no significant differences in the rates of depression by ethnic group or diabetes type.

"Approximately 76 percent reported experience with one or more types of depression treatment," the investigators note in the journal *Diabetes Care*. "A total of 52 percent reported treatment with antidepressant medications, 63 percent from mental health providers, 15 percent with herbal remedies, and 19 percent from alternative healers."

Compared with whites, African Americans were less likely to report receiving any type of depression treatment. No difference between whites and Hispanics in treatment use was observed.

Of the 56 patients with high depression scores, most (63 percent) who received antidepressant drugs were satisfied or very satisfied with the treatment. Fifty-nine percent of patients treated by a mental health provider were satisfied with treatment, while 80 percent of those treated by an "alternative healer" and 38 percent who took herbal remedies were satisfied.

Based on these findings, the investigators think "increased depression screening and treatment may be beneficial for ethnically diverse patients with type 1 and type 2 diabetes."

Diabetes Care March 2006.

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## **DID YOU KNOW:**

**Loneliness Linked to High Blood Pressure in Aging Adults:** Loneliness is a major risk factor in increasing blood pressure in older Americans, and could increase the risk of death from stroke and heart disease. Lonely people have blood pressure readings that are as much as 30 points higher than in non-lonely people, even when other factors are taken into account. The research also showed that the normal increases in blood pressure associated with aging are augmented by loneliness. "*Loneliness is a Unique Predictor of Age-Related Differences in Systolic Blood Pressure,*" published in the journal *Psychology and Aging*.

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Item 5

### **Morphine Plus Gabapentin Better for Neuropathic Pain Than Each Drug Alone**

*The combination of morphine and gabapentin achieves better analgesia for neuropathic pain than each drug alone, according to the results of a randomized trial*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3607>

"The available drugs to treat neuropathic pain have incomplete efficacy and dose-limiting adverse effects," write Ian Gilron, MD, from Queen's University in Kingston, Ontario, Canada. "Painful diabetic neuropathy and postherpetic neuralgia are two neuropathic pain syndromes that have been investigated in mechanism-based studies as well as in many clinical trials of analgesic agents. Both conditions have been shown to respond to opioids and to gabapentin."

In this double-blind, four-period crossover trial, patients were randomized to receive daily active placebo (lorazepam), sustained-release morphine, gabapentin, and a combination of gabapentin and morphine, each given orally for five weeks. The primary outcome was mean daily pain intensity in patients receiving a maximal tolerated dose, rated on a scale from 0 to 10, with higher numbers indicating more severe pain. Secondary outcome measures were pain ratings on the Short-Form McGill Pain Questionnaire, adverse effects, maximal tolerated doses, mood, and quality of life.

Of 57 patients who were randomized, 35 had diabetic neuropathy and 22 had postherpetic neuralgia; 41 completed the study. Mean daily pain at a maximal tolerated dose of the study drug was 5.72 at baseline, 4.49 with placebo, 4.15 with gabapentin, 3.70 with morphine, and 3.06 with gabapentin plus morphine ( $P < .05$  for the combination vs placebo, gabapentin, and morphine alone).

Total scores on the Short-Form McGill Pain Questionnaire, on a scale from 0 to 45, with higher numbers indicating more severe pain, at a maximal tolerated dose were 14.4 with placebo, 10.7 with gabapentin, 10.7 with morphine, and 7.5 with gabapentin plus morphine combination ( $P < .05$  for the combination vs placebo, gabapentin, and morphine alone).

Compared with the maximal tolerated doses of each drug as a single agent, the maximal tolerated doses of morphine and gabapentin were lower ( $P < .05$ ). At the maximal tolerated dose, frequency of constipation and of dry mouth was higher for gabapentin plus morphine than for gabapentin alone ( $P < .05$  for both).

"Gabapentin and morphine combined achieved better analgesia at lower doses of each drug than either as a single agent, with constipation, sedation, and dry mouth as the most frequent adverse effects," the authors write.

The results of this trial unequivocally show that gabapentin significantly enhances the efficacy of morphine," the authors conclude. "Given the potential benefits (e.g., improved efficacy and fewer adverse effects) and drawbacks (e.g., adverse drug interactions) of any drug combination, trials are needed to compare other analgesic combinations with their respective single agents."

"This study clearly shows the advantages of concurrent titration of gabapentin and morphine, though the perceived risks of addiction and diversion with opioids and the fear of scrutiny by regulatory agencies may present barriers to the acceptance of this combination as first-line treatment," the authors write. "

N Engl J Med. 2005;352:1324-1334, 1373-1375

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#### Item 6

#### **Better Initial Glycemic Control With Metformin Linked to Longer Effectiveness**

*In patients taking metformin as monotherapy to treat type 2 diabetes, achieving a low level of glycosylated hemoglobin level (HbA1c) during the first year predicts a longer period of effectiveness for the medication, investigators report.*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3606>

Because diabetes is a progressive disease, patients typically undergo a succession of antihyperglycemic therapy adjustments, Dr. Gregory A. Nichols and his associates point out. "Maximizing the effectiveness at each stage should increase therapeutic flexibility and reduce glycemic burden in the long term," they add.

To identify predictors of failure with metformin, Dr. Nichols' group evaluated the records of patients treated between 1996 and 2003 at Kaiser Permanente Northwest HMO in Portland, Oregon. They identified 1547 patients with diabetes whose first antihyperglycemic drug was metformin.

They then followed the 1288 patients who achieved an HbA1c  $< 8\%$  during the first year. They defined secondary failure as the addition or switch to another antihyperglycemic drug after 6 months of treatment with metformin, or the first HbA1c measurement of  $8\%$  or higher that occurred during follow-up.

According to their report in the March issue of Diabetes Care, the most important factor predicting long-term success with metformin was the reduction of HbA1c achieved during the first year.

For example, more than four out of five patients whose HbA1c level remained  $> 7\%$  during the first year regained an HbA1c level  $> 8\%$ ; in contrast, approximately half of those with levels  $< 7\%$  in the first year kept their level  $< 8\%$  over time.

Compared with patients who achieved an HbA1c < 6%, those who achieved a level of 6% - 6.9% were 3.29 times more likely to add or switch medication. Those who achieved levels of 7.0 - 7.9% were 6.54 times more likely.

The time to reach a 50% rate of adding/switching drugs was 36 months among those whose best HbA1c was 7% - 7.9%, versus 84 months for those with levels below 6%.

Another important factor predicting metformin failure was weight loss. The authors report that those who needed to add or switch drugs lost a mean of 1.9 kg, compared with an average loss of 5.0 kg among those who remained on metformin monotherapy.

"Our results indicate that if glycemic control is achieved initially with metformin monotherapy, it can be successfully maintained for several years," Dr. Nichols and his associates conclude.

*Diabetes Care* 2006;29:504-509.

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Item 7

### **Cardiac Medications Prolong Survival in Peripheral Artery Disease**

*Statins, beta blockers, aspirin and angiotensin-converting enzyme (ACE) inhibitors all decrease mortality in patients with peripheral artery disease (PAD), investigators report.*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3605>

Despite treatment guidelines that call for aggressive management of risk factors and lifestyle to slow the progression of PAD, the effects of medications on reducing mortality have not been well-studied, note Dr. Harm H. H. Feringa of Erasmus Medical Center in Rotterdam, the Netherlands, and colleagues.

The team enrolled 2,420 patients with PAD (mean age 64 years, 72% men, ankle-brachial index of 0.90 or less) in an observational study of the effects of cardiac medications and a high-risk lifestyle on longevity.

Of the total, 436 (18%) were diabetics, 581 (24%) had hypercholesterolemia, 837 (35%) were smokers, 1,162 (48%) were hypertensive, 1,056 (44%) had coronary artery disease and 214 (9%) had heart failure.

During a follow-up period of around 8 years, 44% patients died. After adjusting for risk factors, the researchers found that statin therapy had a hazard ratio of 0.46, beta blockers had a hazard ratio of 0.68, aspirin had a hazard ratio of 0.72 and ACE inhibitors carried a hazard ratio of 0.80. All were significantly associated with higher survival.

Dr. Feringa's team points out that the findings conflict with other studies showing that beta blockers can increase mortality in PAD. They note that adding walking or other exercise and risk factor modification, plus multi-drug therapy, could further decrease mortality in patients with PAD.

*J Am Coll Cardiol* 2006;47:1182-1187

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**Ask Dr. Bernstein is a one hour live teleconference call that over 600 people listened too.** A chance to [listen to the call for free](#) and hear Dr. Richard K. Bernstein reply to questions from the listeners, such as What is a Normal Blood Sugar? How to Treat Gastroparesis, and many other questions are answered. [www.diabetes911.net](http://www.diabetes911.net) Sign up for next call on April 27<sup>th</sup>

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Item 8

### **FDA's Approval of Continuous Glucose Sensor Accelerates Development of Artificial Pancreas**

The approval of the 2<sup>nd</sup> CGMS into the market place will push forward research on the closed loop artificial pancreas.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3604>

"Continuous glucose sensors represent a giant leap forward in care for people with diabetes, allowing them to monitor their glucose levels and precisely dose their insulin based on that real-time information," said Aaron Kowalski, PhD, Director of Strategic Research Projects at JDRF. "This technology should greatly improve glycemic control -- which research has shown to be the key to reducing or even eliminating both short and long-term complications of diabetes."

The new device, called the STS Continuous Glucose Monitoring System, from San Diego-based DexCom, Inc., was approved by the Food and Drug Administration for use in people with diabetes. It's the latest product in what is expected to become a competitive market for continuous glucose monitoring products.

Dr. Kowalski noted that research continues to confirm that current diabetes technology is inadequate. Some studies, he said, have found that even those patients who were intensively managing their disease -- measuring their glucose an average of nine times a day -- spent less than 30 percent of the day in normal glucose range. The rest of the time their glucose was either too high (which can cause eye, heart, kidney, and nerve disease), or too low (which can cause seizures, comas, and death). But studies have also found that patients using continuous glucose sensors spent 26 percent more time in normal glucose range, and have statistically significant improvements in HbA1c levels, an important measure of longer-term glucose control.

Monitors such as these are the keys to the eventual development of a closed-loop glucose testing and insulin delivery system, or an "artificial pancreas." Continuous glucose sensors read glucose levels on a minute-by-minute basis using a small sensor that is inserted under the skin, which transmits data to a hand-held device. These devices not only provide actual glucose readings, but can tell a patient whether their glucose level is trending upwards or downwards, allowing them to continually adjust their medication, diet and exercise to prevent high and low glucose levels.

Closed loop technology will provide patients and their doctors with far more information about their daily glucose fluctuations and trends, and allow for far tighter control. Patients who aggressively manage their diabetes typically test their glucose up to eight times a day, and provide insulin injections based on that information. The artificial pancreas will test glucose approximately 1,400 times a day, and make insulin dosing information based on that real-time information.

"The development of an artificial pancreas has been one of JDRF's top research goals, and we are cautiously optimistic that these new products will be as successful and beneficial to people with diabetes as we hope," added Dr. Kowalski. "The next critical steps are for Medicare and private sector insurers to provide reimbursement for these technologies."

*The Juvenile Diabetes Research Foundation*

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**FACT:**

**Once-Weekly Byetta Begins Clinical Study for Type 2 Diabetes:** The 30-week open-label, noninferiority study will assess whether once-weekly exenatide LAR is at least as effective in improving glucose control as twice-daily BYETTA. Approximately 300 subjects with type 2 diabetes who are not achieving adequate glucose control using diet and exercise with or without the use of oral antidiabetic agents will be randomized to one of two treatment groups. All participants who complete the randomized portion of the study will have the opportunity to continue in an extension study and receive once-weekly exenatide LAR. Amylin, Lilly, and Alkermes are working together to develop the sustained release, subcutaneous injection of exenatide for the treatment of type 2 diabetes based on Alkermes' proprietary Medisorb® technology

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Item 9

**Ankle/brachial Index Helps Identify Peripheral Artery Disease in Diabetics**

*Measurement of the ankle/brachial index (ABI) is a simple way of identifying patients with diabetes who are at increased risk of future cardiovascular disease.*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3603>

Dr. Paul E. Norman and colleagues from the University of Western Australia, Fremantle, examined the natural history of peripheral artery disease (PAD) complicating type 2 diabetes. Specifically, they assessed the influence of PAD on the risk of cardiovascular death and whether PAD risk factor management is adequate. The team used data from the Fremantle Diabetes Study (FDS), a prospective community-based observational study of diabetics recruited between 1993 and 1996.

Included in the current analysis were 1294 type 2 diabetics and a subgroup of 531 type 2 diabetics with complete data at baseline and at least five subsequent annual reviews. A range of clinical and biochemical variables were assessed, including ABI. The investigators defined PAD as an ABI of no more than 0.90 at two consecutive reviews or any PAD-related lower-extremity amputation.

The prevalence of PAD at baseline was 13.6%. The incidence of new PAD was 3.7 per 100 patient-years. A strong independent association was observed between both prevalent and incident PAD and increasing age, systolic blood pressure, total serum cholesterol, and smoking. While risk factor management improved, it remained suboptimal during follow-up, according to the authors. An association was found between a baseline ABI of no more than 0.90 and an increased risk of cardiac death of 67%.

"PAD is relatively common in diabetic patients, even when stringent criteria for the diagnosis of prevalent and incident disease are used," Dr. Norman and colleagues explain. "This further supports the American Diabetes Association's recommendation for regular screening in the context of optimized vascular risk management."

*Diabetes Care* 2006;29:575-580

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Item 10

**FDA Accepts New Drug Application for Diabetes Drug Galvus**

*Clinical studies show significant blood sugar reductions (HbA1c) sustained for one year - Trials also show no association with weight gain; overall incidence of side effects, including hypoglycemia and edema, similar to placebo - Regulatory submission includes results from more than 4,300 patients.*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3602>

Novartis announced today that the new drug application (NDA) for Galvus(R)\* (vildagliptin, formerly LAF237) was accepted for standard review by the U.S. Food and Drug Administration (FDA). If approved, Galvus will provide a new, once-daily oral treatment option for people with type 2 diabetes. Submission for approval in Europe is on track to be completed later in 2006.

Galvus, a DPP-4 inhibitor, works through a novel mechanism of action targeting the pancreatic islet dysfunction that causes high blood sugar levels in people with type 2 diabetes. Galvus affects both pancreatic alpha and beta cells, leading to a reduction in sugar production from the liver together with an increase in production of insulin needed to keep blood sugar under control.

The submission includes data from clinical trials involving more than 4,300 patients worldwide evaluating the use of Galvus as monotherapy and also in combination with commonly prescribed anti-diabetic agents. Galvus is suitable for once-daily dosing. Overall, Galvus has shown clinically significant HbA1c reductions out to one year of treatment, with good overall tolerability and without causing weight gain. The most common side effects were cold-like symptoms, headache and dizziness.

"Most of the treatments that we use today focus primarily on stimulating insulin secretion or lowering resistance," said Vivian Fonseca, MD, Professor of Medicine, Chief of Endocrinology and Metabolism, Tulane University Health Sciences Center, New Orleans, Louisiana. "The positive clinical results we've seen to date with Galvus underscore the importance and promise of addressing the dysfunction of both the pancreatic beta- and alpha-cells."

About Galvus

In clinical studies, Galvus has demonstrated significant reductions in blood sugar for one year. Galvus is suitable for once-daily dosing and has been evaluated both as monotherapy and in combination with other anti-diabetes agents. Galvus was not associated with overall weight gain, a key benefit for people with diabetes who struggle to keep their weight under control. The overall incidence of side effects with Galvus including hypoglycemia (excessively low blood sugar) and edema (fluid retention) was similar to placebo. Galvus lowers blood sugar by targeting islet dysfunction, i.e., it improves the ability of the islet's alpha- and beta-cells to appropriately sense and respond to sugar in the blood. *Looks like vildagliptin (LAF237) is the current leader over sitagliptin (MK 0431) and saxagliptin (BMS-477118)*

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Item 11

**Low-Carb Diet Controls Diabetes Without Weight Loss Or Insulin Use**

*A new study released in the scientific journal Nutrition & Metabolism found that type 2 diabetes can be managed and controlled simply by minor changes in the diet alone without the need for weight loss or the use of insulin medications.*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3601>

**Dr. Mary C. Gannon** and **Dr. Frank Q. Nuttall**, both from the **Center For Diabetes Research** at the University of Minnesota, Minneapolis, wanted to test a theory that you can bring about improvements in patients with type 2 diabetes that do not require weight loss or insulin to control the blood glucose concentration. What they wanted to know was if it was possible to do this by changing the KIND of foods eaten rather than the AMOUNT of food consumed.

For the study, they looked at the protein:carbohydrate:fat ratios of three groups of patients with untreated type 2 diabetes over a 5-week period.

One group had a 15:55:30 ratio (commonly known as the low-fat diet), another group had a 30:40:30 ratio (which closely resembles The Zone diet), and the final group had a 30:20:50 ratio (you know as livin' la vida low-carb).

The 30:40:30 ratio diet saw a moderate but significant decrease in 24-hour integrated blood glucose area and percentage of total glycohemoglobin (%GHb). But, even more exciting, was the 30:20:50 ratio diet group (low-carb) which saw an amazing 38 percent drop in the 24-hour glucose area, which was a reduction in fasting glucose that resemble close to "normal" readings and the %GHb fell more than two percentage points from 9.8% to 7.6%. The 30:30:40 ratio diet saw similar results.

Based on these results, Dr. Gannon and Dr. Nuttall concluded that changes in diet alone could indeed help control diabetes without the need for weight loss or medication.

*"Altering the diet composition could be a patient-empowering method of improving the hyperglycemia of type 2 diabetes without weight loss or pharmacologic intervention," the researchers explained.*

**Take away notes:**

*"The protein in the low-carb diets that aided the production of insulin in the study participants because protein actually stimulates the production of insulin."*

*"If you increase insulin, then you decrease glucose," Dr. Gannon explained at the conference.*

*"Fats can delay the digestion of carbohydrates which is why consuming fat is so important as part of a healthy eating plan, especially for diabetics who want to control their blood glucose levels.*

*Since starchy foods are 100% glucose, they are directly responsible for raising blood glucose levels to dangerous levels for type 2 diabetics."*

*Nutrition & Metabolism 2006, 3:16*

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**DID YOU KNOW:**

**Diabetes Risk Increased Three-fold By More Than Eight Hours Sleep Per Night:** Men who sleep too much or too little are at an increased risk of developing Type 2 diabetes, according to a study by the New England Research Institutes in collaboration with Yale School of Medicine researchers. The data were obtained from 1,709 men, 40 to 70 years old and followed for 15 years. Six to eight hours of sleep was found to be most healthy. In contrast, men who reported they slept between five and six hours per night were twice as likely to develop diabetes and men who slept more than eight hours per night were three times as likely to develop diabetes. *Diabetes Care 29: 657-661 (March 2006)*

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Item 12

**Empire Study: Effects of Rosiglitazone + Submaximal Doses of Metformin Verses Increasing Does of Metromin in Type 2 Diabetes**

*Addition of Rosiglitazone to submaximal doses of MET may be a suitable alternative to the maximal effective dose of MET monotherapy.*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3600>

The study was designed to compare the efficacy, safety and tolerability of rosiglitazone (RSG) added to submaximal doses of metformin (MET) with dose escalation to the maximal effective dose of MET monotherapy in type 2 diabetes mellitus.

In this multi-center, double-blind, randomized, parallel-group study, 766 subjects with a baseline MET dose of 1000 mg/day were randomized to receive either RSG 4 mg/day (4 mg/1000 mg) or MET 500 mg/day (1500 mg/day total dose) for 8 weeks. Only the RSG dose was increased in the combination group - to 8 mg/day (8 mg/1000 mg) - and only the MET dose was increased in the MET monotherapy group - to 2000 mg/day for the remaining 16 weeks.

The results showed that after 24 weeks, RSG added to MET (8 mg/1000 mg/day) was at least as effective as 2000 mg/day of MET in improving HbA(1c), with mean reductions of -0.93% and

-0.71%, respectively, from baseline in subjects that completed the study according to the investigator (mean treatment effect/difference of -0.20%). In addition, a higher percentage of subjects in the RSG + MET group achieved American Diabetes Association

target levels of HbA(1c) < 7% (58.1% versus 48.4%) and American Association of Clinical Endocrinologists target levels of HbA(1c) <or= 6.5% (40.9% versus 28.2%). This combination provided significantly greater reductions from baseline in fasting plasma glucose (FPG; -2.29 mmol/L and -1.12 mmol/L, respectively), with a treatment difference of -0.85 mmol/L.

For the intent-to-treat (ITT) population, the percentage of subjects experiencing a gastrointestinal side-effect was 27.9% and 38.7% for the RSG + MET and MET groups, respectively. Mean body weight (+/- SD) increased in all randomized subjects treated with the combination therapy (+ 1.79 +/- 4.15 kg) compared with a mean weight loss in the up-titrated MET group (-1.78 +/- 3.50 kg).

From the results it was concluded that this study suggests that addition of RSG to submaximal doses of MET may be a suitable alternative to the maximal effective dose of MET monotherapy.

*Curr Med Res Opin.* 2005 Dec;21(12):2029-35. Weissman P, Goldstein BJ, Rosenstock J,

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Item 13

### **Therapeutic Efficacy of Mitiglinide + Glargine Vs. Basal Bolus Therapy**

*Mitiglinide plus insulin glargine combination therapy is useful for lowering both fasting and postprandial hyperglycemia in a subpopulation of type 2 diabetes.*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3599>

In this study, researchers evaluated the effects on control of fasting and postprandial hyperglycaemia of pre-meal mitiglinide therapy when used in combination with once daily insulin glargine in inpatients with type 2 diabetes.

Mitiglinide is novel class of rapid-acting insulin secretagogues, which have been widely used alone or in combination with other oral hypoglycemic drugs to improve postprandial hyperglycemia in early type 2 diabetes. While mitiglinide enhances postprandial requirement of insulin, the efficacy of mitiglinide combined with insulin has yet to be established. We investigated the efficacy of mitiglinide combined with insulin glargine, the first soluble insulin analog that has a flat and prolonged effect.

After control with the intensive regimen (daily aspart insulin and glargine), 30 inpatients with type 2 diabetes were switched to premeal mitiglinide combined with once daily insulin glargine (mitiglinide regimen), and daily profiles of blood glucose level were compared under each regimen. Fifteen patients showed similar control of hyperglycemia with mitiglinide regimen and intensive insulin regimen, assessed by M value (<32), while the remaining 15 showed worsening under the mitiglinide regimen. The patients who were well controlled with mitiglinide regimen were significantly younger (51.9 +/- 16.0 years, p<0.005) and heavier (body mass index: 25.7 +/- 3.3 kg/m<sup>2</sup>), p<0.05) than those who were not (67.9 +/- 8.7 and 23.0 +/- 3.1, respectively).

Moreover, insulin doses of aspart per body weight were significantly fewer in effective group than in ineffective group. Duration of diabetes was shorter in the effective group, albeit insignificantly. Previous treatment before starting intensive insulin regimen, such as insulin and sulfonylurea, was not different between the two groups.

Our results suggest that mitiglinide plus insulin glargine combination therapy is useful for lowering both fasting and postprandial hyperglycemia in a subpopulation of type 2 diabetes. The long-term effects of such treatment need to be established in future studies.

*Endocr J.* 2006 Feb;53(1):67-72. Yoshihara T, Kumashiro N, Kanazawa Y, Mita T, Sakurai Y,

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## FACT:

**Glufast Is A New Insulinotropic Agent With Rapid Onset, which may be coming to market soon.** Mitiglinide calcium hydrate (mitiglinide, Glufast) is a new insulinotropic agent of the glinide class with rapid onset. Mitiglinide is thought to stimulate insulin secretion by closing the ATP-sensitive K(+) (K(ATP)) channels in pancreatic beta-cells, and its early insulin release and short duration of action would be effective in improving postprandial hyperglycemia. In studies mitiglinide \was more potent than that of nateglinide, and mitiglinide controlling postprandial hyperglycemia. *Folia Pharmacologica Japonica Vol. 124 (2004) , No. 4 245-255, Ojima K, Kiyono Y, Kojima M. See Item #1 from this weeks newsletter.*

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Item 14

### **Three-Week Diet/Exercise Study Shows 50% Reversal in Type 2 Diabetes**

*Obese and overweight individuals suffering Type 2 diabetes showed significant health improvements after only three weeks of diet and moderate exercise even though the participants remained overweight.*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3598>

"The study shows, contrary to common belief, that Type 2 diabetes and metabolic syndrome can be reversed solely through lifestyle changes," according to lead researcher Christian Roberts of University of California, Los Angeles.

"This regimen reversed a clinical diagnosis of Type 2 diabetes or metabolic syndrome in about half the participants who had either of those conditions. However, the regimen may not have reversed damage such as plaque development in the arteries," Roberts said.

"However, if Type 2 diabetes and metabolic syndrome continue to be controlled, further damage would likely be minimized and it's plausible that continuing to follow the program long-term may result in reversal of atherosclerosis."

"The results are all the more interesting because the changes occurred in the absence of major weight loss, challenging the commonly held belief that individuals must normalize their weight before achieving health benefits," Roberts said. Participants did lose two to three pounds per week, but they were still obese after the 3-week study.

The study, "Effect of a diet and exercise intervention on oxidative stress, inflammation, MMP-9, and monocyte chemotactic activity in men with metabolic syndrome factors." The study involved 31 men who ate a high-fiber, low-fat diet with no limit to the number of calories they could consume. The participants also did 45-60 minutes of aerobic exercise per day on a treadmill.

Fifteen of the men had metabolic syndrome, a condition that is characterized by excessive abdominal fat, insulin resistance, and blood fat disorders such as high levels of triglycerides (fat in the blood) or low levels of HDL (high density lipoprotein, or "good" cholesterol). Thirteen of the participants had Type 2 diabetes. There was also some overlap between the two groups and some participants who had neither metabolic syndrome nor Type 2 diabetes, but were overweight or obese.

"The diet, combined with moderate exercise, improved many factors that contribute to heart disease and that are indirect measures of plaque progression in the arteries, including insulin resistance, high cholesterol, and markers of developing atherosclerosis," Roberts said. "The approach used in this experiment of combining exercise with a diet of unlimited calories is unusual."

The participants in the current study, who ranged in age from 46 to 76 years old, took part in a 21-day residential program at the Pritikin Longevity Center, formerly in Santa Monica, combining the Pritikin diet and exercise program. The daily diet was low fat (12-15% of calories), moderate protein (15-20% of calories), and high in unrefined carbohydrates (65-70% of calories) and fiber (more than 40 grams).

Natural foods -- whole grains (five or more servings daily), vegetables (four or more servings), and fruits (three or more servings) -- were the main source of daily carbohydrates. The sources of protein were plants (such as soy, beans, and nuts), nonfat dairy (up to two servings daily), and fish and poultry (3.5-ounce portion once a week and

in soups and casseroles twice a week). The remainder of the calories came from fat with a polyunsaturated-to-saturated fatty acid ratio of 2.4 to 1.

"Aside from meat and dairy, the study participants could eat as much as they wanted," Roberts said. "Because the food was not as high calorie as a typical American diet, the participants ate less before feeling full. This is a departure from most diets, which usually leave the dieter feeling hungry," he said.

The men also exercised daily on a treadmill, including level and graded walking, for 45 - 60 minutes. The exercise program was tailored to ensure each individual reached 70 -85% of maximum heart rate.

Scientists also need to determine whether long-term lifestyle change can prevent or reverse end-organ damage noted in those with metabolic syndrome or Type 2 diabetes, Roberts said. These changes may be difficult to make but the payoff for individuals and society could be enormous.

*online edition of the Journal of Applied Physiology published by the American Physiological Society. Researchers were Christian K. Roberts, Dean Won, Sandeep Pruthi, Silvia Kurtovic, and R. James Barnard, all of UCLA; Ram K. Sindhu of Charles R. Drew University, Los Angeles; and Nosratola D. Vaziri of University of California, Irvine.*

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Item 15

### **Postprandial Glucose Regulation: New Implications**

*Physicians and educators should be also targeting postprandial regulation, which has been shown to improve glucose control and to reduce the progression of atherosclerosis and CV events.*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=3597>

Type 2 diabetes is characterized by a gradual decline in insulin secretion in response to nutrient loads; hence, it is primarily a disorder of postprandial glucose (PPG) regulation. However, physicians continue to rely on fasting plasma glucose (FPG) and glycosylated hemoglobin (HbA1c) to guide management.

The objectives of this article are to review current data on postprandial hyperglycemia and to assess whether, and how, management of type 2 diabetes should change to reflect new clinical findings.

Articles were selected from MEDLINE searches (key words: postprandial glucose, postprandial hyperglycemia, and cardiovascular disease) and from our personal reference files, with emphasis on the contribution of postprandial hyperglycemia to overall glycemic load or cardiovascular (CV) risk.

The results showed that about 33% of people diagnosed as having type 2 diabetes based on postprandial hyperglycemia have normal FPG. PPG contributes > or =70% to the total glycemic load in patients who are fairly well controlled (HbA1c <7.3%). Furthermore, there is a linear relationship between the risk of CV death and the 2-hour oral glucose tolerance test (OGTT). Increased mortality is evident at OGTT levels of approximately 90 mg/dL (5 mmol/L), which is well below current definitions of type 2 diabetes. Biphasic insulin aspart was shown to be more effective at reducing HbA1c below current ly recommended levels than basal insulin glargine (66% vs 40%; P < 0.001), and it reduced endothelial dysfunction more effectively than regular insulin (P < 0.01). Repaglinide achieved regression of carotid atherosclerosis (intima-media thickness) in 52% of patients versus 18% for glyburide (P < 0.01) over 1 year, although levels of HbA1c and CV risk factors were similar for both treatment groups. Finally, acarbose reduced the relative risk of CV events by 49% over 3.3 years versus placebo in patients with impaired

glucose tolerance (2.2% vs 4.7%; P = 0.03) and by 35% over > or =1 year in patients with type 2 diabetes (9.4% vs 6.1%; P = 0.006).

From the results it was concluded that all components of the glucose triad (ie, FPG, HbA1c, and PPG) should be considered in the management of type 2 diabetes. Therapy targeted at PPG has been shown to improve glucose control and to reduce the progression of atherosclerosis and CV events; therefore, physicians should consider monitoring and targeting PPG, as well as HbA1c and FPG, in patients with type 2 diabetes.

*Clin Ther.* 2005;27 Suppl B:S42-56. Leiter LA, Ceriello A, Davidson JA, Hanefeld M, Monnier L, Owens DR, Tajima N, Tuomilehto J; International Prandial Glucose Regulation Study Group.

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## Quote of the Week!

*“As I grow older, I pay less attention to what men say. I just watch what they do.”*

**Andrew Carnegie (1835-1919)**

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