

# DIABETES IN CONTROL.com Newsletter

The Newsletter for Professionals in Diabetes Care

May 16, 2007 - Issue #364

See this week's articles on the new direction for a possible Cure for Diabetes!

Do you or your patients use a shallow angle set for your pump? Please [Click here](#) to learn about a new set with a built in self-injector.

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

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## Top Diabetes Stories:

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**Using PET Scan to Validate Beta-Cell Growth and Regeneration\***

<http://www.diabetesincontrol.com/results.php?storyarticle=4808>

**The Stem Cells That Weren't There\***

<http://www.diabetesincontrol.com/results.php?storyarticle=4807>

**Do Precursor Beta-Cells Exist After Birth?\***

<http://www.diabetesincontrol.com/results.php?storyarticle=4806>

**Short-Term Risk for Stroke Is Doubled in Newly Diagnosed Type 2's\***

<http://www.diabetesincontrol.com/results.php?storyarticle=4804>

**Low-Dose Aspirin Best for CVD Prevention\***

<http://www.diabetesincontrol.com/results.php?storyarticle=4803>

**Low-fat Dairy Foods Can Reduce the Risk of Type 2 Diabetes\***

<http://www.diabetesincontrol.com/results.php?storyarticle=4800>

**iPods Can Make Pacemakers Malfunction\***

<http://www.diabetesincontrol.com/results.php?storyarticle=4798>

**New Communication Method Helps Families Change Lifestyle Behaviors\***

<http://www.diabetesincontrol.com/results.php?storyarticle=4796>

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## From the editor's desk

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This week our publisher **Steve Freed, BSPHarm** has put together 3 exciting articles that discuss the possible new direction for a diabetes cure. We know that if we can provide new beta-cells that produce insulin, then we might have a possible cure for Type 1 diabetes and a new treatment for Type 2 diabetes. There are many questions that still need to be answered, including the auto-immune reaction that kills our beta-cells, but if we can find a way to continue to produce our own beta-cells, then we can learn how to keep the bucket filled enough so our bodies will continue to produce insulin. The first article, "*Using PET Scan to Validate Beta-Cell Growth and Regeneration*", discusses ways to measure the growth of beta-cells in the pancreas in live people, which was not available before. The second article, "*The Stem Cells That Weren't There*", talks about the discovery that stem cells do not turn into beta-cells, that they regenerate and grow themselves. And the third article, "*Do Precursor Beta-Cells Exist After Birth?*," discusses how we have precursor cells already that can become beta-cells.

This year at ADA in June, our reporters will focus on all the new studies and evidence that is directed to finding a possible cure with the regeneration of beta-cells and will report back to you our findings.

Have you ever had a patient ask, how much do our genes contribute to our risk of developing diabetes? Or, "Diabetes seems to run in my family. Am I doomed to developing the disease too?" **Phil Wood DVM, MS, PhD** gives us a way to answer in his feature *Genetics of Type 2 Diabetes: Concepts of Risk Rather Than Cause*.

<http://www.diabetesincontrol.com/results.php?storyarticle=4809>

If your patients are going to start any new exercise program then they need to know how to avoid injuring and what to do about the inevitable muscle. **Dr. Sheri Colberg** has an excerpt from her book *The 7 Step Diabetes Fitness Plan: Living Well and Being Fit with Diabetes, No Matter Your Weight*. *Dealing with Injuries or Muscle Soreness Due to Exercise*

<http://www.diabetesincontrol.com/results.php?storyarticle=4810>

We need a few more people for a new study for patients who use a shallow angle set with their pump. Please [click here](#) to find out more.

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

### dLife May 20, 7PM ET on CNBC

The state of diabetes care in America – are we making the grade? Plus, diabetes education in a beauty salon, and an exclusive, behind-the-scenes look at diabetes advances at the National Institutes of Health. Tune in for an encore 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 #4: Being Thin, Doesn't Mean You Are Not Fat
- Item #7: Sitagliptin+Metformin Effective in Type 2 Diabetes
- Item #8: Treating vs. Screening Asymptomatic Diabetics for CAD
- Item #10: Antioxidant Achieves a 64% Reduction In the Onset of Diabetes
- Item #12: Diabetes and Heart Failure Is Double Trouble for Older Women
- Item #14: Long-Term Adult-Strength Aspirin Use May Reduce Overall Cancer Incidence
- Item #15: Coronary Calcification Independently Predicts All-Cause Mortality

Check out this weeks **“Test Your Knowledge”** question.

<http://www.diabetesincontrol.com/results.php?storyarticle=4811>

Dave Joffe, *Editor-in-Chief*

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### NEWS FLASH:

#### Senate Passes Watered-Down Drug Importation Amendment

After nearly a week of debate, the Senate passed by voice vote an amendment allowing drug importation, but only after approving a modification to the measure that makes it essentially meaningless. An amendment sponsored by Sens. Byron Dorgan (D-N.D.), Olympia Snowe (R-Maine) and Chuck Grassley (R-Iowa) that would allow prescription drugs to be imported from certain countries passed the Senate May 7.

However, the Senate also passed a second-degree amendment from Sen. Thad Cochran (R-Miss.) that would require the secretary of HHS to certify that allowing imported drugs would not endanger American citizens and would result in lower prices. **That move seemingly gutted Dorgan's amendment, as the FDA has previously said it is unable to ensure the safety of imported drugs.**

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### Tools for your Practice:

#### Eight Dieting Strategies That Work

Consumer Reports highlights strategies based on the latest research and statistics gleaned from the National Weight Control Registry, which enrolls people who have documented that they lost 30 pounds and kept the weight off for at least a year. Here are the 8 top strategies outlined in the report: [Eight Dieting Strategies That Work](http://www.diabetesincontrol.com/issues/Issue%20364/Eight%20Dieting%20Strategies%20That%20Work.pdf)  
<http://www.diabetesincontrol.com/issues/Issue 364/Eight Dieting Strategies That Work.pdf>

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### New Product:

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- Mild compression
- Latex Free

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## This Week's Items:

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<http://www.diabetesincontrol.com/results.php?storyarticle=4808>
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<http://www.diabetesincontrol.com/results.php?storyarticle=4807>
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15. **Coronary Calcification Independently Predicts All-Cause Mortality**  
<http://www.diabetesincontrol.com/results.php?storyarticle=4794>

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## ITEMS For The Week:

Item 1

### Using PET Scan to Validate Beta-Cell Growth and Regeneration

*We now might have a non-invasive way to measure beta-cell growth and apoptosis for determining effectiveness of new treatment therapies that can cause beta-cell regeneration or increase of beta-cell mass instead.*

<http://www.diabetesincontrol.com/results.php?storyarticle=4808>

Fluorine-18-dihydroxyphenylalanine (18F-DOPA) positron emission tomography (PET) can be used to localize insulinoma or beta-cell hyperplasia in adult patients, according to a report in the April issue of The Journal of Clinical Endocrinology & Metabolism.

Conventional imaging studies have long been used for tumor localization in patients with insulinoma or beta-cell hyperplasia, the authors explain, but all such methods either have limited sensitivity or are invasive procedures.

Dr. Pirjo Nuutila from Turku University Hospital, Finland and colleagues compared the diagnostic sensitivity of 18F-DOPA PET with conventional methods in 10 hyperinsulinemic and hypoglycemic adults.

The PET images localized the lesion in 6 of 7 patients with insulinoma, in the case of insulinoma metastatic to the liver, and in the two patients with beta-cell hyperplasia, the authors report.

18F-DOPA PET was more sensitive (90%) than CT (30%) or MRI (40%) in identifying the disease focus, the report indicates, and 18F-DOPA provided additional information for surgery that was obtained with none of the other imaging procedures.

Symptoms of hypoglycemia resolved after operation in 9 of the 10 patients, the researchers note.

"Because L-DOPA also accumulates physiologically in the normal pancreas, 18F-DOPA PET is a useful diagnostic tool only for patients with confirmed inappropriate insulin secretion," the investigators say.

"Future studies are likely to be performed with hybrid PET/CT scanners, which enable correlation of anatomical and functional information within one imaging session," they add, concluding: "18F-DOPA PET has the potential to become the functional imaging method of the future, once the results reported here are confirmed in a larger patient population."

*J Clin Endocrinol Metab* 2007;92:1237-1244.

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Item 2

### **The Stem Cells That Weren't There**

*The stem cells that make the beta-cells May Not Exist!*

<http://www.diabetesincontrol.com/results.php?storyarticle=4807>

*Diabetes researchers, investigating how the body supplies itself with insulin, discovered to their surprise that adult stem cells, which they expected to play a crucial role in the process, were nowhere to be found. Instead, the insulin-producing beta cells themselves divide and replenish their own population. The basic science finding may point to new future diabetes treatments.*

Diabetes researchers, investigating how the body supplies itself with insulin, discovered to their surprise that adult stem cells, which they expected to play a crucial role in the process, were nowhere to be found. Many researchers had proposed that adult stem cells develop into insulin-producing cells, called beta cells, in the pancreas. Instead, the beta cells themselves divide, although slowly, to replenish their own population.

"Ultimately, if diabetes researchers learn how to control insulin production, we can better treat patients who now can't produce insulin--children and adults with type 1 diabetes," said study leader Jake A. Kushner, M.D., a pediatric endocrinologist at The Children's Hospital of Philadelphia. "This research tells us that we need to better understand what regulates the growth of beta cells, rather than searching for adult stem cells that give rise to beta cells."

The discovery does not have immediate implications for diabetes treatment. Rather, it advances basic knowledge of insulin biology that could form a foundation for eventual therapies.

Currently, patients with type 1 diabetes depend on life-saving insulin injections or medication. Looking to future techniques, medical researchers hope to fulfill a promise of regenerative medicine: restoring the body's ability to produce its own insulin. One solution is to transplant tissues called the islets of langerhans, small masses within the pancreas containing the beta cells that normally secrete insulin. Islet transplants have already been performed experimentally, but typically fail after a few years in a patient's body.

Moreover, islets are taken from cadavers, and supplies are very limited, so researchers are seeking ways to grow islets in the laboratory. Another potential implication of the research is for beta cell regeneration, a controversial area of diabetes research. Patients with longstanding type 1 diabetes have small amounts of islets that escape destruction by the immune system. With sufficient biological knowledge and the appropriate techniques, it might even be possible to someday stimulate these residual beta cells inside patients to proliferate and produce healthy amounts of insulin.

“We expected to find adult stem cells that differentiate into beta cells,” said Kushner. “Such adult stem cells are important in renewing skin, intestines and other tissues.” (Adult stem cells are different from the embryonic stem cells found in human embryos that are a current focus of social and political controversies.)

“However,” he added, “we found no evidence for adult stem cells that give rise to beta cells or other pancreatic tissue. We found that all beta cells can replicate, and are, in a sense, their own stem cells.”

Kushner’s group found that beta cells renew themselves and grow slowly. Unexpectedly, the researchers found the beta cells undergo a prolonged waiting period before dividing. This delay, which they call a replication refractory period, had never been observed in mammalian development.

The researchers made use of a novel cell labeling technique that allows them to view the fates of individual cells throughout multiple rounds of cell divisions. “Although the cell labeling technique had been described previously by other groups, our group was the first to use it over long periods of time,” said Kushner.

By providing rats with a timed sequence of colored dyes in their drinking water, the researchers were able to see discrete beta cells in the rat pancreas, shining in single colors that indicated a sequence of cell divisions. In contrast, the rapidly dividing cells in the rats’ intestine showed blended colors, indicating that they had divided multiple times from specialized cells—possibly from adult stem cells.

If these findings open up a new avenue of investigation into how insulin-producing cells develop, diabetes researchers may be a step closer to manipulating the process to benefit patients. “This research also has implications for type 2 diabetes, in which the body fails to produce and respond to insulin,” added Kushner.

*Dr. Kushner’s team reported their findings, based on animal studies, in the May issue of Developmental Cell.*

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## **DID YOU KNOW:**

**Ingestion of even small amounts of alcohol may impair the ability to detect hypoglycemia.** Mild alcohol intoxication may also contribute to impaired recovery of blood glucose in patients with type 1 diabetes. This may, at least in part, be explained by an attenuated growth-hormone response to hypoglycemia associated with mild alcohol intoxication. *Diabetic Medicine*, 24 (312-316): Kerr D, Cheyne E, Thomas P, Sherwin R Influence of acute alcohol ingestion on the hormonal responses to modest hypoglycaemia in patients with Type 1 diabetes

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Item 3

### **Do Precursor Beta-Cells Exist After Birth?**

*If precursor beta-cells exist, then it can give focus to the development of innovative therapeutic techniques which can possibly stimulate the formation of new endogenous beta-cells.*

<http://www.diabetesincontrol.com/results.php?storyarticle=4806>

Diabetes occurs when there is an inadequate functional mass of insulin-producing pancreatic  $\beta$  cells. Replacement of  $\beta$  cells by islet transplantation is a novel therapy for diabetes, although a major obstacle has been the limited amount of islet tissue available. A rigorous demonstration of the existence of postnatal pancreatic progenitor cells would clearly give focus to the development of innovative therapeutic techniques, including possibly stimulating formation of new endogenous  $\beta$  cells.

Throughout life,  $\beta$ -cell mass is dynamic with compensatory changes to meet demand and replenish the slow turnover of cells, suggesting either a capacity of  $\beta$  cells to regulate their mass and/or the presence of stem cells or progenitor cells that can differentiate into insulin-producing cells by the process of NEOGENESIS. In mice, rats, and humans the  $\beta$ -cell mass remains linear with body weight or BMI. The mass of  $\beta$ -cells increases by replication of existing  $\beta$  cells and increases in cell volume (hypertrophy). Additionally, islet neogenesis has long been assumed to contribute throughout much of life.

Although ongoing lineage-tracing studies might prove conclusively whether neogenesis actually happens, the current, overwhelming evidence is that it does. In rats, they have found two waves of neogenesis: one immediately after birth and the second before weaning. It was estimated that between days 20 and 31, the  $\beta$ -cell number triples and that at least 30% of the new  $\beta$  cells are not derived from replication of pre-existing  $\beta$  cells. After 90% pancreatectomy, adult rats show substantial pancreatic regeneration that is achieved by both replication of pre-existing endocrine or exocrine cells and proliferation of ducts and their subsequent

differentiation into new pancreatic lobes. Judged by the increased presence of hormone-producing cells in the ductal epithelium, increased neogenesis has also been reported in a number of other experimental conditions, including treatment with glucagon-like peptide 1 or exendin 4. In these models, transient ductal expression of the transcription factor Pdx1 precedes any increase in the number of hormone-positive cells. In human pancreas, neogenesis could potentially have a more important role than increased replication in the compensation of  $\beta$ -cell mass seen with obesity. Replication is very low in human  $\beta$  cells; in individuals with obesity, pancreatic neogenic regions with many ductal cross-sections containing hormone-positive cells are seen more commonly than the enlarged islets that would result from enhanced replication. Both mechanisms for adding new  $\beta$  cells (replication and neogenesis) are likely to be functional after birth in all species, but they might make different contributions in different species.

If neogenesis occurs, it implies the existence of stem cells or progenitor cells. Although there have been recent reports of multipotential clonogenic stem cells or progenitor cells isolated from pancreas, estimating the number of progenitors needed to make a new islet could support the role of a particular cell type. As the nature of the progenitor cells is unknown, we can only estimate their doubling time from the data for rodent cell-cycle length (=10 or 12 h). In the adult rat pancreatectomy model, we find islets in newly forming lobes at 3 days postsurgery—48 h after increased replication is seen in the pancreatic remnant. For each typical islet (150  $\mu$ m diameter, composed of ~1,500 endocrine cells) formed within this 48 h window, at least 32 (5 doublings of 10 h each) or 64 (4 doublings of 12 h each) progenitor cells would be required. Hence, we expect that significant numbers of progenitor cells must replicate to give rise to the multiple new islets formed by 72 h. Also, hormone-producing cells are observed within the basement membrane of ducts, which are composed of ductal epithelial cells with occasional undifferentiated basal cells. We therefore consider that ductal epithelial cells are likely to be the progenitors. As ductal cells replicate they transiently express Pdx1, which is also widely expressed in the embryonic pancreatic progenitors but restricted to  $\beta$  and  $\delta$  cells by the time of birth. We hypothesize that a rapidly replicating, mature duct cell transiently assumes a less-differentiated and less-restricted phenotype that can redifferentiate into any of the pancreatic cell types. Such plasticity would provide abundant multipotent progenitors in adult pancreatic ducts for the normal renewal process. Additional support for this dedifferentiation concept comes from *ex vivo* studies with human islet-depleted pancreatic tissue, which, after expansion and manipulation of the culture conditions, forms glucose-responsive, insulin-containing islet tissue budding from ductal cysts. Similar *in vitro* plasticity has been suggested for acinar cells and even pancreatic  $\beta$  cells.

The concept of a ductal origin of new  $\beta$  cells has been supported by the identification of markers expressed in the  $\beta$  cells of newly formed islets after partial pancreatectomy. Gene expression profiles of  $\beta$  cells excised by laser capture microdissection from islets in both old and new lobes of the same adult pancreas were compared. Six differentially expressed genes have been confirmed by reverse transcription polymerase chain reaction and immunostaining to have high expression in  $\beta$  cells of new islets and very low expression in older islets. Additionally, these genes were highly expressed in adult ductal cells and  $\beta$  cells of neonatal rats. The transient expression of these multiple markers in both newly regenerated and neonatal  $\beta$  cells, but not mature adult  $\beta$  cells, and their sustained expression in pancreatic ducts strongly support a ductal origin of the  $\beta$  cell.

One implication of the pancreatic ducts as a progenitor pool is that they might be unlimited *in vivo* and, if triggered to differentiate, could meet the demand for insulin secretion caused by obesity or insulin resistance. Unlimited islet formation, however, could result in life-threatening hypoglycemia, so there must be regulatory mechanisms to control ductal proliferation and differentiation, thus limiting neogenesis. Consequently, understanding the regulation of neogenesis following stimulation could lead to islet replacement therapies *in vitro*, as well as *in vivo*.

*Nat Clin Pract Endocrinol Metab.* 2006;2(5):240-241.

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## **Being Thin, Doesn't Mean You Are Not Fat**

*Because internal deposits can cause trouble then really is what's on the inside that counts and a lot of thin people might be in trouble.*

<http://www.diabetesincontrol.com/results.php?storyarticle=4805>

Some doctors now think that the internal fat surrounding vital organs like the heart, liver or pancreas -- invisible to the naked eye -- could be as dangerous as the more obvious external fat that bulges underneath the skin.

"Being thin doesn't automatically mean you're not fat," said Dr. Jimmy Bell, a professor of molecular imaging at Imperial College, London.

Since 1994, Bell and his team have scanned nearly 800 people with MRI machines to create "fat maps" showing where people store fat. The data show that people who maintain their weight through diet rather than exercise are likely to have major deposits of internal fat, even if they are otherwise slim.

"The whole concept of being fat needs to be redefined," said Bell, whose research is funded by Britain's Medical Research Council. Doctors worry that thin people, lacking a clear warning signal, such as a rounder middle, may be lulled into assuming falsely that because they're not overweight, they're healthy. "Just because someone is lean doesn't make them immune to diabetes or other risk factors for heart disease," said Dr. Louis Teichholz, chief of cardiology at Hackensack University Medical Center in New Jersey, who was not involved in Bell's research.

Even people with normal body mass index scores, a standard obesity measure, can have surprising levels of fat deposits inside. Of the women Bell and his colleagues scanned, as many as 45 percent of those with normal BMI scores (20 to 25) actually had excessive levels of internal fat. Among men, the percentage was nearly 60 percent.

Relating the news to what Bell calls TOFIs -- people who are "thin outside, fat inside" -- is rarely uneventful. "The thinner people are, the bigger the surprise," he said, adding the researchers even found TOFIs among people who are professional models.

According to Bell, people who are fat on the inside are essentially on the threshold of being obese. They eat too many fatty, sugary foods, and exercise too little to work it off, but they are not eating enough to actually be fat.

Scientists believe we naturally accumulate fat around the belly first, but at some point, the body may start storing it elsewhere. Still, most experts think that being of normal weight is an indicator of good health, and that BMI is a reliable measurement.

"BMI won't give you the exact indication of where fat is, but it's a useful clinical tool," said Dr. Toni Steer, a nutritionist at Britain's Medical Research Council.

Doctors are unsure about the exact dangers of internal fat, but some suspect it contributes to the risk of heart disease and diabetes. They theorize that internal fat disrupts the body's communication systems. The fat enveloping internal organs might be sending the body mistaken chemical signals to store fat inside organs such as the liver or pancreas. This could lead to insulin resistance, type 2 diabetes or heart disease.

The good news is that internal fat can be easily burned off through exercise or even by improving your diet. "Even if you don't see it on your bathroom scale, caloric restriction and physical exercise have an aggressive effect on visceral fat," said Dr. Bob Ross, an obesity expert at Queen's University in Canada.

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## FACT:

**CVD burden and prevention in diabetes;** The well-reputed Framingham study has analyzed the relative burden of cardiovascular disease (CVD) due to diabetes over the past five decades. It has shown that the relative risk of CVD associated with diabetes has remained constant over the past 50 years. The increased prevalence of diabetes has, however, increased the proportion of CVD attributable to diabetes. This finding emphasizes the need for increased efforts to prevent diabetes, as well as the need for aggressive treatment and control of CVD risk factors among people with diabetes. *Circulation, 115 (1544-1550): Fox C, Coady S, Sorlie P, D'Agostino R Sr, Pencina M, Vasan R, Meigs J, Levy D, Savage P Increasing cardiovascular disease burden due to diabetes mellitus: the Framingham Heart Study*

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Item 5

### **Short-Term Risk for Stroke Is Doubled in Newly Diagnosed Type 2's**

*Cardiovascular risk factors are suboptimally treated in diabetes, possibly because of the impression that there is a long delay between diagnosis and the development of macrovascular complications such as stroke.*

<http://www.diabetesincontrol.com/results.php?storyarticle=4804>

The purpose of the study was to determine the incidence of stroke in people newly treated for type 2 diabetes.

They conducted an inception cohort study with the use of linked administrative databases from Saskatchewan Health. Subjects entered the type 2 diabetes cohort on receipt of their first prescription for an oral antidiabetic drug. They defined incident stroke as any hospital admission with International Classification of Diseases, Ninth Revision, codes 430 to 438 inclusive. Age-standardized incidence rates were compared between the diabetes cohort and the general population.

The results showed that there were 12 272 subjects in the diabetes cohort, the mean+/-SD age was 64+/-13.6 years, and 55% were male. During a mean 5-year follow-up, 9.1% of the diabetes cohort had a stroke. The age-standardized incidence rate for stroke was 642 per 100 000 person-years in subjects with diabetes, compared with 313 per 100 000 person-years in the general population (rate ratio=2.1, 95% CI=1.8 to 2.3). The relative short-term risk for stroke in the diabetes cohort compared with the general population ranged from 1.8 (95%=CI 1.6 to 1.9) in persons >75 years to 5.6 (95% CI=2.5 to 9.3) in the 30- to 44-year category.

From the results, it was concluded that, the risk of stroke is high within 5 years of treatment for type 2 diabetes and more than double the rate for the general population. This further supports the need for aggressive early cardiovascular risk factor management in type 2 diabetes.

*Stroke. 2007 May 3*

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Item 6

### **Low-Dose Aspirin Best for CVD Prevention**

*More evidence that lower doses of aspirin are just as effective in preventing cardiovascular events as higher doses comes from a systematic review.*

<http://www.diabetesincontrol.com/results.php?storyarticle=4803>

The authors, led by Charles L. Campbell, MD, from the University of Kentucky, in Lexington, conclude: "Currently available clinical data do not support the routine, long-term use of aspirin dosages greater than 75 to 81 mg/day in the setting of cardiovascular disease prevention. Higher dosages, which may be commonly prescribed, do not better prevent events but are associated with increased risks of gastrointestinal bleeding."

Dr. Campbell stated that: "Recommendations vary but most state aspirin should be taken chronically at a dose anywhere between 75 mg and 325 mg daily, and some even include doses up to 1300 mg. We need to rethink this advice. We know that the risk of bleeding increases with higher doses, and this is now even more of an issue

as more patients are also taking clopidogrel. But the beneficial effect of aspirin on clinical events does not appear to increase with increasing doses. So the guidelines should change to just recommend low doses — 75 or 81 mg. A lot of people buy aspirin over the counter and they need clear information about which dose to take." He added that there was much evidence that aspirin is beneficial for high-risk patients, but the evidence is less robust for lower risk patients (ie, primary prevention)."

Co-author Steven R. Steinhubl, MD, from the University of Kentucky in Lexington pointed out that even 75 or 81 mg is probably overdosing aspirin, as studies have shown that platelet thromboxane is completely inhibited with just 30 mg of aspirin taken long term. "The 75- to 81-mg dose has been arrived at completely arbitrarily as these doses are just one quarter of a 300- or 325-mg tablet," he said.

Dr. Campbell explained that the current results are consistent with those published by the Oxford Antithrombotic Trialists' Collaboration in 2002, but the analyses differed. "They compared trials using higher doses of aspirin with other trials using low doses of aspirin, but we looked at trials which included some patients taking high doses and others taking low doses. We also included a large amount of observational studies. So our findings agree with their findings but we've added a 'real world' spin," he said.

Dr. Campbell said, "There is a disconnect in the aspirin resistance story in that many small studies have shown a significant interpatient variability in platelet response to low-dose aspirin, but there is no clinical evidence that a higher dose would overcome this. There is no large trial that has suggested higher doses are any better in terms of clinical effects."

#### Practice Pearls

- ?? Current clinical data support a daily dose of aspirin of 75 or 81 mg for CVD protection.
- ?? Dosages of aspirin greater than 81 mg daily used for CVD protection are associated with significantly higher risk for bleeding vs lower doses.

JAMA. 2007;297:2018-2024.

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#### Item 7

##### **Sitagliptin+Metformin Effective in Type 2 Diabetes**

*Mean HbA<sub>1c</sub> change from baseline was -2.9%, for patients with an HbA<sub>1c</sub> value greater than 11%.*

<http://www.diabetesincontrol.com/results.php?storyarticle=4802>

Initial combination therapy with sitagliptin and metformin is effective in improving glycemic control in patients with type 2 diabetes mellitus, according to the results of a study.

"Initial antihyperglycemic monotherapy is often unsuccessful at getting patients with type 2 diabetes to glycemic goals, and as the glycemic targets recommended by standard guidelines are lowered, even fewer patients will achieve the goal with single agent treatment," write Barry J. Goldstein, MD, PhD, from the Jefferson Medical College in Philadelphia, Pennsylvania, from the Sitagliptin 036 Study Group. "Sitagliptin, an oral and highly selective dipeptidyl peptidase-4 (DPP-4) inhibitor, represents a novel therapeutic approach for the treatment of patients with type 2 diabetes.... Since sitagliptin and metformin lower glucose concentrations through different, but potentially complementary mechanisms, the initial combination of sitagliptin and metformin should provide effective, potentially additive, glycemic control."

The objective of this 24-week, placebo-controlled, parallel-group study was to evaluate the efficacy and safety of initial combination therapy with sitagliptin and metformin in patients with type 2 diabetes mellitus and inadequate glycemic control with diet and exercise.

In this double-blind trial, 1091 patients with type 2 diabetes mellitus and HbA<sub>1c</sub> values of 7.5% to 11% were randomized to 1 of 6 daily treatments: 100 mg of sitagliptin and 1000 mg of metformin (S100/M1000), 100 mg of sitagliptin and 2000 mg of metformin (S100/M2000), 1000 mg of metformin (M1000), 2000 mg of metformin (M2000; all as divided doses administered twice daily), 100 mg of sitagliptin every day (S100), or placebo.

In the randomized patients, the mean baseline HbA<sub>1c</sub> value was 8.8%. The placebo-subtracted HbA<sub>1c</sub> change from baseline was -2.07% (S100/M2000), -1.57% (S100/M1000), -1.30% (M2000), -0.99% (M1000), and -0.83% (S100;  $P < .001$  for comparisons vs placebo and for coadministration vs respective monotherapies). In the S100/M2000 group, the proportion of patients who achieved HbA<sub>1c</sub> values less than 7% and less than 6.5% was 66% and 44%, respectively ( $P < .001$  vs S100 or M2000).

In the open-label cohort treated with S100/M2000, the within-group mean HbA<sub>1c</sub> change from baseline was -2.9%. The incidence of hypoglycemia was low (0.5% - 2.2%) across active treatment groups and was not significantly different from that seen in the placebo group (0.6%). The incidence of gastrointestinal adverse experiences was similar for coadministration therapies compared with their respective metformin monotherapies.

"The initial combination of sitagliptin and metformin provided substantial and additive glycemc improvement and was generally well-tolerated in patients with T2DM," the authors write. "As with other antihyperglycemic agents including sitagliptin, patients with more severe baseline hyperglycemia (ie, HbA<sub>1c</sub> value = 9%) had the largest reductions with coadministration of sitagliptin and metformin."

### Practice Pearls

- ?? In adults with type 2 diabetes mellitus who have inadequate glycemc control with diet and exercise regimens, initial sitagliptin and metformin combination therapy results in greater improvement in HbA<sub>1c</sub> and greater incidence of HbA<sub>1c</sub> values less than 7% over time and vs monotherapy.
- ?? Sitagliptin and metformin combination therapy has similar incidence of adverse effects vs metformin monotherapy and low incidence of hypoglycemia in patients with type 2 diabetes mellitus. High-dose metformin combination or monotherapy is associated with gastrointestinal adverse effects.

Diabetes Care. Published online May 7, 2007.

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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

#### **Treating vs. Screening Asymptomatic Diabetics for CAD**

*Unconditionally treating all asymptomatic diabetics with statins would be cheaper and prevent more cardiovascular events than routinely screening the same subjects for subclinical atherosclerosis and treating only those with a positive test.*

<http://www.diabetesincontrol.com/results.php?storyarticle=4801>

Using what they call a "back-of-the-envelope" calculation, Drs George Diamond, Sanjay Kaul, and Prediman Shah (Cedars-Sinai Medical Center, Los Angeles, CA) predict that treating all asymptomatic diabetics with statins would be cheaper and prevent more cardiovascular events[1].

By their analysis, treating all 14 million asymptomatic diabetics in the US with statins would prevent 84 000 events (30% of the expected total events) at a cost of \$10.1 billion, gaining 1 092 000 life-years, for a cost-effectiveness ratio of \$9249 per life-year. By contrast, the alternative strategy of screening all 14 million asymptomatic diabetic subjects using myocardial perfusion scintigraphy at an estimated cost of \$809 per person would cost \$11.3 billion and identify the 20% of subjects among whom 80% of events would occur. If these test-positive patients were

then treated with statins, to the tune of an additional \$2 billion, the life-years gained would be 873 600 and the cost-effectiveness ratio would be \$15 224 per life-year. This number is likely an underestimation of costs, given that a positive perfusion imaging test would also like to lead to further tests, Diamond et al write.

"The belief among test advocates is that we should throw more technology at patients," states, Diamond.. "Fine-tuning these selection processes is not going to solve the problem fundamentally, because no test can save a life. Only treatments save lives, and testing excludes treatment."

But in a counterpoint article, Dr George Beller (University of Virginia, Charlottesville, VA) argues that the question is not whether or not diabetics should be universally screened to make decisions about statin treatment because *all* asymptomatic diabetics should have their LDL cholesterol below 100 mg/dL, and most would require statin therapy to reach this goal.

"The issue is really, what do you do to identify those type 2 diabetics who might require even *more* aggressive medical therapy and even further testing for silent extensive coronary disease?"

In response, Diamond stated, "That would be fine if there were evidence to support an outcomes benefit of aggressive management among diabetics. There isn't."

Diamond, however, insists that Beller and others who have argued for a strategy of screening high-risk asymptomatic diabetics need to first answer three "critical" questions: how much does it cost, how much is it going to benefit, and where is the money going to come from?

The screening debate, Diamond argues, detracts from the simple fact that diabetics are not getting the proven medical therapies they need. "There should be a global strategy to minimize their risk across the board, and that would include predominantly unrestricted use of proven medications like statins and ACE inhibitors. If we're not going to treat diabetics with all these medications, we better have a real good reason why we're not, and the reason *shouldn't* be, I gave a test and it wasn't positive."

*Diamond GA, Kaul S, Shah PK, et al. Screen testing: Cardiovascular prevention in asymptomatic diabetic patients. J Am Coll Cardiol 2007; 49:1915-1917. Beller GA. Noninvasive screening for coronary atherosclerosis and silent ischemia in asymptomatic type 2 diabetic patients: Is it appropriate and cost-effective? J Am Coll Cardiol 2007; 49:1918-1923.*

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**FACT:**

**Hypoglycemia and risk of cancer;** The Västerbotten Intervention Project is a study of a subcohort of the Northern Sweden Health and Disease Cohort. A statistically significant association between hyperglycemia with overall cancer risk was demonstrated. The authors suggest that this observation of an increase in the risk of cancer at many sites in women and men is in accordance with the observations in other large cohort studies. They present the hypothesis that abnormal glucose metabolism is a general risk factor for cancer development. Lifestyle modifications aimed at decreasing plasma glucose levels may reduce the overall cancer risk. *Diabetes Care,30 (561-567): Stattin P, Bjor O, Ferrari P, Lukanova A, Lenner P, Lindahl B, Hallmans G, Kaaks R Prospective study of hyperglycemia and cancer risk*

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Item 9

**Low-fat Dairy Foods Can Reduce the Risk of Type 2 Diabetes**

*Study finds men who consume more dairy products have lower incidence of diabetes*

<http://www.diabetesincontrol.com/results.php?storyarticle=4800>

The consumption of low-fat dairy foods may reduce men's risk of developing type 2 diabetes, according to a new study. The report from researchers at Massachusetts General Hospital (MGH), Harvard School of Public Health (HSPH) and Brigham and Women's Hospital (BWH) - the first large-scale, prospective examination of a relationship between dairy intake and diabetes risk - analyzes data from the HSPH-based [Health Professionals Follow-up Study](#).

"Our study found that men consuming higher levels of dairy products, especially low-fat dairy foods, had a significantly lower risk of developing type 2 diabetes during a 12-year period," says Hyon Choi, MD, DrPH, director of Outcomes Research and lead author. "However, individuals should consider both the benefits and risks

of dairy foods before considering changing their diets."

Several recent studies have suggested that dairy consumption may help control weight and blood pressure and reduce the risks of health problems such as coronary artery disease and gout. Other research has implied that dairy foods could help prevent insulin resistance, a precursor of type 2 diabetes. The researchers conducted the current study to directly examine the relationship between dairy consumption and diabetes.

Initiated in 1986, the Health Professionals Follow-up Study has gathered information regarding the relationship between dietary factors and several illnesses from more than 50,000 men employed in the health professions.

The current study evaluated information from more than 41,000 participants who did not have diabetes, cardiovascular disease or cancer when the study began. Those men who reported developing type 2 diabetes during the study period completed a supplementary survey, which confirmed the diagnosis in about 1,200 participants. The researchers then analyzed the dietary information all participants provided in 1986, 1990 and 1994 to determine how diet related to their risk of developing diabetes.

Results showed that those men consuming higher levels of dairy foods had significantly less risk of developing type 2 diabetes than did those consuming the lowest levels, and further analysis showed the risk reduction was almost exclusively associated with low-fat or non-fat dairy foods. In general, each serving-per-day increase in dairy intake resulted in a 9 percent reduction in the risk of developing the disorder. Controlling for consumption of several other types of food, activity level and family history did not change the association.

"Additional studies will be required both to confirm this relationship and to see if the results apply to women or to men younger than this group, who were in their 50s when they joined the study," says Choi. "Another question to be investigated would be whether adjusting dairy intake could be helpful to people with established type 2 diabetes, and the mechanism behind any relation between dairy intake and diabetes risk also needs to be clarified."

*Archives of Internal Medicine, May 9, 2007*

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Item 10

**Antioxidant Achieves a 64% Reduction In the Onset of Diabetes**

*Succinobucol, a novel antioxidant with anti-inflammatory properties, achieved a 64% reduction in new-onset diabetes in patients with a recent acute coronary syndrome.*

<http://www.diabetesincontrol.com/results.php?storyarticle=4799>

In results come from the phase III Aggressive Reduction of Inflammation Stops Events (ARISE) trial.

Use of the investigational agent also was linked to significant reductions in cardiovascular death, MI, and stroke, compared with optimal current therapy in the 6,144-patient double-blind randomized trial, Dr. Jean-Claude Tardif reported at the annual meeting of the American College of Cardiology.

But these were prespecified secondary outcome measures. Succinobucol failed to achieve a significant impact on the primary end point, a composite of "hard" atherosclerotic outcomes and the "soft" end points of coronary revascularization and hospitalization for unstable angina, said Dr. Tardif, professor of medicine at the University of Montreal and director of research at the Montreal Heart Institute.

"I'm pretty bullish," added Dr. Marc A. Pfeffer, ARISE co-principal investigator. "We're all looking for the next step [in cardiovascular risk reduction], and I think this is as promising as anything I've seen in terms of developments."

"We didn't hit our primary end point, but we're the ones who established that primary. We made it more inclusive. We wish we hadn't, we wish we'd made it the firmer one, but there it is. The firm end points are there, and the diabetes effect was pretty profound. If we can come back here with another study aiming specifically at those end points and we can show positive results, then that would be the highest compliment for a clinical trial—it would change the practice of medicine. That's our aim," said Dr. Pfeffer, professor of medicine at Harvard Medical School, Boston.

The 6,144 ARISE participants were randomized to 300 mg/day of succinobucol or placebo for a mean of 2 years starting shortly after hospitalization for an acute MI or unstable angina. All were deemed at high risk for further atherosclerotic events. Rates of utilization of secondary preventive therapies were high: 90% of patients were on a statin at baseline, 80% on a  $\beta$ -blocker, 92% on aspirin, and 74% on an ACE inhibitor or angiotensin receptor blocker.

At baseline, 37% of subjects had diabetes, with a mean HbA<sub>1c</sub> of 7.2%. Among the other nearly 4,000 participants, the incidence of new-onset diabetes was 4.2% with placebo and 1.6% with succinobucol, a 64% relative risk reduction. In patients with diabetes at entry, succinobucol resulted in a mean 0.5% lower HbA<sub>1c</sub> than placebo did at 12 months, and an improvement in fasting blood glucose. The combined "hard" secondary atherosclerotic end point of cardiovascular death, cardiac arrest, MI, or stroke occurred in 8.2% of the placebo group and 6.7% with succinobucol, for a significant 19% relative risk reduction.

The chief side effect of succinobucol was diarrhea, reported by 23% of patients, although only one in seven of those affected discontinued the study. The incidence of liver function abnormalities was similar to that with placebo.

Discussant Dr. Robert A. Harrington, director of cardiovascular clinical trials at the Duke Clinical Research Institute, Durham, N.C., said ARISE sends mixed signals, including unwelcome trends toward more heart failure hospitalizations, lower HDL, and higher LDL. Succinobucol, a potent lipophilic antioxidant, is the monosuccinic acid ester of probucol. The drug's appeal, he said, is that it operates by mechanisms not changed by conventional risk factors such as blood pressure and lipids.

*Presented by Dr. Jean-Claude Tardif at the American College of Cardiology Annual Scientific Session, New Orleans, LA, March 2007.*

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#### Item 11

### **iPods Can Make Pacemakers Malfunction**

*The tunes pumped out by iPods may be off beat to patients with pacemakers, whose devices could be subjected to potentially dangerous interference, reported investigators here.*

<http://www.diabetesincontrol.com/results.php?storyarticle=4798>

Among 83 patients with either single- or dual-chamber pacemakers, iPods placed on the chest caused over-sensing, telemetry interference, and, in one patient, pacemaker inhibition.

So reported Jay Thaker, a Michigan high school student, in collaboration with cardiologist Krit Jongnarangsin, M.D., and colleagues at Michigan State University and the University of Michigan, *at the Heart Rhythm Society meeting.*

"We found interference in 50% of patients," the investigators reported. "Our observations are disconcerting because implantable pacemakers have become commonplace worldwide and the iPod has become a ubiquitous personal digital entertainment device. Other mp3 players may also possibly interact with pacemakers."

iPods, and, presumably other types of MP3 players appear to produce electromagnetic fields that can interfere with pacemaker function, the authors said. Similar effects are known to occur when pacemakers are in proximity to theft-detection systems and airport metal detectors, according to the FDA.

The investigators conducted a prospective, single-blind study to evaluate potential interactions between iPods and pacemakers in 35 women and 48 men with a mean age of 76.1 ± 8.6. Most (74) had dual-chamber devices, and nine had single-chamber devices.

The authors tested four different types of iPod (Apple brand) devices, including a hard-drive-based music player and photo, video, and "nano" models.

All devices were evaluated with pacemakers in both unipolar and bipolar configurations. The devices were tested in random order, and the technician who monitored ECG/pacemaker telemetry was blinded to both the pacemaker settings and the type of iPod test.

Both intradiac electrograms and a surface ECG were monitored while the iPods were placed two inches away from the pacemaker for five to 10 seconds and were switched on and off.

The authors defined interference or interaction between the audio and heart devices as either:

- ?? Over sensing, defined as defined as spurious atrial/ventricular sensed events on the marker channel associated with atrial/ventricular inhibition, mode switching or high atrial/ventricular rates on rate histograms;
- ?? Telemetry interference, defined as any other interference that did not affect pacing function and was not detected by pacemaker interrogation; or
- ?? Pacemaker inhibition, defined as a failure to pace when pacing was expected.

They found that over sensing occurred in 20% of patients, telemetry interference occurred in 29%, and pacemaker inhibition occurred in 1.2% (one patient).

Both the over sensing and the telemetry interfere were persistent, occurring for more than 50% of the application time, and both events occurred more commonly with the hard-drive based music player (iPod 3G) and photo models, with the pacemakers in both unipolar and bipolar configurations.

None of the patients with interference reported experiencing symptoms, however, the investigators noted. They are reportedly investigating what constitutes a safe distance from pacemakers for iPod users.

*Heart Rhythm Society 2007 meeting: Source reference: Thaker JP et al. "Pacemaker Interference with iPod mp3 Players."*

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## DID YOU KNOW:

**Beta-cells can regenerate:** Throughout life, β-cell mass is dynamic with compensatory changes to meet demand and replenish the slow turnover of cells, suggesting either a capacity of β cells to regulate their mass and/or the presence of stem cells or progenitor cells that can differentiate into insulin-producing cells by the process of NEOGENESIS. In mice, rats, and humans the β-cell mass remains linear with body weight or BMI. The mass of β-cells increases by replication of existing β cells and increases in cell volume (hypertrophy). Additionally, islet neogenesis has long been assumed to contribute throughout much of life. **See this week's Item #3**

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Item 12

### Diabetes and Heart Failure Is Double Trouble for Older Women

*New research from the University of Alabama at Birmingham shows that the effect of diabetes on the severity of illness and risk of death for patients with heart failure is much worse in women than men. The effect is even more pronounced in older patients.*

<http://www.diabetesincontrol.com/results.php?storyarticle=4797>

The UAB research team, led by Ali Ahmed, M.D., MPH, associate professor in the division of gerontology, geriatrics and palliative care and director of UAB's Geriatric Heart Failure Clinic and Geriatric Heart Failure Research, found that diabetes was associated with a significant increase in the risk of death and hospitalization in patients with heart failure. Women over age 65 had worse outcomes than men or younger women.

"Our results suggest that heart failure patients should be thoroughly evaluated for the presence of diabetes and if it is present, should be intensively managed based on published guidelines," said Ahmed. "Further studies should test current interventions and develop new ones to reduce the adverse effects of diabetes in heart failure patients in general, and among older adults in particular."

Ahmed and his colleagues examined 2,056 heart failure patients with diabetes compared to the same number of non-diabetic heart failure patients who had similar characteristics at baseline. They used a technique called propensity score matching to design their study while remaining blinded to study outcomes as in a randomized clinical trial. Patients were followed on average for 38 months and analysis performed in two stages; one to see if the effect of diabetes differed in male or female heart failure patients and a second to examine if the age of the patient contributed to the effect of diabetes.

Patients in this study were participants in the Digitalis Investigational Group (DIG) trial, a multi-center trial funded by the National Heart Lung and Blood Institute, one of the National Institutes of Health. The DIG trial examined 7788 patients at 302 sites in the U.S. and Canada.

*Published online in Heart on May 8.*

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Item 13

### **New Communication Method Helps Families Change Lifestyle Behaviors**

*The average body mass of participants who received motivational interviewing had decreased by 2.6 points on the body mass index scale.*

<http://www.diabetesincontrol.com/results.php?storyarticle=4796>

Physicians and registered dietitians who are trained in a new communication method called motivational interviewing may be able to help families change lifestyle behaviors, according to a study by a pediatrician at Brenner Children's Hospital, part of Wake Forest University Baptist Medical Center.

Robert Schwartz, M.D., and colleagues conducted a nonrandomized clinical trial in which they asked 91 families about their dietary habits and lifestyle choices.

"This is an exciting new approach to personal counseling in the pediatrician's office," Schwartz said. "We know that knowledge will not necessarily change behaviors; we are working to find ways to motivate patients to adopt healthier lifestyles. The unique thing about this study is we are learning how to get parents motivated to change their behavioral patterns."

Schwartz and 15 other pediatricians who participate in the Pediatric Research in Office Settings, a national practice-based research network, and five registered dietitians divided families into three groups: a control group, a minimal intervention and an intensive intervention. The control group received no motivational interviewing by a physician or registered dietitian. The minimal intervention group received physician-only counseling and the intensive group received motivational counseling by both a physician and a registered dietitian.

Families were asked about their eating habits, TV viewing, and activity behaviors in all three groups. They used new techniques to help patient's address health issues.

"We know that just talking to patients about good food choices doesn't work," Schwartz said. "Most families know whether they are making good lifestyle choices, but there are skills that pediatricians can learn to help families move toward making changes in their health behaviors. For example, we teach physicians to ask open-ended questions. Open-ended questions yield more information for emotional and behavioral issues like obesity and help the physician understand the patient's perspective as well as barriers to behavior changes."

“We also give physicians tools to help them assess their patient’s interest and confidence in making a behavior change. Ultimately, we are placing the responsibility for health behavior change in the family’s lap and we are hopeful that this will result in improved outcomes.”

Overall, 94 percent of the parents who received motivational interviewing said it helped them think about changing their family’s eating habits. And at a follow-up six months later, the average body mass of participants who received motivational interviewing had decreased by 2.6 points on the body mass index scale. There was a decrease of 0.6 points in the control group and 1.9 points in the minimal intervention group. Based on the small size of the study, these results were not statistically significant, which means they could have occurred by chance.

“We encourage small changes which can lead to success,” Schwartz said. “We help families find new alternatives to dining out, drinking sugary drinks, TV viewing and ways to increase the family’s physical activity. We ask parents ‘What are your goals’ and help them find ways to change their behavior in order to achieve those goals.”

“This was a pilot study and a preliminary step to begin turning this obesity epidemic around,” he said. “We are looking to develop more motivational strategies. The physicians and health care providers who participated in this study say it helped them talk with their patients more effectively. That’s a win-win for everyone.”

*Results from his study are in the May issue of Archives of Pediatrics and Adolescent Medicine.*

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## **FACT:**

**Association between metabolic syndrome and CVD can not be explained entirely by hyperglycemia.** A Chinese study of the cardiovascular incidence relating to diabetes, pre-diabetes, and the metabolic syndrome showed that the Both hypertension and dyslipidemia, which are common in people with metabolic syndrome, are likely to play an equal or greater role in the causation of CVD. Thus, the increased CVD risk in individuals with impaired fasting glucose or diabetes was largely driven by the coexistence of multiple metabolic disorders, rather than hyperglycemia alone. *American Heart Journal, 153 (552-558): Liu J, Grundy S, Wang W, Smith S Jr, Vega G, Wu Z, Zeng Z, Wang W, Zhao D Ten-year risk of cardiovascular incidence related to diabetes, prediabetes, and the metabolic syndrome*

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Item 14

### **Long-Term Adult-Strength Aspirin Use May Reduce Overall Cancer Incidence**

*Adult-strength aspirin taken daily for 5 years or more was associated with a 15% reduced overall cancer incidence, according to the results of a large cohort study.*

<http://www.diabetesincontrol.com/results.php?storyarticle=4795>

"Epidemiologic evidence indicates that aspirin use is associated with reduced risks of colon cancer and possibly several other cancers, including prostate and breast cancers," write Eric J. Jacobs, PhD, from the American Cancer Society in Atlanta, Georgia, and colleagues. "Recent results from the Women's Health Study randomized trial indicate that long-term use of low-dose aspirin (100 mg every other day) does not substantially reduce cancer risk. However, the potential effect of long-term daily use of higher doses of aspirin on cancer incidence remains uncertain."

The investigators determined associations between long-term daily use of adult-strength aspirin (= 325 mg/day) and overall cancer incidence, as well as incidence of 10 types of cancer in 69,810 men and 76,303 women participating in the Cancer Prevention Study II Nutrition Cohort, a relatively elderly population. Information on aspirin use was collected at enrollment in 1992 - 1993 and updated in 1997, 1999, and 2001.

Through follow-up ending in June 2003, cancer was diagnosed in 10,931 men and 7196 women. Compared with no use, daily use of adult-strength aspirin for 5 years or more was associated with lower overall cancer incidence in men (multivariable-adjusted RR, 0.84; 95% confidence interval [CI], 0.76 - 0.93) and non-statistically significant lower overall cancer incidence in women (multivariable-adjusted RR, 0.86; 95% CI, 0.73 - 1.03).

After standardization to the age distributions of men and women in the study, overall cancer incidence per 100,000 person-years with long-term daily aspirin use and no aspirin use was 1858 and 2163, respectively, among men, and 1083 and 1169, respectively, among women. Long-term daily aspirin use was linked to reduced

incidence of colorectal cancer, among men and women combined) and prostate cancer and a non-statistically significant lower risk for female breast cancer

"Long-term daily use of adult-strength aspirin may be associated with modestly reduced overall cancer incidence in populations among whom colorectal, prostate, and breast cancers are common," the authors write.

"Confirmation from randomized trials is necessary before a reduction in cancer risk could be considered a benefit of using adult-strength aspirin," the authors conclude. "Our results indicate that a randomized trial examining the effect of aspirin on cancer incidence would need to be both large and long term, probably lasting a minimum of 10 years.... If daily adult-strength aspirin use is ultimately found to meaningfully reduce overall cancer risk, there could be important clinical implications with respect to who should be taking aspirin and at what dose."

Practice Pearl: Long-term use of adult-strength aspirin for 5 years or more is associated with an overall reduction in cancer incidence that is significant among men but not women. Also that long-term use of adult-strength aspirin is associated with significant reductions in colorectal (30%) and prostate (20%) cancers and a nonsignificant reduction in female breast cancer *J Natl Cancer Inst.* 2007;99:608-615.

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Item 15

**Coronary Calcification Independently Predicts All-Cause Mortality**

*The results of a new study show that, the coronary artery calcification (CAC) score, measured by electron beam tomography, provides incremental information independent of traditional risk factors on all-cause mortality risk.*

<http://www.diabetesincontrol.com/results.php?storyarticle=4794>

Dr. Matthew J. Budoff, of Harbor-UCLA Los Angeles Biomedical Research Institute, Torrance, California, and colleagues conducted an observational outcome study of a cohort of 25,253 consecutive patients referred by their primary physicians for CAC measurement.

Overall, CAC scores ranged from 0 in 44% of the subjects to over 1000 in 4%. The mean duration of follow-up was 6.8 years, during which time there were 510 deaths (2%).

The CAC independently predicted mortality in a multivariable model controlling for age, gender, ethnicity, and cardiac risk factors, the investigators found.

Compared to a CAC of 0, adjusted relative mortality risk ratios ranged from 2.2 for a CAC score of 11-100, up to 12.5 with a score greater than 1000.

After adjustment for risk factors, 10-year survival was 99.4% for a CAC score of 0 compared with 87.8% for a score greater than 1000 (p < 0.0001).

"This large observational data series strongly indicates that CAC is an independent estimator of all-cause mortality," Dr. Budoff and colleagues conclude.

*J Am Coll Cardiol* 2007;49:1860-1870.

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## Quote of the Week!

*“When I meet vegetarians who might have diabetes, pre-diabetes or massive obesity, I tell them they would be better off if they gave up their Vegetarianism.”*

.....Robert Atkins

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