

DIABETES IN CONTROL.com Newsletter

The Newsletter for Professionals in Diabetes Care

July 4, 2007 - Issue #371

Top Diabetes Stories:

ADA: Rosiglitazone Debated at ADA Meeting*

<http://www.diabetesincontrol.com/results.php?storyarticle=4935>

Markers of "Prediabetes" Independently Raises Mortality Risk 60%*

<http://www.diabetesincontrol.com/results.php?storyarticle=4933>

ADA: For Diabetes/Prediabetes Screening, Random Blood Sugars are Cheaper and Easier Than OGTT*

<http://www.diabetesincontrol.com/results.php?storyarticle=4930>

Stone-Age Low-Carb Diet Is Best to Lower Blood Sugars**

<http://www.diabetesincontrol.com/results.php?storyarticle=4927>

Early Tight Control and Aggressive Treatment Pays Off**

<http://www.diabetesincontrol.com/results.php?storyarticle=4926>

ADA: Diabetes-Related Education Cuts Hospitalizations and Charges*

<http://www.diabetesincontrol.com/results.php?storyarticle=4924>

New Beta-Cell Regeneration Drug Shows Improvements Post Treatment*

<http://www.diabetesincontrol.com/results.php?storyarticle=4922>

Teach Doctors To Cook And Walk*

<http://www.diabetesincontrol.com/results.php?storyarticle=4921>

From the editor's desk

There was a lot of great info at the ADA and we have it all for you. But how do you use it all? I recommend you print out each item from this weeks newsletter and just read one article when you stop at a red light, wait at the restaurant or while you are on hold with an insurance company.

Last week I had the great opportunity to meet **Dr. Phil Wood** at the ADA conference in Chicago, we chatted about fat and other things and he prepared this week's article based on his review of the abstracts. Be sure to read Dyslipidemia In Insulin Resistance: Hypertriglyceridemia And Low HDL Cholesterol

<http://www.diabetesincontrol.com/results.php?storyarticle=4936>

Whenever we are at a conference professionals ask me where they can find a comprehensive diabetes continuing education course. Typically, they are looking for a course to take at their own pace at convenient times, and they don't want to travel far from home or spend a lot of money. The options for this type of education have been limited, and often they have to view 5 or 6 programs to get what they want. Novo Nordisk partnered with the University of Pittsburgh School of Pharmacy to create DM Educate?, a unique internet-based, comprehensive diabetes continuing education course. To learn more about this course [click here](#)

<http://www.diabetesincontrol.com/results.php?storyarticle=4904>

To often our patients tell us they are not allowed to have any physical activity because of the Cardiovascular concerns. **Dr. Sheri Colberg**, author of The 7 Step Diabetes Fitness Plan: Living Well and Being Fit with Diabetes, has the right things to do in this weeks feature Exercising Safely with Cardiovascular Disease. I printed this out last week and handed to every one of my patients who said they could not be more active.

<http://www.diabetesincontrol.com/results.php?storyarticle=4937>

Would you be interested in going on a diabetes cruise? We are planning a 9 day Diabetes Education Cruise with Dr. Richard K. Bernstein for next spring or fall. We will provide 16-20 Hours of CME and CE for medical professionals to learn Dr. Bernstein's treatment methods and education for patients with diabetes. Medical professionals who attend will be offered the opportunity to become part of the referral list for patients. If you might be interested, just send us an email with "Diabetes Cruise" in the subject line. THIS IS A ONCE IN A LIFETIME OPPORTUNITY! We will need a least 100 participants to make this happen. Send to

publisher@diabetesincontrol.com

July 8, 7PM ET on CNBC

Wired for diabetes control – how technology helps and hinders. Plus, the holy grail of diabetes – the closed loop system; a special babysitting service that caters to kids with diabetes; and a marvelous marinara over spaghetti

squash from Chef Michel Nischan. Watch this exciting episode of dLifeTV on: Sundays on CNBC at 7 PM ET, 6 PM CT, and 4 PM PT Check your local listings for details.

We can make a difference!

This week's overview:

- Item #2: ADA: Diabetics at Increased Risk of Hearing Loss**
- Item #4: U.S. Survey Shows Uninsured Numbers 43.6 Million**
- Item #5: Exubera Manufacturer Cuts Jobs Due to Poor Sales**
- Item #7: ADA: Investigational Diabetes Drug Lowers Glucose Via New Mechanism**
- Item #8: ADA: Neuropathy Most Likely to Strike in Type 2 Diabetes Not in Type 1**
- Item #11: U.S. White Youths Have Highest Incidence of Type 1 Diabetes**
- Item #13: Value of Glucose Monitoring for Non-insulin Using Diabetes Patients?**

Check out this weeks "Test Your Knowledge" question. This week's question deals with CGMS. <http://www.diabetesincontrol.com/results.php?storyarticle=4938>

Dave Joffe, Editor-in-Chief

CE CREDITS

ARE NOW AVAILABLE FOR DM EDUCATE? , COMPREHENSIVE ONLINE DIABETES MANAGEMENT COURSE - DM Educate was created by the University of Pittsburgh, in partnership with Novo Nordisk to provide pharmacy students with the tools to meet the needs of patients with diabetes. Currently 75 colleges and universities throughout the world are registered and using the course. [Learn more here](http://www.diabetesincontrol.com/results.php?storyarticle=4904) <http://www.diabetesincontrol.com/results.php?storyarticle=4904>

NEWS FLASH:

News Flash: FDA Approves a new combo pill for hypertension called Exforge- Exforge, a single-tablet combination of two of the world's most prescribed high blood pressure medicines, has been approved for sale in the U.S. Exforge is the first medicine of its kind to combine the active ingredients of an angiotensin receptor blocker - Diovan (valsartan) - and a calcium channel blocker - Norvasc (amlodipine) - with the convenience of a single, once-daily tablet.

Sanofi pulls Acomplia drug application in U.S.

Sanofi-Aventis SA is withdrawing its application to sell obesity drug rimonabant --its biggest new drug hope --in the United States, the drugmaker said on Friday. It is currently approved in 42 countries and marketed in 20 to treat obesity. They may try to get an FDA approval to treat diabetes.

Tools for your Practice:

[Exercising with Complications: Cardiovascular Disease and Hypertension.](http://www.diabetesincontrol.com/results.php?storyarticle=4937) **Printout this one pager and hand to your patients when they give you an excuse about exercising.**

<http://www.diabetesincontrol.com/results.php?storyarticle=4937>



New Product:

GlucoTel Patient uses GlucoTel meter to measure blood sugar level. measurement takes 10 seconds and requires less than a 1 nL (nanoliter) sample of blood. Using Bluetooth, GlucoTel meter transmits measurement information to cell phone. Patient may enter additional information (e.g.,

weight, meals, workouts, etc.) directly into the cell phone. Complete data set is transmitted to secure GlucoTel website via SMS, 2G or 3G. Medical professional logs in and reviews data. Can securely send message directly back to patient. Patient may also log in to see data, read messages, network with user community and purchase blood testing strips from GlucoTel. Quality of care is greatly enhanced as a result of consistent monitoring and keeping physician well-informed. <http://www.glucoTel.com/>

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This Week's Items:

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ITEMS For The Week:

Item 1

ADA: Rosiglitazone Debated at ADA Meeting

They were waiting in a long line outside the hall to see Dr Steven Nissen (Cleveland Clinic, OH).

<http://www.diabetesincontrol.com/results.php?storyarticle=4935>

*He arrived to a packed auditorium to tell the audience what he knew about **rosiglitazone** (Avandia, GlaxoSmithKline), when he knew it, and what he believes needs to be done next. Although he has been much in the spotlight in the past month, his audience this time, instead of politicians on Capitol Hill, was a house full of doctors and researchers in a hastily added panel discussion at the American Diabetes Association (ADA) 2007 Scientific Sessions in Chicago, IL.*

Discussing the cardiovascular safety of a drug that has shaken up the cardiovascular and diabetic communities, Nissen outlined his rationale for performing and publishing a meta-analysis that linked the popular diabetes drug to increased cardiovascular events. Speaking during the panel discussion, Nissen defended his decision to put the results of his analysis into the scientific realm, despite the expected tumult the findings would generate, as well as the confusion that might ensue among patients taking the drug.

"We didn't call for the withdrawal of the drug, and we didn't call for regulatory action," said Nissen. "We simply said that we want you and others who treat these patients to be aware of the findings. There was a lot of criticism--should this have been published or shouldn't it--but let me say to you the alternative to us was unacceptable. The alternative would be to keep the scientific community in the dark, to not tell you that a pooled analysis of all these data showed a pretty substantial increase in the risk of the most serious complication of diabetes."

Some audience members weren't having anything of this argument, however, and one in particular said publishing the results was irresponsible, mainly because patient dropouts in ongoing rosiglitazone trials would be a natural consequence. The failure of those trials, he said, would fall squarely on Nissen's shoulders.

The meta-analysis in question, published in the May 21, 2007 issue of *New England Journal of Medicine* (Nissen SE and Wolski K. *N Engl J Med* 2007; 356:2457-71), suggested that rosiglitazone increased the risk of MI 43% and might also increase the risk of cardiovascular death, an end point that met only borderline statistical significance. Nissen noted that GlaxoSmithKline, the maker of rosiglitazone, as well as the FDA conducted similar meta-analyses, and both of these showed an increase in ischemic events.

Like all meta-analyses, Nissen said there are weaknesses to his study. He did not have access to patient-level data, and the cardiovascular events, which were not adjudicated, were not the primary end point in any of the 42 trials included in the meta-analysis.

"This is an important weakness," said Nissen. "We're always on firmer ground when we have prospective, adjudicated, carefully collected end points. These end points were primarily collected as serious adverse events." Despite these limitations, however, "patients and providers should consider the potential for serious cardiovascular effects of treatment with rosiglitazone for type 2 diabetes."

Dr Philip Home (Newcastle University, Newcastle upon Tyne, UK), who spoke during the panel discussion, said he believes the meta-analysis should have been published, as did all panel members, including Drs David Nathan (Harvard University Medical School, Boston, MA), Barry Goldstein (Thomas Jefferson University, Philadelphia, PA), and John Buse (University of North Carolina Medical School, Chapel Hill). However, Home said study was "data snooping on quite a big scale" and that the results should be used only to generate future studies.

Home, who is the lead author of the Rosiglitazone Evaluated for Cardiac Outcomes and Regulation of Glycemia in Diabetes (RECORD) trial, pointed out that an interim analysis of this trial, conducted in light of the recent rosiglitazone concerns and published online June 5, 2007 in the *New England Journal of Medicine*, showed no statistically significant differences in the overall risk of hospitalization or death from cardiovascular causes. The RECORD study, he noted, is specifically designed to examine cardiovascular events, unlike the trials included in the meta-analysis. The results, he said, suggest that rosiglitazone should continue to have a role in glucose-lowering therapy and that studies like Nissen's meta-analysis, while important for raising awareness, form a "a poor basis for making decisions."

While it is important to wait for cardiovascular-end-point trials before making regulatory decisions, Nissen lamented the fact that in the eight years since the approval of rosiglitazone no definitive end-point trials have been published, despite the signal of increased risk of ischemic events observed in the earliest studies. The RECORD study, said Nissen, is too flawed to answer the question of whether or not rosiglitazone increases cardiovascular risk.

One of the biggest criticisms leveled by Home, as well by other audience members, was aimed squarely at last month's editorial accompanying Nissen's meta-analysis. Written by Drs Bruce Psaty (University of Washington, Seattle) and Curt Furberg (Wake Forest University, Winston-Salem, NC), the editorialists shared Nissen's concerns, but Home called it a "half-baked editorial with an axe to grind."

In a later discussion with Dr Richard Kahn, the chief scientific and medical officer of the ADA, when asked if they would start a patient on rosiglitazone, Nathan, Goldstein, and Buse said they would not, at least not until the cardiovascular issues were settled. They would be reluctant to take a well-controlled patient off the drug, however, but might switch if the patient failed to reach glycemic targets with the drug. Nathan reminded the audience that rosiglitazone, at this time, is intended for glycemic control to prevent microvascular and neurologic complications, not for the prevention of cardiovascular disease.

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<http://www.diabetesincontrol.com/rebuilder/index.php>

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Item 2

ADA: Diabetics at Increased Risk of Hearing Loss

Diabetics should be screened for hearing loss because they have twice the risk of developing hearing loss as are nondiabetics, researchers reported at the American Diabetes Association 67th Scientific Sessions (ADA).
<http://www.diabetesincontrol.com/results.php?storyarticle=4934>

Catherine C. Cowie, PhD, director, diabetes epidemiology program, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Bethesda, Maryland, United States, reported data in 5,140 individuals aged 20 to 69 years who underwent audiometric testing from 1999 through 2004 as part of the National Health and Nutrition Examination Survey (NHANES).

"The pathologic changes that accompany diabetes could plausibly affect the vasculature or the neural system of the inner ear, resulting in sensorineural hearing impairment," Dr. Cowie explained in a presentation on June 24th.

In the NHANES trial, pure tone thresholds over lower frequency were obtained for each ear at 500, 1000, 2000, 3000, 4000, 6000, and 8000 Hz using a calibrated audiometer in a soundproof booth. A pure tone average exceeding 25 decibels over a given frequency range in both ears indicated hearing impairment.

After adjusting for age, 31.6% of self-reported diabetics had hearing impairment at the lower frequency range versus 14.5% of the nondiabetic subjects. The figures were 56.8% and 35.8% for the two groups, respectively, at the higher frequency range.

The analysis also revealed that diabetics had higher age-adjusted mean pure tone thresholds at all frequencies than nondiabetics.

Dr. Cowie pointed out that the mechanism for hearing loss in diabetics has not been clarified but may be vascular or neurological.

"The high prevalence of hearing impairment among people with diabetes in our nationally representative sample suggests that screening diabetic patients for hearing impairment is appropriate," she said.

[Presentation title: Diabetes and Hearing Impairment: Audiometric Evidence From the National Health and Nutrition Examination Survey, 1999-2004. Abstract 991-P]

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DID YOU KNOW:

“Eating daily small amounts of dark chocolate lowers blood pressure”: If you’re worried about high blood pressure, you may want to add dark chocolate to your Independence Day diet. A new study suggests that eating daily, small amounts of dark chocolate can help lower some people’s blood pressure. Researchers at University Hospital of Cologne, Germany, studied 44 otherwise healthy people with high blood pressure for 18 weeks. Half the people got about a quarter-ounce of daily dark chocolate, half got the same amount of daily white chocolate. No one gained weight, but only the dark-chocolate eaters saw their blood pressure come down. On average, systolic blood pressure, the upper number, came down by almost three units, and the diastolic blood pressure, or bottom number decreased by almost two units. The researchers say their study provides sufficient evidence to recommend low amounts of dark chocolate as an addition to a healthy diet. *JAMA Advisory July 3, 2007*

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Item 3

Markers of "Prediabetes" Independently Raises Mortality Risk 60%

Markers of impaired glucose metabolism in nondiabetics were independently related to increased risks of all-cause and cardiovascular death in a large population-based study.

<http://www.diabetesincontrol.com/results.php?storyarticle=4933>

The follow-up time, averaging only about five years, suggests that such indicators of "prediabetes" may represent significant mortality risk factors in their own right, not simply predictors of a later high-risk condition, the investigators speculate.

Elizabeth LM Barr (International Diabetes Institute, Caulfield, Victoria, Australia) reported, in the Australian Diabetes, Obesity, and Lifestyle Study (AusDiab), that 65% of all cardiovascular deaths occurred in people with previously known or newly identified diabetes or otherwise impaired glucose metabolism at baseline, report

Compared with participants initially with normal glucose tolerance and after researchers controlled for traditional CV risk factors, the group writes, those with impaired fasting glucose metabolism or impaired glucose tolerance showed a significant 50% to 60% increase in the risk of death from any cause. The risk of CV death was more than doubled among those initially with impaired fasting glucose (fasting plasma glucose = 6.1 and < 7.0 mmol/L with two-hour plasma glucose < 7.8 mmol/L).

Taken together, "these findings suggest that strategies to prevent premature mortality, particularly cardiovascular-disease death, need to be targeted not only to people with diabetes mellitus but also toward people with milder forms of abnormal glucose metabolism."

In the analysis encompassing 10,428 participants, 298 (2.86%) died over a median of 5.2 years. Of the 260 deaths for which a cause was known, a third were due to CV disease. Of the 88 cardiovascular deaths, 57 (65%) were among the participants initially with previously recognized or new diabetes or impaired fasting glucose levels or tolerance, all of which — except for newly diagnosed diabetes — were significant independent risk factors for death from any cause.

Those initially with known diabetes or impaired glucose tolerance had independently elevated risks of non-CV death: HR 2.3 (95% CI, 1.5-3.6) and 1.6 (1.1-2.3), respectively. Of the 172 deaths with a known non-CV cause, 59% were attributed to "malignant neoplasm," the authors write.

Noting that the risk of all-cause mortality, but not CV-mortality, reached significance for those initially with impaired glucose tolerance, Barr et al write that even with the small sample size, "it is possible to infer that in the present study cohort, impaired glucose tolerance may increase the risk of cancer mortality."

Often in prior studies tracking mortality associated with impaired glucose metabolism in nondiabetics, the group notes, it has been difficult to distinguish any risk from baseline glucose abnormalities from risk directly related to diabetes developing later. In the current study, the glucose-related markers predicted mortality "after only a relatively short period of follow-up," suggesting that later diabetes onset "was not a major pathway to death and that impaired fasting glucose and impaired glucose tolerance are genuine risk factors for mortality and not just precursors of diabetes mellitus."

Practice Pearls

- ?? In the AusDiab study, impaired fasting glucose was associated with increased risk for all-cause mortality and CVD mortality.
- ?? In the AusDiab study, impaired glucose tolerance was associated with increased risk for all-cause mortality but not for CVD mortality.

Circulation. Published online June 18, 2007.

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Item 4

U.S. Survey Shows Uninsured Numbers 43.6 Million

Just under 44 million Americans had no health insurance in 2006, according to a survey by the U.S. Centers for Disease Control and Prevention released last Monday.

<http://www.diabetesincontrol.com/results.php?storyarticle=4932>

Their survey of 100,000 Americans is lower than previous federal estimates of 46 million. "In 2006, there were 43.6 million Americans of all ages who did not have health insurance (at the time of the interview), or 14.8 percent of the population," the CDC said in a statement.

The survey, by the CDC's National Center for Health Statistics, found that 54.5 million Americans of all ages, or 18.6 percent of the population, had no insurance for at least part of the year in 2006.

"Among working-age Americans (those ages 18-64), there were 19.8 percent who did not have health insurance in 2006, a slight increase from 18.9 percent in 2005," the CDC added.

Providing health insurance to everyone is one of the top political issues leading up to the 2008 national election. The United States has no organized system for providing health care; most people are covered by employer-sponsored insurance.

About 43 million people over 65 are covered by Medicare, the \$408 billion state-federal health insurance system for the elderly and disabled. The poor and some younger disabled people are eligible for Medicaid, another state-federal health insurance plan.

The CDC report found that 18 percent of poor adults under the age of 65 were on Medicare or Medicaid. "Almost one-third of children (32.3 percent) were covered by a public plan, compared with 12.4 percent of adults 18 to 64 years," the report reads.

"Approximately 9.3 percent of children under the age of 18 did not have health insurance in 2006, a decrease from 13.9 percent in 1997," the CDC report read.

Texas had the largest percentage of people without health insurance in 2006, with 23.8 percent of the population not covered, and Michigan had the lowest, at 7.7 percent, according to the report, published on the Internet at <http://www.cdc.gov/nchs/pressroom/07newsreleases/insurance.htm> .

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FACT:

15,000 Children and Teens Diagnosed with Type 1 Diabetes Annually: Approximately 15,000 children and adolescents in the United States are diagnosed with type 1 diabetes, and about 3,700 youth are diagnosed with type 2 diabetes annually, according to estimates from a major national study called SEARCH for Diabetes in Youth. *JAMA, June 26, 2007*

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Item 5

Exubera Manufacturer Cuts Jobs Due to Poor Sales

The UK-based drug delivery device manufacturer said that following the slow take-up of Exubera by diabetes patients, Nektar Therapeutics and Pfizer have revised their short term forecasts for the inhalation device, which will result in a reduction in production.

<http://www.diabetesincontrol.com/results.php?storyarticle=4931>

Exubera is a powdered insulin product that is inhaled into the lungs before a meal, using a proprietary inhalation device made under contract on a 50:50 split by Bsepak along with The Tech Group, which is part of West Pharmaceuticals Services.

Bsepak has been developing the inhaler's manufacturing process since July 1999 and the company's Milton Keynes facility is

almost exclusively geared towards the high volume production of the Exubera device. However, the company does not disclose the amount of devices that have been made so far.

Bespak said it is embarking on a consultation process with the 160 staff involved in the production of the Exubera inhaler and expects to reduce the team involved in the Exubera contract.

Jonhathan Glenn, Bespak's financial director, stated that, *"The procedure will take three months after which we will make a significant number of redundancies."*

But Glenn said his company was confident about the future of Exubera, especially with the huge forthcoming advertising campaign Pfizer is launching in the US, and which is expected to kick off in September.

"Pfizer and Bespak expect that the direct consumer advertising operation will have a great impact on sales and will hopefully lead to a significant ramp-up in production," *said Glenn.*

"We know that once patients use Exubera, they don't give it up so the key issue is to increase significantly the up-take."

On the other hand, Exubera could represent an expensive flop for Pfizer if it does not achieve the blockbuster status the industry had hoped for.

Exubera was expected by its makers as well as many analysts, to be a revolution for the treatment of Type II diabetes and to be an important step for patients who are postponing insulin therapy to avoid injections, and thus a major blockbuster.

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Item 6

ADA: For Diabetes/Prediabetes Screening, Random Blood Sugars are Cheaper and Easier Than OGTT

For diabetes and prediabetes screening, random plasma glucose testing alone appears to be at least as good as the full gamut of metabolic syndrome tests, and is easier and cheaper to boot, researchers found.

<http://www.diabetesincontrol.com/results.php?storyarticle=4930>

Lawrence S. Phillips, M.D., of Emory University in Atlanta, at the American Diabetes Association meeting stated that, nonfasting plasma glucose was as predictive of "gold-standard" oral glucose tolerance test results as metabolic syndrome testing with fasting plasma glucose as a component (0.714 versus 0.733).

And it was more predictive than metabolic syndrome testing without the fasting glucose component (0.714 versus 0.675), Dr. Phillips and colleagues found.

Although there has been interest in using the metabolic syndrome as a marker of unrecognized glucose intolerance, "clinicians ought to pay more attention to random plasma glucose," Dr. Phillips said.

The researchers' study included 1,155 adults not known to have diabetes and without acute illness. The group of volunteers was 63% female and 54% black, with an average age of 48 and an average body mass index of 30.3 kg/m².

Participants came for an initial visit at which a plasma sample was taken for glucose testing. This was considered "random" because there were no dietary restrictions before the test and the visits could have occurred at any time in the morning or afternoon.

At the second visit, two or three weeks later, participants underwent a 75g oral glucose tolerance test in the morning after an overnight fast. Their lipids, blood pressure, and waist circumference were also measured. Among the volunteers, 5.1% had unrecognized diabetes and 20% had pre-diabetes, which was defined as impaired glucose tolerance or a fasting plasma glucose level of 110 to 125 mg/dL or both.

The metabolic syndrome was present among 27% of the group overall. Metabolic syndrome criteria were a waist circumference over 102 cm for men or 88 cm for women, blood pressure at least 130/85 mm Hg, triglycerides at least 150 mg/dL, and HDL over 40 mg/dL for men or 50 for women.

The researchers compared accuracy of the metabolic syndrome and plasma glucose tests in identifying glucose intolerance in an area under the curve in receiver-operator-characteristic analysis.

This analysis showed that random plasma glucose was as good or better at screening as the metabolic syndrome testing parameters. The area under the curve findings were better for diabetes screening with random plasma glucose than the metabolic syndrome testing whether it included or excluded fasting plasma glucose (0.815 versus 0.796 and 0.694, respectively).

For diabetes and prediabetes screening, accuracy was similar between random plasma glucose and metabolic syndrome when it included fasting plasma glucose (0.714 versus 0.733). But it was better with random plasma glucose than the metabolic syndrome when fasting plasma glucose was not included (0.714 versus 0.675).

The same pattern was seen when screening for all three criteria-diabetes and prediabetes defined both by impaired glucose tolerance and impaired fasting glucose (0.725 for fasting plasma glucose versus 0.76 and 0.685 for the metabolic syndrome with and without fasting plasma glucose).

"The contribution of metabolic syndrome testing to diabetes screening is mainly fasting plasma glucose," Dr. Phillips said. "People don't realize how much that contributes."

Interestingly, the pattern of predictive ability seen in the area under the curve analysis held true for all subgroups, except for younger, slimmer participants.

For patients with a body mass index less than 25 kg/m² and those younger than 40, metabolic syndrome testing was significantly better than random plasma glucose at predicting diabetes regardless of whether fasting plasma glucose was included or excluded as a component.

"We don't know what it means biologically," Dr. Phillips said. But, it may be important clinically because this is a population that is often overlooked for screening because they are assumed to be at lower risk, he said.

"There's something going on in these people's bodies that even though they are younger and even though they are slimmer, they may be more insulin deficient than you think," he said.

For most patients, though, the researchers concluded that both random plasma glucose and metabolic syndrome testing with fasting plasma glucose are good predictors of diabetes.

But, random plasma glucose testing is more convenient for patients and costs less, Dr. Phillips said. He did note, however, that metabolic syndrome testing has added usefulness in that it can be used to predict cardiovascular risk as well.

Bassuoni EA, et al "Metabolic Syndrome Is No Better Than Random Plasma Glucose To Screen For Unrecognized Glucose Intolerance" ADA meeting 2007; Abstract 916-P.

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

<http://www.diabetesincontrol.com/ads/liposcience/dest.php>

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Item 7

ADA: Investigational Diabetes Drug Lowers Glucose Via New Mechanism

Dapagliflozin, a novel investigational antidiabetic agent that increases excretion of glucose in urine, independent of insulin secretion or insulin action, appeared safe and effective in early clinical trials.

In a randomized double-blind study, dapagliflozin in each of three doses significantly increased the excretion of excess glucose in urine compared with placebo, reported Bernard Komoroski, PharmD., Ph.D., an investigator for drug-maker Bristol-Myers Squibb, at the American Diabetes Association meeting.

The drug seemed to be well tolerated. Although there were two case of hypoglycemia, both occurred in patients also taking metformin (Glucophage) after a long fast, Dr. Komoroski said.

Dapagliflozin (BMS-512148), developed jointly by Bristol-Myers Squibb and AstraZeneca, is the first drug to reach clinical trials in a new category of agents, called selective inhibitors of the sodium-glucose uptake transporter 2 (SGLT2).

The novel action in this class involves inhibition of glucose reabsorption in the proximal renal tubule, although glucose reabsorption still occurs farther downstream in the kidney, Dr. Komoroski said.

In animal studies, SGLT2 inhibition activity modulated reabsorption of glucose by the kidney, causing the excess glucose to be excreted in urine. The end result is a decrease in serum glucose independent of either insulin secretion or insulin action.

The investigators conducted a phase II study in 47 adults with type 2 diabetes. The patients, ages 18 to 77, were all either naïve to antidiabetic agents, or on a stable dose of metformin for at least four weeks before randomization.

Baseline glycosylated hemoglobin (HbA1c) levels ranged from 6% to 10%, and the patients had fasting serum glucose levels of 240 mg/dL or less.

The participants were randomized to receive either placebo (eight patients) or dapagliflozin at doses of 5 mg (11 patients), 25 mg (12 patients), or 100 mg (16 patients) once daily for two weeks. The drugs were taken in addition to the patients' stable metformin dose or diet. The study was conducted with patients staying in an inpatient clinical research unit.

The primary outcomes were safety and tolerability of multiple doses of dapagliflozin. Secondary endpoints included fasting serum glucose, and post-challenge glucose excursions.

The authors found that on day 13, the fasting serum glucose was significantly reduced in participants receiving dapagliflozin with or without metformin, compared with levels measured two days before they received their first doses.

Among patients on the 5 mg dose there was a 14.5% reduction in fasting serum glucose ($P<0.05$). The reduction was 17.3% in the 25 mg group ($P<0.05$) and 21.9% in the 100-mg group ($P<0.001$). In contrast, patients on placebo with or without metformin had a 6.3% decrease in fasting serum glucose. The mean amount of glucose eliminated in the urine within 24 hours of the first dose was 45.2 g in the 5-mg group, 75.3 g in the 25-mg dose group, and 81.3 g in the 100-mg dose group.

Dapagliflozin also significantly reduced the response to a 75 g oral glucose tolerance test ($P<0.001$). There were no apparent changes in body weight, urine volume, or urinary sodium excretion, Dr. Komoroski said.

Adverse events included hypoglycemia in two patients, both on metformin and dapagliflozin, and two vulvovaginal infections, one occurring in a patient on dapagliflozin alone, and the other in a patient on the SGLT2 inhibitor plus metformin.

American Diabetes Association 2007 Scientific Sessions: Komoroski B et al. "Dapagliflozin (BMS-512148), a Selective Inhibitor of the Sodium-Glucose Uptake Transporter 2 (SGLT2), Reduces Fasting Serum Glucose and Glucose Excursion in Type 2 Diabetes Mellitus Patients Over 14 Days." Abstract 0188, presented June 24

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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

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Item 8

ADA: Neuropathy Most Likely to Strike in Type 2 Diabetes Not in Type 1

Painful neuropathy is more common in patients with type 2 diabetes than in those with type 1, due to metabolic syndrome, researchers suggest, because of a link with the metabolic syndrome.

<http://www.diabetesincontrol.com/results.php?storyarticle=4928>

In an observational study, painful diabetic polyneuropathy was three times more common among type 2 patients than type 1 patients (17.9% versus 5.8%), reported Ides M. Colin, M.D., Ph.D., of CHR-S. Joseph Medical Center in Mons, Belgium, and colleagues.

This type of neuropathy was independently associated with three components of the metabolic syndrome-obesity, low HDL cholesterol, and high triglyceride levels -- they said at the American Diabetes Association meeting.

"The higher prevalence of diabetic polyneuropathy in type 2 diabetic patients could be due to the involvement of metabolic syndrome-associated disturbances," they wrote.

Because the epidemiology of painful diabetic polyneuropathy had not been well characterized, the researchers conducted a cross-sectional study that included 1,111 patients at 40 Belgian diabetes clinics; 344 had type 1 diabetes and 767 had type 2.

The researchers tested for neuropathy in patients' feet using a monofilament for sensory perception and a device called the Neuropen for pain sensation. Participants also completed a questionnaire on characteristics of the pain sensation. Nearly half of the patients overall complained of pain on the visual analog scale. Patients with type 2 diabetes reported it more frequently than did those with type 1 (53.6% versus 34.9%).

The occurrence of diabetic polyneuropathy was significantly higher among type 2 diabetes patients than type 1 patients (50.8% versus 25.6%, $P=0.0007$). The prevalence of painful diabetic polyneuropathy showed the same significant difference (17.9% versus 5.6%).

Factors associated with higher diabetic neuropathy in a multivariate analysis were male gender ($P=0.02$), increasing age ($P<0.0001$), type 2 diabetes ($P=0.02$), increasing duration of the disease ($P=0.0006$), and HDL cholesterol at or below 40 mg/dL for men or 50 mg/dL for women ($P<0.0001$).

The strongest predictors of neuropathy in a bivariate analysis were foot problems (odds ratio 10.5, $P<0.0001$) and low HDL cholesterol (OR 2.14, $P<0.0001$).

Independent predictors of painful diabetic neuropathy were:

- ?? Low HDL cholesterol (OR 2.17, 95% confidence interval 1.38 to 3.41, $P=0.0008$).
- ?? Triglyceride levels at or above 150 mg/dL (OR 1.76, 95% CI 1.13 to 2.75, $P=0.01$).
- ?? Obesity (OR 1.62, 95% CI 1.05 to 2.49, $P=0.03$).
- ?? Nephropathy (OR 1.69, 95% CI 1.10 to 2.59, $P=0.02$).
- ?? Age (OR 1.47 per decade, 95% CI 1.20 to 1.81, $P=0.0003$).
- ?? Diabetes duration (OR 1.14 per five years, 95% 1.02 to 1.28, $P=0.02$).

The researchers concluded that neuropathy and painful neuropathy are mainly associated with type 2 diabetes, potentially via the metabolic syndrome, which encompassed the majority of the strong predictors found.

"Diabetic neuropathy and painful neuropathy are often associated with other complications, as well as modifiable risk factors including some of those related to the metabolic syndrome," they wrote.

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FACT:

Diabetes-Related Education Cuts Hospitalizations and Charges: Diabetes education, especially counseling from nutritionists, can reduce hospitalizations and lower hospital charges by 14 thousand dollars, for urban, low-income patients. In an observational study, hospital charges for diabetes patients who had any sort of education about their disease were \$14,251 to \$22,000 lower over eight years than charges accumulated by those who did not receive any education, reported Jessica M. Robbins, Ph.D., of the Philadelphia Department of Public Health, and colleagues. *See this week's Item #10*

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DM Educate(is an online comprehensive, diabetes management course designed to provide both foundational and advanced education in the principals of diabetes management. With outstanding educators and practitioners from the fields of pharmacy, nursing, medicine, psychology, nutrition and exercise physiology serving as the faculty, DM Educate(offers participants the opportunity to increase or reinforce their knowledge of issues relating to comprehensive diabetes management. This online course is divided into five sections and is accredited for 31 hours of continuing education credits for pharmacists, nurses and CDEs renewing their certification. Participants may complete as many of the CE sections as they wish.

<http://www.pharmacy.pitt.edu/dmeducatece>

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Item 9

Stone-Age Low-Carb Diet Is Best to Lower Blood Sugars

According to a new study you can toss out the Mediterranean cookbooks and turn back to the Stone Age if you're looking to lower your blood-sugar levels.

<http://www.diabetesincontrol.com/results.php?storyarticle=4927>

The 2 million-year-old hunter-gatherer diet is three times more effective at lowering glucose levels than the Mediterranean diet, according to a new study from Lund University, in Sweden.

Patients who ate lean meat, fish, fruits, vegetables, yogurt and pasta for three months saw their blood sugar levels fall 7 percent, the study found. Those who adopted that regimen and excluded dairy and grains, what the researchers called the Stone Age diet, fared even better. They had a sugar drop of 26 percent.

Foods of the kind that were consumed during human evolution may be the best choice to control diabetes type 2. A study from Lund University, Sweden, found markedly improved capacity to handle carbohydrate after eating such foods for three months.

During 2.5 million years of human evolution, before the advent of agriculture, our ancestors were consuming fruit, vegetables, nuts, lean meat and fish. They did not have access to processed foods high in carbohydrates. In contrast, cereals, dairy products, refined fat and sugar, which now provide most of the calories for modern humans, have been staple foods for a relatively short time.

Staffan Lindeberg at the Department of Medicine, Lund University, has been studying health effects of the original human diet for many years. In earlier studies his research team have noted a remarkable absence of cardiovascular disease and diabetes among the traditional population of Kitava, Trobriand Islands, Papua New Guinea, where modern agrarian-based food is unavailable.

In a clinical study in Sweden, the research group has now compared 14 patients who were advised to consume an 'ancient' (Paleolithic, 'Old stone Age') diet for three months with 15 patients who were recommended to follow a Mediterranean-like prudent diet with whole-grain cereals, low-fat dairy products, fruit, vegetables and refined fats generally considered healthy. All patients had increased blood sugar after carbohydrate intake (glucose intolerance), and most of them had overt diabetes type 2. In addition, all had been diagnosed with coronary heart disease. Patients in the Paleolithic group were recommended to eat lean meat, fish, fruit, vegetables, root vegetables and nuts, and to avoid grains, dairy foods and salt.

The main result was that the blood sugar rise in response to carbohydrate intake was markedly lower after 12 weeks in the Paleolithic group (-26%), while it barely changed in the Mediterranean group (-7%). At the end of the study, all patients in the Paleolithic group had normal blood glucose.

The improved glucose tolerance in the Paleolithic group was unrelated to changes in weight or waist circumference, although waist decreased slightly more in that group. Hence, the research group concludes that something more than caloric intake and weight loss was responsible for the improved handling of dietary carbohydrate. The main difference between the groups was a much lower intake of grains and dairy products and a higher fruit intake in the Paleolithic group. Substances in grains and dairy products have been shown to interfere with the metabolism of carbohydrates and fat in various studies.

"If you want to prevent or treat diabetes type 2, it may be more efficient to avoid some of our modern foods than to count calories or carbohydrate," says Staffan Lindberg.

This is the first controlled study of a Paleolithic diet in humans.

The study will be published later this year in the European Association for the Study of Diabetes's journal Diabetologia and is available now on the Web.

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Item 10

Early Tight Control and Aggressive Treatment Pays Off

There seems to be a point of no return in the onset of diabetes and scientists have speculated exposure to high glucose levels quickly creates a metabolic memory due to glycation, in which diabetes persists long after the glucose levels are corrected.

<http://www.diabetesincontrol.com/results.php?storyarticle=4926>

British medical scientists have discovered how the body's metabolism is "locked" into a diabetic state after only limited high glucose exposure. The researchers said their finding confirms the need for very early tight control of glucose levels to avoid diabetic complication.

Researchers were already aware that there seems to be a point of no return in the onset of diabetes. This was apparent in the Diabetes Complications and Control Trial (DCCT) in the 1990s when Type 1 diabetic patients were either placed on standard or intensive treatment regimens to normalize their glucose levels. Because complications were so profoundly reduced in patients with tight glucose control, all the remaining DCCT patients were switched early onto intensive therapy. However a follow-up study found that several years after switching to intensive therapy the patients who started the trial on only the standard treatment regimen continued to have more complications than those who received intensive therapy throughout the trial.

Research since has speculated that exposure to high glucose levels quickly creates a metabolic memory in which diabetes persists long after glucose levels have been corrected. Research to date suggested that oxidation played a role but the exact mechanism was unknown.

The Warwick research team, led by Dr Antonio Ceriello, have now proven that the damage seems to be done in a process called glycation when early on in a period of high glucose levels glucose sugar molecules are able to bind to proteins in the mitochondria of cells (the parts of cells governing the production and regulation of energy). This persists even if glucose levels later fall to normal. This inhibits and distorts the mitochondria's normal function and results in an overabundance of the production of free radicals (or Reactive Oxygen Species – ROS) which cause oxidation and thus continued diabetic complications.

The Warwick Medical School researchers proved their hypothesis by taking tissue and exposing it to 2 weeks of high levels of glucose, followed by one week of normal glucose – however for half the tissue they also applied

several antioxidants at the end of the two weeks of high glucose. The tissue without antioxidants levels of glucose stress remained high but where antioxidants had been applied there was a dramatic fall in the incidence of free radicals and there was also a significant drop in 5 of the 6 key markers for high glucose stress.

The Warwick Medical School research confirms the need for very early tight control of glucose levels to avoid diabetic complication and that that control must be supplemented with the use of antioxidant agents to mitigate the progression of complications.

However long term use of antioxidants can in itself produce health problems so in a further research published this month the Warwick Medical School team have tested the use of the AT-1 receptor blocker Telmisartan and found it can be used in exactly the same way to suppress the build up of free radicals without the side affects that long term use of antioxidants would cause.

Dr Ceriello is now beginning to look at how to move beyond simply suppressing the problematic production of free radicals and actually finding ways of reversing the glycation process itself thus erasing the harmful "metabolic memory".

Dr Ceriello's paper "Reactive oxygen species mediate a cellular 'memory' of high glucose stress signaling" has just been published in Diabetologia DOI 10.1007/s00125-007-0684-2. The second paper, about to be published in Diabetes Care, is entitled "Antioxidants and Free Radicals, Endothelial Dysfunction, Oxidative and Nitrosative Stress covers his work on the AT-1 receptor blocker Telmisartan. Papers concerning the study appear in the current issue of the journal Diabetologia and are soon to be published in the journal Diabetes Care.

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Item 11

U.S. White Youths Have Highest Incidence of Type 1 Diabetes

Non-Hispanic white youth have the highest rate of diabetes of all racial/ethnic groups for children in the U.S., with type 1 being the predominant kind of diabetes among youth.

<http://www.diabetesincontrol.com/results.php?storyarticle=4925>

Estimates of the incidence of type 1 diabetes mellitus (DM) show an increase in incidence worldwide during the past two decades. Type 2 DM has traditionally been viewed as a disorder of adults, most likely persons who are middle-age or elderly. But as the prevalence of obesity has increased in recent decades, some studies have reported an increasing proportion of youth with type 2 DM, especially among racial/ethnic minority populations. However, data are limited regarding the types and incidence of DM among U.S. youth of different racial/ethnic backgrounds.

Dr. Dabelea and colleagues with the SEARCH for Diabetes in Youth Study Group identified the cases of DM among individuals younger than 20 years in the U.S. to estimate the population incidence of type 1 and 2 DM overall and by age and race/ethnicity. The study included 2,435 multi-ethnic youth with newly diagnosed DM in 2002 and 2003, from 10 locations in the U.S.

Overall, the incidence rate (per 100,000 person-years [the number of individuals in the study times the number of years of follow-up per person]) of DM was 24.3. The incidence rate was highest among 10- to 14-year-old youth (33.9), and slightly higher in females vs. males. Overall, the highest incidence rates of DM were observed among non-Hispanic white (26.1), African American (25.4), and American Indian youth (25.0), with lower rates among Hispanic and Asian-Pacific Islander youth.

For children age 0 to 4 years and 5 to 9 years, most DM was type 1, regardless of race/ethnicity. The incidence of type 1 DM was highest among non-Hispanic white children, and lowest among American Indian and Asian-Pacific Islander children. Similarly, for older youth (10-14 years and 15-19 years), the incidence of type 1 DM was highest among non-Hispanic white children, followed by African American and Hispanic youth.

"... taken together [with other studies], these data suggest that the incidence of type 1 DM may be increasing in the United States, consistent with worldwide trends," the authors write. "We estimate that the annual number of newly diagnosed youth with type 1 DM in the United States is approximately 15,000."

Overall, type 2 DM was relatively infrequent, but the highest rates were documented among 15- to 19-year-old minority groups, including American Indian youth, followed by African American, Asian-Pacific Islander, and Hispanic youth. "Although the evidence of the presence of type 2 DM in youth is still developing, it is consistent with the increasing prevalence of type 2 DM in adults, and the increasing prevalence of obesity in both adults and children."

"The SEARCH study provides unique population-based data on the incidence of DM among youth of various racial/ethnic backgrounds, according to DM type.

JAMA. 2007;297:2716-2724.

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DID YOU KNOW:

Generex to Initiate Phase III Clinical Trial of Generex Oral-lyn: The six month trial is expected to include 750 patients with Type 1 diabetes mellitus. Patient enrollment is expected to begin during the third or fourth quarter of calendar year 2007 and expand to several global centers over the course of the study. The primary objective of the study is to compare the efficacy of Generex Oral-lyn(tm) and the RapidMist(tm) Diabetes Management System with that of standard regular injectable human insulin therapy as measured by HbA1c, in patients with Type-1 diabetes mellitus.

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Item 12

ADA: Diabetes-Related Education Cuts Hospitalizations and Charges

Diabetes education, especially counseling from nutritionists, can reduce hospitalizations and lower hospital charges by 14 thousand dollars, for urban, low-income patients.

<http://www.diabetesincontrol.com/results.php?storyarticle=4924>

In an observational study, hospital charges for diabetes patients who had any sort of education about their disease were \$14,251 to \$22,000 lower over eight years than charges accumulated by those who did not receive any education, reported Jessica M. Robbins, Ph.D., of the Philadelphia Department of Public Health, and colleagues.

Attendance at a class was associated with six fewer hospitalizations per 100 person-years and each nutritionist visit resulted in 16 fewer hospitalizations per 100 person-years, she told attendees at the American Diabetes Association meeting.

"I think we can conclude education in any form probably reduces hospitalizations," she said.

Dr. Robbins and colleagues linked data from eight public safety-net primary care clinics in urban Philadelphia to hospital discharge data from the Pennsylvania Health Care Cost Containment Council.

The study included all 18,416 patients seen at the clinics who were diagnosed with diabetes from March 1, 1993 through December 31, 2001. In total, there were about 87,000 person-years of follow-up for patients after their first diabetes diagnosis.

Among them, 26% of patients were hospitalized at least once for an average of \$34,421 in total hospital charges per patient during follow-up. A small percentage attended at least one diabetes class (5.6%), had at least one visit with a nutritionist (8.9%), or had another type of health education visit (1.8%).

Predictors of hospitalization were male gender, older age, earlier diagnosis, and non-Hispanic white race. The patient population was 73% African American, 10% Hispanic, and 3% Asian. After controlling for these factors,

one or more of any type of education visit was associated with 0.1185 fewer hospitalizations per year than among those who did not have any education.

Again, nutritionist visits appeared to have been more beneficial than diabetes classes. Hospital charges for those who had at least one visit with a nutritionist were \$22,889 lower than charges for patients who had no education visits and \$19,148 lower than charges for patients who'd attended classes.

The same pattern was seen for each visit. Each education visit in general was associated with \$1,824 lower hospital charges. Each diabetes class was associated with \$1,074 lower charges, and each visit with a nutritionist was associated with \$10,786 lower charges compared with patients who had no visits.

The only statistically significant predictor of hospital charges was having had at least one nutritionist visit. However, having had three or more visits was not a significant predictor.

Controlling for major comorbidity made the effects even greater, and older patients and those with kidney disease appeared to have the biggest benefit.

Dr. Robbins cautioned that the study was based on administrative data so the savings reported reflect hospital charges rather than true costs. She also warned that at least some of the effect was likely because of residual confounding.

Furthermore, "the big question is how do you get any of this to happen," Dr. Robbins noted, because such programs are hard to get patients to attend without incentives. But, "if you can get even one, you can make a difference," she concluded.

Robbins JM "Nutritionist Visits, Diabetes Classes, and Hospitalization Rates and Charges: the Urban Diabetes Study" ADA meeting 2007; Abstract 346-OR

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Item 13

Value of Glucose Monitoring for Non-insulin Using Diabetes Patients?

A new study published on [bmj.com](http://www.bmj.com) questions the value of blood glucose monitoring among patients with well-controlled, non-insulin dependent (type 2) diabetes. See Publishers Note.

<http://www.diabetesincontrol.com/results.php?storyarticle=4923>

Publishers Note: We had a lot of response from this study which, we reported in last week's newsletter. All the responses made the point that when patients are educated properly and understand what they can do to improve their readings, it can be very beneficial in controlling and improving their blood sugars. When giving a patient a blood glucose monitor and they are not educated, then it will have no beneficial effect for type 2's.

A new study questions the value of blood glucose monitoring among patients with well-controlled, non-insulin dependent (type 2) diabetes.

The research, presented at the American Diabetes Association Conference, suggests that current guidelines for self-monitoring among these patients should be reviewed.

Non-insulin dependent (type 2) diabetes usually develops in people over 40, especially when the person is overweight. In most cases, insulin injections are not needed. Instead, a combination of dietary measures, weight reduction, and oral medication controls the condition.

Self monitoring for type 2 diabetes is costly, but many doctors believe that it helps to control blood glucose levels and it is commonly recommended. Although some studies have suggested benefits, evidence of effectiveness is still inconclusive.

So Dr Andrew Farmer and colleagues set out to test whether self-monitoring can improve blood glucose control in non-insulin using patients compared with standard care. They identified 453 non-insulin using type 2 diabetes patients from 48 general practices.

Patients were randomly assigned to one of three groups. The control group received standard care with three-monthly HbA1c measurements by a health professional.

The second group was given a meter with advice to contact their clinician for interpretation of results (less intensive self-monitoring), while the third group was given a meter and trained to interpret the readings and apply the results (more-intensive self monitoring).

At 12 months, there was no difference in HbA1c between the groups. There was also no evidence that intensity of monitoring was related to improvements in glucose control.

This trial provides no convincing evidence of an effect of blood glucose monitoring, with or without instruction, in improving glucose control compared with usual care, say the authors.

Routine self-monitoring of blood glucose for reasonably well-controlled non-insulin treated patients with type 2 diabetes appears to offer, at best, small advantages, is not well accepted, and the cost, effort and time involved in the procedures may be better directed to supporting other health-related behaviors, they add.

They suggest that current guidelines for the use of self-monitoring among these patients should be reviewed.

View full paper: <http://press.psprings.co.uk/bmj/june/diabetes.pdf>

BMJ, June 24, 2007

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FACT:

Novartis Continues Talks On Approval for Galvus: Novartis AG said it expects the European Union to decide by year-end on approval for its experimental diabetes drug Galvus, while discussions with the Food and Drug Administration on steps needed to gain U.S. approval are continuing. The Swiss drug maker said Galvus produced an additional 0.6% reduction in a key measure of blood sugar control, when added to Sanofi-Aventis SA's Amaryl, compared with Amaryl alone. *Presented at the annual meeting of the American Diabetes Association 06/07*

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Item 14

New Beta-Cell Regeneration Drug Shows Improvements Post Treatment

Transition Therapeutics Announces Results of 6-Month study with Their E1-INT Drug

Final results from exploratory Phase IIa Clinical Trial in type 2 diabetes patients after once a day injections for 28 days and then followed for 6 months, lead to sustained reductions in blood glucose levels for the next 5 months.

<http://www.diabetesincontrol.com/results.php?storyarticle=4922>

The gastrin-based therapy, E1-I.N.T.(TM), showed sustained reductions in blood glucose control parameters, including haemoglobinA1C (HbA1c), for 6 months post-treatment. The type 2 diabetes patients enrolled in this study were using metformin with/without thiazolidinediones (TZD).

Chief investigator Doctor Sherwyn Schwartz and CEO Dr. Tony Cruz held a conference call to report the results last Friday. This is the first time that a drug to control diabetes showed positive results 6 months post treatment.

In the E1-I.N.T.(TM) treated group of patients, the mean HbA1c level was reduced by 0.94% to 1.21% vs. baseline levels in months 2 to 6 post-treatment. More specifically, the mean HbA1c level among treated patients was reduced 0.43%, 0.94% (p<0.05), 1.09% (p<0.05), 1.12% (p<0.05), 1.21% (p<0.05), and 1.14% in months 1, 2, 3, 4, 5, and 6 post-treatment, respectively. In contrast, the mean HbA1c levels of the placebo group ranged from a reduction of 0.1% to an increase of 1.0% over the same period. In addition to the HbA1c reductions, the data demonstrated decreases in fasting blood glucose levels as well as improvements in glucose tolerance over a six month period following treatment with E1-I.N.T.(TM).

Trends in increased insulin levels as measured with an oral glucose tolerance test were also observed, particularly in patients where the HbA1c levels decreased over 1% with E1-I.N.T.(TM) therapy. These data are consistent with the increased glucose control observed in diabetes animal models where a short treatment with E1-I.N.T.(TM) resulted in a sustained increase in beta cell mass and function. These clinical improvements, including HbA1c reductions greater than 1% in patients six month post-treatment, highlight the potential that E1-I.N.T.(TM) therapy could provide patients significant clinical benefit in excess of 6 months.

"These data are very encouraging and show the potential of a regenerative therapy in diabetes," said Sherwyn Schwartz, MD, a noted diabetes researcher and the Director of the Diabetes & Glandular Disease Research Associates in San Antonio, Texas who was the lead investigator of the study. "Achieving sustained improvements in glucose control for many months post-treatment following a 4-week therapy is unprecedented in type 2 diabetes.

The improvements in HbA1c correlated with changes in multiple other clinical parameters suggesting that gastrin-based therapies, and specifically E1-I.N.T.(TM), have the potential to re-engage the body's natural mechanism to regulate glucose," said Dr. Tony Cruz, Chairman and Chief Executive Officer of Transition. "The immediate goal is to optimize the dosing regimen in a larger phase II study".

The results from the Type 1's also in the study where not reported.

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Item 15

Teach Doctors To Cook And Walk

Walk two miles and call me in the morning. That's what doctors could soon prescribe if the new leaders of two major medical groups have their way.

<http://www.diabetesincontrol.com/results.php?storyarticle=4921>

"We're trying to get every physician to prescribe exercise," says Robert Sallis, a California physician who recently became president of the American College of Sports Medicine. "Physicians have a moral responsibility to inform patients of the danger of inactivity and the health benefits of being more active."

That's also the message from the new head of the American Medical Association. "We are in lockstep with them on that concept," says incoming AMA President Ronald M. Davis, who is also the director of the Henry Ford Health System's Center for Health Promotion and Disease Prevention in Detroit. "We need to get doctors to prescribe exercise more and we need to get patients to follow that advice."

More than half of Americans fail to get the 30 minutes of physical activity recommended daily to provide health benefits, according to the Centers for Disease Control and Prevention.

So many Americans are inactive that some experts have coined a new term for it: sedentary death syndrome. The condition helps cut short an estimated 250,000 lives annually, according to Frank Booth, professor of physiology at the University of Missouri. Research suggests that people who are sedentary spend about \$1,500 more annually on medical bills than do their more active counterparts.

"There are also studies to show that they miss more work and are not as productive," says Sallis. Research shows that regular physical activity improves health by cutting the risk of heart disease, stroke, colon cancer, diabetes and high blood pressure. Even brief bouts of activity several times a day can help control weight and relieve arthritis, anxiety and depression. "Exercise is medicine," Sallis says. "We know that it works very well. We just don't have the proper way to administer it."

That's where the doctors come in. Sallis is leading the charge to get doctors and other health professionals to ask every patient at every office visit about their exercise habits.

It isn't just activity that doctors are being asked to encourage. Harvard Medical School and the Culinary Institute of America recently teamed up to teach physicians to cook more healthfully for their own personal consumption.

The theory is that by teaching doctors how to cook, they may be more likely to encourage their patients to do the same. Harvard also is considering establishing teaching kitchens in hospitals. The goal would be to take patients

who have recently been diagnosed with diabetes, heart disease or other nutritionally related conditions, and show them how to make healthier meals.

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Quote of the Week!

"Every Time I Walk Past a Bakery, I'm Just Happy To Be Alive"

.....Richard K. Bernstein, MD

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Richard K. Bernstein's New Book, Diabetes Solution 2007 is available. Containing new and revised information, this new book is on special at <http://www.diabetes911.net>. Also Dr. Bernstein's New 5 CD Set "Secrets to Normal Blood Sugars" is available. Recorded Individually For Type 1 and Type 2 Diabetes, These "LIVE" 5 CD Sets Contain The Personal Diabetes Education Program taught by Dr. Bernstein to his patients.

LIVE WEBCAST:

Dr. Bernstein will participate in another 60 minute Tele-Seminar on August 8, 2007, at 7:00 PM CST, 8:00 PM EST and 5:00 PM West Coast time, that we invite you to attend, and ask your patients to attend. In addition to calling in, this upcoming call will also be broadcast through a LIVE web-cast on the Internet. Don't miss it. Click here to register for this free teleconference.
<http://www.diabetes911.net/askdrb/index.php>

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