

# DIABETES IN CONTROL.com Newsletter

The Newsletter for Professionals in Diabetes Care

October 11, 2006 Issue #333

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## Top Diabetes Stories:

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### No Clear Evidence for Ultra-Low Cholesterol Targets\*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4206>

### New Joint Guidelines for CVD and Diabetes from 2 European Associations\*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4203>

### Exenatide As Effective As Insulin\*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4202>

### Diabetes is Now Diagnosed in 1 in 523 Young People\*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4200>

### Antihypertensives Cut New-Onset Diabetes by a Third\*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4198>

### Are Your Diabetic Patients Part of the 21% Who do Not Take Their Meds?\*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4197>

### Effect of Weight Loss on Arterial Stiffness in Type 2 Diabetes\*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4194>

### New Diabetes Drug Galvus Matches Avandia in Control of Blood Sugars\*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4192>

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## From the editor's desk

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The Dream Study results have a lot of people talking and Pharma companies salivating but will it really make a big difference? Our Publisher, **Steve Freed**, has an interesting slant on the study and a candid interview with **Dr. Bakris**, one of the chief investigators. [Click here to read If Only in a Dream](#)

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4207>

Thomas J. Lamb, Attorney at Law, continues his series this week by explaining how Medication Errors Can Be Reduced By Better Prescribing Methods. [Read part 3, by clicking here](#)

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4208>

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We all have **comfort foods** to offset depression, anxiety or stress and these are always high in Carbohydrates. Why are these foods so addictive?? **Richard K. Bernstein, M.D., F.A.C.E., F.A.C.N., C.W.S** has the answer in this week's feature. COMFORT FOODS

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4209>

### October 15, 7PM ET on CNBC

The heroic story of Eva Saxl, a Holocaust refugee who survived World War II through determination, ingenuity, and her husband's homemade insulin. Plus, Jim Turner explores "politically-correct" diabetes lingo. Tune in to this 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 #2: Fruit and Vegetables Cut Heart Disease Risk, Says Study

Item #3: Americans Unaware of Significance of Triglycerides

Item #6: Progression of Retinopathy Common Among Blacks With Type 1 Diabetes

Item #8: One-Third of U.S. Youth Not Physically Fit

Item #11: Role of Blood Glucose Self-Monitoring in Medicare Patients with Type 2 Diabetes

Check out this weeks "Test Your Knowledge" question.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4210>

Dave Joffe, *Editor-in-Chief*

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## NEWS FLASH:

**Generic Plavix (Clopidogrel) may not be here to stay.** Apotex is challenging a patent that's not due to expire until 2011. They felt they had a good case so they launched the generic. Bristol-Myers and Sanofi got an injunction to stop the sales until a final ruling is made, but the generic is already in distribution and is still legal to sell. Supplies could last until early 2007, so consider having your patients stock up on the generic before it is gone and they lose the case.

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## New Product:



**Monitoring Diabetes Wirelessly :** New software is about to be tested that relies on wireless technology to transmit diabetes patients' data from their cellphones to an online server that checks their blood-sugar level and asks questions. The system after getting the info from the cell phone determines if a patient's glucose level is above or below his doctor-recommended range, an automated voice-response unit will call and ask the patient yes-or-no questions about his or her diet, exercise, medication intake and other behavior. The information may be forwarded to a nurse call center or the patient's physician. "The system monitors you passively in the background," "If you're doing fine, it leaves you alone. If you're not, it may call you and ask you a couple of questions

like, 'I saw you had a low blood pressure. Did you take your medication today? Did you exercise?' " MedApps plans to first market the device to disease-management companies that oversee care for Medicare and Medicaid patients. Eventually, the system could be available for any diabetes patient.

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## This Week's Items:

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**1. No Clear Evidence for Ultra-Low Cholesterol Targets\***

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4206>

**2. Fruit and Vegetables Cut Heart Disease Risk, Says Study**

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4205>

**3. Americans Unaware of Significance of Triglycerides**

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**11. Role of Blood Glucose Self-Monitoring in Medicare Patients with Type 2 Diabetes**

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4196>

**12. Efficacy of Angiotensin II Receptor Blockade in Elderly Patients With Diabetes**

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4195>

**13. Effect of Weight Loss on Arterial Stiffness in Type 2 Diabetes\***

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4194>

**14. Prevention of Hypoglycemia During Exercise in Children With Type 1 Diabetes**

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4193>

**15. New Diabetes Drug Galvus Matches Avandia in Control of Blood Sugars\***

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4192>

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## **ITEMS For The Week:**

Item 1

### **No Clear Evidence for Ultra-Low Cholesterol Targets**

*There is no scientifically valid evidence to support the ultra-low LDL target of 70 milligrams/deciliter for very high-risk patients. Further, they suggest that the evidence previously cited to support an LDL goal of less than 100mg/dL for high risk patients also has major flaws.*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4206>

Americans have been trying to get their cholesterol levels down for decades, ever since studies showed a strong link between high cholesterol and heart disease. But in recent years, experts have suggested that some people should aim even lower, recently recommending very low levels of the type of cholesterol called low-density lipoprotein for some high-risk people — even if it means they had to take multiple medications to get there.

In a new paper in the October Annals of Internal Medicine, a team of researchers from the VA Ann Arbor Healthcare System and the University of Michigan, show that the current studies do not support treating cholesterol levels to below and LDL of 70 or even less than 100mg/dL.

After performing an exhaustive review of existing research on LDL cholesterol and heart health, they conclude that there is no scientifically valid evidence to support the ultra-low LDL target of 70 milligrams/deciliter for very high-risk patients that has been advocated by some members of the federal government's National Cholesterol Education Program. Further, they suggest that the evidence previously cited to support an LDL goal of less than 100mg/dL for high risk patients also has major flaws.

That evidence may come someday, but until that day, it may be better for society to concentrate less on cholesterol and more on getting people with multiple heart disease risk factors on medications called statins — regardless of their cholesterol levels. Statins are great at lowering a person's LDL cholesterol, but it is not yet clear if lowering cholesterol is the main reason that statins prevent heart attacks and save lives. A focus on statin therapy may provide more public benefit than focusing on getting high-risk patients' levels as low as they can go using multiple drugs.

"Our review suggests that we in the medical community have misunderstood the scientific evidence on whether very low LDL is important, or whether adequate doses of statins are what is really important," says lead author Rodney Hayward, M.D., director of the VA Center for Health Services Research and Development and professor of internal medicine at the U-M Medical School. "Current practice guidelines and recommendations often focus on getting LDL as low as possible, but the literature to date doesn't demonstrate that low LDL is what is truly important — but it does show that statins save lives in high cardiac risk patients regardless of a person's LDL level."

In fact, Hayward and his colleagues say, it may be that the other effects of statin drugs help reduce the risk of heart disease and heart attacks as much or more than the drugs' LDL-lowering power does. Statins inhibit inflammation and clotting, as well as reduce cholesterol, attributes that can be important for preventing heart attacks.

People who have survived a heart attack or have risk factors that put them at high risk of future heart problems should probably be on a moderate or high dose of a statin and stay on it no matter what happens to their exact LDL level, Hayward says.

However, the benefits and safety of using multiple medications to get LDL levels low is open to debate, and is not supported by valid clinical evidence, he adds. Still, many physicians recommend using statins in combination with medications such as niacin, gemfibrozil, fenofibrate and newer drugs to try to bring LDL levels down to low levels.

“Going beyond statin therapy is becoming more common, but when you do that you are also going beyond the current evidence,” Hayward says. “Neither the benefit nor the long-term safety of using multiple medicines to lower LDL cholesterol has been studied to date. There is a temptation to believe that lower cholesterol is always good, but recently two treatments that improve cholesterol profiles, hormone replacement therapy and muraglitazar, were found to actually harm people. We would never have known this if we hadn’t insisted on scientifically rigorous assessments of these treatments.”

For the new paper, the authors examined every study cited by the NCEP panel in their 2004 report that led to the current ultra-low recommendations, and other studies that assessed the relationship between LDL cholesterol and cardiovascular outcomes in patients with LDL under 130 mg/dL. They also contacted more than 20 experts from around the world and none could identify any valid clinical evidence supporting that achieving a low LDL level was important independent of statin therapy.

The problem is not solely a lack of studies, but how past studies have been analyzed, says Hayward. Many studies have looked at associations between LDL and outcomes, but such studies didn’t distinguish between whether the LDL level achieved was important or whether the statin dose given was important. They also didn’t assess whether patients actually took their statins regularly — a crucial factor — and often didn’t consider whether the accuracy of the blood test that measures LDL is adequate to guide patient therapy.

“This is an ongoing problem in the medical literature,” says Hayward. “We do randomized controlled trials well, but when it comes to analyzing subgroups or a treatment’s mechanism of action, we often get the science all wrong. We need to do better, and in this paper we have tried to lay out a better statistical approach to analyzing treatment goals and clinical trials in the future, including those examining LDL cholesterol.”

Also, almost all the published clinical trials on this topic were designed to see how well a statin did against a placebo, or how well patients did on different doses of statins. None were based on getting patients to a specific LDL target using multi-drug therapy and seeing how they did once they were there.

In fact, he says, the evidence strongly suggests that a high dose of a statin produces the same benefit in a person who has an LDL level of 100 mg/dL as it does in a person with an LDL level of 200 mg/dL if the two have the same overall heart attack risk. High-risk individuals are defined by NCEP as those who have survived a heart attack or who have clogged arteries or diabetes or multiple heart disease risk factors such as high blood pressure, smoking and a strong family history of heart disease.

The distinction between concentrating on LDL versus concentrating on statins is not a minor issue, the authors suggest. The paper notes that compared to simply treating all high CV-risk patients with statins, titrating cholesterol therapy to recommended LDL goals entails considerably greater complexity, frequent use of multi-drug therapy and greater societal and patient out-of-pocket costs, which can result in increased patient burden and lower adherence to all treatments.

“Pharmaceutical companies, which pay for most drug studies, have a natural and understandable interest in wanting to sell their medications to as many people as possible, but the scientific community has a public and moral responsibility of guarding the scientific integrity of the evidence,” Dr. Hayward notes. “In this instance, our analyses suggest that we should have done a better job.”

Until more evidence is available, the authors emphasize the importance of getting more people to modify their diet, exercise more, understand their overall risk of heart disease, and take a statin if their risk is high. “Statins are lifesaving medicines when used in high-risk patients. They can reduce the risk of heart attacks and strokes by 30 percent to 35 percent and the risk of dying by 20 percent to 25 percent, and we need to work harder to help people at risk take them and afford them,” says Hayward. “We do not have many instances where medicines can save lives and money, but this may be one of those instances.”

Individuals who know their cholesterol levels can assess their heart risk using the NCEP online

<http://hp2010.nhlbihin.net/atp/iii/calculator.asp>

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Item 2

**Fruit and Vegetables Cut Heart Disease Risk, Says Study**

*Every extra of fruit or vegetable consumed daily could cut the risk of heart disease by four percent, says a meta-analysis of almost a quarter of a million people, giving people even more reason to seek out the nutrient-rich foods.*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4205>

The Five-a-day message is well known, but applying this does not seem to be filtering down into everyday life. Indeed, recent studies have shown that the average consumption of people in developed countries is three portions a day.

The meta-analysis by scientists from France's INSERM in Paris, Lille's Pasteur Institute, and Rouen's Department of Epidemiology and Public Health, pooled nine cohort studies giving an overall study population of 91,379 men, 129,701 women, and 5,007 coronary heart disease events.

Studies were included in the meta-analysis if they reported relative risks for coronary heart disease or mortality and if fruit and vegetable intake was quantitatively assessed.

The analysis, found that the risk of coronary heart disease (CHD), conditions that cause of 20 per cent of deaths in the US and 17 per cent of deaths in Europe, was cut by four per cent for each additional fruit and vegetable portion consumed, and by seven per cent for fruit portion intake.

The link between the risk of CHD and vegetable intake however was mixed with a more beneficial relationship observed for general cardiovascular mortality (26 per cent risk reduction) than for the more specific fatal and nonfatal heart attacks (myocardial infarction) (five per cent).

*"This meta-analysis of cohort studies shows that fruit and vegetable consumption is inversely associated with the risk of CHD,"* concluded the reviewers.

*"The causal mechanism of this association, however, remains to be demonstrated."*

The analysis has several strengths, including the well-defined inclusion criteria and the large sample population, but some limitations are inherent. The analysis is based on cohort studies that are observational by nature and therefore subject to errors. Also, no distinction could be made between different fruit and vegetables. Indeed, the researchers suggest that the calculated relative risks were *"probably overestimated"*.

*the Journal of Nutrition (Vol. 136, pp. 2588-2593),*

**DID YOU KNOW:**

**Do You Want Diabetes with Your Order of Fries?** : Women who splurged on french fries just once a week were 21 percent more likely to get diabetes than those who ate none, in a 20-year Harvard School of Public Health study of 84,500 women. Eating five servings per week of any white potatoes, including mashed and baked, raised the risk by 14 percent over those who ate less than half a serving per week. Blame it on spuds' high glycemic index, or GI; potatoes break down quickly in your stomach, creating a fast, steep blood sugar rise. Obese women were even more likely to get diabetes from high potato intake. If you're overweight and/or sedentary, switch to sweet potatoes.

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Item 3

**Americans Unaware of Significance of Triglycerides**

*A survey conducted by the National Lipid Association (NLA) has revealed that 87% of patients are unaware of the importance of high triglycerides in risk of heart disease. Fewer than half say they have discussed the topic with their physicians.*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4204>

"NLA spokesman Dr. Jerome D. Cohen of St. Louis University Health Sciences Center stated that, "We need to get physicians and consumers... more educated about the importance of triglycerides in heart disease.

The survey, which involved 2,089 patients and 510 physicians, revealed that 17% of physicians are unaware of the National Cholesterol Education Program's triglyceride recommendations. Results also show that only 83% of physicians are aware that the triglyceride target level is below 150 mg/mL. Only 13% of patients were aware of the cut-off value.

Two-thirds of physicians (67%) said that they discuss the importance of controlling triglyceride levels with their patients, yet only 43% of patients recall having had such a conversation. However, one positive finding was that patients who remembered the discussion were more likely to be aware of target values.

Fewer women than men were aware of the importance of controlling triglyceride levels, despite the fact that hypertriglyceridemia is associated with a higher risk of heart disease for women than men. Furthermore, only 15% of diabetics were aware of the cut-off value for triglycerides.

"The real message," concluded Dr. Cohen is "that high triglycerides are treatable." A suitable education program, he added, "can be modeled after the cholesterol education program, which was modeled after the blood pressure program that was established in 1972."

*Survey conducted by the National Lipid Association (NLA)*

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Item 4

**New Joint Guidelines for CVD and Diabetes from 2 European Associations**

*European Society of Cardiology(ESC) and the European Association for the Study of Diabetes EASD) issue aggressive guidelines for coronary heart disease and diabetes.*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4203>

Diabetes and cardiovascular diseases (CVD) often appear as the two sides of a coin: on one side, diabetes has been rated as an equivalent of coronary heart disease, and conversely, many patients with established coronary heart disease (65-70 %) suffer from diabetes or its pre-states.

The two leading European scientific organisations ESC and EASD accepted this challenge and developed for the first time joint, evidence based guidelines on the proper management of such patients. The content covers the whole spectrum, i.e. 1) definition, classification and screening of diabetes and pre-diabetes, 2) epidemiology of diabetes, impaired glucose homeostasis and cardiovascular risk, 3) identification of subjects at high risk for CVD or diabetes, 4) pathophysiology, 5) treatment to reduce cardiovascular risk, 6) management of CVD, 7) heart failure and diabetes, 8) arrhythmias – atrial fibrillation and sudden cardiac death, 9) peripheral and cerebrovascular disease, 10) intensive care, 11) health economics and diabetes.

Although altogether 14 individual experts from both fields and all over Europe were assigned to draft the manuscripts according to their specific area of expertise, the guidelines were then extracted and harmonized as a true team effort. They

were thereafter extensively reviewed by 18 experts from ESC and EASD, whose identity was disclosed only after the approximately 1500 comments and suggestions had been dealt with by the writing group.

There are a total of 72 recommendations, an executive summary being published in parallel in the two leading journals, Diabetologia and Euro Heart Journal, and a full text including 711 references on the website: [www.escardio.org](http://www.escardio.org). Pocket guidelines will follow shortly.

Key messages are: 1) diabetes and CVD are much more common than imagined, 2) the negative impact of dysglycemia is apparent before the onset of diabetes, 3) the prognosis is principally amenable to major progress, yet still unfavorable, 4) an investigational algorithm needs to be employed to detect the alternate side of the disease either starting from diabetes or from coronary artery disease (see figure attached), 5) an oral glucose tolerance test is the best method to diagnose previously unknown diabetes or prediabetes, 6) to minimize resources, primary screening for the potential of diabetes can be effectively done by a non-invasive risk score to define high risk, 7) prevention both of diabetes and CVD is possible, 8) therapeutic success depends on collaboration across speciality borders, 9) treatment comprises multifactorial risk intervention and targeted management of CVD, 10) structured life-style counselling is a very important therapy for these patients and needs to be improved, 11) targets for treating blood pressure, blood glucose and lipids have been defined and are more strict than before and 12) the joint ESC/EASD approach provides the state-of-the-art evidence base.

These interdisciplinary guidelines are now being given to the community of cardiologists, diabetologists and primary care physicians, aiming at optimising the quality of care for our common patients and at fostering innovative research in this field of tremendous importance.

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### **DID YOU KNOW:**

**Diabetes is a cardiovascular disease?** Whilst it is defined on the basis of the likelihood of progression to microvascular disease, large epidemiological studies have shown that the risk of CVD is increased 4-fold in patients with type 2 diabetes, compared with that in non-diabetic individuals.<sup>[1]</sup> Overall, up to 80% of patients with type 2 diabetes die from cardiovascular complications and the average life expectancy is reduced by approximately ten years.<sup>[2]</sup>

1. American Diabetes Association. Consensus development conference on the diagnosis of coronary heart disease in people with diabetes. *Diabetes Care* 1998;21:1551-9. 2. Donnelly R. Managing cardiovascular risk in patients with diabetes. *Br J Diabetes Vasc Dis* 2005;5:325-9.

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Item 5

### **Exenatide As Effective As Insulin**

*Patients on exenatide lost weight, while insulin patients gained weight.*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4202>

Results from a study indicating that exenatide improves blood sugar levels as effectively as biphasic insulin aspart 30/70 (NovoMix 30(R), NovoNordisk) for people with type 2 diabetes failing to achieve acceptable blood sugar control on both metformin and a sulfonylurea. This long-term clinical trial is the second study conducted at European clinical centers demonstrating that exenatide can control blood sugar as effectively as insulin.

501 patients were enrolled in the 52-week, multi-center, open-label, randomized trial. The trial was designed to determine if exenatide can be used as safely and effectively as biphasic insulin aspart in patients with type 2 diabetes inadequately treated with metformin plus a sulfonylurea. Study participants were randomized into two treatment arms. The first group received a dose of exenatide (5 micrograms twice-a-day for first four weeks, then 10 micrograms twice-a-day for the remainder of the study), in conjunction with metformin and a sulfonylurea. The second group received biphasic insulin aspart (titrated to achieve an optimal balance between glycemic control and risk of hypoglycemia as dictated by best clinical

practice), again with metformin and a sulfonylurea. The average HbA1C at baseline was 8.6 percent in both treatment groups.

During the one year (52-week) study, patients using exenatide showed improvements in three important measures of blood glucose control: fasting blood glucose, postprandial blood glucose, and hemoglobin A1C (HbA1C). Exenatide treatment also resulted in an average reduction in body weight.

Thirty-two percent of study participants using exenatide reached target HbA1C of 7 percent or less and 18 percent of patients in the exenatide group achieved an HbA1c level of 6.5% compared to 9 percent in the biphasic insulin aspart group. These Patients on exenatide lost an average of 2.5 kilograms (5.5 pounds), while those receiving biphasic insulin aspart gained an average of 2.9 kilograms (6.4 pounds). Weight gain is a common side effect of insulin therapy. In addition, exenatide reduced peak blood sugar levels after meals. Both treatments were associated with low rates of daytime and nighttime hypoglycemia (low blood sugar).

"These data show that exenatide, without the inconvenience of dose titration, is a potential alternative to biphasic insulin aspart for the treatment of patients with type 2 diabetes not adequately treated with metformin and a sulfonylurea, commonly used oral antidiabetic agents."

Other Key Findings: Reduced fasting and postprandial blood sugars greater than biphasic insulin aspart. Wt. loss in the exenatide arm: Patients treated with exenatide experienced an average weight reduction of 2.5 kilograms (5.5 pounds). Weight gain in the biphasic insulin aspart: On average, patients treated with insulin gained 2.9 kilograms (6.4 pounds). After 52 weeks, the total weight difference between treatments was -5.4 kilograms (11.9 pounds).

The most common adverse event for exenatide was nausea (33.2 percent exenatide, 0.4 percent biphasic insulin aspart), which was generally mild-to-moderate and tended to decrease in frequency and severity over time.

*Findings were presented at the 42nd annual meeting of the European Association of the Study of Diabetes (EASD) in Copenhagen, Denmark.*

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Item 6

### **Progression of Retinopathy Common Among Blacks With Type 1 Diabetes**

*Over a 6-year period, 56.1% of African Americans with type 1 diabetes and retinopathy showed progression of their eye disease.*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4201>

The report is published in the Archives of Ophthalmology for September. Poor glycemic and blood pressure control were identified as risk factors for progression.

The findings stem from a study of 483 subjects who were part of The New Jersey 725 cohort, which comprised African-American patients who were diagnosed with diabetes and treated with insulin before 30 years of age. The current cohort included only those with type 1 diabetes.

As part of the study, structured clinical interviews, ocular examinations, fundus photographs, and blood pressure measurements were taken at baseline and 6 years later.

"At the 6-year evaluation, 72.3% of the patients at risk for incidence of diabetic retinopathy had developed any diabetic retinopathy," report Dr. Monique S. Roy, from the University of Medicine and Dentistry in Newark, and Dr. Mahmoud Affouf, from Kean University in Union, both in New Jersey.

As noted, 56.1% of patients with baseline retinopathy showed disease progression, including 15.0% who progressed to proliferative retinopathy and 15.9% who developed macular edema.

High glycosylated hemoglobin levels at baseline and systemic hypertension were significant predictors of retinopathy progression and macular edema, the team found.

Older age, renal disease, and severe retinopathy all correlated with progression to proliferative retinopathy. For macular edema, the risk factors included older age, lower socioeconomic status, severe retinopathy, and high total cholesterol levels.

"Because glycemic and blood pressure control in this population are poor, measures to improve medical care and ensure regular dilated eye examinations to detect vision-threatening diabetic retinopathy may reduce morbidity from the disease," the authors conclude.

*Arch Ophthalmol* 2006;124:1297-1306.

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Item 7

### **Diabetes is Now Diagnosed in 1 in 523 Young People**

*This places diabetes among the more common chronic illnesses of youth, the researchers report, striking 1.82 children per 1,000, compared with 1.24 per 1,000 with cancer and 120 per 1,000 with asthma.*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4200>

About one in every 523 young people have been diagnosed with diabetes, according to the first comprehensive assessment of the disease in Americans under 20.

The national study, provides a baseline for future studies of diabetes prevention and control, says study co-author Jean Lawrence, a research scientist with Kaiser Permanente Southern California in Pasadena. Previous estimates have been drawn from smaller studies that focused mainly on white children and type 1 diabetes, she says.

Until now, estimates of type 2 in children have been based on anecdotal reports from doctors' offices and diabetes clinics. "We didn't have uniform national information on rates of diabetes and children and youth," Lawrence says. This study "describes the scope of the problem," she says.

The researchers found that diabetes is more common in non-Hispanic whites than in other ethnic groups, and that type 1 diabetes is the most common form in young people of all racial and ethnic groups, except for American Indians, in whom more than three-quarters of cases are type 2.

Though the prevalence is increasing, the numbers are small. Of the 6,379 identified with diabetes at six sites in the study, type 2 was found in 11 children under 10 and 758 in the 10-19 age group.

The researchers note that the study only counted diagnosed cases, and because type 2 can remain undiagnosed for a period of time, they may be underestimating its prevalence in youth.

Type 2 diabetes was unheard of in children 20 years ago, Deeb says. Now, "I frequently see a 55-year-old grandmother who developed diabetes last year, a 35-year-old mother who developed diabetes last year and a 14-year-old who developed diabetes today."

That does not bode well for the future, because diabetes over time can lead to heart and kidney problems, blindness and nerve damage that can result in amputation. If it starts in young people, he says, the complications may occur early.

"All my colleagues are worried about 25- and 30-year-olds who are at risk for having heart attacks," Deeb says. "The most important thing is that we recognize the enormity of what's happening and document the extent of it, so we can identify it and intervene."

The study, which was paid for by the U.S. Centers for Disease Control and Prevention and the National Institutes of Health, found that the average age of diagnosis was 8.4 years, and 96% of children under 10 with diabetes had type 1. Girls had a higher prevalence, at 1.88 per 1,000, than boys, at 1.77 per thousand.

Journal Pediatrics Oct. 2006

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Item 8

### **One-Third of U.S. Youth Not Physically Fit**

*Approximately one-third of boys and girls age 12 to 19 in the United States do not meet standards for physical fitness. Low physical fitness during adolescence tends to track into adulthood, so it becomes obvious why we are seeing more kids with type 2 diabetes*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4199>

Dr. Russell R. Pate, a researcher at the University of South Carolina's Arnold School of Public Health, led the study that also found that physically fit young people are less likely to have high blood pressure, high cholesterol levels or other risk factors for chronic diseases.

"Between the 1950s and the 1980s, regular surveys of youth physical fitness were conducted in the United States. An increasing proportion of children have become obese since the 1980s, which may be explained by a decrease in physical activity," Pate said. "If so, it is likely that average physical fitness also has declined among youth in the same time period, since the last national survey."

Pate and colleagues from the Centers for Disease Control and Prevention and The Cooper Institute assessed the physical fitness of 3,287 youth ages 12 to 19 who participated in the government-conducted National Health and Nutrition Examination Survey between 1999 and 2002. The participants were interviewed in their homes and then visited a mobile examination center, where they had a treadmill exercise test consisting of a two-minute warm-up, two three-minute periods of exercise and a two-minute cool-down.

During the test, researchers measured blood pressure, heart rate and rate of perceived exertion, determined by asking participants to rate how hard they feel their bodies are working. Heart rate readings during the three-minute periods of exercise were used to estimate maximal oxygen uptake (VO<sub>2</sub>max), which is the amount of oxygen consumed by the body during maximum exertion: Higher uptake levels mean an individual is more fit.

Estimated VO<sub>2</sub>max, and therefore physical fitness levels, were higher on average in males than in females and in youth of normal weight than those who were overweight. However, there were no differences across racial or ethnic groups.

Older males were more physically fit than younger males, while the opposite was true for females. Participants who reported more sedentary behavior, such as watching television or playing video games, and those who spent less time being physically active were more likely not to be physically fit.

"This represents a significant public health problem because low physical fitness during adolescence tends to track into adulthood, and adults who are less physically active are at a substantially increased risk for chronic disease morbidity (illness) and mortality (death)," the authors wrote in the study.

Because active youth tend to be more physically fit, experts recommend that physicians counsel children and parents about guidelines for physical activity, said Pate, who was the author of a recent report by the American Heart Association that called on schools to offer more physical education programs.

"This study is another indicator of the importance of physical activity in the lives of young people," Pate said. "Clearly, we must do more as a nation to support fitness among all youth."

Oct. 2006, *The Archives of Pediatric and Adolescent Medicine*

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**FACT:**

**Despite knowledge of the benefits of fish oil, family physicians infrequently recommend fish oils for their CVD patients.** Since consumption of fish oil has been shown to reduce mortality in patients with cardiovascular disease (CVD), this study by US researchers aimed to determine the frequency and associations of dietary fish prescribing by family physicians via a survey to Washington State family physicians. They found that nearly all agreed that nutrition is important in CVD prevention (99%) and felt that they have an essential role in giving dietary advice (92%). The majority (57%) knew of fish oil's effectiveness in secondary prevention of CVD. However, only 17% of respondents were identified as high fish prescribers. Knowledge of fish oil's benefit in sudden death reduction was associated with higher fish prescribers in the analysis. The researchers concluded: "Despite knowledge of fish oil's benefit and favorable attitudes toward nutritional therapy, family physicians infrequently recommend fish oils for their CVD patients. Strategies improving awareness of fish oil's effects on sudden death and reducing time barriers associated with dietary counseling should be explored further to increase recommendation of this important advice." *The Journal of the American Board of Family Medicine* 19:459-467 September-October 2006.

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Item 9

**Antihypertensives Cut New-Onset Diabetes by a Third**

*A new analysis of the ASCOT study shows the clearest proof so far that antihypertensive treatment with an ACE inhibitor and calcium channel blocker limits new-onset diabetes, while treatment with a  $\beta$ -blocker (atenolol), and thiazide diuretic (bendroflumethiazide) helps cause it,*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4198>

An antihypertensive treatment regimen of amlodipine plus perindopril led to 34% fewer cases of new-onset diabetes, compared with a regimen of atenolol plus bendroflumethiazide, in a controlled study with more than 14,000 hypertensive patients.

This new, prespecified analysis of data collected in the Anglo-Scandinavian Cardiac Outcomes Trial (ASCOT) also identified a fasting plasma glucose level above 90 mg/dL (5 mmol/L) as the most powerful baseline predictor of a hypertensive patient's risk of developing diabetes, producing a 5.8-fold increased risk of diabetes, compared with patients with lower baseline sugar levels, Dr. Ajay K. Gupta reported a joint meeting of the European Society of Cardiology and the World Heart Federation.

The results from several prior studies had suggested that ACE inhibitors, like perindopril, angiotensin-receptor blockers, and calcium channel blockers like amlodipine, could cut the risk of new-onset diabetes. But interpretation of the earlier results was hampered because new diabetes was not a prespecified outcome or the size of the study was small. As a result, the new ASCOT analysis is the clearest proof so far that antihypertensive treatment with an ACE inhibitor and calcium channel blocker limits new-onset diabetes, while treatment with a  $\beta$ -blocker (atenolol), and thiazide diuretic (bendroflumethiazide) helps cause it, said Dr. Gupta, an epidemiologist at the National Heart and Lung Institute at Imperial College in London.

Main results from ASCOT were first reported a year ago and showed that in more than 19,000 patients followed for a median of 5.5 years, a treatment strategy using amlodipine followed by perindopril for patients with hypertension plus at least three other cardiovascular risk factors led to significantly fewer cardiovascular-disease events than did a strategy that used atenolol followed by a thiazide diuretic (*Lancet* 2005;366:895-906). The ASCOT study was sponsored by Pfizer Inc., which markets amlodipine (Norvasc).

A prespecified subanalysis focused on the 14,120 patients who did not have diabetes at baseline. The incidence of new-onset diabetes during follow-up was 8.0% in patients treated with amlodipine followed by perindopril when needed, and in 11.4% of those who were treated with atenolol first followed by the thiazide diuretic.

in a multivariate analysis, patients in the amlodipine and perindopril group were 34% less likely to develop new diabetes, compared with patients in the other control group, a statistically significant difference.

Other important protective factors were HDL cholesterol and total cholesterol. Risk for new diabetes fell by 28% for every 39 mg/dL (1 mmol/L) rise in HDL cholesterol, and risk fell by 11% for every 39 mg/dL (1 mmol/L) drop in total cholesterol, reported Dr. Gupta.

Several features of these drugs probably explain these effects, but one plausible explanation of the detrimental effect of  $\beta$ -blockers is that they increase peripheral vasoconstriction, thereby cutting blood flow to skeletal muscle and cutting its ability to metabolize blood sugar, said Dr. Peter Sever, professor of clinical pharmacology and therapeutics at Imperial College and a principal investigator for ASCOT.

The results also implicate thiazide diuretics in boosting new-onset diabetes, but many patients need a diuretic as a third-line drug to help reach their goal pressure, and these results shouldn't discourage physicians from prescribing a diuretic if needed, said Dr. Sever. Some patients might also need a fourth drug, such as a  $\beta$ -blocker. In that case, a more vasodilating  $\beta$ -blocker, such as carvedilol, should be used, commented Dr. Lars Rydén, professor emeritus of cardiology at the Karolinska Institute in Stockholm.

The most important factor by far for boosting the risk of new-onset diabetes was fasting plasma glucose at baseline, followed by body mass index. Diabetes risk rose by 49% for every body mass index rise of 5 kg/m<sup>2</sup>.

Dr. Gupta used the results of the multivariate analysis to develop a scoring system to calculate the risk faced by hypertensive patients for developing diabetes. Dr. Gupta plans to report details of the scoring system in the future. He used the system to divide all patients in the diabetes analysis into quartiles based on their risk. The risk levels ranged from 2.5-fold higher in the second quartile to 5-fold higher in the third quartile and 19-fold higher in the fourth quartile.

Patients at each of these four levels of risk showed a similar magnitude of drop in their risk when they were treated with amlodipine and perindopril. It was a "surprising finding" that the risk reduction was so consistent across all four risk strata, Dr. Gupta said.

*Family Practice News* Volume 36, Issue 19, Pages 1-2 (01 October 2006)

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Item 10

**Are Your Diabetic Patients Part of the 21% Who do Not Take Their Meds?**

About 21 percent of individuals with diabetes do not regularly take their blood-sugar lowering, blood-pressure lowering or cholesterol-lowering pills, researchers found in study of 11,532 diabetes patients.

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4197>

The study patients who were nonadherent to treatment had higher blood pressure, higher levels of artery-clogging LDL cholesterol and higher blood sugar levels, indicating poor diabetes control.

Importantly, Dr. P. Michael Ho of the Denver VA Medical Center and colleagues report, patients who did not adhere to their medications had a 58-percent higher odds of being hospitalized and an 81-percent higher odds of dying than those who took their medications as prescribed. This was true even after the researchers accounted for factors that may also have contributed to these outcomes.

"Incremental increases in medication adherence were associated with improved outcomes," Ho and colleagues report in the Archives of Internal Medicine.

The lower risk of being hospitalized or dying among patients who took their medications is likely due to the benefit of the medications as well as the fact that patients who take their medications on a regular basis are likely to practice other healthy behaviors that lead to their lower risk."

This study, Ho said, highlights just how important it is for diabetic patients to take their medications as directed. "It may be helpful to incorporate medication taking into the daily routine," Ho said.

Patients who have trouble taking their medications on a regular basis, should discuss this with their physician "so that together the patient and physician can address the problem." Patients who were nonadherent were younger than adherent patients and had fewer other illnesses.

**Publishers Note:** This is where pharmacists can play a role as part of the diabetes team: doctors, nurses and other medical professionals should be checking with the patient's pharmacy as to whether or not the patient is filling their medications in a timely manner.

*Archives of Internal Medicine, October 2006.*

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Item 11

**Role of Blood Glucose Self-Monitoring in Medicare Patients with Type 2 Diabetes**

*The Centers for Medicare and Medicaid Services is questioning whether or not Patients with Type 2 Diabetes benefit from self-monitoring of their blood glucose and should they pay for monitor and strips.*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4196>

Medicare currently pays for up to 100 glucose testing strips per month for diabetics who use insulin, and up to 100 strips every 3 months for those not using insulin. Higher amounts are covered if the physician provides written documentation of need. In 2003, the most recent year for which data are available, the program paid more than \$908 million for glucose testing strips.

Among current "problem areas" are skilled nursing facilities and home health agencies that perform multiple daily glucose tests on type 2 diabetic patients without any adjustment of medication dose based on the results. Inappropriate marketing of glucose testing to Medicare beneficiaries has also become a problem. "The question is how often to test, should we be testing, and are changes being made to improve the disease?"

At the hearing, a series of presenters summarized the current literature addressing the relationship between the use of both fingerstick monitoring and continuous glucose monitoring, and clinical outcomes in patients with type 1 and type 2 diabetes. At the end of the day, panel members were asked to answer a series of questions regarding the role of self-monitoring of blood glucose (SMBG) and glycemic control in patients with diabetes.

One question was: "How confident are you that an increased frequency of outpatient glucose monitoring translates to decreases in chronic complications (specifically cardiovascular morbidity and mortality) in Medicare-age patients (older than 65 years) with diabetes?" The overall average response of the 12 panelists—comprising 7 voting members and 5 nonvoting guests—was 2.67 on a scale of 1 ("very unconfident") to 5 ("very confident"). One nonvoting guest panelist was an endocrinologist; none of the voting members were.

Other questions addressed the degree to which data on hypoglycemia generated in populations with type 1 diabetes can be extrapolated to those with type 2 (overall scores were 2.92 for insulin-using type 2 patients and 1.92 for non-insulin-using type 2 patients), and whether the optimal frequency of SMBG in Medicare-age patients with type 2 diabetes is known in terms of strips per day, strips per week, or continuous monitoring (overall average was 1.83).

Ms. Rutzy, diabetes nurse-educator at Mercy Medical Center, Baltimore, said in her presentation "If the committee were to consider recommending reductions in Medicare coverage for diabetes needs, it would do a great disservice to the nearly 7 million Medicare beneficiaries with diabetes. ... Instead, I hope the committee's questions were asked to help determine how to optimize current coverage."

Dr. Steve Phurrough, of the agency's Coverage and Analysis Group, stated in an interview following the hearing, "This meeting has nothing to do with whether we're going to reimburse for anything. ... The purpose of this meeting was to have the discussion about what's best for the adult type 2 Medicare diabetic. A whole host of people think that any monitoring might not benefit the diabetic population aged 65 and older who develop type 2 diabetes and have no complications. Should we be monitoring them at all? It's a question for scientists, not a question of whether we're going to pay for it. So remove from your mind any thoughts that we're going to make payment decisions based upon this committee."

According to MCAC's charter, its role is to advise CMS "on whether specific medical items and services are reasonable and necessary under Medicare law."

The meeting had opened with two speakers who outlined how few of the available data directly address the relationship between glucose monitoring and clinical outcomes in general, and in the Medicare-age population in particular.

Dr. Elizabeth Koller, of CMS's Office of Clinical Standards and Quality, led off with a summary of the data from several prospective trials including the Diabetes Control and Complications Trial (DCCT) and the United Kingdom Prospective Diabetes Study (UKPDS), both considered benchmark studies in demonstrating the value of intensive glucose management for patients with diabetes.

Studies that did look at older type 2 populations, such as the UKPDS, the Veterans Affairs Cooperative Study, and others, still failed to show a direct correlation between intensive blood glucose control—achieved via frequent glucose monitoring—and cardiovascular outcomes, she noted.

Family Practice News Volume 36, Issue 19, Page 1,4 (01 October 2006)

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## DID YOU KNOW:

**50% of people with diabetes do not get the flu shot:** even though they are three times more likely to die from the flu. This year, there will be over 100 million doses of available influenza vaccine, ready and waiting for the flu season. Vaccinations are scheduled to begin in October. There are many people who can benefit from the protection an influenza vaccine can provide, especially health care providers, children between 6 months and up to 5 years of age, people with chronic diseases such as diabetes, asthma, and heart disease, and people 50 years old and older" said Dr. Julie Gerberding, CDC Director. "Our goal, and the goal of those who provide influenza vaccine, is to use every available dose so that we protect as many people as possible." Children with diabetes are also considered "high risk" when it comes to getting the flu. Schedule your child's flu shot as soon as possible. CDC

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Item 12

### **Efficacy of Angiotensin II Receptor Blockade in Elderly Patients With Diabetes**

*Underuse of ACEI and ARB therapy in elderly patients because of the perceived lack of efficacy or a greater risk of adverse events appears unjustified.*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4195>

While national guidelines recommend ACE inhibitor (ACEI) or angiotensin receptor blocker (ARB) therapy in patients with diabetes and nephropathy, guidelines concerning elderly patients with diabetes have not endorsed these drugs. We sought to assess the nephroprotective efficacy and safety of ARB therapy in elderly patients by conducting age-specific subgroup analyses using data from the Reduction of Endpoints in NIDDM with the Angiotensin II Antagonist Losartan (RENAAL) study.

1,513 patients were studied with type 2 diabetes and nephropathy who randomly received either losartan or placebo. We tested for effect modification by age of the effect of losartan on the incidence of the predefined end points (doubling of serum creatinine, end-stage renal disease [ESRD], or death) and the risk of adverse events.

Of 1,513 participants, 421 (27.8%) were aged >65 years (maximum age 74 years). Age did not modify the efficacy of losartan in reducing the risk of the primary outcome, a composite of doubling of serum creatinine, ESRD, or death (P(interaction) = 0.66) or its individual components (all P(interaction) > 0.44). In patients aged >65 years, losartan reduced the risk of ESRD by 50% (95% CI 30-81, P = 0.005). We found no evidence that older patients were more likely to experience adverse events from losartan such as a rise in serum creatinine or hyperkalemia than younger patients.

From the results it was concluded that elderly patients had the same level of benefits and risks as younger patients from treatment with losartan. Underuse of ACEI and ARB therapy in elderly patients because of the perceived lack of efficacy or a greater risk of adverse events appears unjustified.

*Diabetes Care*. 2006 Oct;29(10):2210-2217.

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Item 13

### **Effect of Weight Loss on Arterial Stiffness in Type 2 Diabetes**

*Moderate weight loss improves arterial stiffness in type 2 diabetes.*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4194>

There is increased stiffness of the large central arteries in type 2 diabetic patients, and obesity is a risk factor. However, the effect of intentional weight loss on arterial stiffness is uncertain, and the purpose of the current study was to assess this effect.

Arterial stiffness was assessed by measuring aortic pulse wave velocity (aPWV) at baseline and at completion of a 1-year weight loss intervention. Metabolic control of type 2 diabetes was also appraised.

Mean weight loss at 1 year in 38 volunteers with type 2 diabetes was 7.8%. There were improvements in HbA<sub>1c</sub>, LDL cholesterol, homeostasis model assessment of insulin resistance, and inflammatory markers (plasminogen activator inhibitor-1, tumor necrosis factor- $\alpha$ , interleukin-6, and C-reactive protein). There was also a significant improvement in aPWV at completion of weight loss intervention, from 740 to 690 cm/s ( $P < 0.05$ ).

Hypertension is strongly associated with arterial stiffness, and prior intervention studies have shown that treatment of hypertension improves arterial stiffness. However, in the current study, we can reasonably conclude that this was not the mechanism for weight loss-induced improvement in aPWV since blood pressure was well controlled at baseline and did not change during the 1-year weight loss intervention. There was a significant improvement in fasting hyperglycemia and A1C at 1 year, consistent with the effect now expected from 5 to 10% weight loss. There was a more modest, but nevertheless significant, reduction in LDL cholesterol and HOMA-IR. As well, there were significant decreases in PAI-1, TNF- $\alpha$ , IL-6, and C-reactive protein. Improvement in aPWV following weight loss may be related to improved metabolic control and changes in obesity-related inflammation. However, these metabolic factors did not significantly correlate with the improvement in aPWV. Greater improvement also occurred in the tertile of largest weight loss. These findings suggest that in overweight and obese patients with type 2 diabetes and elevated values for aPWV, moderate weight loss is an effective intervention to improve arterial stiffness.

*Diabetes Care* 29:2218-2222, 2006

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### **FACT:**

**Sex And The Heart: It's Not What You Think:** A surprising new study finds that women in their 60s have as many risk factors for heart disease as men, and by their 70s have more, according to research. [Read and print the full news article at: http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4211](http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4211)

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Item 14

**Prevention of Hypoglycemia During Exercise in Children With Type 1 Diabetes**

*Suspending basal insulin during exercise in children with type 1 diabetes can effectively control hypoglycemia.*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4193>

Strategies for preventing hypoglycemia during exercise in children with type 1 diabetes have not been well studied. The Diabetes Research in Children Network (DirecNet) Study Group conducted a study to determine whether stopping basal insulin could reduce the frequency of hypoglycemia occurring during exercise.

Using a randomized crossover design, 49 children 8–17 years of age with type 1 diabetes on insulin pump therapy were studied during structured exercise sessions on 2 days. On day 1, basal insulin was stopped during exercise, and on day 2 it was continued. Each exercise session, performed from ~4:00–5:00 P.M., consisted of four 15-min treadmill cycles at a target heart rate of 140 bpm (interspersed with three 5-min rest breaks over 75 min), followed by a 45-min observation period. Frequently sampled glucose concentrations (measured in the DirecNet Central Laboratory) were measured before, during, and after the exercise.

The results showed that hypoglycemia ( $\leq 70$  mg/dl) during exercise occurred less frequently when the basal insulin was discontinued than when it was continued (16 vs. 43%;  $P = 0.003$ ). Hyperglycemia (increase from baseline of  $\geq 20\%$  to  $\geq 200$  mg/dl) 45 min after the completion of exercise was more frequent without basal insulin (27 vs. 4%;  $P = 0.002$ ). There were no cases of abnormal blood ketone levels.

In the present study, we demonstrated that stopping the basal insulin infusion at the start of a prolonged period of moderate aerobic exercise in the late afternoon was an effective strategy for reducing the risk of hypoglycemia during the exercise period. While this maneuver did not completely eliminate the risk of hypoglycemia, a fall in glucose that required treatment was infrequently observed if the pre-exercise plasma glucose level was  $>130$  mg/dl. Moreover, the response to treatment of hypoglycemia with oral carbohydrate was more effective under basal-stopped conditions, since none of the subjects required more than one treatment with carbohydrate snacks compared with approximately one-third of the subjects during the basal-continued visit. Discontinuation of basal infusion was associated with a modest increased risk of hyperglycemia (12 vs. 4%,  $P = 0.11$ ) during exercise, but blood ketone levels remained suppressed.

Because of its complexity, trial and error remains the principal method of regulating plasma glucose levels during exercise. However, the results of the present study can be used to guide recommendations for managing youth receiving insulin pump treatment during similar late-afternoon exercise. The plasma glucose should be checked before exercise, and 15–30 g of carbohydrate should be taken if the glucose is  $<130$  mg/dl, or a small correction bolus should be given if the glucose is  $>200$  mg/dl. Although in most patients the pump can then be safely suspended or disconnected for up to 2 h, glucose levels should be measured every 60–90 min during and after exercise and insulin administered when needed. The child and parents can also be informed that if hypoglycemia develops during exercise, it will be easier and more consistently treated with 15–30 g carbohydrate if the basal insulin infusion has been temporarily interrupted.

The ability to suspend or reduce basal insulin during increased physical activity is another example of the flexibility of insulin pump therapy that distinguishes it from multiple daily injection regimens that use long-acting insulin analogs for basal insulin replacement.

*Diabetes Care 29:2200-2204, 2006*

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Item 15

**New Diabetes Drug Galvus Matches Avandia in Control of Blood Sugars**

*The new diabetes drug from Novartis, Galvus cuts blood sugar levels as much as GlaxoSmithKlines established medicine Avandia and without the side effects.*

<http://www.diabetesincontrol.com/modules.php?name=News&file=article&sid=4192>

Galvus, which is awaiting regulatory approval in the United States and Europe, reduced levels of hemoglobin A1C -- a common measure of blood sugar -- by an average 1.8 percent, comparable with Avandia, in a head-to-head monotherapy clinical study.

The reduction was achieved without overall weight gain and with a lower incidence of fluid retention. Both are common side effects associated with insulin sensitizers such as Avandia.

"Many patients and physicians have come to unfortunately regard the side effects of current therapies as normal and accept them as part of their treatment," Professor Emanuele Bosi of Milan's San Raffaele University Hospital told the European Association for the Study of Diabetes.

"These results are very reassuring for patients who have to take medications to treat their diabetes for a long time."

The six-month study, involving 697 patients, tested 100 milligrams daily of Novartis's Galvus, or vildagliptin, against 8 mg of Avandia, or rosiglitazone.

The Phase III trial is one of several on Galvus being presented at the medical meeting in Copenhagen. Novartis hopes the data will underline the potential of its new product for Type 2 diabetes.

Another 279-patient study showed Galvus was just as effective given once-daily as when taken twice a day.

Galvus is tipped by analysts to become a \$1 billion-a-year plus seller, but it faces fierce competition from Merck & Co Inc.'s new drug, Januvia.

Galvus and Januvia represent the first of a class of drugs called DPP-IV inhibitors, which work by enhancing the body's own ability to lower blood sugar levels. Analysts believe DPP-IV drugs could become a popular treatment in the oral anti-diabetes market, since they are not associated with weight gain.

Both drugs have already been filed for approval with the U.S. Food and Drug Administration and, if given a green light, could be launched next year in a neck-and-neck race.

*EASD: Sept. 2006 European Association for the Study of Diabetes.*

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**Quote of the Week!**

***"Man is a genius when he is dreaming"***

.....**Akira Kurosawa.** Japanese filmmaker.

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