

# DIABETES IN CONTROL.com Newsletter

The Newsletter for Professionals in Diabetes Care

August 8, 2007 - Issue #376

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## Top Diabetes Stories:

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### The Final Word on Avandia: Diabetes Drug Should Stay Despite Heart Risks\*

<http://www.diabetesincontrol.com/results.php?storyarticle=5027>

### Stephen Covey, Presents a Patient Education Program at AADE\*

<http://www.diabetesincontrol.com/results.php?storyarticle=5025>

### Mediterranean Diet Works For Those With Diabetes\*

<http://www.diabetesincontrol.com/results.php?storyarticle=5023>

### Over One-Third of Diabetics Have Sleep Apnea\*

<http://www.diabetesincontrol.com/results.php?storyarticle=5022>

### Hidden” Syndrome Could be the Key to Preventing Diabetes and CVD\*

<http://www.diabetesincontrol.com/results.php?storyarticle=5020>

### Normal BP In The Office, Means Little for Determining Hypertension\*

<http://www.diabetesincontrol.com/results.php?storyarticle=5019>

### Lettuce May Be The Next Big Diabetes Treatment\*

<http://www.diabetesincontrol.com/results.php?storyarticle=5016>

### Stress Responses and Memory Abnormal in Type 2 Diabetes\*

<http://www.diabetesincontrol.com/results.php?storyarticle=5015>

## From the editor's desk

Steve and I are just back from the AADE annual meeting in St. Louis. Thanks to all of you who stopped by and said hi.

There were a lot of interesting programs and studies and programs, and posters focused on the AADE7™ Self-Care Behaviors and we are going to help you learn more about these behaviors in the future.

One of the biggest self-care behaviors is being active and to that end we are happy to let you know that all 3 of your Diabetes in Control team participated. Our Publisher, **Steve Freed** finished 3<sup>rd</sup> in the 5K run in his age bracket, **Jonathan Marquess**, one of our writers and education partners finished 2<sup>nd</sup> in the 5K run in his age bracket and even I managed to get a certificate for finishing first in my age bracket in the 5K walk.

I recently received a book for review. Living With Diabetes: A Guide For Patients and Parents by **James W Reed, M.D., M.A.C.P., F.A.C.E.**; and **Agia Heath, M.D.**. I had my Dr. of Pharmacy candidate **James Wengard** review the book. James can offer great feedback as he just spent the last 4 weeks living as an insulin dependent diabetes patient. To read his review and see why you may want to recommend this book to your patients, [click here](#)

<http://www.diabetesincontrol.com/results.php?storyarticle=5028>

**FREE LIVE WEBCAST: August 8, we will be having another live webcast and teleconference call with Dr. Richard K. Bernstein, who will answer questions from medical professionals and patients and it is free. Just go to [www.diabetes911.net](http://www.diabetes911.net) and register.**

### August 12, 7PM ET on CNBC

dLife talked to “Biggest Loser” Erik Chopin and the experts, to find out more about weight loss challenges and success strategies for people with type 2. Plus, a senior that discovered weight lifting is a big benefit to his diabetes control. And dLife’s Jim Turner speaks out on why marijuana and diabetes don’t mix (parental discretion advised). Tune in for another brand new 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:

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- Item #2: Statin Use in Patients With LDL's of 40mg/dL or Less is Safe and Beneficial
- Item #4: Physicians Unlikely to Document Obesity in Patient Records
- Item #8: Trial Using Cancer Meds To Control And Possibly Reverse Diabetes
- Item #10: Heart Care Sub Par In Older Diabetics
- Item #11: New Inhaled Insulin Qdose Shows Positive Results in Study
- Item #14: Visceral Obesity A Major Metabolic Risk-Factor Regardless of BMI
- Item #15: Dietary Glycemic Index Tied to Risk of Age-Related Macular Degeneration

Check out this weeks "Test Your Knowledge" question. This week's question deals with CGMS <http://www.diabetesincontrol.com/results.php?storyarticle=5029>

Dave Joffe, *Editor-in-Chief*

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## 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](#)

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## NEWS FLASH:

**Takeda Responds to the FDA Advisory Committee Recommendation:** With all the publicity about TZD's and the cardiovascular ischemic/thrombotic risks the Drug Safety and Risk Management Advisory Committees to the U.S. Food and Drug Administration (FDA) made some blanket statements about all drugs in the class. Takeda makers of Actos, responded to these blanket claims with data from studies showing not all TZD's are the same. [Click here to read more.](#)  
<http://www.diabetesincontrol.com/results.php?storyarticle=5030>

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## Tools for your Practice:

**"The 7 Habits of Highly Effective People with Diabetes"** is available for **free**. In the booklet, The 7 Habits of



Highly Effective People® with Diabetes, written by Covey in collaboration with the American Association of Diabetes Educators (AADE) and with support from Bayer Diabetes Care, you will learn habits that will help you become more effective in

managing your diabetes on your own, with your medical team, family and friends. For Your Free Copy See, This Week's Item #3

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## New Product:

### CalorieKing-Joslin Food Awareness Toolbar

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**Search CalorieKing Food Database, Recipes and Library Articles Anywhere.** Americans are very fortunate; food is everywhere. But this abundance can be challenging if you are struggling to manage weight or control diabetes. To help, CalorieKing and Joslin Diabetes Center want you to have your own food-search browser tool on your desktop -- free of charge! It works just like a Google search, but for food data. All you have to do is click on the browser you use, to download and install the food search browser tool to your computer. Then, any time you are curious about a food's nutritional content, the answer is only keystrokes away.

The toolbar can also be downloaded through a link from the Joslin website at [www.joslin.org/calorieking](http://www.joslin.org/calorieking).

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14. Visceral Obesity A Major Metabolic Risk-Factor Regardless of BMI  
<http://www.diabetesincontrol.com/results.php?storyarticle=5014>
15. Dietary Glycemic Index Tied to Risk of Age-Related Macular Degeneration  
<http://www.diabetesincontrol.com/results.php?storyarticle=5013>

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## ITEMS For The Week:

Item 1

### **The Final Word on Avandia: Diabetes Drug Should Stay Despite Heart Risks**

*FDA panel says Avandia offers benefits to people with type 2 disease, **but....***

<http://www.diabetesincontrol.com/results.php?storyarticle=5027>

The widely prescribed type 2 diabetes drug Avandia should remain on the market, despite studies that suggest it could increase the risk of heart attacks, U.S. health advisers said Monday.

The U.S. Food and Drug Administration advisory panel voted 22-1 to keep the drug on the market, although it recommended Avandia should carry new safety warnings. That vote was preceded by another vote, 20-3, in which panel members agreed that available data does show Avandia increases heart risks.

"The committee felt, almost uniformly, that there is a risk to some patients," said Dr. Clifford Rosen, the acting committee chairman from the Maine Center for Osteoporosis, St. Joseph Hospital, in Bangor.

"There was some increased risk of cardiac events to some patients. The signal for increased risk was there, with some qualifications," he told reporters at a teleconference.

Patients at risk include those with congestive heart failure, heart disease or patients using insulin, Rosen said, adding, "There are clear-cut reasons not to prescribe this drug to certain patients."

But the decision to keep the drug on the market, according to an FDA official, came about because the committee wasn't convinced that the data presented about the risk was conclusive. "If we have a clear answer, we don't take this to an advisory committee," Dr. Robert Meyer, the director of the FDA's Office of Evaluation II, Center for Drug Evaluation and Research, told reporters.

Dr. Gerald Dal Pan, director of the FDA's Office of Surveillance and Epidemiology, said, "We will go back and formulate what we think should be on the label." Panelists' suggestions included a black box warning or other warning for heart attack, but there was no consensus on how the label should be changed, he said. The FDA had previously asked the drug's manufacturer, GlaxoSmithKline, to add a black box warning about heart failure.

While the FDA isn't bound to follow the recommendations of its advisory panels, it typically does so.

Concerns about Avandia (rosiglitazone), part of a class of drugs for diabetes called thiazolidinediones, are based on a meta-analysis of published studies that suggested the drug increases the risk of heart attack by 43 percent.

That finding was first published May 21 in the *New England Journal of Medicine*, in a paper co-authored by Dr. Steven Nissen, chairman of cardiovascular medicine at the Cleveland Clinic and one of the earliest critics of the arthritis drug Vioxx, which was withdrawn from the market in 2004 due to heart attack concerns.

Dr. Larry Deeb, president for medicine and science at the American Diabetes Association, said before Monday's vote that he believes Avandia should continue to be available to diabetics because the increased risk of heart attack has not been proven conclusively.

"A decision to do something should not be based on a nebulous risk," Deeb said. "There probably should be a warning on the box, because there is enough concern." Deeb believes the FDA should call for a study to thoroughly review any heart risks associated with the drug's use. "It's premature to withdraw the drug. I am anxious about pulling [a drug] that has done some good off the market based on a meta-analysis," he added.

Dr. Sidney Wolfe, director of Public Citizen's Health Research Group, who has previously spoken out against Avandia, was among the speakers at the hearing. "Does the overall risk-benefit profile of Avandia support its continued marketing in the United States? The answer is clearly no," he said in a prepared statement.

According to Wolfe's prepared testimony, FDA adverse-reaction reports filed since Avandia hit the market in 1999 have shown the drug had a 15.2 times higher adjusted rate of heart failure than did the older diabetes drug Glucotrol. The adjusted rate of liver toxicity with Avandia was 9.5 times higher, and 14.8 times higher for liver failure, he said.

"There is no evidence of any uniquely beneficial clinical outcome for Avandia and growing evidence of unique risks in multiple organ systems," Wolfe said. "If Avandia were up for approval today, based on what is now known, it would be summarily rejected. There should not be a double standard for removing it from the market."

For its part, Avandia's maker, GlaxoSmithKline, insisted before the meeting that the drug does not increase the risk of heart attack. "We don't believe that a warning about heart attack should be on the label," said Dr. Andy Zambanini, director of clinical development at GlaxoSmithKline.

"Avandia is one of the most studied medicines in the diabetes field," Zambanini said. "We have looked at all the available data both from short-term trials, long-term trials and real-world data, in terms of epidemiology. There is really no evidence of an increase in cardiovascular death with Avandia. And when you look at Avandia and compare it with all the other similar agents, there really is no difference in heart attack risk."

One of the studies that GlaxoSmithKline is relying on to make its case is the RECORD (Rosiglitazone Evaluated for Cardiac Outcomes and Regulation of Glycemia in Diabetes) trial. The study, sponsored by Glaxo, was specifically designed to determine the risks for heart attack from Avandia.

Dr. David Graham, associate director for science and medicine in the FDA's Office of Surveillance and Epidemiology and an Avandia critic, disagreed with Glaxo's interpretation of the RECORD study. In a report submitted by the FDA to the advisory panel before the hearing, Graham concluded:

"RECORD does not now, nor will it at completion, provide meaningful evidence to demonstrate with any degree of certainty that RSG [Avandia] does not increase the risk of acute myocardial infarction [heart attack] or sudden death, or the APTC outcome. The biased design of RECORD renders it useless as an objective measure of Avandia's cardiovascular safety."

Zambanini countered by saying that the RECORD study has seen very few cardiac deaths. "To say that this study is of no value isn't true," he said.

During Monday's testimony, Graham was supported by his boss, Dal Pan, who said the risks posed by Avandia outweighed the benefits. But another agency official, Dr. Robert Meyer, head of the FDA office that reviews new diabetes drugs, urged panel members to keep an open mind about Avandia, the AP reported. "It is important that the committee understand there is a fundamental disagreement within (the FDA's drugs office) on the scientific conclusions that should be drawn," Meyer said.

That rift revealed a division between FDA officials responsible for approving new medicines and those who monitor their safety once on the market, the AP said.

Currently, there is a warning on Avandia's label that it increases the risk of another cardiovascular problem called congestive heart failure, a chronic condition caused by the heart's failure to pump normally, allowing fluid to build up in the body.

In May, the FDA said it wanted a stronger warning about the risk of heart failure on Avandia's label. Glaxo is "still in negotiation with the FDA about a new warning label on heart failure and we expect to release that information soon," Zambanini said.

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

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Item 2

**Statin Use in Patients With LDL's of 40mg/dL or Less is Safe and Beneficial**

*Statins used in patients with extremely low LDL cholesterol levels are safe and may lead to improved survival, according to the results of a new study. This survival benefit of a reduced mortality of 42% was observed across multiple subgroups, including patients with LDL cholesterol levels <40 mg/dL and those without documented coronary artery disease.*

<http://www.diabetesincontrol.com/results.php?storyarticle=5026>

Lead investigator Dr Nicholas Leeper from the Stanford University School of Medicine, CA stated that, "We're seeing more and more people coming back to clinic with cholesterol levels well below the goal we had intended." "If you start a patient after his acute coronary syndrome on a statin, and he comes back a few months later and his LDL is 50 mg/dL, or even 40 mg/dL, we were realizing that we didn't know what to do with these patients, whether it was safe to continue, whether we had to back off or stop treatment. We also didn't know what happens to patients who come in with very low LDL levels, for whatever reason, if they are to be started with a statin."

The results of the study, showed that not only are the drugs safe, with no risk of cancer at two years, but they also might improve survival in patients with very low LDL cholesterol levels, said Leeper.

Although there has been a recent shift in clinical care toward more aggressive lipid management, including treatment in patients with acute coronary syndrome and those with stable atherosclerotic vascular disease, there have been concerns raised about the safety of treating patients with very low LDL cholesterol levels. Some reports, for example, have shown an association between very low cholesterol levels and adverse outcomes, such as noncardiac mortality and malignancy, said Leeper. One report, published last month, showed a highly

significant inverse relationship between achieved LDL-cholesterol levels and rates of newly diagnosed cancer, a surprising finding that researchers said needed further study.

Treating with high-dose statin therapy, said Leeper, often results in patients getting well below the LDL goal of 70 mg/dL, but the long-term safety of statin use in these patients is still unclear. For this reason, the Stanford investigators sought to investigate the safety and clinical outcomes associated with statin therapy in patients with very low LDL levels, such as less than 60 mg/dL.

"When I first started practicing, we had LDL goals of 130, and then it was 100, and now in the wake of TNT and PROVE-IT, we're starting to be more aggressive," said Leeper. "For most patients that we see in cardiology, that goal is now 70 mg/dL or less. We're using a lot of high-potency statins and they can profoundly reduce cholesterol levels; it's very reasonable to see patients come back with these very low LDL levels, but we need to know if they're safe."

In total, more than 6000 consecutive patients were identified from a tertiary-care medical center or affiliated community clinic. Statin therapy was defined as a prescription during the 150 days after the low LDL value--less than 60 mg/dL--was obtained. Of the 6000 patients, 4295 had a prescription for any medication during the observation period, with statins prescribed to 60% of patients with LDL cholesterol levels <60 mg/dL. Patients were, on average, 65 years old, and approximately half had diabetes mellitus or ischemic heart disease.

During a median follow-up of two years, there were 510 deaths. After controlling for the propensity to receive a statin, statin therapy was associated with a significant 35% reduction in the risk of death. The lower mortality was observed across various subgroups, including a 42% reduction in total mortality among those treated with a statin at baseline, a 49% reduction among those with LDL cholesterol levels <40 mg/dL, and a 42% reduction among those without ischemic heart disease.

Based on the findings, Leeper said the investigators began to joke that "you can't be too rich, too thin, or have too low a cholesterol level."

In terms of potential side effects, statin therapy was not associated with an increase in any adverse events. No cases of rhabdomyolysis were reported, nor was there a risk of developing liver enzyme elevations. Importantly, there was no increase in the risk of malignancy or renal insufficiency.

"We wanted to look at various different side effects because statins appear to be a wonder drug from many perspectives, but of course we're always reticent to go so aggressive until we have long-term outcomes," said Leeper. "There have been some trials suggesting possible hazards for certain cancers, renal dysfunction, rhabdomyolysis, but in this analysis, in two years of follow-up, we didn't find any risk associated with low LDL levels."

Like other analyses, the study did not address the possible mechanisms of benefit, although it is clear that the benefit of statins extends beyond their ability to lower LDL cholesterol levels. Continued plaque stabilization and the prevention of atheroma development are possible, said Leeper, as are other benefits that have not yet been outlined.

*Leeper NJ, Ardehali R, deGoma EM, Heidenreich PA. Statin use in patients with extremely low low-density lipoprotein levels is associated with improved survival. Circulation 2007; 116:613-618.*

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**DID YOU KNOW:**

**The House OK's Prescription Drug Imports:** The House passed legislation Thursday effectively permitting the importation of lower-cost prescription drugs from places such as Canada, Australia and Europe. The bill, passed by a 237-18 vote, faces a promised veto from President Bush over its price tag, and the administration also opposes the drug importation provision.

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<http://www.diabetesincontrol.com/ads/atkins/dest.shtml>

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Item 3

**Stephen Covey, Presents a Patient Education Program at AADE**

*Dr. Stephen Covey, author of the bestselling book *The 7 Habits of Highly Effective People*<sup>®</sup>, and an internationally respected leadership authority, has teamed up with The American Association of Diabetes Educators (AADE) and Bayer Diabetes Care to introduce a unique patient education tool, *The 7 Habits of Highly Effective People*<sup>®</sup>.*

**Available for Free, see this week's Tools For Your Practice**

<http://www.diabetesincontrol.com/results.php?storyarticle=5025>

Currently, more than 14 million people in the US have been diagnosed with diabetes. It is estimated that another 6.2 million people are undiagnosed. Diabetes is a chronic disease that needs to be carefully managed and closely monitored. If diabetes is not managed well or is left untreated it can lead to serious, sometimes life-threatening complications, such as heart disease, stroke, kidney failure, blindness and limb amputations. According to a new GfK Roper Public Affairs survey of people with diabetes, sponsored by Bayer Diabetes Care, 80 percent reported that they are not managing their disease well.

"I have spent my life teaching people how to set and accomplish goals in their personal and professional lives, and am now applying my habits to help people better manage their diabetes," said Covey. "I know diabetes can be challenging to live with, and I have gained an even deeper understanding of that fact since my wife was diagnosed with type 2 diabetes. Together, with changes in behavior, we turned the diabetes 'curve ball' into an opportunity to learn, grow and deepen our lives."

*The 7 Habits of Highly Effective People*<sup>®</sup> with Diabetes booklet is a practical resource guide to help people with diabetes adapt life management skills as defined by Covey's "7 Habits" and apply them to the AADE7<sup>™</sup> Self-Care Behaviors to achieve better disease management.

The booklet advises people to take small steps to manage their chronic illness and to incorporate each of the self-care behaviors into their lives. For example, by applying Covey's Habit 1: Be Proactive, people with diabetes are encouraged to actively take responsibility for managing their condition by following the AADE7<sup>™</sup> Self-Care Behaviors, such as healthy eating, being active and monitoring blood glucose levels. Also included is an action plan for setting easy-to-achieve self-care goals, one at a time.

"With the increasing epidemic of diabetes, the time is right to provide people living with this chronic illness a new approach to facilitate the needed behavior change to positively impact their disease," said Donna Rice, MBA, BSN, RN, CDE, president of the AADE and a diabetes educator. "Covey's habits, paired with the AADE7<sup>™</sup> Self-Care Behaviors, do just that. We're grateful to Bayer Diabetes Care for supporting the development of this important resource, which is also valuable for family, friends and caretakers of those diagnosed with diabetes."

The GfK Roper Public Affairs March 2007 survey, conducted among 1,069 U.S. adults with diabetes, was designed to identify the specific points when managing one's life and managing one's diabetes do not match up, as well as the barriers that adults living with diabetes need to overcome. To gather these findings, the survey questions were based on the life management habits outlined in Covey's *The 7 Habits of Highly Effective People*<sup>®</sup> and the American Association of Diabetes Educators' AADE7<sup>™</sup> Self-Care Behaviors. Survey data were weighted

to reflect the demographic profile of the U.S. adult population, doctor-diagnosed with diabetes. The margin of sampling error is plus/minus five percentage points.

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**Covey's 7 Habits**

**AADE7™ Self-Care Behaviors**

Habit 1 – Be Proactive

1. Healthy Eating

Habit 2 – Begin with the End in Mind

2. Being Active

Habit 3 – Put First Things First

3. Monitoring

Habit 4 – Think Win/Win

4. Taking Medication

Habit 5 – Seek First to Understand, Then to Be Understood

5. Problem Solving

Habit 6 – Synergize

6. Reducing Risks

Habit 7 – Sharpen the Saw

7. Healthy Coping

Using the habits outlined in Covey's *The 7 Habits of Highly Effective People*®, as well as the AADE7™ Self-Care Behaviors, survey respondents were classified into the following four segments and compared:

- ?? those that manage both their life and diabetes well; 12 percent
- ?? those that manage neither their life nor diabetes well; 56 percent
- ?? those that manage their life, but not their diabetes well; 24 percent
- ?? those that manage their diabetes, but not their life well; 8 percent

The survey suggests that successfully mastering specific life management skills can have a very positive impact on one's diabetes as well. For instance, prioritizing is critical. Adults with diabetes who manage their lives and diabetes well are twice as likely as those who manage neither their lives nor their condition effectively to say they excel at prioritizing and acting on important issues in their lives (90 percent vs. 46 percent). When it comes to diabetes management, it should be a high priority for people to monitor their blood sugar daily in order to maintain consistent blood glucose level control. The survey found that those who manage their lives and diabetes well are more likely than those not managing either well to test their blood sugar seven days a week (75 percent vs. 59 percent).

For more information about *The 7 Habits of Highly Effective People*® with Diabetes, or to receive a copy at no charge, please go to [www.diabetes7.org](http://www.diabetes7.org)

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Item 4

**Physicians Unlikely to Document Obesity in Patient Records**

*Obesity is more than twice as likely to be treated seriously if physicians jot the formal diagnosis down in medical records -- a relatively uncommon act by clinicians.*

<http://www.diabetesincontrol.com/results.php?storyarticle=5024>

Only about one in five obese patients have a diagnosis of obesity documented, according to a review of the records of almost 10,000 patients, Aditya Bardia, M.D., of the Mayo Clinic, and colleagues, reported.

Of 2,543 patients who met a standard criterion for obesity -- a body mass index of 30 or more -- only 505 had obesity listed by Mayo physicians as a diagnosis, they wrote.

Mayo staff physicians were 45% less likely to diagnose obesity than residents ( $P<0.001$ ), they found. The authors speculated that "staff physicians may not conceptualize obesity as a disease (perhaps because Medicare did not initially allow it as a billable diagnosis), may spend less time with patients than residents, and may be more concerned about reimbursement issues."

A BMI of more than 35, obstructive sleep apnea, and/or a diagnosis of diabetes increased the likelihood that obesity would be noted in patients' charts ( $P<0.001$  for BMI > 35 and obstructive sleep apnea,  $P=0.007$  for diabetes).

Nonetheless, patients who did have that diagnosis were 2.39 times more likely to have an obesity management plan documented in the charts ( $P<0.001$ ).

Dr. Bardia and colleagues used the clinic's primary care database to identify 9,827 patients who had general medical examinations from Nov. 1, 2004 to Oct. 31, 2005. Patient files included demographic information, BMI, and comorbidities, as well as documentation of obesity diagnosis and management plans.

Among the findings:

- ?? Among the 2,543 obese patients, 40% were men and the median age was 58.
- ?? The mean BMI of obese patients was 35.4 ( $\pm 10.6$ ).
- ?? Most of the obese patients -- 1,717 -- were seen by staff physicians.
- ?? Men were about 40% less likely to be diagnosed with obesity and the likelihood of diagnosis declined about 3% per year for every year over 58 ( $P<0.001$  for both).

The authors acknowledged it was "possible that physicians discussed obesity with their patients but did not document it," a possibility that could explain why some patients had documentation of an obesity management plan with no notation of obesity in their records.

The study was limited by its single-institution design, as well as by the lack full evaluation of a number of variables including race, education, and income. Finally, they said they did not "directly evaluate" whether documented obesity management plans resulted in weight loss.

Mayo Clinic Proceedings: Bardia A et al "[Diagnosis of Obesity by Primary Care Physicians and Impact on Obesity Management](#)" *Mayo Clin Proc* 2007; 82:927-932

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### Start your own walking program



**New StepTracker Available** at special prices. See the results of the Step Program Study. <http://www.diabetesincontrol.com/programs/steps/index.shtml>  
Purchase your own pedometers and receive the **Steps to Health** Program at no charge. <http://www.rx4betterhealth.com/steptracker/>  
**The Only Pedometer on the Market That Comes With a Program for Success!**

### **FACT:**

**Januvia Experiences Significant Growth:** - According to a survey, prescriptions for the diabetes drug Januvia have grown nearly threefold between the first week of 2007 and the week ending July 20, making it one of the fastest-growing drugs in the diabetes market. Januvia had nearly 60,000 prescriptions during the week ending July 20, more than 2,500 of which were new-patient prescriptions. It was reported that patients were switched from metformin 21%, Avandia 17% and Actos 13%.

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Item 5

### **Mediterranean Diet Works For Those With Diabetes**

*Eating a traditional Mediterranean diet -- more vegetables, fruits, and fish, and fewer animal products -- does seem to ward off heart disease, an Australian study shows, and it can be especially beneficial for people with diabetes.*

<http://www.diabetesincontrol.com/results.php?storyarticle=5023>

Mediterranean-born immigrants in Australia have lower death rates from heart disease than native-born Australians, note Dr. Linton R. Harriss, from Monash University in Melbourne, and colleagues. This prompted them to investigate dietary patterns in relation to heart-related mortality "in an ethnically diverse population."

The study involved over 40,000 men and women, aged between 40 and 69 years, 24 percent of whom were native-born Mediterranean while the rest were native-born Australian. They were followed for ten years.

Harriss stated that the researchers used food questionnaires to calculate participants' intake of Mediterranean foods, vegetables, fruits, and meats. "Those people in our study that were in the highest category of the Mediterranean foods pattern (i.e. most frequently consumed traditional Mediterranean foods) had a 30 percent lower risk of dying from cardiovascular disease compared to those who were in the lowest category."

The investigators found that a Mediterranean-style diet "may be most beneficial for persons with diabetes."

Among the study participants with diabetes, Harriss said, "Our results suggest that the Mediterranean diet may lower mortality from ischemic heart disease." The protective effect of a Mediterranean diet pattern against heart-related death was strongest in people who were free of heart disease at the outset. Nonetheless, "the Mediterranean foods pattern showed benefits whether we included or excluded people with a history of cardiovascular disease," Harriss said.

*The American Journal of Clinical Nutrition, July 2007*

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Item 6

**Over One-Third of Diabetics Have Sleep Apnea**

*Study finds that older males are at especially high risk for nighttime awakenings.*

<http://www.diabetesincontrol.com/results.php?storyarticle=5022>

People with type 2 diabetes who drag themselves through the day may be among the 36 percent of diabetics suffering from obstructive sleep apnea, according to new research.

Sleep apnea occurs when impaired breathing due to collapsed airways triggers multiple nighttime awakenings.

Researchers at The Whittier Institute for Diabetes in La Jolla, Calif., analyzed health data from 279 adults with type 2 diabetes. They found that one out of three diabetics also suffered from obstructive sleep apnea. Men, particularly those over the age of 62, were more than twice as likely as women to experience interrupted sleep.

Previous research has indicated a relationship between obstructive sleep apnea, glucose intolerance and insulin resistance, so the connection with type 2 diabetes is not surprising. This is the first study to analyze data from both men and women at a diabetes clinic, the researchers said.

"These findings demonstrate that obstructive sleep apnea has a high prevalence in adults with type 2 diabetes," principal investigator Dr. Daniel Einhorn said in a prepared statement. "Given that treatment of obstructive sleep apnea has the potential to both decrease blood pressure and improve glycemic [blood sugar] control, individuals with type 2 diabetes should be regularly screened for the presence of sleep apnea," he said.

According to previous research, treating people who have both obstructive sleep apnea and type 2 diabetes with "continuous positive airway pressure" therapy not only helps manage the sleep interruptions but also reduces blood sugar levels. The researchers recommend that clinicians screen patients with type 2 diabetes for obstructive sleep apnea.

According to the American Diabetes Association, more than 20 million people in the United States have diabetes, with more than one in five adults over the age of 60 suffering from the disease. Type 2 is the most common form of diabetes, a disease in which the body does not make or use insulin effectively.

The National Sleep Foundation estimates that more than 18 million people suffer from obstructive sleep apnea, although the majority of people have not been diagnosed with the disorder. Obstructive sleep apnea is related to a multitude of health risks, including heart disease, high blood pressure, depression, sexual dysfunction and an increased risk of car accidents.

*Endocrine Practice, August 2007*

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Item 7

**Hidden” Syndrome Could be the Key to Preventing Diabetes and CVD**

*New and important evidence shows that Insulin Resistance Syndrome can lead to elevated risk for cardiovascular disease, breathing and sleep disorders, liver disease, Polycystic Ovarian Syndrome, type 2 diabetes, certain cancers, Alzheimer’s Disease and more.*

<http://www.diabetesincontrol.com/results.php?storyarticle=5021>

“Insulin Resistance Syndrome, an epidemic condition parallel to the obesity epidemic that dramatically increases the risk of developing type 2 diabetes, coronary heart disease, stroke, and various cancers, is estimated to affect at least one in three adults in America” said Dr. Gerald Reaven professor of medicine at Stanford School of Medicine.

The Insulin Resistance Syndrome, often referred to as the Metabolic Syndrome or Syndrome X, has been gaining worldwide attention since it was introduced in 1988 by Dr. Reaven. More than fifty of the world’s foremost medical authorities will be on hand at the WCIRS to discuss the wide-reaching complications of Insulin Resistance. The Congress will examine the far-reaching effects of insulin resistance, its causes, prevention, and treatment. The Congress will also address the many manifestations of insulin resistance – heart disease, diabetes, fatty liver disease, sleep & breathing disorders, cancer, polycystic ovarian syndrome and certain brain disorders like Alzheimer’s Disease.

“This metabolic disorder underlies some of the deadliest and most costly diseases in the U.S. An early intervention for prevention is critical” Said Dr. Yehuda Handelsman of the Metabolic Institute of America.

The World Congress of the IRS is jointly sponsored by PESI LLC and the Metabolic Endocrine Education Foundation, a non-profit foundation dedicated to educating physicians and the public on metabolic diseases and facilitating research in the field.

This evidence will be presented at the 5th Annual World Congress on the Insulin Resistance Syndrome (WCIRS) in Boston, October 11-13, 2007. For more information visit <http://www.insulinresistance.us>

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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.

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Item 8  
**Trial Using Cancer Meds To Control And Possibly Reverse Diabetes**

*Drug can possibly kill off the T-cells that are attacking the betacells*

<http://www.diabetesincontrol.com/results.php?storyarticle=5020>

Type 1 diabetes, an immune system disorder where white blood cells called T-cells attack the insulin-producing pancreas cells called betacells.

Now, for the first time, Indiana University researchers are turning to a cancer drug called rituximab to see if it can increase insulin production. Researchers are testing the cancer drug on recently diagnosed type-one diabetes patients who are at least eight years old.

Dr. Mark Pescovitz, an Immunologist on the study, says they are hoping to shut off the immune attack to the pancreas in type 1 diabetes. He says the medication was originally developed as a drug to kill lymphoma, a type of B-cell cancer. The drug may also work on type 1 diabetes because B-cells feed the T-cells that attack the pancreas.

"If the B-cells aren't serving the T-cells the food, they starve, they die and the immune reaction shuts off" he explains.

If the treatment works, it could help young patients like Kelli avoid long-term complications like vision loss, kidney damage and amputation. Dr. Pescovitz is hopeful "what we're hoping is that we will get rid of the B-cells that are causing the damage, new B-cells will be developing that are not specifically targeting the pancreas and therefore induce what we call a state of tolerance."

It is possible patients could produce their own insulin and depend much less on insulin injections. There's a slight chance it could even reverse the disease.

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**FACT:**

**How safe is your seafood?** You can now check out just how safe your seafood is by just going to the FishWatch website for the Latest Information. The Web site, at <http://www.fishwatch.noaa.gov>, has information on more than 30 of the most popular seafood species, with more species to be added in the near future. FishWatch provides seafood consumers with timely information about seafood, such as red snapper. The Web site includes details on population strength and status, as well as consumer information such as on fat content and vitamins.

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Item 9

**Normal BP In The Office, Means Little for Determining Hypertension**

*Masked hypertension in diabetes can be a potential risk for brain and kidney damage, therefore home monitoring is crucial.*

<http://www.diabetesincontrol.com/results.php?storyarticle=5019>

The prevalence and clinical significance of masked hypertension (MHT) in diabetics have infrequently been described. The authors assessed the association of MHT (defined using a clinic blood pressure [BP] <140/90 mm Hg and daytime ambulatory BP >=135/85 mm Hg) with microvascular and macrovascular end organ damage in 81 clinically normotensive Japanese diabetic persons.

The prevalence of silent cerebral infarcts (SCIs), increased left ventricular mass, and albuminuria were evaluated. Of 81 patients, 38 (46.9%) were classified as having MHT and showed significantly more SCIs (mean +/- SE: 2.5+/-0.5 vs 1.1+/-0.2; P=.017), and more albuminuria (39% vs 16%; P=.025), but no increase in left ventricular mass index, than the normotensive persons in office and on ambulatory BP monitoring group. The prevalence of MHT in this diabetic population was high (47%). Diabetic patients with MHT showed evidence of brain and kidney damage. Hence, out-of-office monitoring of BP may be indicated in diabetics whose BP is normal in the clinic.

*J Clin Hypertens (Greenwich), 2007 Aug;9(8):601-7.*

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Item 10

**Heart Care Sub Par In Older Diabetics**

*A low proportion of elderly individuals newly diagnosed with type 2 diabetes receive heart-protecting drugs like aspirin, blood pressure-lowering drugs and cholesterol-lowering drugs, according to a new study.*

<http://www.diabetesincontrol.com/results.php?storyarticle=5018>

People with diabetes are at increased risk for developing heart and vascular disease. The results of the current study suggest that the management of cardiovascular risk for type 2 diabetes patients is "less than appropriate," the study team concludes in the journal Diabetes Care this month.

In a study of more than 12,000 patients, the researchers found that only about 22 percent received a heart-protecting anti-clotting drug like aspirin in the year after anti-diabetes medication was begun. Only about 40 percent received an antihypertensive and 21 percent received a cholesterol-lowering drug, the investigators report.

Only 7.6 percent received a comprehensive cardioprotective regimen including all three types of medication, they found.

Study investigator Dr. Jean-Pierre Gregoire, from Laval University, Quebec City stated that, "Treating a diabetic person is important. However, controlling (blood sugar) should not be the only treatment goal even in people aged 65 years or over."

Gregoire suggested that doctors "may not be sufficiently aware of the benefits of treating elderly individuals with diabetes using cardioprotective medications. Given their life-expectancy, these individuals can also benefit from pharmacologic cardiovascular protection," the researcher said.

"Elderly individuals with diabetes should also be sensitized to the fact that, relative to those who don't suffer from diabetes, they have an increased cardiovascular risk," Gregoire added.

He noted that the number of type 2 diabetics is likely to increase in this age group in the next decade. "If the actual situation continues to prevail, in the future the suboptimal use of medications in elderly type 2 diabetics may entail substantial healthcare resources," Gregoire concluded.

*Diabetes Care July 2007.*

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Item 11

**New Inhaled Insulin Qdose Shows Positive Results in Study**

*Peak levels achieved more quickly than subcutaneous insulin injection and was safe and effective.*

<http://www.diabetesincontrol.com/results.php?storyarticle=5017>

MicroDose Technologies, Inc., a privately held drug delivery and specialty pharmaceuticals company announced Monday the results from a glucose clamp study of the QDose inhaled insulin product. MicroDose, through its joint venture with Vectura Group plc, QDose Limited, has developed a highly efficient, rapid acting, insulin inhaler, based upon MicroDose's proprietary electronic inhaler technology and Vectura's dry powder insulin formulation. The QDose inhaled insulin product offers dose titration capability over a broad range of dose strengths, in a single inhalation. The inhaler also provides active dose feedbacks to the patient in an easy to use, pocket-sized device.

The study employed the widely used and validated glucose clamp technique, and results demonstrated that:

- The inhaled insulin formulation was safe and effective
- Peak levels of insulin activity were achieved more quickly than those from the subcutaneous insulin injection
- Relative bioavailability of inhaled insulin was approximately 18% during the 3 hour period following dosing; higher than the published values for the currently marketed inhalation product
- Administration of the same total dose of inhaled insulin from either single blister or two "half strength" blisters led to equivalent activity; an advantage over the currently marketed inhalation product

The study was a randomized, crossover, open-label glucose clamp study, designed to confirm the high relative bioavailability of the QDose insulin formulation previously observed, and to demonstrate the product's dose titration capability. The results confirmed the faster onset of action seen with the QDose inhaled formulation compared with subcutaneous insulin. The relative bioavailability observed in this study compares favorably with available information on competitor inhaled insulin programs. The study was conducted in the United States at Profil Institute for Clinical Research Inc (Profil) in San Diego, with 14 healthy male volunteers, using a glucose clamp technique.

*For further information please visit [www.icrodose-tech.com](http://www.icrodose-tech.com)*

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**DID YOU KNOW:**

**Diabetes Increases Hospital Complications for Trauma Patients:** Diabetes complicates hospital trauma care much as it does for in-patient acute care, researchers here reported. Data from Pennsylvania trauma centers over

18 years showed that hospitalized patients with diabetes were almost twice as likely as non-diabetics with injuries of similar severity to have a complication, although mortality rates were the same, reported Robert A. Cherry, M.D., of Penn State, and colleagues. Studies have shown that diabetic patients have more complications and worse outcomes after hospitalization for stroke, myocardial infarction, and cardiothoracic surgery, but little had been known about outcomes for diabetic trauma patients, the authors noted. Ahmad R, et al ["Increased Hospital Morbidity Among Trauma Patients With Diabetes Mellitus Compared With Age- and Injury Severity Score-Matched Control Subjects."](#) *Arch Surg.* 2007; 142: 613-618.

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Item 12

**Lettuce May Be The Next Big Diabetes Treatment**

*Capsules of insulin produced in genetically modified lettuce could hold the key to restoring the body's ability to produce insulin and help millions of Americans who suffer from insulin-dependent diabetes, according to University of Central Florida biomedical researchers.*

<http://www.diabetesincontrol.com/results.php?storyarticle=5016>

A team of scientists at the University of Central Florida thought it could be, and their research is causing a lot of excitement in the medical community.

A ground, dried lettuce pile can contain enough insulin to treat Type one diabetes in six to eight mice.

"We have produced insulin in plant cells -- specifically lettuce -- and orally deliver the lettuce directly in capsules," said Henry Daniell, a professor at UCF.

Dr. Henry Daniell says Type one diabetes is an autoimmune disease. The body doesn't recognize the protein and attacks insulin and insulin-producing cells. This eventually destroys the pancreas, meaning patients will need to be on insulin for life.

But, Daniell said that after eight weeks, the body of a mouse understood insulin was food.

"Once it stops fighting, the pancreas comes back alive because there are a lot of stem cells in pancreas. It's repopulated," Daniell said.

That means patients wouldn't have to take insulin the rest of their lives.

"Once it's put inside a plant cell and when it's ingested in the stomach, that plant cell is surrounded by a cell wall and the cell wall protects it from amino acids in the stomach and also from enzymes for digesting. But, when the plant cell reaches the gut, bacteria pokes holes in the plant cell wall and releases the insulin," Daniell said.

Daniell said the capsules could be used to prevent diabetes before there are any symptoms, treat the disease in later stages, and even eliminate it completely."

"When this is absorbed, we anticipate that this methodology would cure diabetes and not simply provide temporary relief," Daniell said.

It is also more cost-effective. Insulin costs Americans billions of dollars, but by eliminating the fermentation and purification process, Dr. Daniell's insulin capsules will cost pennies to produce.

Daniell said the next step is human clinical trials. He said he expects to enter the third phase in about two years, and that would be open to anyone with Type one diabetes.

Once complete, the capsules will be ready for FDA approval.

*The National Institutes of Health provided 2 million U.S. dollars to fund the study. The findings are reported in the latest issue of Plant Biotechnology Journal.*

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Item 13

**Stress Responses and Memory Abnormal in Type 2 Diabetes**

*Many patients with type 2 diabetes have hypothalamic-pituitary-adrenal (HPA) hyperactivity and declarative memory deficits, researchers report.*

<http://www.diabetesincontrol.com/results.php?storyarticle=5015>

Dr. Antonio Convit of New York University School of Medicine and colleagues studied 30 middle-aged diabetics and a like number of controls to compare HPA axis function and cognition. The average time since diagnosis of diabetes was 7.5 years.

Compared with the controls, the diabetic group had elevated plasma cortisol levels basally and after dexamethasone suppression, and a greater response to corticotropin-releasing hormone (CRH).

Cortisol levels during the dexamethasone/CRH test were positively associated with HbA1c. This was independent of age, body mass index and other factors.

A neuropsychological battery assessing declarative and working memory, attention, and executive function showed that cognitive impairment in the diabetics was restricted to declarative memory.

Moreover, across all subjects, declarative memory was inversely associated with cortisol levels. However, say the investigators, "these associations were subsumed by glycemic control (glycosylated hemoglobin)."

The authors call for further study of the role of the HPA axis in cognition in diabetic patients. In particular, they conclude, "improvements in glycemic control might lead to improvement in cognition."

Commenting on the findings, Dr. Convit pointed out in remarks that "most cases of type 2 diabetes are associated with weight problems and a staple of diabetes treatment is weight control."

He added, "A speculative interpretation of the data presented in the article is that given the dysregulation of the stress system, it may be a good idea to institute stress reductions strategies, such as relaxation or meditation, as part of the weight reduction plan in individuals with type 2 diabetes."

*J Clin Endocrinol Metab* 2007;92:2439-2445.

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**FACT:**

**Mediterranean Diet Works For Those With Diabetes:** Eating a traditional Mediterranean diet -- more vegetables, fruits, and fish, and fewer animal products -- does seem to ward off heart disease, an Australian study shows, and it can be especially beneficial for people with diabetes. Mediterranean-born immigrants in Australia have lower death rates from heart disease than native-born Australians, note Dr. Linton R. Harriss, from Monash University in Melbourne, and colleagues. This prompted them to investigate dietary patterns in relation to heart-related mortality "in an ethnically diverse population." "Our results suggest that the Mediterranean diet may lower mortality from ischemic heart disease." **See This Week's Item #5**

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Item 14

**Visceral Obesity A Major Metabolic Risk-Factor Regardless of BMI**

*A new study shows that among individuals with the same body mass index (BMI), men with lower cardiorespiratory fitness (CRF) levels had almost twice as much abdominal fat than their counterparts who were "fat and fit." The higher levels of abdominal obesity were also associated with poorer metabolic profiles, the researchers found.*

<http://www.diabetesincontrol.com/results.php?storyarticle=5014>

"To the best of our knowledge, this study is the first to show that the poorer metabolic risk profile of men with low CRF is associated with more visceral adipose tissue accumulation even after controlling for BMI," note Benoit J Arsenault (Hôpital Laval, Québec, QC) and colleagues in their "This finding supports the notion that visceral obesity is a major correlate of a metabolic risk-factor profile that predicts the development of cardiovascular disease and type 2 diabetes mellitus resulting from poor CRF," they add.

They note, however, that their study was cross-sectional in design and had a limited sample size, "so prospective studies with measurement of CRF, visceral abdominal tissue accumulation, and hard end points will be needed to further sort out the respective contributions of visceral adiposity and CRF to metabolic risk."

Arsenault et al studied 169 asymptomatic men with diabetes mellitus who were participating in the Quebec Family Study, a population-based study of French Canadian families living in and around Quebec. They measured abdominal adipose tissue accumulation, cardiorespiratory fitness, and indexes of plasma glucose-insulin homeostasis and lipoprotein-lipid profiles.

More visceral fat was seen among men in the lowest tertile of CRF than among those in the highest tertile, and those in the highest tertile of CRF also had more favorable lipoprotein-lipid profiles than those in the lowest tertile.

After matching individuals with similar BMIs, men with low CRF were characterized by more visceral adipose tissue accumulation than men with high CRF (mean 114.4 cm<sup>2</sup> vs 87.8 cm<sup>2</sup>; p<0.007) and by a poorer metabolic profile. When matched for visceral adipose tissue accumulation, however, such differences were no longer significant.

"This study underlines the importance of visceral adipose tissue accumulation in the previously reported association between CRF and metabolic complications predictive of coronary heart disease and type 2 diabetes mellitus," say Arsenault et al.

"Our results suggest that visceral abdominal tissue accumulation could be a key confounding factor when the relationship of CRF, coronary heart disease risk, and metabolic syndrome is examined."

Physical activity should be promoted, irrespective of age, sex, or degree of obesity as a measure to reduce adiposity, to increase energy expenditure, and to potentially decrease atherogenic visceral adipose tissue mass, they conclude.

*Arsenault BJ, Lachance D, Lemieux I, et al. Visceral adipose tissue accumulation, cardiorespiratory fitness and features of the metabolic syndrome. Arch Intern Med 2007; 167:1518-1525.*

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Item 15

**Dietary Glycemic Index Tied to Risk of Age-Related Macular Degeneration**

*Poor dietary carbohydrate quality as defined by the dietary glycemic index -- a modifiable risk factor -- may increase the risk of age-related macular degeneration (AMD), according to study results.*

<http://www.diabetesincontrol.com/results.php?storyarticle=5013>

"AMD appears to share several carbohydrate-related mechanisms and risk factors with diabetes-related diseases, including retinopathy and cardiovascular disease (CVD)," write Dr. Allen Taylor, of Tufts University, Boston, Massachusetts, and colleagues. "However, to date, only one small study has addressed this issue."

To investigate further, the researchers conducted a cross-sectional study of 4099 participants, aged 55 to 80 years, in the Age-Related Eye Disease Study (AREDS).

The team classified a total of 8125 eyes at baseline into one of five AMD groups based on the size and extent of drusen, the presence of geographic atrophy, and neovascular changes.

The dietary glycemic index (dGI) for each subject was calculated from the weighted average of the glycemic index scores for each item on a food questionnaire. The glycemic index values for the foods "were either derived from published values based on white bread as the reference food or were imputed from glycemic index values of comparable foods."

The investigators report that eyes in the fourth and fifth quintiles of dGI had a significantly "or suggestively" higher risk of large drusen, geographic atrophy, and neovascularization compared to eyes in the first quintile. There was a significant positive association between dGI and severity of AMD (p for trend <0.001).

"There was a 49% increase in the risk of advanced AMD (geographic atrophy plus neovascularization) for persons with a dGI higher than the sex median," Dr. Taylor's team found. They calculate that 20% of prevalent cases of AMD would have been prevented if subjects had consumed diets with a dGI below the median.

*Am J Clin Nutr 2007;86:180-188.*

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**Quote of the Week!**

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

.....George S. Patton

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