

DIABETES IN CONTROL.com Newsletter

The Newsletter for Professionals in Diabetes Care

May 30, 2007 - Issue #366

Top Diabetes Stories:

Sleep Apnea Increases Risk of Heart Attack and Diabetes*

<http://www.diabetesincontrol.com/results.php?storyarticle=4846>

Elderly Diabetics Life Expectancy is Reduced*

<http://www.diabetesincontrol.com/results.php?storyarticle=4845>

Oral Contraceptive Use May Raise Gestational Diabetes Risk*

<http://www.diabetesincontrol.com/results.php?storyarticle=4842>

Type 2 Diabetes Devastating for Teens*

<http://www.diabetesincontrol.com/results.php?storyarticle=4841>

Lack of Diabetes Care in Nursing Homes*

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Quality Improvement Effort Pays Off in Diabetes Care*

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Resistance to Daily Aspirin Therapy Seen in Diabetics*

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Postprandial Glucose Levels Tied To CVD Risk in Type 2 Diabetes*

<http://www.diabetesincontrol.com/results.php?storyarticle=4833>

From the editor's desk

With all the press last week about Avandia and heart disease, patients have been on the phones to their prescribers asking for a change. **Stephen Freed, Publisher, Diabetes Educator and Pharmacist**, worked with **Dr. Richard K. Bernstein, MD**, to find the real message in all the hype. To find out what Steve and Dick have to say be sure to read *Cardiovascular Risk With Avandia? Let's put it in perspective!*

<http://www.diabetesincontrol.com/results.php?storyarticle=4847>

Trash to treasure: Recently I was reviewing some articles from one of our nutritional newsfeeds and found that there is a growing desire to use the waste products of food production to improve health (and profits).

In the Journal Food Chemistry, researchers from the City University, Madrid, and the University of Barcelona report that, Cocoa husks, a waste product from the chocolate industry, could offer a valuable source of dietary fibre for the low-calorie food segment. In addition to being rich in both soluble and insoluble fibre, the husks also contain antioxidant compounds that open up possibilities for health.

In another example, the National Botanical Research Institute in Lucknow, India investigated the antioxidant potential of 30 soy variety seeds and agri-waste (leaves, twigs and pod pericarp), and found significantly high levels of flavonoids, along with phenolic acids and other antioxidant phytochemicals present. In fact they believe these waste products can be better than the synthetic versions.

Dr. Sheri Colberg, author of *The 7 Step Diabetes Fitness Plan: Living Well and Being Fit with Diabetes*, has her own take on what Dick and Steve are recommending. Be sure to read *What Does It Take to Break the Cycle*, and find out more about the best replacement.

<http://www.diabetesincontrol.com/results.php?storyarticle=4848>

Would you be interested in going on a diabetes cruise? We are planning a 7-9 day Diabetes Education Cruise with Dr. Richard K. Bernstein for next spring or fall. We will provide CME for medical professionals to learn Dr. Bernstein's treatment methods and education for patients with diabetes. If you might be interested, just send us an email with "Diabetes Cruise" in the subject line. Send to publisher@diabetesincontrol.com

June 3, 7PM ET on CNBC

To pump or not to pump? dLife looks at insulin pumps and why they may, or may not, be right for you. Plus, a leading cardiologist talks about diabetes and heart risk, and an ex-cop with some straight talk about control and complications. Tune in to another episode of dLifeTV: Sundays on CNBC at 7 PM ET, 6 PM CT, and 4 PM PT. Check your local listings for details.

We can make a difference!

This week's overview:

- Item #3: Patients Need More Education on High Blood Pressure
- Item #4: Impaired Glycemic Control Reversible When Stopping Diuretics
- Item #7: Lawyers Forecast Flood of Avandia Litigation
- Item #8: Avandia Study for Cardiovascular Risk in Jeopardy
- Item #10. Insulin Making Cells From Umbilical Cord Blood
- Item #13: Valsartan Cuts C-Reactive Protein Levels in Prediabetics
- Item #15: Fish-Oil Supplements Plus Regular Aerobic Exercise Benefit Overweight Patients

Check out this weeks **“Test Your Knowledge”** question.
<http://www.diabetesincontrol.com/results.php?storyarticle=4849>

Dave Joffe, *Editor-in-Chief*

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NEWS FLASH:

Data from miscoded meters cannot be used!



Miscoded blood glucose meters can be problematic for people with diabetes and may result in significant insulin dosing errors. Charles H. Raine III, MD, with the Diabetes Control Center in Orangeburg, SC and colleagues conducted a study of automatically coded, manually coded and intentionally miscoded blood glucose meters. The results of their study were published in the *Journal of Diabetes Science and Technology*. Dr. Raine stated that, data from miscoded meters cannot be used, and “people who are checking their blood glucose with miscoded meters are literally poking their finger for nothing.”

Automatically coded meters had superior results compared with manually coded meters. “The probability of insulin mis-dosing with either manually, correctly coded or auto-coded meters was significantly lower than that with miscoded meters,” the researchers wrote.

The probability of a two-unit insulin dosing error range using a miscoded blood glucose meter was as high as 50%, compared with 7.1% for correctly and manually coded meters. The probability of three-unit insulin dosing error range was as high as 22.3% for miscoded meters and 0.49% for correctly and manually coded meters.

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Tools for your Practice:

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of all parameters within a short period of time. With the program versions for mobile devices you can track and analyze your data everywhere at any time. You will become much more motivated to continue tracking data because of immediate feedback for your readings. The smartphone version enables you to get your diabetes managed even with a cellphone (Handy). This version also follows the one screen data tracking philosophy so that you can enter all data like bg levels, carbs etc. for the whole day on this single screen. Your data will be synchronized automatically to any other device and can be graphed on any machine. Of course you can print your logs for discussion with your physician, but even an electronic data exchange is easy and completed within a few seconds.

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New Product:

GLUFAST: Approval of an Additional Indication of Combination Therapy of Glufast and Alpha-

glucosidase Inhibitor in Japan: Takeda Pharmaceutical announced approval for an additional indication of “combination therapy with alpha-glucosidase inhibitor (“alpha-GI”) for Glufast® (generic name: mitiglinide) 5mg tablet and 10mg table. Glufast was approved on May 24 by the regulatory authority in Japan. Glufast is a diabetic medicine that promotes insulin secretion by stimulating the pancreatic β -cells. It demonstrates effects promptly after dosing, thereby it brings insulin secretion closer to its natural patterns and improves postprandial hyperglycemia.

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ITEMS For The Week:

Item 1

Sleep Apnea Increases Risk of Heart Attack and Diabetes

Patients diagnosed with sleep apnea had more than two-and-one-half times the risk of developing diabetes and increases a person's risk of having a heart attack or of dying by 30 percent compared with those without the nighttime breathing disorder

<http://www.diabetesincontrol.com/results.php?storyarticle=4846>

These findings and another Yale study linking sleep apnea and diabetes were presented last week at the American Thoracic Society 2007 International Conference in San Francisco.

In obstructive sleep apnea, the upper airway narrows, or collapses, during sleep. Periods of apnea end with a brief partial arousal that may disrupt sleep hundreds of times a night. Obesity is a major risk factor for sleep apnea.

Sleep apnea triggers the body's "fight or flight" mechanism, which decreases the amount of blood pumped to the heart, said Neomi Shah, M.D., clinical fellow in the Department of Internal Medicine, pulmonary section.

The study included 1, 123 patients referred for sleep apnea evaluation. They were followed for the next four to five years to see how many had a heart attack, coronary angiography, bypass surgery, or died. Previous studies showed a correlation between sleep apnea and heart disease, but this is the first large study to follow patients for five years and to adjust the findings for other traditional risk factors for heart disease.

The most effective treatment for sleep apnea is a technique called nasal CPAP (continuous positive airway pressure), which delivers air through a mask while the patient sleeps, keeping the airway open. "There is some evidence to make us believe that when sleep apnea is appropriately treated, the risk of heart disease can be lowered," Shah said.

In another Yale study presented at the conference, researchers found patients with sleep apnea are at increased risk for developing Type II diabetes, independent of other risk factors. The study looked at 593 patients at the VA Connecticut Health Care System referred for evaluation of sleep-disordered breathing.

The researchers followed the patients for up to six years and found that patients diagnosed with sleep apnea had more than two-and-one-half times the risk of developing diabetes compared with those without the nighttime breathing disorder. The more severe a patient's sleep apnea, the greater the risk of developing diabetes.

Nader Botros, M.D., a fellow in the pulmonary section, said the exact reasons for the link between sleep apnea and diabetes are not known, but researchers suspect that when the "fight or flight" response is triggered by sleep apnea, a cascade of events occurs, including the production of high levels of the hormone cortisol that ultimately leads to insulin resistance and glucose intolerance. These are pre-diabetic conditions that, if left untreated, can lead to the development of diabetes. Low oxygen levels also appear to play an important role.

American Thoracic Society 2007 International Conference in San Francisco.

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Item 2

Elderly Diabetics Life Expectancy is Reduced

People who develop diabetes late in life often suffer from a range of diabetes-related complications, and their life expectancy is shorter than that of nondiabetic individuals of the same age, a new study shows.

<http://www.diabetesincontrol.com/results.php?storyarticle=4845>

In a recent article in the Archives of Internal Medicine, Dr. Frank A. Sloan, of Duke University, and colleagues point out that "little is known about the impact of diabetes mellitus in elderly populations."

The researchers examined illness and mortality rates in 33,772 Medicare beneficiaries with diabetes and in 25,563 similar people without diabetes ("controls") over a 14 year period.

The death rate was over 9 percentage points higher among the people with diabetes than the control patients. Being newly diagnosed as diabetic translated into a loss of life expectancy of just over 2 years.

Overall, 92 percent of the diabetes group experienced an adverse health event compared with 72 percent of the control group.

Disorders affecting the legs and complications associated with surgery were higher among patients with diabetes. Furthermore, 58 percent of those with diabetes were diagnosed with heart failure, compared with 34 percent of the control group. While kidney disease and retinal eye disorders were less common, both increased markedly in the diabetic group.

"Although the present data provide no insight into the cause of these patterns, the burden of diabetes mellitus complications on the individual and on the health care system is enormous," the researchers conclude.

Archives of Internal Medicine, May 14, 2007.

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DID YOU KNOW:

TV linked with poor diabetes control: Diabetic children who spent the most time glued to the TV had a tougher time controlling their blood sugar, according to a Norwegian study that illustrates yet another downside of too much television. The study involved 538 children with an average age of 13. In Norway, about 25,000 people have Type 1 diabetes. In the United States, there are 3 million with the condition and about 30 million worldwide.

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Item 3

Patients Need More Education on High Blood Pressure

New study shows that nearly a quarter of all African-Americans still believe that high blood pressure means that a person is tense or anxious

<http://www.diabetesincontrol.com/results.php?storyarticle=4844>

More than 90% of hypertensive patients are aware that increased blood pressure is a major risk factor for cardiovascular disease, according to research presented at the 22nd Annual Meeting of the American Society of Hypertension (ASH).

Marvin Moser, MD, President, Hypertension Education Foundation, Scarsdale, New York, United States, presented results of an on-line questionnaire taken by 1,245 hypertensive patients (45 years of age or older) aimed at providing updated information on the status of blood pressure control in different patient groups.

More than 90% of respondents correctly associated high blood pressure with heart attacks and stroke. About two-thirds correctly associated high blood pressure with kidney failure, atherosclerosis, and an enlarged heart.

The study also found, however, that misconceptions related to hypertension are common. In fact, roughly 12% of all respondents and nearly a quarter of all African-Americans still believe that high blood pressure means that a person is tense or anxious.

Approximately a quarter of respondents incorrectly believed that weight loss is sufficient to reduce blood pressure and that perception tended to be more common in higher socioeconomic groups. More than a quarter of respondents believed that they do not have to do exercise regularly because they are taking medication to control blood pressure and 40% cited a joint condition as the reason for not exercising regularly.

The analysis also revealed that while more than 90% of respondents who had elevated blood pressure were taking medications to treat it, between 28% and 40% did not have their medication changed when blood pressure remained too high. More than one-third of respondents had uncontrolled hypertension the last time their blood pressure was checked.

The survey also found that more than 60% of hypertensive respondents were obese, defined as a body mass index (BMI) greater than 30 kg/m².

"Overall, the data suggest that awareness of blood pressure and its effects is high and that patients are being treated but that the impact of factors such as obesity and reported provider inertia on achieving optimal blood pressure must be re-emphasized," Dr. Moser said.

Presentation Title: Hypertension Management: A National Survey. Abstract Number 165-BJ

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Item 4

Impaired Glycemic Control Reversible When Stopping Diuretics

Results from a six-month extension study have shown that impairment in glycemic control after one year of diuretic-based combination treatment is reversible by switching to treatment not involving a diuretic, in this case, an ACE inhibitor and calcium-channel blocker.¹

<http://www.diabetesincontrol.com/results.php?storyarticle=4843>

Dr George Bakris (University of Chicago, IL), commented that, "When we looked at who developed new-onset diabetes, the plan was to then switch these patients over to the ACE-inhibitor/calcium-channel-blocker combination to see whether we could regress or bring back to baseline these metabolic changes." "This effect of new-onset diabetes, at least if you intervene within a short time of starting the therapy, does not appear to be permanent."

The hypothesis-generating study, an extension of the Study of Trandolapril/Verapamil SR And Insulin Resistance (STAR), was presented last week at the American Society of Hypertension 2007 Scientific Sessions. In the original STAR study, published in 2006, investigators showed that in patients with impaired glucose tolerance, normal kidney function, and hypertension, the fixed-dose combination of trandolapril and verapamil reduces the risk of new-onset diabetes compared with a losartan/hydrochlorothiazide-based therapy.

Dr. Bakris said clinicians previously believed marrying diuretic therapy to an ACE inhibitor or angiotensin receptor blocker (ARB) might provide protection from new-onset diabetes, although this turned out not to be true. The risk of new-onset diabetes is also dose dependent, he said, such that at 25-mg hydrochlorothiazide (HCTZ) there is substantial risk of impairing the glucose response.

Testing the hypothesis that impaired glycemic control might be reversible early in the diuretic/losartan-combination treatment by switching to an ACE-inhibitor/calcium-channel-blocker combination, investigators assessed glycemic changes after six months of additional treatment with trandolapril and verapamil in both treatment groups in the STAR study. Bakris noted that only 53% of the original cohort stayed in the extension trial, although there were no statistically significant demographic differences between those who stayed and those who did not continue in the trial.

Those patients switching from losartan/HCTZ to trandolapril/verapamil experienced greater improvements in glucose and insulin response. The primary outcome measure, change in two-hour glucose using the oral glucose tolerance test (OGTT), decreased from 154 mg/dL at baseline to 131 mg/dL at six months in those who switched from the diuretic to the ACE-inhibitor/calcium-channel-blocker combination. At baseline, 10 patients in the losartan/HCTZ-treatment arm had diabetes, but six months after they switched to trandolapril/verapamil, this number was cut in half.

Blood pressure was sacrificed to some degree, noted Bakris, increasing from 128 mm Hg systolic at baseline to 137 mm Hg at six months. He said that while diuretics are cheap and have decades of outcomes data to support their use, clinicians might decide the cost of using the drug with respect to new-onset diabetes is too high.

"Looking at this overall, from a cost perspective, from a morbidity perspective, and from a patient perspective, why would you use a therapy to treat one condition only to express another condition that now requires additional medicine and has a potentially greater cardiovascular risk?" he said.

1. Bakris G, Molitch M, Sowers J et al. Reversal of new onset diabetes by nondiuretic based fixed dose antihypertensive drug combinations? Results of the STAR 6-month extension (STAR-LET). American Society of Hypertension 2007 Scientific Sessions; May 20, 2007; Chicago, IL.

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FACT:

Type 2 diabetes costs the U.S. health system an extra \$23 billion a year in direct medical

costs: A study released last month at the American Association of Clinical Endocrinologists' annual meeting in Seattle found that poorly managed type 2 diabetes costs the U.S. health system an extra \$23 billion a year in direct medical costs. Diabetic complications cost almost \$10,000 per patient each year, concluded the author of that study, Willard Manning, PhD, a University of Chicago health economist.

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Item 5

Oral Contraceptive Use May Raise Gestational Diabetes Risk

The results of this study suggest that the use of certain types of hormonal contraceptives during the 5 years leading up to a pregnancy may be associated with the risk of developing gestational diabetes.

<http://www.diabetesincontrol.com/results.php?storyarticle=4842>

Dr. Monique M. Hedderson from the Kaiser Permanente Medical Care Program of California, stated that, "The risk associated with gestational diabetes varied depending on the type of progestin in the hormonal contraceptive."

"We found evidence suggesting that use of hormonal contraceptives with a highly androgenic progestin was associated with a 43% increased risk of gestational diabetes," Dr. Hedderson said. On the other hand, she added, "use of hormonal contraceptives with a low androgenic progestin was associated with a 16% decreased risk of gestational diabetes."

The findings are based on 356 women with gestational diabetes and 368 women without the condition selected from a multiethnic cohort of 14,235 women who delivered a single live infant between January 1996 and June 1998.

The women were screened for gestational diabetes at 24 to 28 weeks of pregnancy and were members of Kaiser Permanente for at least 5 years before pregnancy. Information on contraceptive use in the 5 years before pregnancy was obtained from medical records and pharmacy data.

"Our data support an association between hyperandrogenicity and insulin resistance," Dr. Hedderson and her associates maintain.

The findings, which "need to be confirmed by other studies," the investigator said, support other studies suggesting that hormonal contraceptives, particularly the more androgenic formulations, can alter glucose tolerance.

Diabetes Care 2007;30:1062-1068.

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Item 6

Type 2 Diabetes Devastating for Teens

With the incidence of type 2 diabetes and its complications among young people on the increase worldwide, aggressive measures are needed to treat and prevent the disease, two diabetes experts say in the current issue (May 26) of The Lancet.

<http://www.diabetesincontrol.com/results.php?storyarticle=4841>

Dr. Orit Pinhas-Hamiel, of the Pediatric Endocrinology and Diabetes Department at Sheba Medical Center in Tel-Hashomer, Ramat-Gan, Israel state that, ".The complications associated with adolescents' type 2 diabetes seems to behave differently than in children and adolescents with type 1 diabetes."

These complications may be present at the time of diagnosis, and their rate of progression may be higher than in children and adolescents with type 1 diabetes, "We need to develop improved approaches to awareness and early treatment of type 2 diabetes and associated abnormalities."

These complications, including high blood pressure, kidney disease, eye disease and problems with blood fat levels, may already be present when type 2 diabetes is diagnosed, while they rarely exist at the onset of type 1 diabetes, noted Pinhas-Hamiel.

"In addition, studies to date suggest that early onset of type 2 diabetes is associated with a more rapid progression of these complications compared with adolescents with type 1 diabetes," Pinhas-Hamiel said.

Moreover, psychiatric problems are also associated with type 2 diabetes. In a study in Philadelphia, one in five such teens suffered from conditions such as depression, obsessive-compulsive disorder or other psychiatric conditions.

Another study found that the deaths of seven young black males, aged 13 to 21, with undiagnosed diabetes, met the criteria for high blood sugar and diabetic coma, the authors added.

Type 2 diabetes also puts unborn infants at risk. In a Canadian study of 51 pregnant adolescent girls with type 2 diabetes, only 35 had live births, and the pregnancy loss rate was 38 percent, the authors reported.

Pinhas-Hamiel thinks that adolescents with type 2 diabetes should be screened for signs of these complications when they are first diagnosed. "In addition, there is a need for well-established guidelines for the initiation of antihypertensive and anti-lipid treatments for adolescents with type 2 diabetes," she said. "Type 2 diabetes mellitus in children and adolescents is associated with significant morbidity and mortality."

One expert thinks this review confirms that type 2 diabetes in teens has become a serious public health problem.

"Recent studies have confirmed what most of us have long suspected, that the rate of what used to be called adult onset diabetes is rising rapidly in children and adolescents," said Dr. David L. Katz,

Dr. David L. Katz, director of the Prevention Research Center at Yale University School of Medicine states that, this study confirms another suspicion that even greater dangers are around the next corner should current trends persist.

"In adults, type 2 diabetes is a potent risk factor for cardiovascular disease and other complications, from kidney failure to nerve damage," Katz said. "There is every reason to expect, and now findings to confirm, that these relationships hold in youth as well. When formerly adult onset diabetes develops in 7-year-olds, the threat of heart disease in 17-year-olds clearly looms," he said.

"Anyone who was waiting for an even more strident alarm before accepting that epidemic obesity and type 2 diabetes in our children is a public health crisis of the first order -- this is it," Katz said.

Another expert thinks that overweight adolescents who lead a sedentary life need to be tested for diabetes.

"Here we have a situation where we are not examining our youngsters for diabetes, and they already have complications present or developing," Dr. Stanley Mirsky, of Lenox Hill Hospital in New York City and a board member of the Juvenile Diabetes Foundation, said in a statement.

"We have to test these kids that spend all their time in front of the televisions or computers eating junk food instead of being outside exercising and eating right, especially when there already is a family history of diabetes," Mirsky said.

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Item 7

Lawyers Forecast Flood of Avandia Litigation

GlaxoSmithKline Plc is expected to be hit with a wave of lawsuits from users of the diabetes drug Avandia, plaintiff's lawyers said last Wednesday.

<http://www.diabetesincontrol.com/results.php?storyarticle=4840>

Lawyers who bring product liability cases say they are fielding calls from Avandia users who are contemplating suing Glaxo, following a pooled analysis of trials in the New England Journal of Medicine this week that concluded the drug raised the risks of cardiac-related deaths and heart attacks.

Glaxo could face potential liability in "the tens of billions of dollars," said Barry Knopf, a plaintiff's lawyer and partner in the New Jersey law firm of Cohn Lifland Pearlman Herrmann & Knopf.

"If the increased risk of cardiac death is as high as (the study) suggests, it should be possible to draw the connection to cardiac events" among people taking Avandia, "especially patients who had not had previous heart disease or heart attacks," he said.

"There is definitely an increased risk for heart attacks, the question is how great it is," said Weitz, whose firm also represents thousands of plaintiffs in cases against Merck & Co Inc. involving the withdrawn painkiller Vioxx.

Glaxo CEO Jean-Pierre Garnier said on Wednesday it was too early to say whether Avandia would be the subject of product liability lawsuits, although he was not aware of any yet.

Speaking to reporters after the company's annual meeting in London, Garnier said he was confident the full data would vindicate the drug's safety profile.

Glaxo, Europe's biggest drugmaker, has said it strongly disagreed with the conclusions of the New England Journal of Medicine study, which it said were based on incomplete evidence and questionable methodology.

Avandia is Glaxo's second-biggest seller, bringing in nearly \$3.2 billion last year. Most analysts have said they do not expect the drug to be pulled from the market.

Shaojing Tong, a pharmaceuticals analyst at Mehta Partners in New York, said he expected Glaxo's liability would be limited because of data already in Avandia's package insert label about heart risks.

"We are just going to have to wait to see what develops in the science," he said. "It is very early in the game in this case."

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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

Avandia Study for Cardiovascular Risk in Jeopardy

A large clinical study meant to test the heart safety of the diabetes treatment Avandia may be in jeopardy as a result of recent reports of the drug's risks.

<http://www.diabetesincontrol.com/results.php?storyarticle=4839>

Dr. Ronald L. Krall, the medical director for GlaxoSmithKline, said in a telephone interview yesterday that some of the 4,450 patients enrolled in the drug trial, called Record, have dropped out this week because of safety concerns about Avandia.

Dr. Krall said he did not yet know how many patients have withdrawn, but said Glaxo was now worried about whether it could complete the drug trial, which has been scheduled to run through next year. The company has been counting on a successful outcome from the study to dispel widespread concerns that Avandia carries a higher risk of heart attacks than other diabetes drugs.

Now, though, the independent research committees overseeing the study "are concerned about the ability of the study to continue" and are "considering what to do to prevent people from dropping out of the trial," Dr. Krall said.

Yesterday, the F.D.A. said its own recent analysis of more than 40 clinical studies of Avandia seemed to confirm the findings in The New England Journal of Medicine's study, whose lead author was the influential Cleveland Clinic heart specialist Steven E. Nissen.

But an agency spokeswoman yesterday urged caution in interpreting those results.

"Dr. Nissen's meta-analysis and the F.D.A.'s meta-analysis both arrived at a similar figure of 40 percent" the F.D.A. spokeswoman, Julie Zawisa, wrote in an e-mail message. "But this alone, is not conclusive of anything. What it does mean is that we need to try to reconcile the meta-analysis finding with clinical trial data that DO NOT show this increased risk."

People with Type 2 diabetes are already at risk of heart attacks, facing a 20.2 percent chance of such an attack over seven years. One of the main reasons for controlling blood sugar in diabetic patients is to manage that risk.

But if Dr. Nissen's analysis is an accurate reflection of Avandia's increased risk, it appears the drug would do more cardiovascular harm than good. Diabetics taking Avandia would run a 28.9 percent chance of heart attack over the same seven-year period, according to his analysis.

GlaxoSmithKline's own meta-analysis, submitted to the F.D.A. last August, showed a slightly lower 31 percent increased risk of heart attack.

GlaxoSmithKline has urged regulators and the public not to rush to judgment based on the New England Journal of Medicine article and has said that the Record trial, which began in 2000, would be a more reliable way to estimate the drug's cardiovascular risks.

In that study, half of the 4,450 patients are being treated with Avandia in combination with another diabetes drug, while the others are being treated with two other drugs.

The trial is designed to determine whether patients taking Avandia are more likely to have a range of cardiovascular problems, including heart attack and stroke.

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FACT:

Type 2 Diabetes Takes Toll on Teens: With the incidence of type 2 diabetes and its complications among young people on the increase worldwide, aggressive measures are needed to treat and prevent the disease, two diabetes experts say. These complications, including high blood pressure, kidney disease, eye disease and problems with blood fat levels, may already be present when type 2 diabetes is diagnosed, while they rarely exist at the onset of type 1 diabetes. In addition, studies to date suggest that early onset of type 2 diabetes is

associated with a more rapid progression of these complications compared with adolescents with type 1 diabetes. See this weeks Item # 6

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Item 9

Lack of Diabetes Care in Nursing Homes

We have guidelines on how to manage diabetes for the outpatient and the hospital patient, ~~but~~ we have no guidelines for treating people in nursing homes and the results of a study showed that only 38 percent are at goal.

<http://www.diabetesincontrol.com/results.php?storyarticle=4838>

Ohio University College of Osteopathic Medicine researchers find that elderly diabetics in extended-care facilities need improved treatment protocols for diabetes. Current standards of care fail to meet American Diabetes Association standards for outpatient diabetics.

Entitled “Diabetes Care in Extended Care Facilities: Appropriate Intensity of Care?”, a study authored Jay Shubrook, D.O., assistant professor of family medicine at OU-COM; Frank Schwartz, M.D., assistant professor of endocrinology at OU-COM, examined the quality of care that diabetic patients receive in nursing homes through a retrospective chart review of 108 residents at 11 extended health-care facilities in Ohio and West Virginia over a period of one year.

“Our study is based on the principle that there are guidelines on how to manage diabetes for the outpatient adult, and there are new guidelines for how to manage diabetes for patients in the hospital, but there are no guidelines for treating people in nursing homes,” Shubrook said.

According to the study, only 38 percent of the patients monitored (98 percent) met blood glucose (sugar) goals. Only 55 percent of the patients monitored (94 percent) had satisfactory blood pressure levels. Only 31 percent of patients had lipids (serum total cholesterol) checks yearly, with 58 percent having acceptable levels. These three are critical areas that affect life expectancy for diabetics: control of hypertension (elevated blood pressure); cardiovascular risk factors, such as cholesterol; and blood sugar. Since heart disease is a most significant and common complication of diabetes, controlling hypertension and lipids are the number one and two treatment areas for the elderly diabetic. Blood glucose control is third.

Diabetes is expected to increase 336 percent by 2050 and will produce an enormous economic burden according to the study, making nursing home diabetes care a critical avenue to explore. The Centers for Disease Control estimates that one out of three people born in the United States in 2000 will develop the disease in his or her lifetime.

According to Holt, an analysis of the data revealed the lack of a systematic approach to diabetes treatment in the facilities studied. The findings demonstrated that practice guidelines for this population must be developed in order to offer optimal care standards to nursing home residents.

Research released by the American Association of Clinical Endocrinologists indicates that three out of five people with type 2 diabetes have at least one other serious health problem related to their disease. These problems can be heart disease, diabetic retinopathy, kidney disease and foot problems.

Based on their findings, Shubrook and Schwartz are now developing treatment protocols for diabetes in nursing homes. These will be offered to medical directors of these facilities in order to improve the quality and consistency of patient care.

“Some things are done extremely well in nursing homes — for instance, foot exams and influenza vaccinations,” Shubrook said. “Others are not done as well.”

Phase two of the study, which gets underway later this year, includes a second review of patients’ charts to determine if following the treatment protocols proposed by Shubrook and Schwartz results in quality of life changes for the residents.

It is only a matter of time before we see a major increase in diabetes in nursing homes.

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Item 10

Insulin Making Cells From Umbilical Cord Blood

Stem cells taken from the umbilical cords of newborns can be engineered to produce insulin and may some day be used to treat diabetes, US and British researchers say.

<http://www.diabetesincontrol.com/results.php?storyarticle=4837>

They say they were able to first grow large numbers of the stem cells and then direct them to resemble the insulin-producing cells of the pancreas that are damaged in diabetes.

"This discovery tells us that we have the potential to produce insulin from adult stem cells to help people with diabetes," said Dr Randall Urban of the University of Texas's Medical Branch at Galveston, who directed the study.

"It doesn't prove that we're going to be able to do this in people - it's just the first step up the rung of the ladder," Dr Urban said in a statement.

Writing in the journal *Cell Proliferation* the researchers, who included a team at Britain's University of Newcastle, say they hope to eventually produce an alternative to using controversial embryonic stem cells.

In the United States, Congress has been fighting over whether to increase federal funding of embryonic stem cell research, with opponents saying it is wrong to experiment on human embryos and supporters saying the work is needed to transform many fields of medicine.

Most of the science aims to create a new field of regenerative medicine in which stem cells from a patient's blood are grown and tweaked in the laboratory and used to replace defective or damaged blood or tissue.

Other researchers are trying to learn how embryonic stem cells give rise to all the tissues and parts of the body, while remaining virtually immortal themselves, in the hope of eventually coaxing perhaps an ordinary skin cell to do the same.

The researchers in Texas and Newcastle used human umbilical cord blood because it is an especially rich source of fresh "adult" stem cells. One big hope is to create new pancreatic tissue for people with diabetes. In type 1 diabetes, the body no longer produces insulin because those cells have been destroyed.

Larry Denner of the University of Texas, who worked on the study, says his team had addressed this issue because the cells also produced a compound called C-peptide, which is not found in the culture medium - the broth used to nourish cells in the lab.

"It is a part of the insulin precursor protein and is only present when cells produce insulin. So the state-of-the-art criteria for insulin production is the demonstration of the presence of C-peptide," Dr Denner said in an email.

Last week, Geron Corp said it had transformed human embryonic stem cells into the pancreatic cells that produce insulin.

Journal of Cell Proliferation May 2007

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Item 11

Quality Improvement Effort Pays Off in Diabetes Care

Spending 500 dollars a year to improve diabetes care is a sound investment, according to one of the first studies to examine the clinical and economic impact of quality improvement on diabetes care.

<http://www.diabetesincontrol.com/results.php?storyarticle=4836>

In the June 2007 issue of Health Services Research, a University of Chicago-based research team reports that a relatively inexpensive national effort to improve the process of care at selected clinics was able to make enough difference in its first four years that, if sustained, it could reduce patients' lifetime risk of blindness, end-stage kidney disease and coronary artery disease -- all common complications of diabetes.

At a cost of less than \$500 per patient each year, this modest quality improvement effort is projected to reduce the incidence of major complications, such as end-stage renal disease, which can cost \$44,000 per patient each year.

"In this setting, we found that the economic value of improving the delivery of existing diabetes care was roughly equal to the benefits of developing a new treatment, such as a novel diagnostic technology or a better drug," said study author Elbert Huang, MD, assistant professor of medicine at the University of Chicago. "A small investment in upgrading the delivery of health care brought about a substantial improvement in health that justified the costs of the program."

"Unfortunately," he added, "the people who make such financial investments are not the people who directly benefit from them."

Federally qualified community health centers (FQHCs) routinely lose money on health care improvement programs. The added costs are borne by the health centers and by state and federal government programs; the benefits accrue to society. "Cost-effective medicine," Huang said, "depends entirely on an ongoing societal commitment to providing chronic care for vulnerable patients."

The researchers studied how diabetes care changed at 17 Midwestern FQHCs that participated in the Health Disparities Collaboratives -- a national, federally funded quality-improvement initiative launched in 1998.

The program was designed to make certain that patients at these FQHCs, which provide primary care services in underserved urban and rural communities, received the current standard of care. This includes regular testing for glycosylated hemoglobin, assessment of fats and cholesterol in the blood, eye exams and blood pressure checks, with appropriate follow-up. It also involves preventive treatments such as the use of ACE inhibitors, which can treat high blood pressure and heart failure, and aspirin, which can prevent heart attacks and strokes.

After reviewing four years of charts for 80 patients from each of the 17 centers, the researchers reported that "multiple components of care improved from 1998 to 2002." Annual glycosylated hemoglobin testing increased from 71% to 92% of patients. Blood lipid testing rose from 15% to 44%. Eye exams went from 25% to 44%. Prescriptions for ACE inhibitors rose from 33% of patients to 55%, and aspirin prescriptions rose from 22% to 45%.

These improvements added very little expense. The diabetes quality-improvement program cost about \$700 per patient the first year, \$600 the second year, \$500 the third year and leveled off at \$378 per year beginning in year four.

The researchers then estimated how much the patients' risk for the major complications from diabetes would be decreased if these improvements were maintained. Better care, they concluded, should reduce the lifetime incidence of blindness from 17% of patients down to 15%, of kidney failure from 18% down to 15%, and of coronary artery disease from 28% to 24%.

Next they tried to place a dollar value on the benefits of the program -- a longer life with fewer complications. In medical cost-effectiveness analysis, a commonly accepted standard is to say that a new device, medication or program that generates one year of extra life for a healthy person at less than \$100,000 is a good value. Another commonly used standard is \$50,000 per one year of extra life in perfect health.

The diabetes quality-improvement initiative passed all these standards. Even at twice the price and with the benefits deeply discounted, the value added by the program exceeded commonly accepted standards. "Since diabetes is so common and is increasing rapidly, whatever enhances diabetes care is worth looking at," Huang said.

A study released last month at the American Association of Clinical Endocrinologists' annual meeting in Seattle found that poorly managed type 2 diabetes costs the U.S. health system an extra \$22.9 billion a year in direct

medical costs. Diabetic complications cost almost \$10,000 per patient each year, concluded the author of that study, Willard Manning, PhD, a University of Chicago health economist.

Multiple quality-improvement programs have been found to produce improvements similar to those generated by the Health Disparities Collaboratives' diabetes program, Huang said, but "the economic value of these programs is generally unknown." The lessons learned from this evaluation, he added, "can provide important insights for policy makers."

University of Chicago Medical Center

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DID YOU KNOW:

Duct Tape and Moleskin Similarly Effective in Treating Common Warts : Duct tape and moleskin are equally effective in treating common warts in adults. "Several reports have suggested that occlusion with adhesive tape is an effective treatment for warts," write Rachel Wenner, MD, from the University of Minnesota in Minneapolis, and colleagues. "Given that duct tape therapy is inexpensive and relatively painless, we were interested in further evaluating this therapy." We found no statistically significant difference between occlusive therapy with transparent duct tape and therapy with moleskin alone for treatment of common warts in adults," the authors conclude. "Further studies are warranted to determine whether specific types of adhesive resins are important for a therapeutic effect of duct tape." Arch Dermatol. 2007;143:309-313.

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Item 12

Resistance to Daily Aspirin Therapy Seen in Diabetics

Diabetic patients exhibit a higher prevalence of aspirin resistance at a dosage of 81 mg/day than do nondiabetics with coronary artery disease.

<http://www.diabetesincontrol.com/results.php?storyarticle=4835>

"In selected diabetic patients, an 81-mg dose of aspirin may not be sufficient protection against the formation of platelet aggregations, the pivotal event that causes heart attacks," said Dr. Gurbel, director of the center for thrombosis research at Sinai Hospital and a cardiologist at Johns Hopkins University, both in Baltimore.

A second key finding of his study of aspirin resistance in 120 patients with stable CAD, including 30 with diabetes, was that not all of aspirin's antiplatelet effects in diabetic patients were mediated by inhibition of cyclooxygenase-1, the pathway previously believed to be solely responsible for the drug's antithrombotic efficacy.

"Our findings suggest that in diabetic patients there may be another pathway or pathways by which aspirin affects platelet inhibition beyond the way we conventionally think of how aspirin works," he said.

Participants in the double-blind, crossover trial got aspirin at a daily dosage of 81, 162, and 325 mg for 4 weeks each in a randomized sequence. At the end of each 4-week treatment period, platelet aggregation was measured in a host of ways, including arachidonic acid-induced light transmittance aggregation, thromboelastography, urinary thromboxane levels, the VerifyNow aspirin resistance assay, and adenosine phosphate- and collagen-induced aggregation.

The prevalence of aspirin resistance at 81 mg/day was less than 5% in nondiabetic patients, but markedly higher in the diabetics. In most instances, however, boosting the dose in the diabetic patients reduced the prevalence of aspirin resistance to nearly the same low level that was seen in nondiabetics.

For now, in the absence of clinical outcomes data from large trials, Dr. Gurbel considers 162 mg/day better than 81 mg/day for cardioprotection in diabetic patients, while recognizing that as the dose goes up, so does the bleeding risk.

An intriguing novel finding was that a dose-dependent increase in inhibition of platelet stickiness was seen in the diabetic patients even though their cyclooxygenase-1 activity was maximally inhibited at 81 mg/day.

"There's a disconnect between inhibition of the pathway that we thought was the sole pathway that conferred antiplatelet and antithrombotic effects, [and] the dose-dependent effect we see on other pathways," he explained.

The two additional pathways that appeared to be important in diabetic but not the nondiabetic patients involved collagen- and ADP-induced platelet aggregation.

Blood gets exposed to collagen in sections of the arterial wall that are denuded or damaged by chronic inflammation. No aspirin dose effect was observed with respect to how collagen activates platelets in nondiabetic patients, whereas collagen's ability to stimulate platelet aggregation in diabetics went down markedly and in dose-dependent fashion at higher aspirin doses.

Session chair Dr. Robert S. Rosenson, of the department of medicine and director of the preventive cardiology center at Northwestern University, Chicago, commented that he found fascinating the suggestion that diabetic patients not only have more reactive blood components than do nondiabetic patients, but also a "hotter," more reactive arterial wall. These observations could help explain their higher acute MI rates, compared with nondiabetics with CAD.

"I think a one-size-fits-all concept for dosing antiplatelet therapy is flawed," Dr. Gurbel said. "I think the day is coming when we will measure the aggregability of platelets as a cardiovascular risk factor. It's the fundamental event that drives the lethality of heart disease, so why are we not measuring it?"

Presented by Dr. Paul A. Gurbel said at the annual meeting of the American College of Cardiology, May 2007.

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Item 13

Valsartan Cuts C-Reactive Protein Levels in Prediabetics

Results from a current study showed that, Valsartan reduces high sensitivity Greactive protein (hsCRP) levels in prediabetic, hypertensive patients with metabolic syndrome.

<http://www.diabetesincontrol.com/results.php?storyarticle=4834>

"Since high levels of hsCRP are a measure of cardiovascular disease, a reduction in this vasoactive inflammatory marker indicates a positive effect of valsartan use in this patient population," said Willa Hsueh, MD, chief, division of endocrinology, diabetes, and hypertension, UCLA School of Medicine, Los Angeles, California, United States.

Her team evaluated various markers of inflammation in 566 prediabetic patients with abdominal obesity in response to treatment with valsartan 320 mg/d, compared to hydrochlorothiazide 25 mg/d, or a combination of the two agents for 16 weeks.

"It has become increasingly apparent that the metabolic syndrome is also associated with vascular inflammation, and this may be one factor influencing the development of diabetes in some patients," Dr. Hsueh said in her poster presentation. "The choice of antihypertensive therapy is an important determinant of whether their metabolic status in patients susceptible to developing diabetes becomes improved or worsened."

Biomarkers of inflammation such as median hsCRP could be an effective measure to provide a better method of identifying high-risk individuals susceptible to developing diabetes, she added.

In diabetic patients with abdominal obesity, after 16 weeks of hydrochlorothiazide therapy, median hsCRP values were increased 16% (4.9 vs 3.7 mg/L at baseline, $P < .05$) but decreased 9% in patients on valsartan (3.7 vs 4.1 mg/L at baseline, $P < .05$) and 5% in patients on combination therapy. Also, the changes in hsCRP were only evident in patients with elevated levels (greater than 3 mg/L).

At the end of treatment, there were no changes in any of several biomarkers measured except for aldosterone and adinopectin. The investigators documented a significant decrease in plasma adinopectin levels versus baseline in the group treated with hydrochlorothiazide monotherapy. Plasma adinopectin levels were unchanged in the other two treatment groups.

Dr. Hsueh said that the study demonstrates that valsartan decreases hsCRP levels in prediabetic patients with metabolic syndrome and emphasized that additional research is needed to clarify why the thiazide diuretic and angiotensin receptor blocker have opposite effects on this vasoactive inflammatory marker in the study population.

*Presented at the 22nd Annual Meeting of the American Society of Hypertension (ASH).
[Presentation Title: Inflammatory and Metabolic Markers in Pre-Diabetic Patients with the Metabolic Syndrome: Influence of Antihypertensive Therapy. Abstract Number P-317]*

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FACT:

Treatment of elderly patients with type 1 and type 2 diabetes in U.S. nursing homes often fails to meet American Diabetes Association standards, according to a new study. Researchers at the Ohio University College of Osteopathic Medicine studied the quality of care received over a year by 108 diabetic residents living in 11 nursing homes. They found that only 38 percent of patients met blood glucose [sugar] goals, only 55 percent had satisfactory blood pressure levels, and only 31 percent had lipids (serum total cholesterol) checks yearly. Of those who had regular lipids checks, only 58 percent had acceptable levels. See this week's Item #9

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Item 14

Postprandial Glucose Levels Tied To CVD Risk in Type 2 Diabetes

Postprandial glucose levels play an important and often overlooked role in cardiovascular disease in type 2 diabetes patients.

<http://www.diabetesincontrol.com/results.php?storyarticle=4833>

"If you don't look at the postprandial events, you probably are not going to be successful in bringing the [HbA1c] levels into the target ranges that any of us would consider appropriate," said Dr. Hellman, who is an endocrinologist at the University of Missouri-Kansas City and the president of the AACE.

Both the contribution of postprandial hyperglycemia and the cardiovascular risk decrease along a continuum, so the lower the HbA1c level that a patient can achieve, the lower that patient's cardiovascular risk will be, Dr. Hellman added.

The fact that postprandial hyperglycemia can be as crucial as fasting hyperglycemia was elucidated a few years ago in a study that computed the contributions of postprandial and fasting glucose to HbA1c levels in treated patients with diabetes, Dr. Hellman explained.

According to the study, when patients are not well controlled, the largest contribution to the HbA1c level is from fasting glucose.

However, as patients come under better glucose control, postprandial glucose accounts for a greater contribution. For example, the study findings showed that when the HbA1c level is 8.5%–9.2%, postprandial hyperglycemia accounts for a little less than 50% of the HbA1c level, but when the HbA1c is lower than 7.3%, postprandial hyperglycemia accounts for about 70% (Diabetes Care 2003;26:881–5).

Current data from a number of different surveys suggest that, overall, the lipid and glucose levels of patients with type 2 diabetes are not well managed, and that in recent years management has been getting worse, according to Dr. Hellman.

One of those studies recently reported that glycemic control (defined as an HbA1c level below 7%) was being achieved in only 36% of type 2 diabetes patients, compared with 45% of patients in the early 1990s (Diabetes Care 2004;27:17–20).

The optimal way for type 2 diabetes patients to achieve glycemic control—and thereby reduce their cardiovascular risk—is to adopt a multifactorial approach to management.

This approach should include diet modification, exercise, and aggressive treatment of hyperlipidemia, hypertension, and elevated glucose levels, Dr. Hellman said.

Presented by Dr. Richard Hellman said at the annual meeting of the American Association of Clinical Endocrinologists.

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Item 15

Fish-Oil Supplements Plus Regular Aerobic Exercise Benefit Overweight Patients

In overweight patients, fish oil supplements and regular aerobic exercise reduced body fat and improved cardiovascular and metabolic health, according to the results of a new study.

<http://www.diabetesincontrol.com/results.php?storyarticle=4832>

"Regular exercise and consuming long-chain n-3 fatty acids (FAs) from fish or fish oil can independently improve cardiovascular and metabolic health, but combining these lifestyle modifications may be more effective than either treatment alone," write Alison M. Hill, from the University of South Australia in Adelaide, and colleagues.

"Although several studies have investigated the potential for regular aerobic exercise to independently improve body composition and CVD [cardiovascular disease] and metabolic risk factors, few properly controlled studies have investigated the effect of n-3 FA supplementation on these risk factors, particularly body composition."

In this study, 75 overweight volunteers (body mass index [BMI], > 25 kg/m²) with high blood pressure, cholesterol level, or triacylglycerol level were randomized to 1 of the following interventions: fish oil (6 g of tuna fish oil per day), fish oil and exercise, sunflower oil (control; 6 g of sunflower oil per day), or sunflower oil and exercise. The exercise intervention consisted of walking 3 days per week for 45 minutes at 75% of age-predicted maximal heart rate. Plasma lipids, blood pressure, and arterial function were evaluated at 0, 6, and 12 weeks, and body composition was evaluated by dual-energy x-ray absorptiometry at 0 and 12 weeks only.

Compared with the sunflower oil groups, the groups receiving fish oil supplementation had lower triacylglycerol levels, increased high-density lipoprotein (HDL) cholesterol levels, and improved endothelium-dependent arterial vasodilation ($P < .05$). Compared with the groups not receiving the exercise intervention, those in the exercise groups had better arterial compliance ($P < .05$). Both fish oil and exercise were independently associated with reduced body fat ($P < .05$).

"FO [fish oil] supplements and regular exercise both reduce body fat and improve cardiovascular and metabolic health," the authors write. "Increasing intake of n-3 FAs could be a useful adjunct to exercise programs aimed at improving body composition and decreasing cardiovascular disease risk."

The compliance rate was greater than 85%, suggesting that the intervention was well tolerated, probably because of the modest level of physical activity required and because subjects did not need to change their background diet.

"Thus compliance may be sustainable in the longer term," the authors conclude. "Future research should evaluate the efficacy of this combined intervention over a longer duration and investigate the mechanism underlying the improvements in body composition."

Practice Pearls

?? In overweight adults, both fish oil supplementation and exercise independently reduce body fat mass.

?? In overweight adults, fish oil supplementation reduces triacylglycerol levels, increases HDL cholesterol levels, and improves endothelium-dependent arterial vasodilation; exercise improves small arterial compliance.

Am J Clin Nutr. 2007;85:1267-1274.

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Quote of the Week!

"It is no use saying, 'We are doing our best.' You have got to succeed in doing what is necessary."

.....**Sir Winston Churchill**

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