

Burger Study. ... Low incidenceCDC recommendations for DENTISTRY, Fen-Phen patients

Source: <http://sci.tech-archive.net/Archive/sci.med.dentistry/2005-03/3868.html>

From: Joel M. Eichen (joeleichen_at_yahoo.com)

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http://www.ynhh.org/healthlink/cardiac/cardiac_11_99.html

November 30, 1999

News this month

New study shows low incidence of valve disease among fen-phen users

Researchers led by Dr. Andrew Burger of Beth Israel Medical Center in Boston published a study in October's edition of the Journal of the American College of Cardiology showing a low incidence of valve damage among people who had taken fen-phen.

What is fen-phen?

Fen-phen is fenfluramine and phentermine, which were often prescribed together for patients trying to lose weight. In 1997, fenfluramine was voluntarily removed from the market when reports suggested it might cause heart valve damage. Phentermine was not suspect, and it remains on the market.

"...we found no evidence of a high rate of valvular disease among people who took fen-phen...."

The latest study

"In contrast to some previous reports, we found no evidence of a high rate of valvular disease among people who took fen-phen," said Dr. Burger. The Beth Israel study followed 226 people who took the drug combination for as long as 30 months. Patients also were in a program of diet, exercise and behavior modification. All subjects stopped taking the diet drug cocktail after the risk of heart valve defects was announced to the public.

The study population included 183 women and 43 men with a mean age of 46.9 years. The investigation sought to determine the prevalence of valvular heart disease in these patients. Early reports suggesting fenfluramine's association with an increase in heart valve disease were based on small numbers of patients and limited data on both dose

and duration of fen-phen usage.

All subjects in the Beth Israel study underwent echocardiography to detect valve damage within three months of discontinuing the medications. The diagnostic tests were reviewed by two independent readers.

About 8 percent of those in the study had detectable heart valve problems. Fifteen subjects (6.6 percent) showed aortic regurgitation, a condition in which blood leaks from the aorta, and three subjects (1.3 percent) showed evidence of mitral valve leakage, but none of the subjects showed evidence of severe disease. Those with valve disease were experiencing no symptoms and required no medical treatment.

Study participants compared to a control group

Dr. Burger and his research team compared this group to the general population and found the rate of heart valve defects to be similar. The control group was represented by subjects in the Framingham Heart Study who are comparable in age, gender and geographic location. In this group, 1.6 percent had moderate or greater mitral leakage whereas 4.8 percent had mild or greater aortic insufficiency, compared to 1.3 and 6.6 percent in the Beth Israel study.

The study also showed people who took higher doses of fen-phen were no more likely to develop heart valve defects than people who took lower doses.

"I don't think it gives the drug a green light to come back," Dr. Burger said, "but fenfluramine may not be as great a health hazard as thought initially."

Previous concern may be the result of sloppy science

In a commentary in the same journal, Dr. Nelson Schiller of the University of California at San Francisco suggested the early studies that led to the drug's withdrawal may have been sloppily done. "As studies have become more scientifically rigorous, the role of fen-phen in valve disease appears to be approaching the vanishing point," Schiller wrote in his commentary. He complained of an "almost universal misapplication of echocardiography" to evaluating whether people's valves were damaged.

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How dangerous is fen-phen: the jury's still out

This most recent study by Dr. Burger and his colleagues about the relationship between fen-phen and heart valve disease may be reassuring to the millions of people who took the diet drug cocktail before it was taken off the market in 1997.

"It is probably premature to draw any firm conclusions about a causal relationship [between fen-phen and heart value disease]."

In 1996 alone, the total number of prescriptions for the two drugs exceeded 18 million in the U.S., so many people have naturally been concerned about the long-term implications for their health. At this point, it is probably premature to draw any firm conclusions about a causal relationship. This study was well controlled, whereas many of the earlier reports were not, but we still have no long-term data, and many of the reports to date have been anecdotal and conflicting.

Other reports

In August 1997, a report in the New England Journal of Medicine first linked valvular heart disease with the use of fen-phen. The concern stemmed from a report by Mayo Clinic physicians, who found unusual heart problems in 24 women who had used fen-phen for an average of 12 months. Each had a thickening of one or more heart valves, which causes blood to leak back into the heart, making it work harder. Five of the women needed surgery to repair or replace the damaged valves.

In 1997, the FDA received independent echocardiographic surveys of patients from five geographic areas who had received fenfluramine alone or in combination with phentermine. The prevalence of valve disease meeting the FDA definition was similar in all five surveys and ranged from 30 to 38 percent. The prevalence increased with the duration of drug use. But there is no proof of a causal link, and it is not clear that the 113 cases reported to the FDA were representative of the estimated 4.2 million people who were taking the drugs.

"Valve problems may regress after the drug is discontinued."

A new study published in the November 23 issue of *Circulation* showed 7.6 percent of patients treated with the drug dexfenfluramine, which is very similar to fenfluramine, had either mild aortic valve disease

or moderate mitral valve problems, compared to 2.1 percent who did not take the drug. Valve problems were detected at twice the rate among patients who had stopped treatment less than eight months before their echocardiogram compared with those who had been off the medicine for longer than eight months suggesting valve problems may regress after the drug is discontinued.

Despite several additional studies, there is still no consensus among cardiologists on the causal relationship between fen-phen and valve disease, which doesn't offer those who took the drugs much reassurance.

What should you do if you've taken fen-phen?

I would recommend anyone who has taken fenfluramine or dexfenfluramine for any period of time should have a thorough medical history and cardiovascular physical examination, if they have not already done so.

It is possible to have valve disease and experience no unusual symptoms. In fact, the 15 subjects in the Burger study who were found to have valve disease had no obvious symptoms. Many healthy adults have mild valve leakage that poses no threat to their health. Your physician can listen for heart murmurs or detect valve abnormalities with an echocardiogram, which is particularly important if you do have unexplained symptoms such as easy fatigability, shortness of breath, palpitations or chest pain.

The fen-phen experience has confirmed the need to be cautious about medical treatments for obesity. There is no magic bullet to weight loss. Consistent lifestyle changes in diet and exercise are the only long-term solution, but research into the causes and possible treatments for obesity continues. It's obvious that significant obesity is a very serious health concern in the U.S, and we're hopeful that some of the genetic research into the body's regulation of fat storage may result in some effective and safe treatments.

Dr. Blum is a cardiologist on staff at Yale-New Haven Hospital and an assistant professor in the section of cardiovascular medicine at Yale University School of Medicine.

For more information on this story:

Summary of the study published in the Journal of the American College of Cardiology, October, 1999

Summary of the study published in Circulation, Nov. 23, 1999

Previous issues of HealthLINK-Cardiac

Heart failure drug, October 1999.
Mitral valve prolapse, September 1999.
High volume heart hospitals, August 1999.
Mediterranean diet, July 1999.
Aspirin and heart disease, May 1999.
Viagra risk and heart disease, April 1999.
Other cardiac resources

Cardiac Services, Yale-New Haven Hospital
American Heart Association
American College of Cardiology
Healthfinder: Heart Disease

On Wed, 23 Mar 2005 18:08:21 -0500, Joel M. Eichen
<joeleichen@yahoo.com> wrote:

><http://www.pronational.com/news/denrprtr/Fenphen-0698.htm>

>

>*Fen-Phen Litigation.....Picking Up Steam*

>*By Theodore Passineau, J.D., ProNational Senior Health Care Advisor*

>

>*Not since the breast implant cases of the late 1980s and early 1990s*

>*has there been such a flurry of legal activity associated with a*

>*particular form of medical treatment. The weight reduction drugs*

>*commonly known as Fen-Phen, fenfluramine (or its sister drug,*

>*dexfenfluramine) and phentermine, have made their way into headlines*

>*and courtrooms. With over 18 million prescriptions having been written*

>*to an estimated 6 million Americans, the potential for litigation*

>*related to heart and lung damage is significant.*

>

>*The controversy began to take shape in August of 1997 when The New*

>*England Journal of Medicine (NEJM) reported the potential for heart*

>*valve problems and/or pulmonary hypertension resulting from the use of*

>*fenfluramine and phentermine in combination. While each drug had been*

>*approved by the FDA for use individually, the use of the medications*

>*in combination had never been approved. There were reports of*

>*cardiac-related problems in as high as 32 percent of the users of*

>*these combined medications. Subsequent reports have suggested*

>*cardiac-related problems with the use of fenfluramine or*

>*dexfenfluramine alone.*

>

>*The usual defendants in these cases are the pharmaceutical companies*

>*who manufactured the medications and the physicians who prescribed*

>*them. Several cases have been brought as class actions in federal*

>*court (and are being consolidated into one federal court case in*

>*Philadelphia); others have been brought as state class actions. In*

>*addition, many individual suits are being filed in state courts. It is*

>*expected that, in time, cases will have been filed in all 50 states.*

>

>*The Fen-Phen controversy is also important for dentists. Whenever a*

>*condition is associated with increased risk of subacute bacterial*

- >endocarditis, such as cardiac valvulopathy, the dentist must take
- >appropriate prophylactic measures prior to initiating treatment.
- >Prophylactic measures begin with identifying the potentially dangerous
- >condition.
- >
- >In 1992, a ProNational study of office practices found that
- >approximately 94% of general dentists use a patient–completed health
- >history form. This is an excellent means of gathering essential
- >clinical historical information. Health history forms should now be
- >amended to include a question that asks whether the patient has ever
- >taken prescription weight–reduction drugs. (Don't depend on the
- >patient to recognize the names of these drugs.) If a positive response
- >is elicited, you should determine the exact medications taken.
- >
- >Before treating a patient who has taken Fen–Phen or fenfluramine
- >products alone, the CDC (Centers for Disease Control) guidelines
- >should be consulted. (See guidelines below.) Additionally, you should
- >be familiar with the American Dental Association's recommendations,
- >which are listed below.
- >
- >Because dentists weren't involved in the prescribing of Fen–Phen or
- >fenfluramine products, professional liability exposure for dentists
- >should be very limited. However, inattention to the possibility of SBE
- >(subacute bacterial endocarditis) as a result of previous use of diet
- >medications is one way that members of the dental community could be
- >drawn into the Fen–Phen debate. Conscientious history taking and
- >recording and adherence to the CDC guidelines and ADA recommendations
- >should eliminate this potential.
- >
- >You may call ProNational's Risk Management Department at 800/292–1036
- >for further information on issues related to the prescription of
- >Fen–Phen or fenfluramine products.
- >
- >CDC Recommendations Regarding Fen–Phen
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- >
- >1. All persons exposed to fenfluramine or dexfenfluramine, for any
- >period of time, either alone or in combination with other agents,
- >should undergo a medical history and cardiovascular examination by
- >their physician to determine the presence or absence of
- >cardiopulmonary signs or symptoms.
- >
- >2. An echocardiographic evaluation should be performed on all
- >persons who were exposed to fenfluramine or dexfenfluramine for any
- >period of time, either alone or in combination with other agents, and
- >who exhibit cardiopulmonary signs (including a new murmur) or symptoms
- >suggestive of valvular disease (e.g., dyspnea).
- >
- >3. Although the clinical importance of asymptomatic valvular
- >regurgitation in exposed patients and the risk for developing
- >bacterial endocarditis in these patients are unknown, practitioners

>should strongly consider performing echocardiography on all persons
>regardless of whether they have cardiopulmonary signs or symptoms who
>have been exposed to fenfluramine or dexfenfluramine for any period of
>time, either alone or in combination with other agents, BEFORE the
>patient undergoes any invasive procedure for which antimicrobial
>endocarditis prophylaxis is recommended by 1997 AHA (American Heart
>Association) guidelines.

>
>Any echocardiographic findings that meet the AHA criteria for
>prophylaxis regardless of whether they are attributable to possible
>fenfluramine or dexfenfluramine use should be recognized as
>indications for antibiotic prophylaxis. The invasive procedures
>include certain medical or dental procedures where antibiotic
>prophylaxis is recommended as defined by the 1997 AHA guidelines. For
>emergency procedures for which cardiac evaluation cannot be performed,
>empiric antibiotic prophylaxis should be administered according to the
>1997 AHA guidelines.

>
>4. Because of the prevalence of minimal degrees of regurgitation in
>the general population, the current case definition of drug–associated
>valvulopathy should include exposed patients with
>echocardiographically demonstrated AR of mild or greater severity
>and/or MR of moderate or greater severity, based on published
>criteria.

>
>ADA Recommendations Regarding Fen–Phen -- 11/12/97

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>Dentists who have patients who were on Fen–Phen (fenfluramine and
>phentermine) or dexfenfluramine or fenfluramine alone, should refer
>them to their physician for the CDC–recommended evaluation and
>treatment before conducting any dental procedures that may cause
>significant bleeding.

>
>Based on what the evaluation reveals, the dentist may then provide
>necessary dental treatment in accordance with the revised 1997
>guidelines titled: "Prevention of Bacterial Endocarditis:
>Recommendations by the American Heart Association and A Statement for
>the Dental Profession." (These guidelines were approved by the ADA's
>Council on Scientific Affairs and published in the August, 1997
>Journal of the American Dental Association.)

>
>Under these guidelines, the dentist may prescribe a single
>pre–procedure dose of antibiotics for appropriate patients who are
>undergoing procedures that put them at risk for significant bleeding.

>
>Examples of dental procedures that might warrant antibiotic treatment
>include, but are not limited to, tooth extractions, periodontal (gum)
>surgery, root canal treatment and the placement of orthodontic bands
>but not brackets.

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>On Tue, 22 Mar 2005 22:40:25 -0500, "Andrew B. Chung, MD/PhD"

><andrew@heartmdphd.com> wrote:

>

>>"Joel M. Eichen" wrote:

>>>

>>> Hello Sharon,

>>>

>>> Here is some more information on the "reversed" case.

>>>

>>> Joel M. Eichen D.D.S.

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>>> **

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>>> Posted on Wed, Feb. 23, 2005

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>>> Judge reverses verdict against Wyeth over diet drug

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>>> Associated Press

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>>> MADISON, N.J. – A judge in Philadelphia reversed a jury verdict

>>> against drug maker Wyeth Wednesday, ruling that a plaintiff who

>>> alleged heart valve injury from use of a diet drug knew the risks

>>> before she took the drug.

>>>

>>> Common Pleas Court Judge Mark I. Bernstein set aside a Nov. 3, 2004

>>> verdict that awarded Geri McMurdie \$780,000 in compensatory damages.

>>> In his ruling, Bernstein said that McMurdie "knowingly and voluntarily

>>> assumed the risks" of heart damage when she signed a consent form

>>> acknowledging the potential risks of Pondimin.

>>

>>*Sigh*

>>

>>What people subject themselves to in order to avoid simply eating less

>>to lose weight.

>>

>>

sci.med.dentistry: Burger Study. ... Low incidenceCDC recommendations for DENTISTRY, Fen-Phen patients

>>*At His service,*

>>

>>*Andrew*