

## Vioxx, Celebrex, now Naproxen! What's the story with pain relievers?

A few months ago, Vioxx was pulled from the market because of concerns over an increased rate of heart attacks among chronic users of the drug. Over the last few weeks, we now have concerns about Naproxyn (Aleve, Naprosyn) and Celebrex.

Naproxen is in a class of drugs called NSAIDS (non steroidal anti inflammatory drugs) which include Ibuprofen (Motrin, Advil) and others. Aspirin, which has been shown to prevent heart attacks in those at high risk, works similarly to NSAIDS. There are two enzymes inhibited by NSAIDS- COX-1 and COX-2. COX stands for cyclooxygenase. Vioxx and Celebrex, along with Bextra, constitute a class of drugs called COX-2 inhibitors.

COX-1 blocking can promote bleeding, including gastrointestinal bleeding. However, there may also be good effects of this "thinning of the blood" in terms of preventing heart attacks and dementia, though studies to date have been inconclusive. COX-2 has the anti-inflammatory effects that reduce pain in patients with headaches, arthritis, menstrual cramps, and other types of pain. NSAIDS, which inhibit both COX-1 and -2, have been around for over 25 years and are available in both prescription and OTC dosages. It is well known that they can promote intestinal bleeding in some patients. Otherwise, up to recently, they have been thought to be safe and it has been hypothesized that the COX-1 suppression might prevent some other diseases.

The COX-2 inhibitors have only been around for about 5 years. They are indicated for patients with the same types of pain as

those given NSAIDS. Because they are much more expensive, they were presumably to be prescribed only in patients who could not tolerate NSAIDS, However, because of effective direct-to-consumer marketing, these drugs have turned out to be "blockbusters" and patient demand for these medications has led to them being prescribed for people who could tolerate NSAIDS.

Although there have been fewer episodes of intestinal bleeding with COX-2 inhibitors, as compared with NSAIDS, there have been persistent problems from the beginning. First, the reduction in serious bleeding events has been small and some people on COX-2 will actually get intestinal bleeds. Second, many people have felt that the potential benefits of arthritis drugs in terms of preventing heart attacks and possibly preventing other conditions may be related to the COX-1 inhibition. Since COX-2 inhibitors do not block COX-1, we may lose this benefit, or even worse. **Third, COX-2 inhibitors such as Vioxx and Celebrex are no more effective in pain relief than Ibuprofen, Acetaminophen (e.g. Tylenol), or Aspirin.** This is probably a shock to most people, because of the way these medications were marketed. Most of the people who received prescriptions for these medications neither had a prior history of gastrointestinal bleeding nor had they had treatment failures with traditional NSAIDS. So there was no medical reason for them to be started on these medications. Physicians have tremendous pressure to prescribe these drugs as a result of patient re-



quests or demands related to effective advertising.

So what did we find out recently? A study, funded by Merck, on the possible prevention of colonic polyps with VIOXX, found that those receiving the VIOXX had twice as many heart attacks or strokes as the placebo. This caused Merck to pull the drug off the market. A similar study, which was supported by the National Cancer Institute, showed an increased rate of heart attacks in people taking Celebrex. There have been some other studies, including the Naproxyn study, which do not show any increased risk of heart attack or stroke receiving Celebrex. This effect seems to be dose related and is also related to the duration of treatment, but clearly, the burden of evidence is now on the manufacturers of the remaining COX-2 inhibitors to prove that they are safe and exactly how they should be used.

The Naproxyn study is more perplexing. This was a National Institutes of Health supported study to see whether these drugs might be useful in preventing Alzheimer's disease. Unfortunately, when the preliminary data were studied and a potential risk was identified, the study was

### Inside this issue:

<i>Pain relievers (cont)</i>	2
<i>Importance of Hand Washing</i>	2
<i>Complementary and Alternative Medicine Web-sites</i>	2
<i>Effectiveness of complementary and alternative therapies in treating anxiety</i>	3
<i>Yogurt to prevent antibiotic associated diarrhea</i>	3
<i>Health Plan Participation</i>	4

## Pain Relievers (continued)

halted, so we will may never know if they could prevent Alzheimer's. As I previously stated, NSAIDS have been around for 25 years and used widely, both by prescription and over the counter. If there were any great risk of increased heart attacks, I would think we would have discovered it by now. In addition, as opposed to COX-2 inhibitors, where there is a biomedical model for increased risk of heart attacks, no such model exists with Naproxen. In fact, the biomedical models would suggest that they are protective to the heart.

*“Celebrex and Bextra should not be used in people at high risk for heart attacks and should only be used for short durations when possible”*

*What does all this mean? First, the remaining COX-2 inhibitors, Celebrex and Bextra should not be used in people at high risk for heart attacks and should only be used for short durations when possible. We will need to see whether there are additional studies in the future which show similar risks for NSAIDS such as Naproxen. At this point, there are no recommendations for physicians to alter their prescribing patterns for this class of drug. Finally, consumers must be more cautious about demanding medications based on drug company advertising and physicians need to exert their own independent judgment about what is best and safest for a patient and be less persuaded by patient demands when they feel these demands may not be supported by medical science.*



## Remember to Wash Those Hands!



A recent study at Boston Children's Hospital showed that consistent use of an alcohol based hand sanitizer (e.g. Purell and others) can reduce the incidence of gastrointestinal diseases. These alcohol based hand washes are now used in operation rooms to disinfect surgeons hands prior to surgery. Those families that used these products regularly has a 59% reduction in the spread of gastroenteritis compared with those families that did not. Although these products do not get rid of dirt like soap and water, they are more effective in killing bacteria that may be potentially spread.

*Comment: this is just another example of the importance of basic good hygiene. There have been other studies that have shown the benefit of good hand washing, especially with alcohol based gel, to reduce the spread of colds. Tissues actually trap and kill respiratory viruses, but these viruses remain on people's hands unless the hands are cleansed. The alcohol based gels now have moisturizing additives to minimize drying.*

## Limited evidence for the treatment of anxiety with herbal preparations or other complementary medicine modalities

The Cochrane registry of Controlled Trials is an organization that systematically reviews clinical trials and analyzes both the quality of the trials and their conclusions. Recently, Cochrane issued a report on the treatment of anxiety with either herbs or other non-traditional therapies. In general, they found that there is very limited evidence that these modalities are effective. They found limited, if any evidence of effectiveness for berocca, ginger, gotu kola, homeopathy, lemongrass, St. John's Wort, Valerian, and Vitamin C.

In addition, there was no evidence of effectiveness for the

following non-traditional therapies/ modalities: Yoga, meditation, prayer, humor. They did find slight evidence for the effectiveness of the supplement inositol, acupuncture, massage, exercise, meditation, and relaxation therapy.

Kava and 5 hydroxyl-L-tryptophan have significant potential side effects and should not be used.

*What does this mean? It does not mean that these modalities are not effective. Some of the modalities have been studied and, based on those studies, they are not effective. Other modalities have not been*

*adequately studied. They may or may not be useful.*

*The other side of the equation is "Are they safe?". Certainly activities such as exercise, meditation, and prayer are safe. So are many of the herbs (see below for good web-sites).*

*The other risk with these modalities is that people with significant symptoms are trying to treat themselves, when seeking appropriate medical attention would be a better option.*



## Complementary and Alternative Medicine Web-sites

There are many web-sites that give people information on the effectiveness of complementary and alternative medicine therapies. Unfortunately, most of these sites do not give unbiased information and are not scientifically grounded. Since there has been relatively little research on the effectiveness and safety of these therapies, information can often be misleading or untruthful. The best sites tend to require a subscription fee. Here are some recommended sites.

Organization	address
Memorial Sloan Kettering Cancer Center	<a href="http://www.mskcc.org/mskcc/html/11570.cfm">http://www.mskcc.org/mskcc/html/11570.cfm</a>
MD Anderson Cancer Center Integrative	<a href="http://www.mdanderson.org/departments/CIMER/">http://www.mdanderson.org/departments/CIMER/</a>
Herb Med	<a href="http://www.herbmed.org">www.herbmed.org</a>
Natural Data Base	<a href="http://www.naturaldatabase.com">www.naturaldatabase.com</a>
Consumer Lab	<a href="http://www.consumerlab.com">www.consumerlab.com</a>
Natural Standard	<a href="http://www.naturalstandard.com">www.naturalstandard.com</a>
National Institutes of Health	<a href="http://www.nccam.org">www.nccam.org</a>

## Yogurt can prevent antibiotic associated diarrhea

Yogurt can come with or without active cultures of a bacteria called lactobacillus which helps break down sugars and can also help combat fungus. A recent study of 202 people who were hospitalized and on antibiotics treated half the subjects with yogurt which had active cultures of three bacteria. They received 8 ounces twice a day for 8 days. The other half received their usual care without the yogurt

supplementation. The patients receiving the yogurt reported less diarrhea (12%) than those who did not (24%). In addition, those who received the yogurt and still got diarrhea had it for fewer days than those who got diarrhea but never took the yogurt.

*This is not a great study. Both the subjects and the investigators knew who was receiving the yogurt. Nevertheless, there is a biologic model*

*for its effectiveness and it certainly can't hurt (unless you are lactose intolerant).*

*Another recent study, however, found that yogurt was not effective in preventing vaginitis in people receiving antibiotics.*





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## **We've Moved!**

On July 1, we moved down the street to  
**123 N. Union Ave., Suite 204.**

There is parking and access to the building (Cleveland Plaza) both on S. Union Ave as well as on Miln St. The new office building has handicapped parking and access as well as a paved parking lot. The office suite is a little more spacious and has greater privacy for patients. We have the same phone number, fax, and e-mail.



## **Health Insurance Participation**

We currently participate in the following health plans:

- Medicare
- Aetna
- Amerihealth
- Beech Street
- Core Source
- Cigna
- First Health
- Health Net
- Horizon
- Multiplan
- Oxford
- PHCS
- United
- Wellchoice

Please remember to bring your health insurance information and co-payment with you. In addition, if your health plan requires you to select a primary care physician, please call before your first visit and select Dr. Eidus



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