



CLINICAL STUDY CENTER

4110 Center Pointe Drive
Suite 219
Ft. Myers, FL 33916
239-936-4421 Phone
239-936-2865 Fax

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Mastalgia (continued from page 3)

Other studies have found that an abnormality in the hormone prolactin may affect breast pain. Hormones can also affect cyclical breast pain as a result of stress - breast pain can increase or change its pattern with the hormone changes that occur during times of stress.

Hormones may not provide the total answer to cyclical breast pain, since pain is often more severe in one breast than in the other (hormones would tend to affect both breasts equally). Many physicians believe that a combination of hormonal activity and something in the breast that responds to this activity may hold the answer. However, more research is necessary in order to draw this conclusion.

Treatment for cyclical breast pain:

Specific treatment for cyclical breast pain will be determined by your physician based on:

- your age, overall health, and medical history
- extent of the condition
- your tolerance for specific medications, procedures, or therapies
- expectations for the course of the condition
- your opinion or preference

Treatments vary significantly and may include the following:

- caffeine avoidance
- vitamin E
- a low-fat diet

In some cases, various supplemental hormones and hormone blockers are also prescribed. Supplemental hormones and hormone blockers may have side effects. In addition, the risks and benefits of such treatment should be carefully discussed with your physician.

These may include:

- birth control pills
- Danazol, a male hormone
- thyroid hormones
- Tamoxifen®, an estrogen blocker

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David D. Michie, PhD
President

HealthScope

Fall 2005

Osteoarthritis—What do I do now?

John E. Ervin, MD, FACP, FACR
President, Medical Director, The Center for Pharmaceutical Research

Patients with osteoarthritis are confused and frustrated. Many are suffering from pain and stiffness after they have stopped Vioxx, Bextra, and, some have also stopped Celebrex, though it is still available. A significant number of these patients have stated they would continue to take these medications if they could, and another significant number are afraid to take any of these medications for fear of cardiovascular side effects. The combination of intense media coverage and daily TV advertising by lawyers emphasizing the association of these medications with cardiovascular side effects has left physicians reluctant to prescribe these medications, and patients either fearful or perplexed or both about what to take for their arthritis pain.

Recently, at the European League Against Rheumatism (EULAR) 2005 meeting Vienna, Austria, researchers have mapped out for clinicians the odds ratios for myocardial infarction (MI) of various products, and some of what they found is quite surprising. The largest nonsteroidal anti-inflammatory drugs (NSAID) study to date—one that is reportedly bigger than all other studies combined—has put COX 2 drugs back in the limelight, this time suggesting a class effect of all NSAIDs. Lead author, Dr Gurkirpal Singh (Stanford University, CA) presented the data taken from California's large Medicaid database.

During an interview Singh said, "The hysteria in the media about COX-2 inhibitors has been a bit of an overreach. All of the news about how these drugs cause heart attacks and kill has been excessive, because we simply did not have data for the other drugs." He added, "Absence of evidence is not evidence of absence." In fact, the results of the study show no difference in the COX 2 class and non-selective NSAIDs. Indeed, valdecoxib (Bextra), which has already been taken off the market, showed no increase in MI at its prescribed doses compared to those not taking

these medications. The group reports that all analyses were adjusted for 38 confounding risk factors as well as concomitant aspirin treatment.

Now What?

What do patients do now? For those at risk of GI side effects, which were significantly decreased with the COX 2 group of drugs, taking a class of medications called proton pump inhibitors (Prilosec, Nexium, Prevacid etc) has been shown to give equal protection of the GI tract. NSAIDs from the lower end of the list above should be considered. Acetaminophen and the milder pain medications (Darvacet, Ultracet) may also be appropriate as first steps for pain in osteoarthritis patients.

What's New?

New experimental drugs are currently being studied which block the action of prostaglandins, rather than interfere with their production, as the NSAIDs and COX 2 drugs do. They are designed to give similar benefit with pain and inflammation reduction, without the likelihood of affecting the bodies clotting mechanism. If proven safe and effective through clinical research, these drugs will offer welcome help to patients in the future who feel they have been left without effective treatment choices.

Many clinical research centers are currently conducting an osteoarthritis research study on a new investigational medication in this class of "receptor blockers". Hopefully, this new group of experimental medications will be part of the future answer to "what do I do now?"

If proven safe and effective through clinical research, these new experimental drugs will offer welcome help to patients in the future who feel they have been left without effective treatment choices.

Risk of acute MI compared with remote use (Odds ratio of 1 = no increase in risk of MI)

| NSAID | Unadjusted odds ratio | Adjusted odds ratio | 95% CI | p |
|---------------------------|-----------------------|---------------------|-----------|---------|
| Indomethacin (Indocin) | 1.65 | 1.71 | 1.35-2.17 | <0.0001 |
| Sulindac (Clinoril) | 1.46 | 1.41 | 1.01-1.96 | 0.04 |
| Meloxicam (Mobic) | 1.34 | 1.37 | 1.05-1.78 | 0.02 |
| Rofecoxib (Vioxx) | 1.34 | 1.32 | 1.22-1.42 | <0.0001 |
| Piroxicam (Feldene) | 1.14 | 1.18 | 0.90-1.54 | 0.22 |
| Other NSAIDs | 1.22 | 1.18 | 0.94-1.46 | 0.15 |
| Ibuprofen (Motrin, Advil) | 1.08 | 1.11 | 1.01-1.22 | 0.02 |
| Celecoxib (Celebrex) | 1.11 | 1.09 | 1.02-1.15 | 0.008 |
| Naproxen | 1.03 | 1.08 | 0.95-1.22 | 0.22 |
| Diclofenac (Voltaren) | 1.04 | 1.05 | 0.93-1.19 | 0.43 |
| Valdecoxib (Bextra) | 1.08 | 0.99 | 0.72-1.37 | 0.97 |
| Ketoprofen (Orudis) | 0.88 | 0.86 | 0.63-1.18 | 0.35 |
| Nabumetone (Relafen) | 0.86 | 0.83 | 0.60-1.14 | 0.26 |

Fall 2005

October is...

Healthy Lung Month
National Lupus Awareness Month
National Glaucoma Awareness Month
National Liver Awareness Month
Children's Health Month

November is...

National Alzheimer's Disease Awareness Month
American Diabetes Month
Great American Smokeout
National Healthy Skin Month
COPD Awareness Month

Thanksgiving Pumpkin Trifle

3 cups cold, fat-free milk
2 (1-oz) packages vanilla sugar-free, fat-free pudding mix
1 (15 oz.) can solid packed pumpkin
3/4 teaspoon ground cinnamon
1/4 teaspoon ground nutmeg
1/4 teaspoon ground ginger
1-2/3 cups ginger snap crumbs, roughly crushed
2 1/2 cups fat-free whipped topping

Place milk in a large mixing bowl. Slowly add pudding mixes while mixer is running. Beat for 2 minutes on high speed. Chill pudding in refrigerator for 5 to 10 minutes. Add pumpkin and spices to pudding and stir well with a spatula. Set aside. To assemble trifle, sprinkle 2/3 cup of ginger snap crumbs in the bottom of a large clear, glass bowl.

Gently spread about 2 cups of the pumpkin pudding over the crumbs. Spread 1 1/2 cups of whipped topping on the top of pudding. (You should see nice, neat layers through the sides of the bowl.) Repeat procedure with another 2/3 cup of crumbs and remaining pudding. Top with 1 cup of whipped topping in a neat, decorative circle and sprinkle with 1/3 cup of crumbs for a garnish. Chill trifle until ready to serve.

Flu 2005 Update

James P. Hampsey, MD
Tampa Bay Medical Research

Flu season is here again and hopefully the flu vaccine will be available in greater supply than last year. There are no problems with production this year. In fact, the FDA has approved a new vaccine, FLUARIX manufactured by GlaxoSmithKline. This product has been sold for 15 years in 79 countries, but is now available in the US. It has been well tolerated and highly effective in those countries. FLUARIX was approved under the accelerated approval process due to the supply shortages last year. Many clinical research centers are participating in an FDA sponsored study comparing FLUARIX to FLUZONE due to start in mid October.

Both vaccines are essentially identical, containing an inactivated virus from three different viral strains. The selection of strains for each year is determined by the prevalence of various strains in the Far East that is, China, Japan and Hong Kong in the previous year. Experience has shown that particular viruses that cause flu in the Far East one year usually cause flu in the US the following year.

Cold Sores

Your lip tingles and a small, hard spot develops. Then a red blister appears. It's another cold sore and there's no way to hide it or make it go away quickly.

Cold sores — also called fever blisters — are common and are caused by the herpes simplex virus. They are very contagious via skin to skin contact. Even though you can't cure or prevent cold sores, you can take steps to reduce their frequency and to limit the duration of an occurrence.

Signs and symptoms of cold sores include:

- Small, painful, fluid-filled blisters on a raised, red, painful area of your skin
- Pain or tingling, called the prodrome, often preceding the blisters by 1-2 days
- Usual duration of seven to 10 days

Cold sores usually appear on your lips. Occasionally, they occur on your nostrils, chin or fingers. And, although it's unusual, they may occur inside your mouth — but only on your gums or hard palate, which is the roof of your mouth.

Symptoms may not start for as long as 20 days after exposure to the herpes simplex virus, and usually last seven to 10 days. The blisters form, break and ooze. Then a yellow crust forms and finally sloughs off to uncover pinkish skin that heals without a scar.

Certain strains of the herpes virus cause cold sores. Herpes simplex virus type 1 usually causes cold sores. Herpes simplex virus type 2 is usually responsible for

Although flu shots do not guarantee protection, it is still the most effective new way of controlling Influenza and preventing complications and mortality in persons at risk. It is strongly recommended for patients age 65 and older, and others with chronic medical conditions such as diabetes, emphysema, and heart disease. Also, it is recommended for residents of nursing homes and long term care facilities, as well as health care workers.

Certain conditions exclude a person from getting the flu shot. These include egg allergy, history of Guillain-Barre syndrome within 6 weeks of receiving the flu shot, history of flu shot allergy, or an acute illness with a temperature over 102 degrees. Additionally, certain medical conditions reduce a person's immunity such as HIV, chronic liver disease and active cancer. These conditions may interfere with the response to a flu shot but in most cases it is still recommended.

In conclusion, a flu shot is still one of the most cost effective and useful means of preventative medicine. For further information see your health care representative.

genital herpes. However, either type of the virus can cause sores in the facial area or on the genitals. You get cold sores from another person who has an active lesion. Shared eating utensils, razors and towels may spread this infection.

Once you've had an episode of cold sores, the virus lies dormant in the nerve cells in your skin and may emerge again as an active infection on or near the original site. You may experience an itch or heightened sensitivity at the site preceding each attack. Fever, menstruation, stress and exposure to the sun may trigger a recurrence.

Cold sores generally clear up on their own without treatment. However, see your doctor if:

- You have a compromised immune system
- The cold sores don't heal within one to two weeks on their own
- Symptoms are severe
- You have frequent recurrences of cold sores

If you have a cold sore, avoid contact with infants, anyone who has eczema or people with a suppressed immune system, such as people with cancer, AIDS or an organ transplant. These people are at higher risk of more severe infection.

Cold sores generally clear up without treatment in 7-10 days. If you experience frequent bouts, your doctor may prescribe an antiviral medication to treat cold sores. Using a medication may shorten the duration of cold sores and decrease your pain.

Clinical Study Center is seeking patients for the following studies. Compensation is available.

We always need volunteers so we can conduct studies to learn more about important new investigational or marketed drugs for diseases. When you volunteer to participate in one of our drug trials, you contribute to the development of medical therapies that can ultimately help thousands of people. Please let us know if you would like to have your name added to our mailing list. If you have a known chronic condition, it is very likely that you will be asked to participate in a study. Please contact our office if you wish to be removed from our mailing list.

We are currently enrolling individuals for these research studies:

Alzheimer's disease
Benign prostatic hyperplasia (BPH)
Constipation caused by pain medicine
Diabetic Neuropathy
Erectile Dysfunction
Female Sexual Dysfunction
Fibromyalgia
Heavy Menstrual Bleeding
HPV Infection of Cervix
Insomnia (Difficulty Sleeping)
Irritable Bowel Syndrome with Constipation (Females)
Osteoarthritis of Knee
Overactive Bladder
Postmenopausal hot flashes
Premenstrual Dysphoric Disorder (PMDD)
Premenstrual Syndrome (PMS)
Prostatic Intraepithelial Neoplasia (PIN)
Skin and Soft Tissue Infection

Mastalgia

Mastalgia is breast pain and is classified as either cyclical (associated with menstrual periods) or noncyclic. Noncyclic pain may come from the breast or from somewhere else, such as nearby muscles or joints and may be felt in the breast. Pain can range from minor discomfort to severely incapacitating pain

What is cyclical breast pain?

The most common type of breast pain is associated with the menstrual cycle and is mostly hormonal. Some women begin to have pain around the time of ovulation which continues until the start of their menstrual cycle. The pain can either be barely noticeable or so severe that the woman cannot wear tight-fitting clothing or tolerate close contact of any kind. The pain may be felt in only one breast or may be felt as a radiating sensation in the under-arm region. Some physicians have women chart their breast pain to determine if the pain is cyclical or not. After a few months, the relationship between the menstrual cycle and breast pain will emerge.

Physicians continue to study the role of hormones and cyclical mastalgia. Studies suggest that some women with cyclical mastalgia have a decreased ratio of progesterone to estrogen in the second half of the menstrual cycle.

(continued on back page)

Science Tries to Help Women who Desire More Desire

David D. Michie, PhD, Clinical Study Center
Ft. Myers, FL

A study conducted by the National Health and Social Life Survey indicated that 33% of women report a lack of sexual interest, 25% do not experience orgasm, 20% report inadequate lubrication and a similar percentage do not find sex pleasurable. Although a loss of sex drive is unfortunate, it is almost universal according to Dr. Andrew Goldstein, co-director of the Sexual Wellness Center in Annapolis, Maryland. Many factors, both physiological and psychological, contribute to low sexual desire in women. The biological mechanisms are, perhaps, the most amenable to treatment by drug intervention. Thus, the pharmaceutical industry has placed an emphasis upon trying to restore these altered factors to the normal state.

The ovaries in premenopausal women produce a variety of hormones, including estrogen and a small amount of the male hormone testosterone. It is believed that testosterone is responsible, in part, for the sex drive in women. During menopause the production of these hormones is greatly reduced. Thus, it is thought by some that the decrease in sex drive experienced by postmenopausal women is brought about by a greatly reduced amount testosterone.

A major pharmaceutical company conducted a number of clinical research trials of an investigational skin patch containing testosterone in postmenopausal women complaining of low libido. The results of some of these studies showed a marked improvement in restoring women's libido; however, the FDA has not approved a product containing only testosterone for women citing a lack of long term safety data.

An increase in blood flow to the vaginal area by enlargement of the blood vessels supplying this area is essential to the changes that occur during sexual arousal. A number of clinical research trials of the famous blue pill for men, Viagra®, were conducted to study an investigational use in women with low libido. Unfortunately, the results were less than gratifying, and it was recently reported that the pill's maker will discontinue further studies of the blue pill in female sexual dysfunction. One of the first FDA approved drugs for erectile dysfunction in men is injected directly into the penis with a small needle. This medicine has been reformulated into an investigational topical gel for direct application to the clitoris and labia. Due to the similarity in structure between the penis and clitoris, it is hoped that this medicine when applied to the surface of this area will increase local blood flow and enhance sexual arousal. One of the most recent developments in this area of research is an investigational nasal spray that increases blood flow to the genital area through a direct action on the central nervous system. It is anticipated that studies of this medicine in women with low sex drive will get underway during the first quarter of next year.

It goes without saying that libido is very important for a relationship. Hopefully, progress will continue to be made in the development of a medication that will benefit women with sexual arousal disorder.