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AMERICAN COLLEGE OF GASTROENTEROLOGY



Ulcers and Gastrointestinal Bleeding: Protecting Your Health

The Essential Facts for Consumers

What You Need to Know

about the Safe &

Appropriate Use of Common

Pain Medications



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GI Bleeding: A Serious Health Problem

Gastrointestinal injury, ulcers and related bleeding are serious health matters that often strike patients by surprise, including those with or without any past symptoms or underlying digestive condition.

Because GI bleeding is internal, it is possible for a person to have GI bleeding without having pain, literally without knowing you are bleeding. That is why it is important to recognize those symptoms which may accompany GI bleeding. The symptoms of possible GI bleeding vary, depending upon whether the source of the bleeding is in the upper part of the digestive tract (the esophagus, stomach or the beginning of the small intestine) or in the lower part (small intestine, colon or rectum).

Symptoms of Upper GI Bleeding:

- vomiting bright red blood
- vomiting dark clots, or material that looks like coffee grounds
- passing black, tar-like stool
- blood in the stool
- tiredness, shortness of breath due to iron deficiency anemia

Symptoms of Lower GI Bleeding:

- passing pure blood or blood mixed in stool
- bright red or maroon colored blood in the stool
- tiredness, shortness of breath due to iron deficiency anemia

Understanding Ulcers – Stress Is Not the Culprit!

Most GI bleeding comes from ulcers. An ulcer is an area of the lining of the stomach or duodenum that has been destroyed by digestive juices and stomach acid. The actual size of the ulcer can be very small, but even small lesions can cause tremendous discomfort and pain. The most common symptom of an ulcer is a gnawing or burning pain in the abdomen located between the navel and the bottom of the breastbone.

In the past, ulcers were incorrectly thought to be caused by stress.

Doctors now know that there are **two major causes of ulcers**:

The largest number of duodenal and gastric ulcers arise because of the presence of a bacterium called *Helicobacter pylori* or *H. pylori*. The use of antibiotics to fight the *H. pylori* infection is a major scientific advance. Studies now show that antibiotics can permanently cure 80 to 90 percent of peptic ulcers. Blocking stomach acid remains very important in the initial healing of an ulcer.

The second major cause for ulcers is irritation of the stomach arising from regular use pain medications called non-steroidal anti-inflammatory drugs, or “NSAIDs”. NSAIDs are available over-the-counter (OTC) and by prescription, and include common products like aspirin, ibuprofen, naproxen sodium and ketoprofen.

GI Bleeding Can Occur without Warning Signs or Symptoms

Serious GI complications such as bleeding, ulceration and perforation can occur with or without warning symptoms in people using chronic NSAID therapy. Of particular concern are patients with arthritic conditions. More than 14 million such patients consume NSAIDs regularly. Up to 60 percent will have gastrointestinal side effects related to these drugs and more than 10 percent will cease recommended medications because of troublesome gastrointestinal symptoms.

If you are taking over-the-counter pain medications on a regular basis, you will want to talk with your physician about the potential for ulcers and other GI side effects.

Treatments for Ulcers

In contrast to past beliefs, diet has little to do with ulcer healing. Doctors now recommend that patients with ulcers only avoid foods that worsen their symptoms. Patients who smoke cigarettes should stop. Smoking has been shown to inhibit ulcer healing and is linked to ulcer recurrence. In general, ulcer patients should not take NSAIDs unless instructed to do so by their physician. Numerous medications which inhibit acid production can rapidly heal ulcers. Antibiotic therapy for *H. pylori* can accelerate healing and prevent recurrence. When an ulcer fails to heal or if complications of bleeding, perforation or obstruction develop, surgery may be necessary.

Important Facts about NSAIDs

Persons using NSAIDs are at a significantly increased risk of gastrointestinal (GI) complications, including injury to the intestinal lining that can result in ulcers and/or gastrointestinal bleeding.

This is not a minor risk. With millions taking NSAID pain medications every day, it is estimated that more than 100,000 Americans are hospitalized each year and between 15,000 and 20,000 Americans die each year from ulcers and gastrointestinal bleeding linked to NSAID use.

Questions about COX-II Inhibitors (Celebrex[®], Bextra[®] and Vioxx[®])

Several years ago when a new class of drugs, called COX-II Inhibitors (Celebrex[®], Bextra[®] and Vioxx[®]), came onto the market, many patients who were regular users of NSAIDs for analgesia or pain relief, were advised by their physicians to switch to the COX-II products based on the premise that they could achieve equivalent benefits with less gastrointestinal risk than traditional NSAIDs.

Clinical studies subsequently confirmed that these newer compounds had a lower incidence of gastrointestinal bleeding. Recent scientific findings, underscored in communications from the FDA, have challenged some of these COX-II compounds, not with respect to claims of reduced risks of ulcers and GI bleeding, but because of data relating to potentially increased cardiovascular complications, including heart attack and stroke.

With the voluntary withdrawal of Vioxx[®] and Bextra[®] from the market and serious new label warnings for Celebrex[®] about increased cardiovascular risks, as well as expanded information about GI risks (ulceration and bleeding) for NSAIDs, it is not surprising that the number of prescriptions for COX-II inhibitors has declined significantly. This raises the question of what pain medications patients are taking if not a COX-II. You should discuss with your physician the best treatment plan that is individualized for your particular healthcare risks.

Personal Medical History is Important to Understanding Your Risk

The determination of the risk associated with use of NSAIDs requires a careful look at the your medical history. The key issues associated with NSAID-induced ulcers, GI injury and related bleeding include:

Previous Ulcer A history of an ulcer, or an ulcer complication are risk factors for complications due to aspirin or NSAIDs use.

Use of Multiple and/or High Dose NSAIDs Adverse effects associated with NSAIDs become more likely as the cumulative amount of NSAID increases, relating both to the size of each dose you take, as well as frequency with which you consume NSAIDs. Patients who take daily aspirin to reduce heart and/or stroke risk should recognize that low dose aspirin therapy represents a major risk factor for GI bleeding, particularly if you take daily doses of 325 mg. Lower doses of 81 mg appear to have generally similar benefits with significant reduction in GI risks. Risks associated with daily aspirin are even more pronounced if patients also take other NSAIDs regularly.

Anti-coagulants Similarly, patients who are taking NSAIDs at the same time they are taking oral prescription anti-coagulants (for example, medications like warfarin [Coumadin[®]]) have been found to have a twelve-fold increase in risk of bleeding.

Age Has been identified as a risk factor in several studies. Older patients also often require pain medications more frequently, or in larger doses, further increasing their risk.

Steroids Patients taking NSAIDs who also are taking a prescription corticosteroid, medications like prednisone (in doses over 10 mg), have been found to have a seven-fold increased risk of having GI bleeding.

Alcohol Alcohol can cause irritation of the GI tract. There are some indications that patients who consume alcohol at the same time they are taking NSAIDs have an increased risk of damage to the intestinal lining. Chronic heavy alcohol users may be at increased risk of liver toxicity from excessive acetaminophen use, and should consult their physician for advice on when and how to take pain relievers.

Taking Pain Medication Seriously

Adverse effects associated with NSAIDs become more likely as the cumulative amount of NSAID increases, relating both to the size of each dose you take, as well as how frequently you consume NSAIDs.

The most important ground rule, however, is to take a medication only as directed, and follow the instructions on your medication. No medication—whether a prescription or over-the-counter drug—should be taken more frequently than is directed in the labeling. Be familiar with potential side effects noted in the labeling and be on the lookout for them.

Some additional guidelines include:

- Tell your doctor about any medications you are taking both prescription or over-the-counter.
- Avoid or limit alcohol usage while taking any NSAID.
- Stick to the minimum dose needed to treat the pain, for the minimum number of days and minimum number of times per day as absolutely necessary.
- Check ingredients and make sure to avoid taking several different medications containing NSAIDs at the same time.

Options for Pain Management in Light of NSAIDs Risks

Physicians can choose to recommend use of acetaminophen for patients needing analgesia or relief for chronic pain, and while this agent is believed to be relatively safe, patients will need to consult with their physicians to determine if there are any limitations or contraindications for this medication, given the patients' age, health history, or use of tobacco or alcohol.

If patient needs require reverting to use of one of the traditional NSAIDs, adopting a combination therapy with either:

(1) Misoprostol (Cytotec®) co-therapy which may provide some protection if patient tolerance of any side effects is acceptable; and/or

(2) co-therapy with specific type of strong acid suppressing medication known as a proton pump inhibitor.

More Information about Co-Therapy with a Proton Pump Inhibitor (PPI)

Medicines that control or decrease acid in the stomach are considered a valuable palliative; if taken regularly while NSAIDs are used, they offer some protection to those who must take NSAIDs. Clinical studies suggest a 50 percent reduction in the formation of bleeding ulcers with the use of PPIs. The FDA recognizes specific benefits for NSAID users who are at high risk for gastric (stomach) ulcers, and who take proton pump inhibitors, citing risk reduction of gastric ulcers developing on continuous NSAID therapy (esomeprazole – Nexium®) and healing and risk reduction of NSAID-associated gastric ulcers (lansoprazole - Prevacid®).

Other proton pump inhibitors include the following medications: pantoprazole – Protonix®; rabeprazole – Aciphex® and omeprazole – Prilosec® (the only one available over-the-counter.) There is another less powerful class of acid-suppressing agents (H₂ receptor agonists), largely over-the-counter products, including cimetidine – Tagamet®; famotidine – Pepcid®; nizatidine – Axid®; ranitidine – Zantac®. H₂ receptor agonists are less effective for acid suppression than proton pump inhibitors.

What to Do If You Are Concerned About GI Bleeding

If you are taking over-the-counter NSAIDs on a regular basis, you will want to talk with your physician about the potential for ulcers and other GI side effects. Most patients contact their family doctor, or primary care physician, when they experience GI problems. Many of these disorders, including *Helicobacter pylori*, can be treated readily by your primary care doctor.

In the case of recurring or more serious problems, you may need to see a gastroenterologist, a physician who specializes in disorders and conditions of the gastrointestinal tract.