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The full report is titled "Gastrointestinal Tolerability and Effectiveness of Rofecoxib versus Naproxen in the Treatment of Osteoarthritis. A Randomized, Controlled Trial." It is in the 7 October 2003 issue of *Annals of Internal Medicine* (volume 139, pages 539-546). The authors are J.R. Lisse, M. Perlman, G. Johansson, J.R. Shoemaker, J. Schechtman, C.S. Skalky, M.E. Dixon, A.B. Polis, A.J. Mollen, and G.P. Geba, for the ADVANTAGE Study Group.

Gastrointestinal Side Effects of Rofecoxib and Naproxen

What is the problem and what is known about it so far?

Osteoarthritis is a joint disease that gradually wears down cartilage and bone. It is the most common joint disorder worldwide, affecting both men and women as they grow older. Symptoms include pain and stiffness of the fingers and weight-bearing joints, such as the knees, back, and hips. Patients often take medicines, such as naproxen or ibuprofen, to reduce or take away the pain. These medicines are called traditional nonsteroidal anti-inflammatory drugs (NSAIDs). Sometimes, NSAIDs cause gastrointestinal side effects, such as stomach pain, ulcers, or bleeding. More recently developed NSAIDs (called coxibs) are thought to have less frequent and less damaging side effects.

Why did the researchers do this particular study?

To compare the gastrointestinal side effects of rofecoxib and naproxen in patients with osteoarthritis.

Who was studied?

5557 patients with osteoarthritis. Their average age was 63 years. Most had used NSAIDs in the past, many had hypertension, and 13% were taking aspirin to help prevent heart attacks or strokes.

How was the study done?

Patients were randomly assigned to 1 of 2 groups. The first group received rofecoxib, 25 mg once daily, and a dummy pill in the morning and afternoon. The second group received naproxen, 500 mg twice daily, and a dummy pill in the morning. Neither the patients nor their doctors were told who got which treatment. The researchers asked patients about side effects at 3-week intervals during 12 weeks of follow-up. They then compared side effects between groups.

What did the researchers find?

About 6% of the patients taking rofecoxib and 8% of those taking naproxen stopped taking the drugs because of gastrointestinal side effects. Among aspirin users, about 5% taking rofecoxib and 9% taking naproxen stopped taking them. Two patients taking rofecoxib and 9 patients taking naproxen had major problems, such as an ulcer or gastrointestinal bleeding. About 9% of patients taking rofecoxib and about 11% taking naproxen took medicines, such as antacids, to relieve gastrointestinal symptoms.

What were the limitations of the study?

The trial tested daily dosages of drugs for a short period (3 months). Many people with osteoarthritis take drugs intermittently over a long period to relieve symptoms when they have them. Side effects of drugs might be different with intermittent long-term use. Rofecoxib pills typically cost more than naproxen pills. The study did not examine overall health care costs for patients with either drug.

What are the implications of the study?

In older patients with osteoarthritis, rofecoxib causes fewer gastrointestinal side effects than naproxen.

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