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COX-2 INHIBITORS

Although COX-2 inhibitors reduce the risk of GI side effects, such as dyspepsia-related health, they may increase the use of GI medical co-therapy and cost significantly more than NSAIDs.

Dr. Loren Laine of California and colleagues used a pharmacy claims database containing data on 50 million lives to assess GI co-therapy use among patients who switched from chronic NSAID therapy to chronic coxib therapy. Chronic therapy was described as at least 120 days of therapy during the 6-month treatment period.

The drugs evaluated were all traditional NSAIDs, coxibs including celecoxib and rofecoxib, and GI co-therapy, which included proton pump inhibitors (PPIs), H-2 Receptor Antagonists (H2RAs), and others (misoprostol and sucralfate).

The study was divided into 3 patient groups: patients who were not taking NSAIDs (non-users; n=372,640); those taking NSAIDs and who did not switch to coxib therapy (non-switchers; n=143,435); and patients initiated on NSAIDs but switched to coxibs (switchers; n=14,001).

Researchers determined the use of GI co-therapy during the 6-month period of chronic NSAID use prior to the date of switching to coxib therapy and compared it with the 6-month period of chronic coxib therapy following the switch.

Findings showed that approximately 5% of non-users were taking GI co-therapy, while 3% and 2% were taking PPIs and H2RAs, respectively.

Of the group of non-switchers, 20.5% used GI co-therapy, 9% used PPIs, and 12% used H2RAs.

Among switchers, 31.8% used GI co-therapy, 17.8% used PPIs, and more than 13% used H2RAs before they made the switch.

After patients switched to coxibs, their utilization of GI co-therapy increased to 35.6%; PPI and H2RA use also rose after the switch to 22.8% and 14.2%, respectively.

Laine questioned the potential reasons for that lack of decrease of Gl drugs with coxib therapy.

One reason, he said, would be that physicians may fail to change their prescribing patterns. He said patients also have other good reasons to be on GI co-therapy, such as for the treatment of GERD.

"[Furthermore, some] patients, at least in my mind, legitimately should be on both a coxib and a preventive GI co-therapy such as a PPI. [Moreover], dyspepsia does occur with coxibs, and this also may require therapy," he said. "All these things may blunt a potential decrease [in GI co-therapy use] with coxibs."

Despite the significant findings, Laine warned that his study does have some limitations. He explained that the study was only a retrospective pharmacy database study.

"We have no medical information in this study, so we can't adjust for confounding factors," he said. "But in any event, I would conclude that despite the decrease in GI events with coxibs in randomized controlled trials, use of GI co-therapy is not decreased in this routine clinical practice database, when patients switch from traditional NSAIDs to coxibs."

In a separate presentation, Brennan Spiegel of Los Angeles, Calif., described a study examining the cost-effectiveness of COX-2 in the management of chronic arthritis.

"NSAIDs remain widely used as first-line agents for chronic arthritis pain relief. But despite their status as the mainstay of treatment, NSAIDs are associated with a wide range of GI complications," Spiegel noted.

For example, he noted that the number of patients needed to treat with a coxib instead of a non-selective NSAID in order to prevent 1 additional ulcer bleed or perforation is 125.

His research team conducted a computerized decision analysis to calculate the cost-effectiveness of 2 therapies—a COX-2 inhibitor administered at the maximum recommended dose or naproxen at 500 mg—for rheumatoid arthritis or osteoarthritis pain relief.

A third-party payer perspective conducted cost estimates. Those estimates included Medicare reimbursement for physician fees, endoscopy, bowel surgery, and hospital stay.

Modeled drug costs were \$2.40 for a COX-2 tablet and \$0.40 per tablet of naproxen.

Under base-case conditions, the treatment strategy using COX-2 inhibitors cost \$1,829 per average patient treated and was 98.4% effective.

The naproxen treatment strategy cost \$436 per average patient treated and was 96.1% effective.

Therefore, the incremental cost to avoid 1 additional ulcer bleed with a COX-2 inhibitor versus naproxen was \$60,565 per year.

Results from the sensitivity analysis showed that the COX-2 inhibitor strategy became more cost effective when the cost of the drugs was reduced to \$0.48 per tablet and when the annual risk of an ulcer bleed with naproxen exceeded 28%.

The incremental cost effectiveness was reduced to \$5,107 when the probability of an ulcer bleed with naproxen was 19%.

"The degree of risk reduction afforded by coxibs is unlikely to offset their increased costs compared to non-selective NSAIDs like generic naproxen, even when accounting for the disparity in dyspeptic symptoms," Spiegel concluded.

By Medical Writer June D. Wilhite

GI COMPLICAITONS IN ARTHRITIS PATIENTS

Rheumatoid arthritis and osteoarthritis patients who are at high risk for gastrointestinal complications should be treated using a COX-2 specific inhibitor, rather than a traditional, nonselective NSAID, clinical data demonstrate.

According to Dr. Richard Hunt of McMaster University Medical Center in Ontario, Canada, traditional NSAID therapy results in dyspepsia in 15% to 25% of patients, gastric ulcer in 15% to 20%

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