Medical Xpress

Serious complication of gastrointestinal procedure can often be avoided with single dose medication

April 11 2012

A study in the current issue of the *New England Journal of Medicine* shows a serious complication of ERCP, a procedure commonly used to diagnose and treat problems of the bile and pancreatic ducts, may be eliminated with a single dose medication.

The finding is significant in helping patients avoid a condition known as post-ERCP pancreatitis, a disabling complication that affects up to 1 in 4 high-risk patients who undergo the gastrointestinal procedure.

Despite decades of research, this clinical trial is the first to clearly demonstrate effective prevention of post-ERCP pancreatitis.

The trial ended early after an interim analysis showed clear safety and benefit for the first 600 patients enrolled. The findings are already changing clinical practice.

"ERCP is a very important procedure that can provide life-saving interventions for people who need it, although it is considered the most invasive of all the endoscopic procedures and it does have risks associated with it," says lead study author and gastroenterologist B. Joseph Elmunzer, M.D., assistant professor of internal medicine at the University of Michigan Health System.

Post-ERCP pancreatitis is a sudden swelling and inflammation of the

pancreas that leads to 300,000 hospitalizations a year and costs an estimated $150 million to treat.

According to the study, hospitalizations for post-ERCP pancreatitis were dramatically reduced by administering a single dose of indomethacin, an anti-inflammatory medication that costs less than $5.

The drug is part of a category of non-steroid anti-inflammatory drugs that's believed to inhibit an inflammatory response by the pancreas that can occur after endoscopic retrograde cholangiopancreatography, or ERCP.

ERCP combines a lighted scope inserted through the mouth and X-ray pictures to examine the tubes draining the liver, gallbladder and pancreas.

In the study, only 9.2 percent of patients who took indomethacin developed post-ERCP pancreatitis compared to 16.9 percent of those who took a placebo – a 46 percent drop in relative risk.

"The results of the study were very impressive," Elmunzer says. "We found that indomethacin was highly protective."

Some patients have the GI procedure repeated as doctors examine the bile duct and pancreatic duct for growths, stones, open a narrowed duct or to seal leaks after surgery.

Funded by grants from the National Institutes of Health, the trial was conducted February 2009 to July 2011 at the U-M Health System, Indiana University, University of Kentucky and Case Western Reserve University.

The study is the first executed by the United States Cooperative for

Outcomes Research in Endoscopy, which provides an open platform for gastrointestinal programs to conduct large-scale patient studies.

Patients like Jessica Calcagno, 24, are benefiting from the research. During an ECRP procedure doctors found and removed a growth, but afterwards Calcagno experienced severe stomach pain that she says was so unbearable she sought help at an emergency room.

She was diagnosed with post- ERCP pancreatitis and hospitalized for five days. Before her next ECRP at the U-M's Division of Gastroenterology, she was given indomethacin.

"Following the procedure, I went home and felt fine. I was a little sore, but that's standard so it was great," she says. "I have many more ERCP procedures to go through in my life. I feel comfort knowing that I can leave after the procedure and not develop pancreatitis."

Given the magnitude of the problem, over the years researchers have studied more than 35 drugs to prevent post-ECRP pancreatitis, with uncertain conclusions.

"Health care costs in the United States are soaring, so it's important for the scientific community, even individual practitioners, to find innovative, low-cost ways to improve health," Elmunzer says.

"I think indomethacin is a perfect example of a widely available, inexpensive, easily administered drug that does exactly that – improves clinical outcomes at extremely low-cost."

Provided by University of Michigan Health System

Citation: Serious complication of gastrointestinal procedure can often be avoided with single