

Endoscopic procedure does not reduce disability due to pain following gallbladder removal

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In certain patients with abdominal pain after gallbladder removal (cholecystectomy), undergoing an endoscopic procedure involving the bile and pancreatic ducts did not result in fewer days with disability due to pain, compared to a placebo treatment, according to a study in the May 28 issue of *JAMA*.

Post-cholecystectomy pain is a common clinical problem. More than 700,000 [patients](#) undergo cholecystectomy each year in the United States, and at least 10 percent are reported to have pain afterwards. Most of these patients have no significant abnormalities on imaging or laboratory testing, and the cause remains uncertain. Many of these patients undergo endoscopic retrograde cholangiopancreatography (ERCP; the use of an endoscope to inspect the pancreatic duct and common bile duct) in the hope of finding small stones or other pathology or in an effort to address suspected sphincter of Oddi (a muscle at the juncture of the bile and pancreatic ducts and the small intestine that controls the flow of digestive juices) dysfunction. Of these patients, some undergo biliary or pancreatic sphincterotomy (surgical incision of a muscle that contracts to close an opening) or both. The value of this endoscopic intervention is unproven and the risks are substantial. Procedure-related pancreatitis rates are 10 percent to 15 percent, and perforations may occur. Many patients have prolonged and expensive hospital stays, and some die, according to background information in the article.

Peter B. Cotton, M.D., F.R.C.P., F.R.C.S., of the Medical University of South Carolina, Charleston, and colleagues randomly assigned patients with pain after cholecystectomy (and with no significant laboratory or imaging abnormalities) to sphincterotomy (n = 141) or sham (placebo; n = 73) therapy, after ERCP. Success of treatment was defined as less than 6 days of disability due to pain in the prior 90 days both at months 9 and 12 after randomization, with no narcotic use and no further sphincter intervention.

The rate of successful outcome at 12 months was 37 percent for the patients assigned to sham procedure, and 23 percent for those assigned to sphincterotomy. The most common reason for failure in both treatment groups (72 percent sphincterotomy, 56 percent sham) was persistent elevation in a [pain](#)-disability score, with or without re-intervention or narcotic use.

No clinical subgroups appeared to benefit from sphincterotomy more than others. Pancreatitis occurred in 11 percent of patients after primary sphincterotomies and in 15 percent of patients in the sham group.

Of the nonrandomized patients in an observational study group, 24 percent who underwent biliary sphincterotomy, 31 percent who underwent dual sphincterotomy, and 17 percent who did not undergo sphincterotomy had successful treatment.

"These findings do not support the use of ERCP and sphincterotomy for these patients," the authors write.

"The finding that endoscopic sphincterotomy is not an effective treatment has major implications for clinical practice because it applies to many thousands of patients."

More information: [DOI: 10.1001/jama.2014.5220](https://doi.org/10.1001/jama.2014.5220)

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