

# Fewer ERCPs needed to treat benign biliary obstructions with use of self-expandable stents

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MUSC Health endoscopist Gregory A. Cote performing ERCP. Credit: Image Courtesy of the Medical University of South Carolina

Placement of a single covered, self-expanding metallic stent (cSEMS)

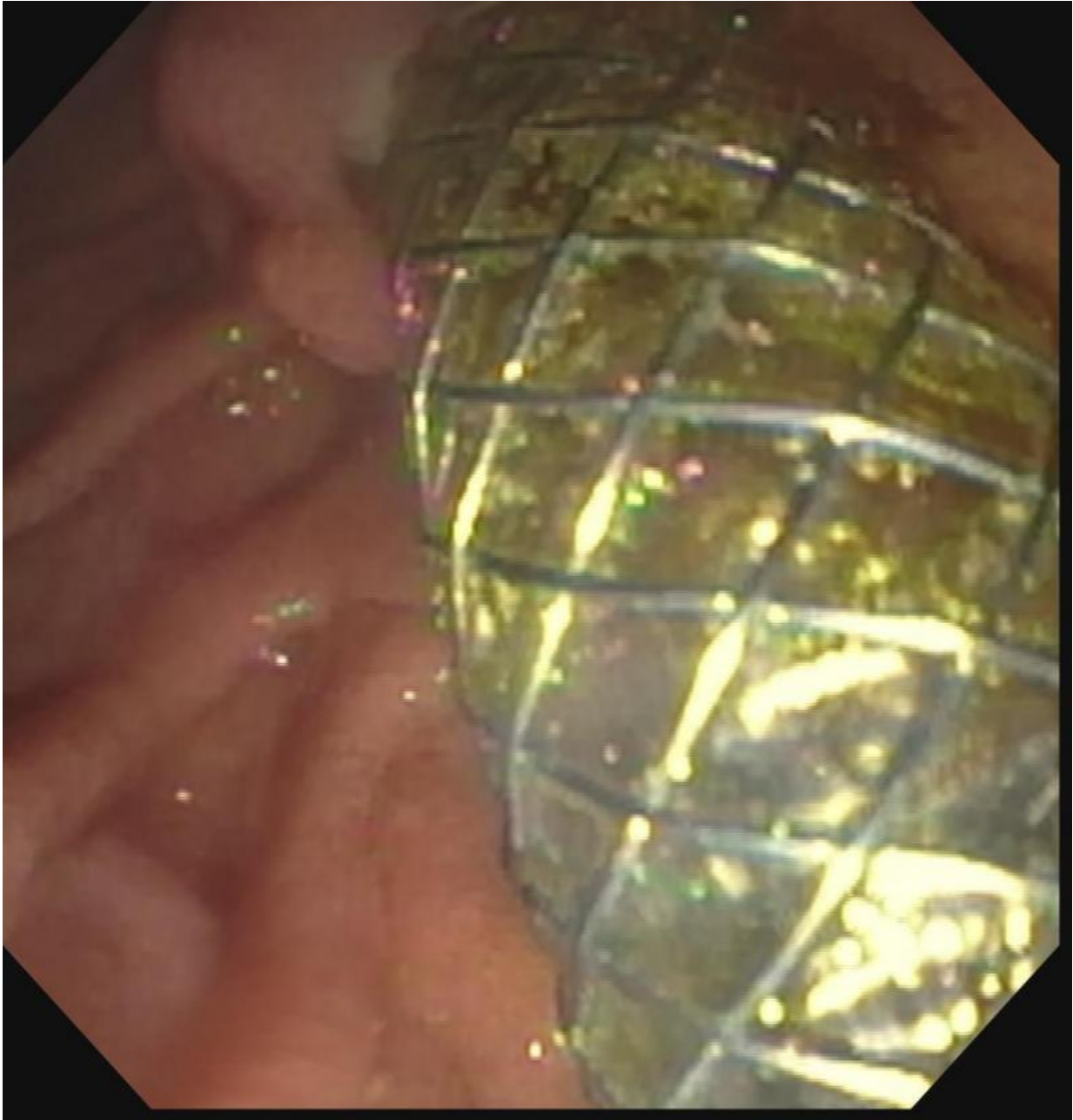
via endoscopic retrograde cholangiopancreatography (ERCP) resolved benign obstructions of the pancreatic and biliary ducts as well as placement of multiple plastic stents, the current standard of care, and required fewer ERCP sessions, according to the results of a randomized controlled trial reported in the March 22, 2016 issue of the *Journal of the American Medical Association*.

These findings will change practice in the opinion of Gregory A. Coté, M.D., an endoscopist at the Digestive Disease Center at the Medical University of South Carolina, lead author of the article, and the national principal investigator for the eight-center study. B. Joseph Elmunzer, M.D., of the MUSC Digestive Disease Center is also a co-author.

"For appropriately selected patients who are presenting the first time with a blockage, many endoscopists will change their strategy and use these newer stents, in an effort to reduce the total procedures that are required," says Coté.

For now, the use of cSEMS in benign biliary strictures would be off-label, as they have been approved by the U.S. Food and Drug Administration only for the treatment of malignant pancreatobiliary strictures, such as those which develop in the setting of unresectable pancreatic cancer.

Left untreated, benign biliary strictures can lead to jaundice, cholangitis (i.e., infection of the bile duct), and secondary biliary cirrhosis. Benign strictures most often occur after liver transplantation and gallbladder surgery or as a result of chronic pancreatitis. ERCP is preferred to surgery in these patients because it is less invasive.



Photograph of a self-expanding metallic stent. Credit: Image courtesy of Gregory A. Cote of the Medical University of South Carolina.

ERCP is an endoscopic procedure in which a camera is introduced through the mouth and advanced first to the proximal duodenum and

then, using endoscopy and fluoroscopy, into the pancreatic and bile ducts. Although highly effective, three to four ERCP sessions are typically required to fully stretch the blockage and minimize the chance of recurrence once the stents are removed.

Because ERCP is not without its risks—complications include pancreatitis, infections, bowel perforation, and bleeding—minimizing the number of sessions needed to successfully treat the stricture benefits patients. Côté designed the trial to determine whether using the larger cSEMS could successfully treat benign strictures with fewer ERCP sessions. cSEMS are coated to prevent in-growth of tumor or other tissue and to facilitate removal.

The primary endpoint of the trial, which enrolled 112 patients, was the rate of benign stricture resolution after no more than 12 months of stenting. cSEMS were found to be noninferior to plastic stents for achieving stricture resolution and they did so more quickly (181 vs. 225 days) and with fewer ERCP sessions (2.14 vs. 3.24). It should be noted that the study had careful enrollment criteria; patients with small (

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