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Study looks at off-label use of biliary stents

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Although approved by the U.S. Food and Drug Administration as a palliative treatment for cancer patients who have developed bile-duct obstructions, biliary stents are sometimes used "off-label" for the treatment of peripheral vascular disease (PVD). A study in today's issue of the *American Journal of Therapeutics* finds that off-label use of biliary stents is increasing, and that the majority of adverse events and device malfunctions associated with the use of these stents occurs during off-label usage.

"Our study found that more than 1 million patients received biliary stents for 'off-label' treatments between 2003 and 2006," explains cardiologist William Maisel, MD, MPH, Director of the Medical Device Safety Institute at Beth Israel Deaconess Medical Center (BIDMC) and senior author of the study. "We also found that more than 80 percent of the reported adverse events and device malfunctions associated with these products have occurred during 'off-label' use."

The most common off-label use for biliary stents is treatment of peripheral arterial disease (PAD), which develops when leg arteries become narrowed by cholesterol plaques. Patients who suffer from PAD can develop pain, skin ulcers, reduced exercise tolerance and even loss of limb. The condition affects millions of patients throughout the U.S. and is a significant cause of morbidity and mortality.

"Clinical management of peripheral artery disease can be challenging," explains Maisel. Although noninvasive treatment strategies such as exercise training can help some patients, for many others, pain and

discomfort persist. In an effort to unblock the vessels, many physicians have turned to stents, flexible tubular devices which can keep the vessels propped open.

Because there is little data supporting the clinical utility and safety of biliary stents for treatment of vascular disorders, Maisel and colleague Jonathan Bridges, MD, of BIDMC's Cardiovascular Institute decided to take a closer look.

The authors determined that biliary stent implants among PVD patients increased 21.4 percent, from 227,145 in 2003 to 275,795 in 2006; approximately 1 million biliary stents were implanted off-label in the peripheral vasculature in total. Additionally, using the publicly available MAUDE (Manufacturer and User Facility Device Experience) database -- a compilation of serious adverse events and malfunctions associated with medical devices that have been reported to the FDA -- the authors reviewed all reports involving biliary stents between 2003 and 2006. During this time period, 1,036 confirmed biliary-stent malfunctions were reported, 81.2 percent of which occurred during off-label use. Malfunctions were most often due to premature stent dislodgement, premature deployment or failure of the catheter/delivery system.

In addition, notes Maisel, 87.9 percent of the 561 adverse events associated with biliary stent use during the study period occurred during off-label use, with retained product, additional catheter procedures or surgery being the most common adverse events. Thirteen patient deaths were reported during off-label use. "Like the malfunctions, we found that many more adverse events occurring during the use of biliary stents in peripheral blood vessels than when they were used in a biliary or gastrointestinal location," he adds.

"Our analysis raises several important issues," says Maisel. "The frequent off-label use of biliary stents for treatment of peripheral vascular disease

implies an unmet clinical need in the management of these patients. With the aging of the U.S. population, the number of patients with vascular disease can be expected to grow. Efforts should be directed at improving the evaluation of devices used to treat peripheral vascular disease in order to better identify those patients that will most benefit from this promising therapy."

Source: Beth Israel Deaconess Medical Center

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