

ADVANCES IN ENDOSCOPY

Current Developments in Diagnostic and Therapeutic Endoscopy

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The SpyGlass® Direct Visualization System for Cholangioscopy

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G&H Could you describe the evolution of the SpyGlass® Direct Visualization system to date?

PD The SpyGlass system (Boston Scientific) is a recently developed system for performing cholangioscopy, the visual examination of the bile ducts. This procedure has been performed since 1976, but prior to the development of the SpyGlass system, the endoscopes used for cholangioscopy were very fragile and difficult to use. The SpyGlass system, which is more practical and an improvement over standard endoscopes, was approved by the US Food and Drug Administration in November 2006. Since then, a newer version of the original SpyScope was released in May of this year. The main difference between the original SpyScope (version 1.0) and the newer one (version 1.5) is improved tip deflection.

G&H Could you outline how the SpyGlass system works?

PD The capital equipment of the system consists of a fairly small cart with a light source, water pump, computer monitor, and electrohydraulic lithotripsy generator. The disposable portion of the system, the SpyScope itself, is a 10 Fr catheter. To perform cholangioscopy, the SpyScope is inserted through the channel of a standard endoscopic retrograde cholangiopancreatography (ERCP) scope and then introduced into the bile duct to visually inspect the

bile duct. The single-use SpyScope also has a dedicated irrigation channel as well as a dedicated accessory channel for obtaining biopsies or applying electrohydraulic lithotripsy fibers.

The main indications for the use of the SpyGlass system include indeterminate or unexplained biliary strictures, difficult-to-remove bile duct stones, primary sclerosing cholangitis, cholangiocarcinoma, and common bile duct nodules or masses.

G&H What have studies reported thus far regarding the use of the SpyGlass system?

PD As this system is a relatively new technology, very few studies have been published in full to date. The studies conducted thus far are relatively small case series (eg, 22 patients) and have shown that procedures performed by the SpyGlass system are feasible and safe. In addition, our experience has shown that the equipment is durable, which was a major concern with earlier versions of cholangioscopes.

G&H What are the advantages of this new system over standard ERCP?

PD The main advantage over standard ERCP is that with the SpyGlass system, the scope can be inserted directly into the bile duct and the pathology can be directly visualized, rather than using radiographs to visualize the bile ducts. This direct visualization allows the endoscopist to obtain a targeted biopsy, if needed, or to use electrohydraulic lithotripsy to crush stones under direct vision.

Another advantage of the SpyGlass system is that it is a single-operator system, as opposed to standard ERCP, which requires two physicians.

G&H Could you discuss any associated limitations or safety concerns? Have there been any efforts to minimize adverse events through the development of operational guidelines?

PD The main limitation is that the optical portion of the system is composed of fiber optics, rather than video imaging, which creates images that are lower in quality than those of standard endoscopes.

Currently, there are no guidelines specifically addressing the use of this new technology. Cholangioscopy has been performed for over 30 years, and this system represents a new generation of cholangioscopy. We are not aware of any increases in risks associated with the use of the SpyGlass system over standard ERCP.

G&H Could you discuss the patient registry that has been established to study SpyGlass procedures?

PD A multicenter international patient registry has been established of 296 patients requiring peroral cholangioscopy for the treatment or diagnosis of biliary stones or indeterminate strictures with suspected pathology. The first results from this patient registry, which were presented at this year's Digestive Disease Week, held in San Diego, California, reported that the SpyGlass system has clinical utility and is safe to perform. Although these results were presented only in abstract form, not in a full peer-reviewed publication, additional data from the registry are expected to be announced in the near future.

G&H What is the learning curve associated with operating the SpyGlass system?

PD Based upon the experience of the three physicians who currently operate the SpyGlass system at my institution, it takes approximately 10 procedures to become thoroughly familiar and proficient with the system.

G&H How widespread has the adoption of this system been thus far?

PD The SpyGlass system is currently used mainly in specialized or academic centers, but it is being adopted

in community settings, even though it is a relatively new technology. For example, in Florida, where I practice, the University of Florida at Gainesville and the University of Miami are two academic centers that use the system, but I am aware of two community practices that also utilize it. I have witnessed much enthusiasm and positive feedback from physicians regarding the system thus far.

G&H What do you foresee as the next steps in the research and development of the SpyGlass system?

PD Although the SpyGlass system is a second-generation tool with the release of version 1.5, room for improvement remains in terms of image quality. As mentioned above, the fiber optic images currently generated by the system are inferior in quality to video images. In addition, the electrohydraulic lithotripsy probe that is currently utilized with the system is borrowed from urology. A probe that is specifically designed for gastrointestinal procedures, one that is not flimsy and is easy to use, is needed. Finally, as the SpyGlass system is a fairly new technology, there has been no cost-effectiveness analysis comparing the system with standard ERCP. This is an area that should be examined in the future.

Suggested Reading

Judah JR, Draganov PV. Intraductal biliary and pancreatic endoscopy: an expanding scope of possibility. *World J Gastroenterol.* 2008;14:3129-3136.

Chen YK, Pleskow DK. SpyGlass single-operator peroral cholangiopancreatography system for the diagnosis and therapy of bile-duct disorders: a clinical feasibility study (with video). *Gastrointest Endosc.* 2007;65:832-841.

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Parsi MA, Neuhaus H, Pleskow D, Binmoeller KF, Hawes RH, et al. Peroral cholangioscopy guided stone therapy—report of an international multicenter registry. Presented at Digestive Disease Week; May 17-22, 2008; San Diego, California. Abstract 865.

Chen YK, Parsi MA, Binmoeller KF, Hawes RH, Pleskow D, et al. Peroral cholangioscopy using a disposable steerable single operator catheter for biliary stone therapy and assessment of indeterminate strictures—a multi-center experience using SpyGlass. Presented at Digestive Disease Week; May 17-22, 2008; San Diego, California. Abstract 868.