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Spyglass Direct Visualization System

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Although endoscopic retrograde cholangiopancreatography is considered the gold standard to manage biliary disorders, it has its own limitations. The single-operator cholangioscopy (SOC) system (Spyglass) may offer an interesting compromise for most advanced biliary endoscopists, in terms of size (10 Fr diameter) and complexity of use. SOC is a great step toward intraductal visualization and therapy but the best is yet to come.

Key Words: Cholangioscopy; Spyglass; Endoscopic retrograde cholangiopancreatography

INTRODUCTION

Millions of endoscopic retrograde cholangiopancreatography (ERCP) procedures are conducted in the world every year for biliary disorders.[1] Although ERCP is considered the gold standard to manage biliary disorders, it has its own limitations. ERCP may fail to provide accurate information about mucosal lesions that don't project into the lumen.[2] Unfortunately, conventional biliary sampling has been disappointing with a reported yield for sampling of indeterminate biliary strictures ranging from approximately 20% to 30% for cytology brushing to approximately 50% with a combined brush/standard biopsy forceps approach.[3,4]

MOTHER BABY SYSTEM AND PERORAL CHOLANGIOSCOPY

Initially introduced in 1975, using the mother baby system, cholangioscopy[1] has been used in evaluating indeterminate biliary strictures[4] and lesions[1] as well as treating biliary stones.[5] However those "two scope systems" are expensive, fragile and require two endoscopists to maneuver.[6] It is time consuming and unrealistic in a world trending towards cost-effectiveness.[7] Peroral cholangioscopy using thin upper endoscope offers an attractive alternative but requires a bile duct of at least 5.3 mm.[6,7] Moreover direct wire-guided cannulation of an ultra slim endoscope or its wire-guided insertion using a previously placed wire by a duodenoscope remains challenging.[6] To facilitate this technique, an anchoring balloon has been developed by Cook Medical (Winston-Salem, NC, USA),[8] but was recalled by the company after several reports of air embolisms; highlighting not only the need to assess novel technology but also the requirement to be more selective on who should be doing those advanced procedures.

SINGLE OPERATOR SYSTEM

The single-operator cholangioscopy (SOC) system (SpyGlass; Direct Visualization System; Boston Scientific, Natick, MA, USA) has been available since 2005[1] and may offer an interesting compromise for most advanced biliary endoscopists, in terms of size (10 Fr diameter) and complexity of use.

Recently, Chen et al.[9] report a multicenter prospective experience in which they evaluate the feasibility of cholangioscopy for biliary diagnostic and therapeutic procedures using SOC. Main outcome measures included procedural success defined as the ability to visualize target lesions and, if indicated, collect biopsy specimens for histological evaluation (diagnostic part of the study) or assess biliary stones and initiate fragmentation and removal (interventional part of the study).

Of the 297 patients enrolled, 277 (93%) completed the study. The overall procedural success rate was 89%. Diagnostic SOC

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was performed without biopsy in 86 cases (31%) and with biopsy in 140 (50.5%). Tissue for histological examination was procured in 88% of the 140 patients biopsied, with 119 out of 140 (85%) biopsied patients having a malignant or benign final diagnosis. A total of 95 patients were included in the final analyses for sensitivity, specificity, accuracy, and positive/negative predictive values for malignancy diagnoses for all 3 diagnostic modalities. Overall sensitivity in diagnosing malignancy was 78% for SOC visual impression and 49% for SOC-directed biopsy, with the sensitivity being higher (84% and 66%, respectively) for intrinsic bile duct malignancies. For ERCP alone, specificity was 54%, accuracy was 53%, positive predictive value was 88%, and negative predictive value was 77%. For SOC and SOC-directed biopsy modalities, specificity was 82% and 98% respectively, accuracy was 80% and 75% respectively, positive predictive value was 80% and 100% respectively, and negative predictive value was 80% and 72% respectively.

SOC is challenged by the size of the biopsy obtained and also due to the stiffness of the forceps (SpyBite; Boston Scientific, Natick, MA, USA) fitting within the working channel of the system. In a recent study by Draganov et al.[10] the mean SpyBite sampling time was 12.1 minutes.

Sensitivity of forceps biopsy through the cholangioscope was far higher for intrinsic (66%) than extrinsic (8%) malignant lesions.

For stone related diagnostics by SOC, investigator rated quality of stone visualization as good or excellent in 85% of patients; and 11% of the 66 patients had one or more stones identified only by SOC but not ERCP.

Diagnostic SOC procedures altered clinical management in 64% (143) of patients. Serious procedure-related adverse events were 7.5% for diagnostic SOC. The most frequent adverse event was early cholangitis (7 patients).

From a therapeutic standpoint, 66 patients underwent stone therapy by electrohydraulic lithotripsy or laser lithotripsy. Complete stone clearance in a single session was achieved in 47 patients (71%). Serious procedure-related adverse events were 6.1% for SOC-directed stone therapy (4 patients) with cholangitis in 2 patients.

In a study of 402 patients, Sethi et al.[11] reported a significantly higher rate of cholangitis (1.0% vs. 0.2%) in the cholangiopancreatoscopy group versus the conventional ERCP group with similar rates of pancreatitis (2.2% vs. 1.3%) and perforation (1.0% vs. 0.3%). However in that study, most cholangioscopies were performed using a mother baby system. Interestingly in a recent study, Draganov et al.[10] exclusively used the SOC system and didn't report any episodes of cholangitis, which is probably a reflection of an aggressive biliary drainage protocol.

Since the creation of the registry, SOC has not only been used as a platform for advanced intraductal imaging with probe based endomicroscopy[12,13] and SOC-guided stone fragmentation;[14] but also for photodynamic therapy to treat bile duct cancer.[15]

CONCLUSIONS

Even if SOC has been incorporated in our arsenal, supporting personnel is still required, image quality needs to be improved with adjunction of digitalization; and strict and specific criteria need to be created and standardized to assess biliary lesions with greater accuracy.[16] In terms of intervention, improving the flexibility of the system will facilitate biopsy sampling and widen its therapeutic potential. SOC is a great step toward intraductal visualization and therapy but the best is yet to come.

Conflicts of Interest

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