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EDITORIAL

What is the current role of endoscopy in primary sclerosing cholangitis?

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Abstract

Endoscopy has important roles in the management of primary sclerosing cholangitis (PSC), ranging from narrowing down the differential diagnoses, screening for complications, determining prognosis and therapy. While the need for a diagnostic endoscopic retrograde cholangiopancreatography (ERCP) may be obviated by a positive magnetic resonance cholangiopancreatography (MRCP), a negative MRCP does not exclude PSC and may therefore necessitate an ERCP, which is traditionally regarded as the gold standard. In this editorial we have not covered the endoscopic management of inflammatory bowel disease in the context of PSC nor of endoscopic surveillance and treatment of portal hypertension complicating PSC.

Key words: Sclerosing cholangitis; Endoscopic retrograde cholangiopancreatography; Endosonography; Cholangiocarcinoma; Stents; Fluorescence *in situ* hybridization technique; Biochemical markers

Core tip: Primary sclerosing cholangitis is a cholestatic disease of unclear etiopathogenesis, often seen in association with inflammatory bowel disease. It is characterized by fibrosis of the intra and extra hepatic bile ducts, resulting in stricturing disease, predisposing to cholangiocarcinoma. Diagnosis requires a high index of clinical suspicion and is often made by magnetic resonance cholangiopancreatography in the appropriate clinical context, although endoscopic retrograde cholangiopancreatography remains the gold standard. The latter being invasive is seldom used as a diagnostic modality and is reserved for management of complications including dilatation and stenting of dominant and anastomotic strictures, brush cytology and for SpyGlass Cholangioscopy.

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INTRODUCTION

Primary sclerosing cholangitis (PSC) is a chronic cholestatic disease characterized by inflammation and fibrosis that may involve the entire biliary tree. Inflammation and fibrosis results in diffuse narrowing of the intra and extra hepatic bile ducts causing persistent biliary stasis eventually leading to secondary biliary cirrhosis. It usually presents in the fourth decade of life with a variable disease progression[1].

Laboratory tests do not play a significant role as there is no definite test to confirm PSC. Non-invasive imaging modalities like trans abdominal ultrasound may pick up nonspecific abnormalities such as bile duct thickening, gall bladder enlargement or wall thickening. Contrast computed tomography (CT) scan and magnetic resonance cholangiopancreatography (MRCP) may detect inflammation, intrahepatic dilations as well as varices and splenomegaly indicative of portal hypertension. CT detects intraabdominal lymphadenopathy, suggestive of underlying cholangiocarcinoma. Even invasive tests like percutaneous transhepatic cholangiography have been used in the past. However none is confirmatory.

PSC recurs in about 10% of patients post orthotopic liver transplantation (OLT), with acute cellular rejection, need for maintenance steroids, HLA-DRB1*08 being positive predictors and pan colectomy being a negative predictor[2,3]. The diagnostic modalities for recurrent PSC (r-PSC) remain the same, with low threshold for biopsy to rule out rejection, which needs to be managed aggressively to prevent decompensation of the liver[2].

It is important to distinguish immunoglobulin (Ig) G4-associated cholangitis (IAC), also called IgG4-related sclerosing cholangitis, a recently described chronic cholangiopathy from PSC and other secondary sclerosing cholangitis, due to the excellent response of the former to steroid treatment. About 10% to 15% of patients with PSC also have elevated IgG4 levels. There is some evidence that the incorporation of IgG4/IgG1 ratio may be used in clinical practice to distinguish PSC from IAC[3,4]. Liver biopsy is rarely used these days, thought, might still be needed in the diagnosis of small duct PSC and when diagnosis is unclear.

Biliary IgG antineutrophilic cytoplasmic antibody and IgA against biliary epithelial cells correlates with the severity of bile duct strictures and may serve in the future as a diagnostic and prognostic marker of the disease progression and biliary complications[5,6]. Biliary protein biomarkers might help in distinguishing benign from malignant strictures, though further studies are warranted[7]. Novel biliary biomarkers like extracellular vesicles containing Micro-RNA's (miRs), U2 small nuclear RNA fragments (RNU2-1f) and oxidized phosphatidyl cholines (ON-PC and S-PC) have been proposed for the early diagnosis of cholangiocarcinoma in PSC, that is stable, reproducible, and has potential clinical utility[7-9].

ENDOSCOPIC DIAGNOSIS

Endoscopic retrograde cholangiopancreatography

Endoscopic retrograde cholangiopancreatography (ERCP) is the mainstay for accurate assessment of the hepatobiliary tree to establish a diagnosis of PSC. Typical cholangiographic findings include multifocal annular biliary strictures interspersed between dilated intra and extrahepatic bile ducts with alternating normal segments, creating the characteristic beaded pattern of PSC.

Even though MRCP is the preferred cholangiographic modality given the high sensitivity, non-invasive nature and lack of exposure to radiation, it has limited accuracy in early PSC, cirrhosis and in the differentiation of Caroli's disease, secondary sclerosing cholangitis and cholangiocarcinoma (CCA)[10]. A retrospective study by Moff *et al*[11] demonstrated that ERCP and MRCP were comparable for diagnosis of PSC. They recommended that MRCP be employed as the initial diagnostic modality given the safety profile as well as sensitivity and specificity of approximately 90% and 88% respectively, although ERCP with its higher specificity of nearly 96% would be necessary for confirmation[11].

Complications occur in about 4% to 16% of patients with PSC undergoing ERCP[12,13]. The complication risk was often dependent on the ease of cannulation, with post ERCP pancreatitis (PEP) reported in up to 7% of procedures[14]. Hence, we recommend routine sphincterotomy, especially in those who are likely to need further procedures, to minimise the risk of PEP[14]. PSC patients undergoing ERCP are routinely given antibiotic prophylaxis to reduce the risk of cholangitis, which is more so in the presence of strictures[12,14,15]. An extra attempt is made to clear the bile duct of all contrast by suctioning or irrigation. Overall, benefits of doing an ERCP outweighed the risks in PSC, when the indications were appropriate[14,15].

A confirmatory ERCP is warranted when clinical suspicion of PSC is moderately high, also in cases with inconclusive MRCP results and or cases being evaluated at centres where the technical expertise with MRCP is not well established[16]. A cost effectiveness analysis comparing ERCP with MRCP by Meagher *et al*[17] in the face of competing technologies revealed that initial MRCP, when negative, followed by subsequent ERCP was the most economic initial approach in the work-up of patients with suspected PSC.

It is crucial to distinguish dominant strictures (DS) in PSC from cholangiocarcinoma, which remains a challenge given that the former predisposes to CCA, which could be found in upto 25% of DS as per some studies[18]. The American Association for the Study of Liver Diseases (AASLD) guidelines recommend those with dominant strictures be assessed with CA 19-9, MRCP and ERCP for tissue acquisition. CCA is one of the major causes of mortality in PSC and

may be detected concurrently at the time of or within months of its diagnosis. However, cholangiocarcinoma related mortality does not diminish with early liver transplantation[19]. Due to the unpredictable natural history and lack of early predictors of cancer, there is no set guideline for surveillance of patients with PSC. Biliary tissue acquisition can be achieved by brush cytology and or intraductal biopsy (for histology using pediatric forceps) to distinguish benign from malignant strictures. Brush cytology being technically easy, safe and less time consuming is more commonly used[20]. The AASLD guidelines recommend performing the above to exclude superimposed malignancy prior to endoscopic therapy for dominant bile duct strictures[21]. A meta analysis by Navaneethan *et al*[7] demonstrated that biliary brush cytology has high specificity (97%) for the diagnosis of CCA, however the low sensitivity limited its role in detecting early CCA[22]. Most cases of malignant DS occur in the perihilar region and accessible to brush cytology[23]. Repeated brush cytology aids early detection of high grade dysplasia before manifest CCA, enabling pre-emptive liver transplantation[24]. A weighted scoring system, proposed by Witt *et al*[25], termed the Atypical Biliary Brushing Score (ABBS) helps to risk stratify the individuals with atypical brush cytology to identify those at high risk of CCA[25]. ABBS considers seven variables including age over 60, pancreatic mass as an indication, distal biliary stricture, CA 19-9 over 300 U/mL scoring one each, endoscopic impression of malignancy, common hepatic duct stricture and a definite diagnosis of PSC with the last three scoring two each. Patients with a score over 4 are considered to be at high risk of harboring malignancy despite atypical results on a biliary brush cytology[25].

There are now advanced techniques in cytology such as digital image analysis (DIA) and fluorescence in situ hybridization (FISH) that enhance the sensitivity and improves diagnostic yield of brush cytology, compared with routine cytology[26-28]. DIA is a method by which microscopic images of a cell are quantified by digital conversion and computer analysis of the image feature[29]. FISH allows fluorescent labeling of DNA probes to target chromosomal regions to detect numerical or structural chromosomal abnormalities, such as trisomy or polysomy which suggest malignant process. The ability of FISH to detect polysomic cells from pancreatobiliary brushings puts it ahead of other pathological or imaging modalities in detecting CCA[30]. FISH of the cytologic specimen has significantly greater sensitivity than conventional cytology for the identification of CCA in patients with PSC, however it has lower specificity compared to biliary brushings[26,31]. Combining FISH with routine cytology can markedly improve the odds of detecting CCA at an early stage[30,32]. By identifying chromosomal abnormalities, DIA and FISH highly improve sensitivity while maintaining specificity. A prospective study from Mayo clinic revealed that composite DIA and FISH yielded 100% specificity and improved sensitivity by fivefold in indeterminate biliary strictures[27]. Many of these techniques once widely available should be used routinely.

Cholangioscopy

In recent years, peroral cholangioscopy as an adjunct to ERCP has gained popularity as it helps overcome diagnostic inaccuracies in biliary diseases, initially described by Chen and Pleskow[33]. In the management of challenging indeterminate biliary strictures, cholangioscopy permits direct intra luminal view of the biliary tree, targeted tissue acquisition and allows endoscopic guidance for therapeutic interventions[34]. The dual operated cholangioscope, "mother-baby" system was the first to be introduced, however the "two scope system" was time consuming, expensive, had limited manoeuvrability, poor irrigation capacity, required two endoscopists, and was easily damaged[35,36] it is therefore seldom used in clinical practise. The single-operator peroral cholangioscopy using SpyGlass direct visualization system appears to have overcome some of the limitations of the conventional peroral cholangioscopy. In addition to having two independent irrigation channels, this provides a 70-degree field of view, though the single use SpyBite forceps has only a maximum jaw separation of 4.1 mm. Hence, negative findings on the mini-forceps biopsy cannot exclude CCA owing to small sample obtained[37]. SpyGlass system was shown to have a lower complication rate, with a potential to become a diagnostic standard for the assessment of indeterminate biliary lesions with further refinements[38]. In a single center prospective study of thirty six patients with indeterminate biliary stricture, Ramchandani *et al*[36] from the Hyderabad group, showed that SpyBite had an overall accuracy of 82% in differentiating malignant from benign ductal lesions on an intention-to-treat analysis. The sensitivity of SpyGlass to obtain adequate tissue from indeterminate strictures could be upto 88%, especially when atleast 3 bites are taken. Sensitivity of diagnosing CCA by visual impression is 78% and by biopsy alone is 49%[39].

Endoscopic ultrasound scan

Endoscopic ultrasound scan (EUS) is a safe, accurate and technically feasible approach for diagnosing extrahepatic PSC. Lutz *et al*[40] demonstrated it to be an efficient tool for confirming suspected PSC, which has eluded diagnosis by ERCP or other modalities. Sensitivity and specificity of EUS-FNA for evaluation of biliary strictures ranges from 43% to 86% and 95% to 100% respectively[40-42]. The specific sonographic features include duct wall thickening greater than 1.5 mm, irregular CBD wall/caliber (change of wall thickness by $\geqslant$ 1 mm over 5 mm and caliber $\geqslant$ 2 mm over 5 mm ductal length) and the presence of perihilar lymph nodes at least 1 cm diameter, with an EUS diagnosis of PSC when two or more of above

criteria positive[43]. EUS enables refinement in disease detection and diminishes need for high risk invasive procedures[40]. In patients with a high index of suspicion of PSC with an inconclusive MRCP and EUS, core biopsy of the liver could be done safely in the same sitting (less than 1% risk of major complication), to look for small duct PSC and also to rule out cirrhosis, which would have prognostic implications[44-47]. Tumour seeding has been rarely reported with the FNA and hence some authorities advocate FNA of only suspicious lymph nodes[48]. Hence, we do not advocate EUS-FNA of the bile duct in a patient with suspected cholangiocarcinoma, who is a possible OLT candidate, until discussion at the tumor meeting with transplant surgeons. Direct biopsy using a cholangioscope would certainly be the preferred modality of tissue acquisition. EUS guided FNA has a significant role in diagnosing CCA when standard modalities are inconclusive, as it allows assessment and aspiration of malignant appearing lymph nodes[49,50].

Intraductal ultrasound

Intraductal ultrasound (IDUS) utilises a standard duodenoscope to insert a high frequency ultrasound transducer over a wire into the biliary system under fluoroscopic guidance. IDUS allows visualisation of the wall layers of the biliary strictures thereby providing an estimate of the extend of potentially cancerous infiltration[51]. This information is valuable in deciding treatment options. IDUS as an adjunct to ERCP guided tissue sampling significantly enhances the ability to distinguish malignant from benign strictures, it however is not an efficient modality assessing lymph nodes associated with malignant strictures[52]. Biliary cannulation with IDUS can be performed with ease, thereby avoiding the need for sphincterotomy; it provides detailed images of ductal and peri ductal tissues with high resolution. Additionally, when CCA is identified, IDUS may be employed for local staging in candidates prior to surgical resection[53].

Confocal laser endomicroscopy

Probe-based confocal laser endomicroscopy (pCLE) is a novel diagnostic technique that provides a virtual biopsy to facilitate subepithelial evaluation of the pancreatobiliary mucosa. It delivers microscopic information in real time and also provides dynamic information such as blood flow, cellular architecture, contrast uptake and leakage[54].

In a small single centre study of pCLE, Heif *et al*[55], showed a high technical success rate in patients with PSC and DS. Sufficient visualization was achieved in 95%, with sensitivity, specificity, positive predictive value and negative predictive values of 100%, 61.1%, 22.2% and 100% respectively, in detecting neoplasia. If verified in larger prospective studies, this could be potentially utilized for risk stratification of dominant strictures in patients with PSC[55].

ENDOSCOPIC THERAPY

PSC is characterized by inflammation and fibrosis leading to bile duct strictures. DS is defined as stenosis with a diameter of 1.5 mm in the common bile duct or 1 mm in the hepatic duct[21,56]. They develop in about forty percent of patients with PSC leading to significant biliary obstruction[57]. These predispose to stone formation, recurrent cholangitis and secondary biliary cirrhosis; also it may be a marker for underlying malignancy.

Traditionally ERCP has been employed for the stone removal that is the main indication for biliary sphincterotomy in PSC; balloon dilation *via* ERCP reduces stenosis thereby improving biliary flow and potentially preventing recurrent cholangitis[58,59]. Current therapy for stricture in PSC including balloon dilation, biliary stent placement and often a combination of both have become the mainstay of treatment, at least as a first line intervention[43,60]. Studies have established that repeated endoscopic therapy in patients with PSC is safe, the prognosis however worse in the subgroup of patients with dominant strictures at increased risk for development of cholangiocarcinoma[56].

An average of 3.46 ERCP's were needed per patient over a 8 year follow up study, with an improved observed survival rate of 82.8% at 4 years compared to 71.3% predicted survival (as per the Mayo Clinic natural history model)[58]. Endoscopic dilatation with short-term stenting is effective in benign dominant strictures and does not have predilection for malignant transformation or complications after transplantation[23]. Gotthardt *et al*[61] in a 20 year follow up of 171 patients have shown that repeated endoscopic therapy helps preserve a functioning common bile duct for many years, improving transplant free survival to 81% at 5 years and 52% at 10 years after initial endoscopic therapy. In a small subset of patients with DS in the extra hepatic duct without signs of cirrhosis, resection or bypass surgery may be performed, especially when endoscopic treatment fails[62].

Biliary sphincterotomy done in PSC is often a limited one, to minimize the reflux of enteric contents and ascending cholangitis[63]. Sphincterotomy prior to stent placement minimizes the chance of post ERCP pancreatitis (PEP)[64]. Stricture dilation could also be done using tapered-tip dilators (Cotton graded dilator) over a guide wire as a stand-alone or in combination with balloon dilatation[65]. In difficult cases, where only the wire could be passed through, a screw-tip dilator (Soehendra screw) could be employed[66]. In high grade stenosis, a Terumo guide wire could be used, since it has the added advantage of a very flexible tip[63]. Following this, stiff dilatation upto 7F facilitates balloon dilatation upto a target of 24F in the common duct and 18F in the hepatic ducts. Stiehl *et al*[57,67] have shown that even long segment stenosis (over 2 cm) of the common bile duct and shorter-segment intrahepatic stenosis within 2 cm of the hilum could be successfully

treated endoscopically.

Although controversial, there are interventional endoscopists, who advocate routine placement of one or more stents with frequent stent exchanges (every 6 to 8 wk), after dilatation with any of the above modalities, to prevent the stricture from reforming immediately due to the underlying fibrosis and elasticity[43]. International bodies like AASLD however, do not endorse this above practice, since there is no strong evidence demonstrating additional benefit of stenting over endoscopic dilatation[68]. Though results have been conflicting, there is evidence from a recent study in favour of additional stenting when clinically appropriate[68]. In cases of hilar strictures, it is preferable to gain access into both ducts first, as dilatation of one system somehow makes access to the other side more challenging[69].

Stents used in PSC could be either plastic or self-expandable metallic stents (SEMS). Teflon (PTFE) stents are the most commonly used ones, with longer patency[70]. However, fully/partially covered SEMS (CSEMS) have also been used for management of dominant strictures, though there are no randomized trials to support this[71-73]. The possible reasons why SEMS has not become standard of care of dominant strictures in PSC, is the theoretical risk of ascending cholangitis in this high risk group due to the larger caliber of the metal stent, in addition to not being cost effective compared to plastic stents in this situation. This is in addition to the potential risk of cholecystitis from obstruction of the cystic duct (in individuals who have not undergone cholecystectomy) and of obstruction of bile flow from the other lobe of the liver in case of hilar lesions.

Uncovered SEMS has been successfully used for palliation of inoperable CCA[56,74,75]. SEMS is preferred over plastic stents for patients with life expectancy over 3 mo[76]. For hilar strictures, stenting of one or both lobes and use of plastic stent or metallic stents continues to be debated, with ongoing research into the design of specifically tailored stents including cross wired stents and new plastic inside stent with thread (IT) stent[77-79].

EUS-guided palliation of malignant obstructive jaundice, when ERCP access fails has been gaining grounds and when expertise available replacing percutaneous drainage, since the latter is less appealing cosmetically with the external bag and inconvenient. This is mostly used for drainage of the obstructed left system (though there have been initial attempts to drain the right duct) using EUS-guided hepaticogastrostomy and of the main duct by a choledochoduodenostomy. Although technically feasible, the challenge is in the controlled deployment of the fully CSEMS, preferably in a single step, to minimize the risk of perforation, biliary peritonitis and stent migration[80-85]. These risks are minimized by the availability of lumen apposing metal stents. Endoscopic placement of nasobiliary drains to decompress the non-atrophic lobe has been done in some centers especially in Japan, to bridge the gap to surgery[79].

Biliary complications can occur in as many as 10% to 35% of patients after orthotopic liver transplantation with PSC recurrence in around 10%[86-88]. The most common biliary complications after OLT include biliary strictures (anastomotic or ischemic), bile duct leaks, common bile duct stones, and biliary casts, sphincter of Oddi/ampullary muscle dysfunction/spasm and r-PSC. With the advances in biliary endoscopy, majority of the complications could be managed with ERCP using regular techniques and tools. ERCP directed brachytherapy for locoregional disease control in cholangiocarcinoma, using photodynamic therapy or radiofrequency ablation, is promising, though still in its early stages[89,90]. They have comparable efficacy for local disease control and safety profile.

APPROACH TO THE PATIENT WITH SUSPECTED PSC

We recommend MRCP to be done as the initial diagnostic modality in suspected patients with PSC. ERCP with brush cytology and or biopsy, to date, continues to be the gold standard for diagnosis especially if the former is inconclusive, due to the surveillance and prognostic implications of making a correct and early diagnosis. EUS, IDUS and cholangioscopy could be utilized in the evaluation of patients, especially those with indeterminate dominant strictures, to get better cytologic yields to exclude early biliary dysplasia and cholangiocarcinoma. With further evidence and validation of EUS criteria for PSC, it might be done before ERCP in the diagnostic algorithm, especially considering its safety profile. Advancements in cytology including DIA and FISH should be considered to improve the yield, when ever available. The role of molecular markers and proteomics in diagnosis is still evolving. ERCP with repeated biliary dilatation with or without stenting is our current practice in management of benign strictures, in addition to routine use of antibiotic prophylaxis, as per BSG and ASGE recommendations. EUS guided biliary drainage procedures could be attempted in cases of failed SEMS deployment by ERCP for palliation of CCA. There is some evidence that endoscopic therapy could delay the need for orthotopic liver transplantation in patients with PSC.

CONCLUSION

Endoscopy has a pivotal role in the diagnosis and management of the condition, both pre and post orthotopic liver transplantation. Advances in endoscopy (complimented by cross sectional imaging) and ancillary cytologic testing would enhance earlier diagnosis, facilitating a surveillance protocol that could be used, to improve survival rates by timely curative therapy.

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