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Society of Gastrointestinal Endoscopy of India Consensus Guidelines on Endoscopic Ultrasound-Guided Biliary Drainage: Part I (Indications, Outcomes, Comparative Evaluations, Training)

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Abstract

Endoscopic management of bile duct obstruction is a key aspect in gastroenterology practice and has evolved since the first description of biliary cannulation by McCune et al in 1968. Over many decades, the techniques and accessories have been refined and currently, the first-line management for extrahepatic biliary obstruction is endoscopic retrograde cholangiopancreaticography (ERCP). However, even in expert hands the success rate of ERCP reaches up to 95%. In almost 4 to 16% cases, failure to cannulate the bile duct may necessitate other alternatives such as surgical bypass or more commonly percutaneous transhepatic biliary drainage (PTBD). While surgery is associated with high morbidity and mortality, PTBD has a very high reintervention and

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complication rate (~80%) and poor quality of life. Almost parallelly, endoscopic ultrasound (EUS) has come a long way from a mere diagnostic tool to a substantial therapeutic option in various pancreatico-biliary diseases. Biliary drainage using EUS-guidance (EUS-BD) has gained momentum since the first report published by Giovannini et al in 2001. The concept of accessing the bile duct through a different route than the papilla, circumventing the shortcomings of PTBD and sometimes bypassing the actual obstruction have enthused a lot of interest in this novel strategy. The three key methods of EUS-BD entail transluminal, antegrade, and rendezvous approach. Over the past decade, with growing experience, EUS-BD has been found to be equivalent to ERCP or PTBD for malignant obstruction with better success rates.

EUS-BD, albeit, is not devoid of adverse events and can carry fatal adverse events. However, neither the technique of EUS-BD, nor the accessories and stents for EUS-BD have been standardized.

Additionally, different countries and regions have different availability of the accessories making generalizability a difficult task. Thus, technical aspects of this evolving therapy need to be outlined. For these reasons, the Society of Gastrointestinal Endoscopy India deemed it appropriate to develop technical consensus statements for performing safe and successful EUS-BD.

Introduction

Endoscopic management of bile duct obstruction is a key aspect in gastroenterology practice and has evolved since the first description of biliary cannulation by McCune et al[1] in 1968. Over many decades, the techniques and accessories have been refined and currently, the first-line management for extrahepatic biliary obstruction is endoscopic retrograde cholangiopancreaticography (ERCP). However, even in expert hands the success rate of ERCP reaches up to 95%.[2] In almost 4 to 16% cases, failure to cannulate the bile duct may necessitate other alternatives such as surgical bypass or more commonly percutaneous transhepatic biliary drainage (PTBD).[3] While surgery is associated with high morbidity and mortality, PTBD has a very high reintervention and complication rate (~80%) and poor quality of life. Almost parallelly, endoscopic ultrasound (EUS) has come a long way from a mere diagnostic tool to a substantial therapeutic option in various pancreatico-biliary diseases. Biliary drainage using EUS-guidance (EUS-BD) has gained momentum since the first report published by Giovannini et al in 2001.[4] The concept of accessing the bile duct through a different route than the papilla, circumventing the shortcomings of PTBD and sometimes bypassing the actual obstruction have enthused a lot of interest in this novel strategy. The three key methods of EUS-BD entail transluminal, antegrade, and rendezvous approach. Over the past decade, with growing experience, EUS-BD has been found to be equivalent to ERCP or PTBD for malignant obstruction[5–7] with better success rates.

EUS-BD, albeit, is not devoid of adverse events and can carry fatal adverse events. However, neither the technique of EUS-BD, nor the accessories and stents for EUS-BD have been standardized.

Additionally, different countries and regions have different availability of the accessories making generalizability a difficult task. Thus, technical aspects of this evolving therapy need to be outlined. For these reasons, the Society of Gastrointestinal Endoscopy India (SGEI) deemed it appropriate to develop technical consensus statements for performing safe and successful EUS-BD.

Aims

The aim is to discuss and develop consensus statements/recommendations on the key technical aspects in EUS-BD to optimize performance, including the choice of scope, needle, wire, and other accessories used as well as certain EUS-BD-technique specific nuances.

Methods

In 2022, the SGEI board convened the SGEI EUS-BD Consensus Working group comprising of experts in the field of therapeutic endosonography, who are involved in training. Topic-specific task was assigned to the working group members and clinical key questions were generated by them for discussion in the consortium. Searches were performed on Medline and the Cochrane Library till March 2022. The level of evidence for each statement was graded as per the Grading of Recommendation, Assessment, Development and Evaluations system.[8] Recommendations were drafted and the strength was ascertained based on the level of evidence. The members of the expert group met in person to discuss and vote on the recommendations. Voting was done by electronic keypads. Statements with more than 80% total or partial agreement were accepted, while those with major disagreements were discarded or modified after discussion.

A second and final round of voting was done to record all statements finally agreed upon. The recommendations developed by this expert group were divided into two parts: (1) general guidance on indications and outcomes, and (2) the technical aspects of "how to do" EUS-BD. This article represents the outcome of the Delphi process resulting in development of guidelines on indications, outcomes, and training.

Recommendation 1

SGEI recommends EUS-BD should be performed in centers having multidisciplinary expertise in interventional endoscopy, interventional radiology, and surgery.

Agreement: 100%, Evidence level- IV, Recommendation grade D

Centers performing EUS-BD should have a multidisciplinary team comprising of interventional endoscopist, surgeons, and intervention radiologists to support EUS-BD.[9,10] Pooled adverse event rates have been reported to be 16% for EUS-BD in a meta-analysis with severe adverse events like perforations, bile leaks, and bleeding with a mortality of 0 to 3%.[11,12] The interventional endoscopist performing the procedure should have vast experience in ERCP and therapeutic EUS as the endoscopist competence determines the outcome of procedure.[13–15]

To manage severe adverse events and failure of EUS-BD interventional radiological and hepatopancreaticobiliary surgical background is a must.[16,17] In patients with failed EUS choledochoduodenostomy (EUS-CDS) with punctures crossing the peritoneal cavity, PTBD is required. In patients with maldeployment of hepaticogastrostomy (HGS) stent, with proximal end in the peritoneal cavity after failure of endoscopic correction emergency salvage surgery with repositioning of the stent may be required.[18]

Recommendation 2

SGEI recommends that the selection of EUS-BD procedures should be individualized depending upon patient's clinical condition, site of biliary obstruction, presence of duodenal obstruction, resectability, and surgical reconstruction.

Agreement: 100%, Evidence level- IV, Recommendation grade D

EUS-BD can be performed either by EUS-assisted rendezvous (EUS-RV), or by EUS-guided transluminal stenting including EUS-CDS or EUS-HGS, or by antegrade transpapillary stent (EUS-AGS) placement. The appropriate procedure should be chosen based on the condition of the patient, location of the bile duct obstruction, presence of duodenal obstruction, resectability, and surgical reconstruction.

In patients with hilar biliary obstruction EUS-CDS is not indicated and thus EUS-RV, EUS-AGS, or EUS-HGS should be used. Similarly, in patients with duodenal obstruction or ampullary invasion, EUS-RV is not indicated. However, in patients in whom different approaches are possible comparative studies are lacking and various algorithms have been proposed. Park et al[19] in his study suggested an algorithm for selection of the type of EUS-BD procedure. He proposed that EUS-RV is the first choice for patients with failed ERCP and an accessible ampulla, whereas EUS-HGS or CDS is the first choice for patients with duodenal obstruction depending on the location of the biliary obstruction. Use of the algorithm yielded a success rate of $>90\%$. In an another study which based procedure selection on the clinical conditions, had a success rate and adverse events similar to those shown by Park et al.[7] Khashab et al proposed a standardized approach for malignant biliary obstruction suggesting EUS-RV should be used first after failed ERCP, and if EUS-RV fails, EUS-CDS/HGS should be done.[20] They showed that the rendezvous and the transluminal techniques have similar efficacy and safety.

Iwashita et al in a prospective pilot study reported the efficacy and safety of EUS-AGS for unresectable malignant biliary obstruction in patients with a surgically altered anatomy and concluded that EUS -AGS is a feasible and safe procedure.[21] Weilert proposed an algorithm, where EUS-AGS using a transgastric intrahepatic bile duct approach was used for patients with failed ERCP.[22] In case of failure of EUS-AGS, EUS-HGS was done and EUS-CDS was performed if HGS failed. Intrahepatic bile duct approach was effective in 80% of cases. In a systematic review of EUS-BD in patients with a surgically altered anatomy it was found that EUS-BD after failed ERCP was as safe and effective as in those with a normal anatomy.[23]

In a study the location of the bile duct obstruction was used to determine whether EUS-CDS or EUS-HGS will be used.[24] For hilar biliary obstruction HGS was used while CDS was used for distal biliary obstruction and they reported technical success of 95.5%, clinical success of 90.5%, and adverse event rates of 9.5%. In another study Gupta et al found that the success rate and adverse event rates were similar between EUS-CDS and EUS-HGS.[25] In a study in patients with combined duodenal and distal biliary obstruction where both EUS-CDS and EUS-HGS can be used, it was shown that EUS-HGS has a significant risk of adverse events and it was proposed that, EUS-CDS may be the first choice in this subset of patients.[26] Li et al[27] compared EUS-HGS and EUS-CDS in a meta-analysis of 12 studies including 2 randomized controlled trials (RCTs) and showed that the cumulative technical success and clinical success for EUS-CDS and EUS-HGS was 95.0% (288/303) and 93.1% (268/288), and 96.6% (309/320) and 91.3% (282/309), respectively. Compared with EUS-HGS, the pooled odds ratio (OR) was 0.74 (95% confidence interval [CI] 0.33–1.65; $p=0.46$) for EUS-CDS technical success and 0.94 (95% CI 0.56–1.59; $p=0.83$) for clinical success suggesting no significant difference between CDS and HGS. The pooled difference in means of procedure time of EUS-CDS and EUS-HGS was –2.68 (95% CI –5.12 to –0.24; $p=0.03$). Compared with EUS-HGS, the pooled OR of early adverse events for EUS-CDS was 0.58 (95%

CI: 0.36–0.93; $p = 0.02$). EUS-CDS and EUS-HGS have equal high technical and clinical success, but EUS-CDS has a slightly short procedure time and less early adverse events compared with EUS-HGS.

Thus, in patients with distal common bile duct obstruction, both procedures are feasible. The choice of the procedure is unclear, but depends on a combination of factors including operator's expertise, stent patency, risk of adverse events, presence of dilated bile duct or biliary radicals, duodenal stenosis, and altered anatomy.

Recommendation 3

SGEI recommends imaging prior to EUS-BD procedures.

Agreement: 100%, Evidence level- IV, Recommendation grade D

High-quality cross-sectional imaging provides site and location of biliary stricture, delineating the type of hilar obstruction and other relevant bile duct anatomy, and a roadmap for stent placement. It provides the site and location of biliary stricture delineating the type of hilar obstruction and other relevant bile duct anatomy. In patients with hilar obstruction roadmap of the biliary anatomy is a must as inadvertent contrast injection in a nondrainable segment could result in cholangitis. Thus, magnetic resonance cholangiopancreatography prior to intervention is required in patients with hilar obstruction. In patients with distal bile duct obstruction, a contrast-enhanced computed tomography could be performed prior to EUS-BD.

There is a lack of evidence regarding the utility of a roadmap in EUS-BD; however, as in ERCP it has a crucial role to play.[28]

Recommendation 4

SGEI suggests cautious approach while performing EUS-BD in patients with ascites and/or coagulopathy.

Agreement: 100%, Evidence level- IV, Recommendation grade D

Concerns of EUS-BD in patients with ascites include the risk of failure of formation of mature fistula after procedure and risk of peritonitis due to leakage of bile and intestinal contents. It has been suggested that EUS-BD should not be performed in cases with moderate or tense ascites or ascites present in the puncture route.[29] In addition, the indications for EUS-BD should be carefully assessed even in cases with a small amount of ascites or without ascites in the puncture route. However the concern due to ascites has not been supported in the available scanty literature. In a retrospective feasibility pilot study of EUS-BD for malignant biliary obstruction associated with ascites, 31 patients were included: 20 patients without ascites (group1) and 11 with ascites (group2).[30] Nineteen patients underwent EUS-HGS (6 in group 2), and 12 underwent EUS-CDS (5 in group 2). The procedure was technically successful in all patients. Clinical success was achieved in 95% in group 1 and 64% in group 2 ($p = 0.042$). Overall rates of procedural-related complications were similar in groups 1 and 2 (20 and 9%, respectively, $p = 0.63$). Similarly, the rates of major complications (15% vs. 9%, respectively, $p = 0.639$) were no different in group 1 and group 2. Stent migration occurred in one patient in each group, intra- or postprocedural bleeding occurred in two patients in group 1, which was conservatively managed, and one patient in group 1 was presented with biliary leakage. Stent patency and the number of reinterventions were not significantly different. However, Kamata et al reported a case of HGS stent migration in patient with lower bile duct obstruction with massive ascites.[31] When a therapeutic EUS procedure is still deemed necessary, a preprocedural paracentesis may be helpful before embarking on such a procedure.

Therapeutic EUS procedures are classified "high risk" based on the guideline on antiplatelet or anticoagulation therapy use in endoscopy.[32] Before a therapeutic EUS procedure like EUS-BD, anticoagulant therapy should be temporarily discontinued, while dual-antiplatelet therapy should be converted to aspirin monotherapy wherever possible. However, case series have described successful EUS-BD in patients on anticoagulant and/or antiplatelet therapy without increased risk of bleeding.[33,34] It has been suggested that the radial expansion forces of the fully covered self-expanding metal stents likely contribute to a reduced risk of periprocedural bleeding by providing a tamponade effect on the intraparietal blood vessels.

Recommendation 5

SGEI recommends prophylactic antibiotics for EUS-BD.

Agreement: 100%, Evidence level- IV, Recommendation grade D

Prophylactic broad-spectrum antibiotics may prevent infectious adverse events especially potential peritonitis or progression of peritonitis due to leakage of bile or gastrointestinal (GI) contents following EUS-BD. However, no study has assessed the effectiveness of prophylactic antibiotics in patients undergoing EUS-BD. Since EUS-BD is similar to other biliary interventions like ERCP with contrast injection and manipulation done in an obstructed biliary system, there is a risk of introducing bacteria. The use of antibiotics has been shown to prevent cholangitis, bacteremia, septicemia, and pancreatitis in ERCP, particularly in obstructed biliary system.[35] Thus, prophylactic antibiotics covering biliary flora

such as enteric Gram-negative organisms and enterococci should be used prior to EUS-BD.

Recommendation 6

SGEI recommends that EUS-BD should preferably be done under deep sedation or general anesthesia.

Agreement: 100%, Evidence III, Recommendation grade C

The main goal of deep sedation for GI endoscopy is to reduce patient discomfort, improve the outcome, and mitigate the patient's memory of the event. Patients undergoing EUS-BD should have adequate airway protection to prevent aspiration Therapeutic EUS may be performed under general anesthesia or in deep sedation without compromising safety.[36]

Recommendation 7

SGEI suggests CO_2 insufflation while performing EUS-BD procedures.

Agreement: 100%, Evidence level- IV, Recommendation grade D

Endoscopy procedures require gas insufflation to allow the progression of the endoscope and proper examination of the mucosa. It is well established that CO_2 causes less abdominal discomfort because it is absorbed faster than air from the gut and then expired through the lungs. In the American Society for Gastrointestinal Endoscopy technology review it is proposed that CO_2 insufflation in many types of digestive endoscopy procedures is safe and associated with less abdominal pain compared with air insufflation.[37] In a study investigating the role of CO_2 insufflation on abdominal discomfort after EUS it was shown that CO_2 insufflation was associated with lower abdominal discomfort scores at 3 hours after the procedure, compared with air insufflation.[38]

Moreover, it was found that better quality of the EUS images were obtained with CO_2 versus air insufflation.

Recommendation 8

SGEI recommends both EUS-BD and ERCP are first-line options for biliary drainage in distal malignant biliary obstruction.

Agreement: 100%, Evidence level: 1-A, Recommendation grade A

EUS-BD has been compared with ERCP in three RCTs for primary drainage of malignant distal biliary obstruction.[6,7,39] The technical and clinical success rates of EUS-BD and ERCP were similar. One of the RCTs reported fewer adverse events, longer stent patency, and lesser reintervention favoring EUS-BD. Self-expanding metal stents was used in all the studies in both EUS-BD and ERCP groups. In a systematic review and meta-analysis of five studies, 361 patients (190 in the ERCP group and 171 in the EUS group), it was found that the technical and clinical success were comparable.[40] The overall adverse events were similar between the two groups. In the ERCP group, 9.5% of patients developed procedure-related pancreatitis while no patient developed pancreatitis in the EUS group (risk difference = 0.08%, $p = 0.02$). The rate of reintervention was similar in the two groups. In another meta-analysis of nine studies including 634 patients comparing EUS-BD and ERCP-guided biliary drainage the technical success, clinical success, and adverse events were similar; however, EUS-BD was associated with significantly less reintervention versus ERCP-BD (OR, 0.36, 95% CI, 0.15–0.86).[41]

EUS-BD done in patients with resectable malignant biliary obstruction has not been reported to complicate subsequent surgical resection; however, only two retrospective studies, including a limited number of patients, have assessed the outcomes of preoperative lumen-apposing metal stent (LAMS) placement on surgical outcome.[39,42]

Recommendation 9

EUS-BD is preferred over PTBD as a rescue option for distal malignant biliary obstruction after failed ERCP.

Agreement: 100%, Evidence Ia, Recommendation grade A

For patients with failed ERCP, PTBD is a widely available effective technique, however, it may be associated with significant morbidity.[43] EUS-BD has emerged as an acceptable alternative in patients with obstructive jaundice and failed ERCP. Multiple studies, prospective or retrospective, have shown similar technical success (86–100%), with similar or higher clinical success and fewer adverse events, when using EUS-BD.[44–48] Lee et al[49] performed an RCT comparing EUS-guided and percutaneous drainage for malignant distal biliary obstruction. The RCT included 66 patients, 34 in the EUS-BD group and 32 in the PTBD group and showed similar technical success (94.1% vs. 96.9%) and clinical success (87.5% vs. 87.1%) in the two groups; however, the EUSB-BD group had a significantly lower incidence of adverse events compared with PTBD (8.8% vs. 31.2%, $p = 0.022$). In a meta-analysis[5] of nine studies including 483 patients, EUS-BD had comparable technical success to PTBD (OR, 1.78; 95% CI, 0.69–4.59), but EUS-BD was associated with higher clinical success (OR, 0.45; 95% CI, 0.23–0.89) and fewer adverse events (OR, 0.23; 95% CI, 0.12–0.47). Hayat et al in a meta-analysis of 10 studies, including 6 RCTs and 4 retrospective studies compared EUS-BD with PTBD.[50] There was no difference between technical and clinical success rates; however, procedural adverse events and total adverse events were significantly higher in the PTBD group. The reintervention

rate which was reported in six of these studies was 3.7% in the EUS-BD group versus 13.8% in the PTBD group. This meta-analysis concluded that EUS-BD is equally effective but safer in terms of immediate and total adverse events than PTBD in patients with malignant biliary strictures with failed ERCP.

Recommendation 10

SGEI recommends multidisciplinary approach for biliary drainage in malignant hilar obstruction based upon the type of block, resectability, and local expertise.

Agreement: 92.85%, Evidence level: III, Recommendation C

In patients with malignant hilar obstruction the endoscopic management is difficult and should be performed only in tertiary referral centers with experienced interventional endoscopist. The exact delineation of the biliary anatomy, the type of block, resectability of the lesion, performance status of the patients, and the primary objective of biliary drainage (preoperative or as palliation) needs to be ascertained. Multidisciplinary team involving interventional endoscopist, surgeon, oncologist, and interventional radiologist is required to decide the optimal biliary drainage strategy, placement of plastic or metal stent, and avoiding drainage of atrophic liver segments. In Bismuth type III and IV strictures, PTBD is preferred over ERCP or a combination of PTBD and ERCP is used.[51] Moole et al[52] in a systematic review and meta-analysis in Bismuth type III and IV strictures showed that PTBD achieved adequate biliary drainage more frequently than ERCP (OR 2.53, 95% CI 1.57–4.08). In Bismuth type III and IV strictures drainage of more than 50% of the liver volume is required, which is achieved by stenting of right and left duct or stenting of both right-sided anterior and posterior ducts which is usually achieved by ERCP.[53]

EUS-BD is usually used in surgically unresectable disease or as salvage therapy after metal stent placement in unresectable malignant hilar strictures. Retrospective studies[54–56] have shown that in malignant hilar biliary obstruction, EUS-BD has a technical success rates of 90%. Kongkam et al[57] in a prospective, multicenter study compared a combination of ERCP and EUS-BD to bilateral PTBD and found that the combined ERCP/EUS-BD approach had a less of recurrent biliary obstruction at 3 and 6 months, with similar adverse events and mortality rates.

Recommendation 11

EUS-CDS provides high technical and clinical success in patients with malignant distal biliary obstruction.

Agreement: 100%, Evidence Level IA, Recommendation A

Several prospective and retrospective studies[6,39,58–76] have shown that the technical success rates of EUS-CDS range from 88.8 to 100%, and the clinical success rate ranges from 85.5 to 100%. Further, the overall technical success rate is 95.0% (939/988), and the overall clinical success rate is 97.0%.[77] The main indication of EUS-CDS in these studies is failed ERCP; however, few studies which have evaluated the clinical efficacy for primary drainage found high technical and clinical success.[6,7,39] EUS-CDS can be performed using self-expandable metal stent (SEMS) or LAMS. Amato et al did a systematic review and meta-analysis of LAMS or SEMS in EUS-CDS which included 31 studies (820 patients).[78] The pooled rates of clinical and technical success were 93.6 and 94.8% for LAMS, and 91.7 and 92.7% for SEMS, respectively. They concluded that the clinical and technical success, postprocedure adverse events, and reintervention rates were similar between LAMS and SEMS.

Recommendation 12

EUS-HGS provides high technical and clinical success in patients with distal malignant biliary obstruction.

Agreement: 100, Evidence Level: IA, Recommendation grade A

The rates of technical and clinical success ranged from 65 to 100% and from 73 to 100%, respectively, in various series of EUS- HGS.[6,13,44,54,60,79–84] Mao et al[85] in a recent systematic review and meta-analysis compared EUS-CDS and EUS-HGS in malignant biliary obstruction. This systematic review included 13 studies and 759 patients (EUS-CDS: 359, EUS-HGS: 400), and reported a comparable technical success (EUS-CDS: 94.2%, EUS-HGS: 94.8%) and clinical success (EUS-CDS: 90%, EUS-HGS: 89.5%). It was concluded that EUS-CDS and EUS-HGS have comparable technical and clinical success rates, adverse events, and overall survival. However, EUS-CDS has less reintervention and stent obstruction. In another meta-analysis of 12 studies with 623 patients (EUS-CDS: 303 and EUS-HGS: 320), the cumulative technical success and clinical success for EUS-CDS and EUS-HGS was 95.0 and 93.1% and 96.6 and 91.3%, respectively.[27] The cumulative early adverse events for EUS-CDS and EUS-HGS was 12.2 and 17.5%, respectively.

Recommendation 13

EUS-HGS provides high technical and acceptable clinical success in patients with malignant hilar biliary obstruction.

Agreement: 100%, Evidence level: III, Recommendation grade C

EUS-HGS in malignant hilar biliary obstruction is indicated in patients who have failed ERCP, surgically altered anatomy, or in patients with failed reintervention of occluded transpapillary stents. EUS-HGS is mainly used for inoperable patients. In patients with hilar block the techniques used for drainage

include EUS-HGS, EUS-guided hepaticoduodenostomy (EUS-HDS), bridging method, or a combination of ERCP and EUS (CERES).[86] Few case series have reported use of EUS-HGS in hilar block. In a case series by Ogura et al EUS-BD as a rescue was done after failed ERCP in 10 patients, with EUS-HGS in 8 patients and EUS-HDS in 2 patients.[87] Technical success was 100% while clinical success was achieved in 90%. In another series by Moryoussef et al,[55] 18 patients with hilar biliary obstruction and failed ERCP underwent EUS-HGS, technical success was achieved in 94% with clinical success being 72% at 1 week and 68% at 30 days. The reintervention rate was 16.4%. The low rate of clinical success was possibly related to the type of block which was, type I/II in 47%, type III in 47%, and type IV in 6%. In another series by Minaga et al of 30 patients, 16.6% had type II block, 43.3% had type III block, and 40% had type IV block.[54] Technical success was 96.6% and clinical success in those with technical success was 75.4%. In this series, 28 patients underwent EUS-HGS and 2 patients underwent EUS-HDS. Median stent patency duration was only 62.5 days. On multivariate analysis, Bismuth type IV block was the only factor associated with clinical ineffectiveness of EUS-BD.

Recommendation 14

EUS-guided antegrade biliary drainage has reasonable technical and clinical success with acceptable adverse events rate.

Agreement: 100%, Evidence level: III, Recommendation C

EUS-guided antegrade stenting for patients with 20 or more patients has been reported only in a few studies. In the study by Iwashita et al[88] of 20 patients, the technical and clinical success was 95%. Rate of adverse events was 20%, including mild pancreatitis in three and mild fever in one patient, which were successfully managed conservatively. In another retrospective study by Vanella et al[89] of 45 patients the technical success was 86.5% and clinical success was 75.1%. The success rate of EUS-AGS is inferior to that of EUS-HGS or EUS-CDS owing to the difficulty of guidewire passage and stent delivery system insertion across the strictures. In a recent large retrospective study on EUS-AGS in 54 patients,[90] indication was palliative in 34 (62.9%) patients and preoperative in 20 (37%) patients. Technical success of EUS-AG was 88.7%. Clinical success was seen in 95.7% patients. No procedure-related severe adverse events were seen.

Recommendation 15

EUS-RV is an acceptable salvage method for failed selective biliary cannulation.

Agreement: 100%, Level of evidence III, Grade of recommendation C

A large number of single-center retrospective studies[91–96] including more than 30 patients has shown technical success ranging from 65 to 98% with adverse events in 8 to 23% with EUS-RV. In a prospective observational study involving 12 centers and 20 patients EUS-RV was done in failed biliary cannulation in benign and resectable malignant biliary disorders with an overall technical success of 85% and adverse events of 15% (pancreatitis and biliary peritonitis).[97] Klair et al[98] did a systematic review and a proportion meta-analysis of EUS-RV after failed biliary cannulation involving 12 studies with 342 patients. The pooled rate of technical success was 86.1% while the pooled rate of clinical success was 80.8%. The pooled rate of overall adverse events was 14% (95% CI: 10.5–18.4). Due to the risk of adverse events EUS-RV should be done in centers with expertise in interventional EUS.

Training Requirements

Recommendation 16

Competence in diagnostic EUS including fine needle biopsy (FNB), and therapeutic ERCP is a prerequisite before initiation of training for EUS-BD.

Agreement: 100%, Evidence level IV, Recommendation grade D

To achieve proficiency in therapeutic EUS, competence in diagnostic EUS is mandatory.[15] As therapeutic EUS require handling of wire and stent placement, hence competence in ERCP is required whereas competence in therapeutic luminal endoscopy is advantageous. Furthermore, it is suggested that EUS-guided fine needle aspiration/FNB can be commenced early in training to acquire safe handling and appropriate positioning of the scope. After acquiring competence in diagnostic EUS, therapeutic EUS should be started with less drainage of pancreatic fluid collection and then to advance EUS interventions like EUS-BD, EUS-guided gallbladder drainage, or EUS-guided gastroenterostomy.

In a study by Tyberg et al[99] about the learning curve in EUS-BD, consecutive 72 patients undergoing EUS-BD by an operator were included over 6 years' period. It was found the operator is able to achieve reduction in procedure time over successive cases, with efficiency reached at 32 cases. For mastery approximately 100 cases are required.

Recommendation 17

Training for EUS-BD should be initiated on models whenever available.

Agreement: 100%, Evidence level IV, Recommendation grade D

To be efficient in EUS-BD the training needs to be initiated in a stepwise manner. Simulation-based training refers to a training tool whereby repetitive instructions are provided in a model without anxiety and risks involved in a live patient.[15] This may include mechanical simulators, animal models, and computer-based simulators. Following simulation-based training, hands-on training may be imparted.

Dhir et al[100] did a prospective observational feasibility study of a novel ex vivo model for hands-on teaching of and training in EUS-guided biliary drainage. A prototype of dilated biliary system was created using computer-aided design and three-dimensional (3D) printing for manipulation of guidewire and EUS-CDS and EUS-AGS. They concluded that the 3D printing bile duct prototype appears suitable for teaching and training in the various steps of EUS-BD.

Conflict of Interest
None declared.

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