Communication from the ASGE Standards of Practice Committee

GUIDELINE

ASGE American Society for Gastrointestinal Endoscopy

American Society for Gastrointestinal Endoscopy guideline on the role of endoscopy in the diagnosis and management of solid pancreatic masses: summary and recommendations

Prepared by: THE ASGE STANDARDS OF PRACTICE COMMITTEE

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This clinical practice guideline from the American Society for Gastrointestinal Endoscopy (ASGE) provides an evidence-based approach for the role of endoscopy in the diagnosis and management of pancreatic masses. This document was developed using the Grading of Recommendations Assessment, Development and Evaluation framework and addresses *needle selection* (fine-needle biopsy [FNB] needle vs FNA needle), *needle caliber* (22-gauge vs 25-gauge needles), *FNB needle type* (novel or contemporary [fork-tip and Franseen] vs alternative FNB needle designs), and *sample processing* (rapid on-site evaluation [ROSE] vs no ROSE). In addition, this guideline addresses *stent selection* (self-expandable metal stent [SEMS] vs plastic stent), *SEMS type* (covered [cSEMS] vs uncovered [uSEMS]), and *pain management* (celiac plexus neurolysis [CPN] vs medical analgesic therapy). In patients with solid pancreatic masses undergoing EUS-guided tissue acquisition (EUS-TA), the ASGE recommends FNB needles over FNA needles. With regard to needle caliber, the ASGE suggests 22-gauge over 25-gauge needles. When an FNB needle is used, the ASGE recommends using either a fork-tip or a Franseen needle over alternative FNB needle designs. After a sample has been obtained, the ASGE suggests against the routine use of ROSE in patients undergoing an initial EUS-TA of a solid pancreatic mass. In patients with distal malignant biliary obstruction undergoing drainage with ERCP, the ASGE suggests using SEMSs over plastic stents. In patients with proven malignancy undergoing SEMS placement, the ASGE suggests using cSEMSs over uSEMSs. If malignancy has not been histopathologically confirmed, the ASGE recommends against the use of uSEMSs. Finally, in patients with unresectable pancreatic cancer and abdominal pain, the ASGE suggests the use of CPN as an adjunct for the treatment of abdominal pain. This document outlines the process, analyses, and decision approaches used to reach the final recommendations and represents the official ASGE recommendations on the above topics. (Gastrointest Endosc 2024;■:1-11.)

This guideline document was prepared by the Standards of Practice Committee of the American Society for Gastrointestinal Endoscopy using the best available scientific evidence and considering a multitude of variables including but not limited to adverse events, patient values, and cost implications. The purpose of these guidelines is to provide the best practice recommendations that may help standardize patient care, improve patient outcomes, and reduce variability in practice. We recognize that clinical decision-making is complex. Guidelines therefore are not a substitute for a clinician's judgment. Such judgements may at times seem contradictory to our guidance because of many factors that are impossible to fully consider by guideline developers. Any clinical decisions should be based on the clinician's experience, local expertise, resource availability, and patient values and preferences. This document is not a rule and should not be construed as establishing a legal standard of care or as encouraging,

advocating for, mandating, or discouraging any particular treatment. Our guidelines should not be used in support of medical complaints, legal proceedings, and/or litigation, as they were not designed for this purpose.

Pancreatic cancer is the second most common GI malignancy and the third leading cause of cancer-related death in the United States.[1] EUS plays an essential role in tissue acquisition (TA) of solid pancreatic masses and histologic diagnosis of pancreatic cancer. Endoscopists performing EUS-guided TA (EUS-TA) of pancreatic masses must select a needle from among a large variety of commercially available needle types (FNA needle or fine-needle biopsy [FNB] needle), calibers, and tip designs. After each needle pass, rapid on-site evaluation (ROSE) has often been used to guide the number of passes needed to obtain an adequate sample. In view of evolving needle designs, there is an impetus to provide guidance in needle selection and use of ROSE for EUS-TA of solid pancreatic masses.

Additionally, patients with a solid pancreatic head mass often present with obstructive jaundice and require biliary drainage with ERCP. Endoscopists performing ERCP need to select between plastic stents, covered self-expandable metal stents (cSEMS), and uncovered self-expandable metal stents (uSEMS). Deciding the optimal stent selection to manage patients with distal malignant biliary obstruction is challenging for endoscopists.

Abdominal pain in patients with pancreatic cancer is common and often severe.[2] Endoscopists have the ability to perform EUS-guided celiac plexus neurolysis (CPN), which aims to ablate the neurons of the celiac ganglia to alleviate pain. However, guidance is limited on the role of CPN for the management of abdominal pain in patients with pancreatic cancer.

In 2016, the American Society for Gastrointestinal Endoscopy (ASGE) released a guideline on the role of endoscopy in the evaluation and management of patients with solid pancreatic neoplasia.[3] In view of several new and pertinent publications over the past 7 years, the ASGE has developed updated evidence-based guidelines on this topic.

METHODS

This document was prepared by the Standards of Practice Committee of the ASGE and was conceptualized and conducted according to the Grading of Recommendations Assessment, Development and Evaluation.[4-6] Evidence was presented to a panel of experts representing various stakeholders including an advanced endoscopist, surgical oncologist, and medical oncologist. A patient advocate was also included. All panel members were required to disclose potential financial and intellectual conflicts of interest, which were addressed according to ASGE policies. In developing these recommendations, we took into consideration the certainty in the evidence, benefits and harms of different management options, feasibility, patient values and preferences, resource utilization, cost-effectiveness, and health equity. The final wording of the recommendations indicating direction and strength were approved by all members of the panel and the ASGE governing board. Stronger recommendations are typically stated as "we recommend…," whereas weaker recommendations are indicated by phrases such as "we suggest…." These guidelines addressed the following clinical questions using the Grading of Recommendations Assessment, Development and Evaluation format:

1. In patients with solid pancreatic masses undergoing EUS-TA, are FNB needles superior to FNA needles?
2. In patients with solid pancreatic masses undergoing EUS-TA, are 22-gauge needles superior to 25-gauge needles?
3. In patients with solid pancreatic masses undergoing EUS-guided FNB sampling (EUS-FNB), are novel or contemporary FNB needles (fork-tip and Franseen) superior to alternative FNB needles?
4. In patients with solid pancreatic masses undergoing EUS-TA, is ROSE beneficial as compared with no ROSE?
5. In patients with distal malignant biliary obstruction undergoing ERCP, are SEMS superior to plastic stents?
6. In patients with distal malignant biliary obstruction undergoing ERCP with SEMS, are cSEMS superior to uSEMS?
7. In patients with pancreatic cancer–related abdominal pain, is CPN better than medical analgesic therapy alone?

Relevant clinical outcomes included survival, diagnostic accuracy, sample adequacy, high-quality specimens, diagnostic yield, number of needle passes, need for reinterventions, stent patency, cholangitis rates, surgical resectability, pain intensity, opioid use, quality of life, and adverse events.

External review

The guideline was reviewed by the *Gastrointestinal Endoscopy* Editorial Board and the ASGE Governing Board and was made available for public comment on the ASGE website.

RESULTS AND SUMMARY OF RECOMMENDATIONS

Details of our literature searches, data analyses, pooled-effects estimates, evidence profiles, forest plots, and panel deliberation for each outcome can be found in the Methodology and Review of Evidence document that accompanies this Summary and Recommendations document. A summary of our final recommendations is listed in Table 1.

TABLE 1. Summary of recommendations

Setting	Grading of Recommendations Assessment, Development and Evaluation recommendation	General concepts
EUS sampling	For patients with a solid pancreatic mass undergoing EUS-TA, the ASGE recommends FNB over FNA needles (strong recommendation/moderate quality of evidence)	• Use a linear echoendoscope to identify the lesion and to advance the needle into the lesion • Use color Doppler to identify and avoid interposing vessels
	For patients with a solid pancreatic mass undergoing EUS-TA, the ASGE suggests 22-gauge over 25-gauge needles (conditional recommendation/moderate quality of evidence)	• If the 22-gauge needle cannot be advanced into the lesion, switch to a 25-gauge needle • A 25-gauge needle may be considered when a 22-gauge needle is expected to have limited manipulability (eg, excessive endoscope torquing)
	Among patients with a solid pancreatic mass undergoing EUS-FNB, the ASGE recommends using novel or contemporary FNB needles (Fork-tip or Franseen) over alternative designs (strong recommendation/ moderate quality of evidence)	• Either a Fork-tip or Franseen needle can be used • Use suction with slow stylet withdrawal and/or a 5- to 20-mL syringe • Sample the lesion using a fanning technique • Maintain echoendoscopic visibility of the needle tip during sampling
	In patients with a solid pancreatic mass undergoing EUS-TA, the ASGE suggests against routine use of ROSE (conditional recommendation/low quality of evidence)	• Express the tissue out of the needle using an air flush; reinsert the stylet if this does not work • If an FNB needle is used, perform 2-4 passes and place the sample directly into a 10% formalin jar • Consider using macroscopic on-site evaluation to guide the number of passes required • If an FNA needle is used, perform 4-7 passes and place the sample in CytoLyt solution or consider using ROSE • Circumstances to consider ROSE: o Prior nondiagnostic EUS o Lesion is not clear on EUS or is obscured by artifact (eg, stent, pancreatitis) o Preliminary diagnosis may guide immediate decisions (eg, biliary stent selection, celiac plexus neurolysis, management of gastric outlet obstruction)
ERCP stent placement	For patients with distal malignant biliary obstruction undergoing ERCP, the ASGE suggests using SEMS over plastic stents (conditional recommendation/low quality of evidence)	• In patients with a native papilla, consider a biliary sphincterotomy before stent insertion • In patients with a pancreas mass who undergo simultaneous EUS-TA and have high suspicion of malignancy, consider covered SEMS • In patients with a pancreas mass who do not undergo simultaneous EUS-TA, consider ERCP with tissue acquisition and plastic stents • In patients with pancreatic head cancer with liver metastasis or expected survival of <3 mo, consider plastic stents • In patients who have planned surgical resection within 3 mo, consider plastic stents
	Among patients with distal malignant biliary obstruction undergoing ERCP with SEMS, the ASGE suggests using covered over uncovered SEMS (conditional recommendation/low quality of evidence) For patients with distal biliary obstruction from a pancreatic mass and unconfirmed malignancy, the ASGE recommends against uncovered SEMS (strong recommendation/low quality of evidence)	• Use 10-mm fully covered or partially covered SEMS • Select the shortest stent length to bridge the stricture for ≥10 mm and be ≥2 cm below the hepatic hilum • When possible, the proximal end of the stent should terminate below the cystic duct take-off in patients with intact gallbladder
Pain management	In patients with unresectable pancreatic cancer and abdominal pain, the ASGE suggests CPN as an adjunct to medical analgesic therapy (conditional recommendation/ low quality of evidence)	• Consider CPN when abdominal pain is refractory to medical therapy or when the adverse effects of opioids are not well tolerated • CPN should be done by EUS or percutaneously • If EUS is selected, use at least a 22-gauge FNA needle (or larger caliber), not the same needle used for EUS-TA • Apply central or bilateral injection of 10-20 mL of 99% alcohol • Administer 1 L of intravenous normal saline solution periprocedurally • Monitor the patient for ~2 h postprocedure with vital signs and orthostatic parameters

EUS-TA, EUS-guided tissue acquisition; *ASGE*, American Society for Gastrointestinal Endoscopy; *FNB*, fine-needle biopsy; EUS-FNB, EUS-guided fine-needle biopsy sampling; *ROSE*, rapid on-site cytopathology evaluation; *SEMS*, self-expanding metal stent; *CPN*, celiac plexus neurolysis.

Question 1: In patients with solid pancreatic masses undergoing EUS-TA, are FNB needles superior to FNA needles?

Recommendation 1: For patients with a solid pancreatic mass undergoing EUS-TA, the ASGE recommends FNB needles over FNA needles.

(Strong recommendation/moderate quality of evidence)

A systematic review and meta-analysis of randomized controlled trials (RCTs) was conducted to address this question. We identified 25 RCTs comparing FNB with FNA needles for 2765 patients with pancreatic masses. Outcomes of interest included diagnostic accuracy, defined as the proportion of lesions sampled that corresponded to the final diagnosis; sample adequacy, defined as the proportion of lesions sampled in which the obtained material was representative of the target site and sufficient for diagnosis; diagnostic yield, defined as the proportion of lesions sampled for which a tissue diagnosis was obtained; number of needle passes; adverse events; and DNA volume.[7]

When compared with FNA needles, FNB needles were associated with higher diagnostic accuracy (15 RCTs; odds ratio [OR], 1.33; 95% confidence interval [CI], 1.07-1.67; I^2 = 0%), higher sample adequacy (10 RCTs; OR, 3.21; 95% CI, 1.65-6.25; I^2 = 69%), fewer needle passes (9 RCTs; mean difference [MD], –.65; 95% CI, –.96 to –.34; I^2 = 89%), and a higher likelihood of reaching a diagnosis with a single pass (7 RCTs; OR, 2.90; 95% CI, 1.78-4.70; I^2 = 39%). In a single study, FNB needles provided a higher DNA volume compared with FNA needles (MD, 2.57 μg/mL; 95% CI, 2.24-2.90).[8]

Although there was a trend toward higher diagnostic yield with FNB needles, this did not reach statistical significance (10 RCTs; OR, 1.53; 95% CI, .94-2.49; I^2 = 49%). No differences were found in overall postprocedure adverse events (16 RCTs; OR, .68; 95% CI, .29-1.57; I^2 = 0%) or postprocedure pancreatitis (15 RCTs; OR, 1.01; 95% CI, .31-3.24; I^2 = 0%). We did not find any studies that compared FNA needles with FNB needles on overall survival or quality of life.

The panel noted that the cost of FNB needles is higher than FNA needles.[9] However, a cost-effectiveness analysis showed that 2 FNB needle passes without ROSE were more cost-effective than FNA passes dictated by on-site cytopathology evaluation of pancreatic masses.[10] No data were identified on patients' values and preferences. However, the patient representative on the panel strongly favored FNB needles, given their higher diagnostic accuracy.

The panel discussed that samples obtained with FNB needles are preferred for ancillary molecular testing in patients with confirmed or suspected pancreatic adenocarcinoma (eg, next-generation sequencing to select targeted therapy).[8,11] With regard to benign pancreatic masses, a meta-analysis of 15 observational studies demonstrated that FNB needles provided better diagnostic yield than FNA needles for diagnosis of autoimmune pancreatitis.[12] The sensitivity of FNA needles in patients with chronic pancreatitis and a pancreatic mass was low; however, studies comparing FNB with FNA needles in this patient population are lacking.[13]

In summary, EUS-TA of solid pancreatic masses with FNB needles provides significantly higher diagnostic accuracy, sample adequacy, and DNA concentrations as compared with FNA needles while requiring fewer passes and with a similar rate of adverse events. In balancing the desirable and undesirable effects of the intervention and given the moderate quality of evidence, the panel made a strong recommendation to use FNB needles for EUS-TA of solid pancreatic masses.

Question 2: In patients with solid pancreatic masses undergoing EUS-TA, are 22-gauge needles superior to 25-gauge needles?

Recommendation 2: For patients with a solid pancreatic mass undergoing EUS-TA, the ASGE suggests 22-gauge over 25-gauge needles.

(Conditional recommendation/moderate quality of evidence)

For this question, we performed a systematic review and meta-analysis of RCTs and found 12 RCTs comparing 22-gauge with 25-gauge needles for 1665 patients with pancreatic masses.[7] EUS-TA was performed using an FNA needle in 8 RCTs and an FNB needle in 4 RCTs. Outcomes of interest were diagnostic accuracy; sample adequacy; high-quality specimens, defined as a total tissue sample >1 × 10 high-power field in length; number of needle passes; and adverse events.

Compared with 25-gauge needles, 22-gauge needles had greater odds of providing a high-quality specimen (2 RCTs; OR, 3.75; 95% CI, 1.64-8.59; I^2 = 66%).[14,15] No difference was found in diagnostic accuracy (7 RCTs; OR, .81; 95% CI, .52-1.25; I^2 = 0%), sample adequacy (6 RCTs; OR, 1.11; 95% CI, .65-1.88; I^2 = 46%), number of passes (4 RCTs; MD, .16; 95% CI, –.1 to .42; I^2 = 13%), adverse events (10 RCTs; OR, 1.94; 95% CI, .60-6.27; I^2 = 56%), or postprocedure pancreatitis (8 RCTs; OR, 2.53; 95% CI, .47-13.63; I^2 = 13%). No RCTs compared both needle gauges on survival, diagnostic yield, and molecular analysis. Subgroup analysis by needle type (FNB vs FNA) was not different from the overall results.

No differences in cost were found between 22- and 25-gauge needles. No cost-effectiveness studies compared both interventions. No data were available on patient values and preferences.

Given the moderate quality of evidence on providing higher tissue quality and similar adverse events, the panel made a conditional recommendation in favor of using 22-gauge needles for EUS-TA of solid pancreatic masses. Although

the clinical benefits of this difference are unclear, better tissue architecture may translate into better samples for personalized medicine and ancillary molecular testing of pancreatic adenocarcinoma. The panel acknowledged that a 25-gauge needle should be selected when a 22-gauge needle is expected to have limited manipulability (eg, excessive endoscope torqueing) or cannot be advanced into the lesion.

Question 3: In patients with solid pancreatic masses undergoing EUS-FNB, are novel or contemporary FNB needles (fork-tip and Franseen) superior to alternative FNB needles?

Recommendation 3: Among patients with a solid pancreatic mass undergoing EUS-FNB, the ASGE recommends using novel or contemporary FNB needles (fork-tip or Franseen) over alternative designs.

(Strong recommendation/moderate quality of evidence)

To address this question, a systematic review and meta-analysis of RCTs was conducted. We identified 3 RCTs of 381 subjects comparing novel or contemporary FNB needles (Fork-tip and Franseen) with alternative FNB designs (side-fenestrated, Menghini, and Tru-cut configurations) for EUS-TA of solid pancreatic masses. An additional meta-analysis of 4 RCTs that included 243 patients undergoing EUS-TA of pancreatic masses was performed to compare the fork-tip and Fransen needle designs. Outcomes of interest were diagnostic accuracy, sample adequacy, and adverse events.

Compared with alternative FNB needles, novel or contemporary FNB needles provided greater diagnostic accuracy (3 RCTs; OR, 4.06; 95% CI, 1.05-15.69; $I^2 = 74\%$) and sample adequacy (3 RCTs; OR, 25.90; 95% CI, 4.96-135.32; $I^2 = 0\%$). The rate of adverse events was similar between the novel or contemporary and alternative FNB needle designs (3 RCTs; OR, 2.41; 95% CI, .51-11.43; $I^2 = 0\%$). No RCTs have compared these FNB needle designs on survival, diagnostic yield, number of passes, and molecular analysis. Also, no differences were found between Fork-tip and Franseen needle designs in diagnostic accuracy (2 RCTs; OR, 1.61; 95% CI, .37-7.03; $I^2 = 0\%$), sample adequacy (4 RCTs; OR, 1.65; 95% CI, .69-3.93; $I^2 = 0\%$), and adverse events (4 RCTs; OR, .61; 95% CI, .14-2.66; $I^2 = 0\%$).

No data were available on costs, cost-effectiveness, and patient values and preferences between the different FNB needle designs. The patient representative on the panel indicated a personal preference for using novel or contemporary needles because they were more accurate with similar adverse events. After considering the benefits and harms and the moderate quality of evidence, the panel made a strong recommendation in favor of using either the Franseen or Fork-tip designs for EUS-FNB of solid pancreatic masses.

Question 4: In patients with solid pancreatic masses undergoing EUS-TA, is ROSE beneficial as compared with no ROSE?

Recommendation 4: In patients with a solid pancreatic mass undergoing EUS-TA, the ASGE suggests against routine use of ROSE.

(Conditional recommendation/low quality of evidence)

A systematic review and meta-analysis found 6 RCTs that compared ROSE versus no ROSE in 1476 patients undergoing EUS-TA for solid pancreatic masses. Outcomes were diagnostic accuracy, diagnostic yield, sample adequacy, need for repeat biopsy sampling, number of needle passes, procedure duration, and adverse events. As compared with not using ROSE, adding ROSE had similar diagnostic accuracy (5 RCTs; OR, .93; 95% CI, .62-1.39; $I^2 = 0\%$), diagnostic yield (3 RCTs; OR, 1.36; 95% CI, .77-2.41; $I^2 = 0\%$), sample adequacy (6 RCTs; OR, .56; 95% CI, .21-1.45; $I^2 = 88\%$), need for repeated biopsy sampling (3 RCTs; OR, .73; 95% CI, .30-1.80; $I^2 = 0\%$), number of passes (6 RCTs; MD, –1.06 passes; 95% CI, –2.18 to .06; $I^2 = 99\%$), procedure duration (6 RCTs; MD, 2.29 minutes; 95% CI, –1.84 to 6.42; $I^2 = 99\%$), and adverse events (4 RCTs; OR, 1.48; 95% CI, .46-4.80; $I^2 = 36\%$).

A subgroup analysis was performed based on needle type. When using FNB needles, the addition of ROSE resulted in lower sample adequacy (2 RCTs; OR, .67; 95% CI, .49-.92; $I^2 = 0\%$) and increased procedure duration (2 RCTs; MD, 6.99 minutes; 95% CI, 3.97-10.02; $I^2 = 38\%$). The difference in sample adequacy was explained by 1 study as a partial use of the sample for touch-imprint cytology required for ROSE and reduction of the overall histologic material.[16] Other differences in outcomes between ROSE and no ROSE with FNB needles were not statistically significant or clinically meaningful. When using FNA needles, ROSE reduced the number of needle passes (3 RCTs; MD, –1.97 passes; 95% CI, –2.93 to –1.01; $I^2 = 97\%$), whereas other outcomes were similar to the overall results. One study showed that EUS-guided FNA with ROSE resulted in lower sample adequacy and required more needle passes and a prolonged procedure duration as compared with EUS-FNB without ROSE.[17]

Three RCTs evaluated the cost related to the addition of ROSE. One RCT showed that the cost of FNA with ROSE was significantly higher compared with FNA without ROSE.[18] In contrast, 2 RCTs showed that the costs of adding ROSE to EUS-guided FNA or EUS-FNB were comparable with the costs when not using ROSE.[17,19] No formal cost-effectiveness studies have compared EUS-TA with and without ROSE, and no data were available on patient values or preferences.

Some additional considerations were discussed by the panel. There may be logistical and personnel challenges to performing ROSE in clinical practice, which makes it not equally available or used in all settings. The panel acknowledged that ROSE may provide a preliminary diagnosis of malignancy, which in some instances may expedite same-session treatment decisions (eg, selection of biliary stent during ERCP, CPN, endoscopic management of duodenal obstruction) and/or prompt coordination of care. However, the panel expressed concerns with the use of a preliminary diagnosis with ROSE given the limited data in the use of ROSE for this endpoint and because the diagnosis may change in the final histopathologic result.

In summary, based on a low quality of evidence and after considering all desirable and undesirable effects, the panel made a conditional recommendation against the routine use of ROSE in patients undergoing initial EUS sampling of a solid pancreas mass. Without ROSE, 2 to 4 needle passes with a contemporary FNB needle should be performed, and the sample should be placed directly into a 10% formalin jar, as described in RCTs of the present systematic review.[16,17] However, future studies are needed to determine the optimal number of passes when EUS-FNB is performed without ROSE. Recent studies have evaluated the role of macroscopic on-site evaluation to guide the number of needle passes, which in 1 RCT showed similar accuracy to EUS-FNB without macroscopic on-site evaluation but required a fewer number of passes.[20,21] In settings where FNB needles and ROSE are not available, 4 to 7 passes with an FNA needle should be performed and the sample placed into a methanol-based buffered cell wash solution (eg, ThinPrep CytoLyt; Hologic Inc, Marlborough, MA, USA).[18,19]

The panel proposed some circumstances in which ROSE may be considered for EUS-TA of solid pancreas masses. These circumstances include an initial nondiagnostic EUS sampling, lesions not clearly seen or those obscured by artifact (eg, stent, pancreatitis changes), use of an FNA needle (which is not recommended in this guideline except when FNB needles are unavailable), and when a preliminary diagnosis is desired to guide immediate treatment decisions

Question 5: In patients with distal malignant biliary obstruction undergoing ERCP, are SEMS superior to plastic stents?

Recommendation 5: For patients with distal malignant biliary obstruction undergoing ERCP, the ASGE suggests using SEMS over plastic stents.

(Conditional recommendation/low quality of evidence)

We conducted a systematic review and meta-analysis to address this question. We found 15 RCTs that compared metal versus plastic stents among 1253 patients with distal malignant biliary obstruction. Outcomes of interest were survival; stent patency, defined in months until developing cholangitis or jaundice; rate of stent failure; cholangitis or sepsis; unplanned reinterventions; post-ERCP adverse events; surgical resectability; and postoperative adverse events.

We found that compared to ERCP with plastic stent placement, SEMS had longer stent patency (8 RCTs; MD, 3.4 months; 95% CI, 1.83-5.02; I^2 = 97%) and reduced risk of stent failure (12 RCTs; OR, .45; 95% CI, .36-.55; I^2 = 0%), acute cholangitis (11 RCTs; OR, .53; 95% CI, .33-.87; I^2 = 44%), and endoscopic reinterventions (4 RCTs; OR, .58; 95% CI, .40-.85; I^2 = 28%). No differences were found between SEMS and plastic stents in mean survival (6 RCTs; MD, .66 months; 95% CI, –.39 to 1.71; I^2 = 69%), 30-day mortality (5 RCTs; OR, 1.65; 95% CI, .78-3.49; I^2 = 0%), post-ERCP adverse events (7 RCTs; OR, 1.21; 95% CI, .41-3.56; I^2 = 62%), post-ERCP pancreatitis (10 RCTs; OR, 1.91; 95% CI, .65-5.63; I^2 = 16%), acute cholecystitis (8 RCTs; OR, 1.61; 95% CI, .62-4.16; I^2 = 0%), surgical resectability (4 RCTs; OR, .90; 95% CI, .77-1.05; I^2 = 20%), and postoperative adverse events (3 RCTs; OR, 1.38; 95% CI, .45-4.25; I^2 = 63%).

Metal stents are more expensive than plastic stents. Despite these cost differences, 2 RCTs showed that metal stents are more cost-effective in patients with survival of more than 6 months and in patients without liver metastasis.[22,23] In patients with survival shorter than 3 months or with liver metastasis, plastic stents appear to be more cost-effective.[22-24] Three RCTs revealed that both stents have similar cost-effectiveness.[25-27] We found no studies reporting on patient values and preferences.

The panel discussed additional considerations. Although plastic stents can be considered in patients with planned surgical resection within a 3-month timeframe, often patients have not yet had a surgical evaluation at the time of ERCP or are not yet scheduled for surgery. Although none of the included studies compared the need for chemotherapy interruptions with plastic or metal stents, the lower risk of stent failure and cholangitis with metal stents leads to fewer interruptions of chemotherapy in clinical practice.

After considering the low quality of the evidence and all the potential desirable and undesirable effects, the panel made a conditional recommendation in favor of metal stents in patients with confirmed malignancy and distal biliary obstruction in whom biliary drainage with ERCP is warranted. In patients with pancreatic head cancer with either liver metastasis, expected survival of <3 months, or planned surgical resection within 3 months, a plastic stent can be considered. The panel acknowledged that the diagnosis of malignancy is often unknown at the time of ERCP and recognized that there are limited data to guide stent selection in this setting. If a patient with biliary obstruction has a pancreatic mass highly suspicious for malignancy and the patient undergoes simultaneous EUS-TA during ERCP, a fully covered SEMS should be considered. If a pancreatic mass is highly suspicious of malignancy and EUS-TA is not

simultaneously performed or if there is low suspicion for malignancy, a plastic stent should be considered.

Question 6: In patients with distal malignant biliary obstruction undergoing ERCP with SEMS, are cSEMS superior to uSEMS?

Recommendation 6:

a. Among patients with distal malignant biliary obstruction undergoing ERCP with SEMS, the ASGE suggests using cSEMS over uSEMS.
(Conditional recommendation/low quality of evidence)

b. For patients with distal biliary obstruction from a pancreatic mass and unconfirmed malignancy, the ASGE recommends against uSEMS.
(Strong recommendation/low quality of evidence)

To address this question, a systematic review and meta-analysis of RCTs was conducted. Ten RCTs were found encompassing 1337 patients with distal malignant biliary obstruction. Of these RCTs, 6 used fully covered SEMS and 4 used partially covered SEMS. Analyzed outcomes were survival; stent patency, defined as months until developing cholangitis or jaundice; rate of stent failure; cholangitis or sepsis; unplanned reinterventions; post-ERCP adverse events; and surgical resectability.

When placing SEMS with ERCP, cSEMS had a 70.5-day longer stent patency than uSEMS (5 RCTs; MD, 70.5 days; 95% CI, 21.09-119.92; $I^2 = 69\%$). No differences were found between cSEMS and uSEMS in terms of survival (9 RCTs; MD, –27.1 days; 95% CI, –72.17 to 17.92; $I^2 = 88\%$), stent failure (10 RCTs; OR, .84; 95% CI, .55-1.27; $I^2 = 60\%$), cholangitis (6 RCTs; OR, .90; 95% CI, .52-1.56; $I^2 = 0\%$), reinterventions (2 RCTs; OR, 1.20; 95% CI, .79-1.83; $I^2 = 0\%$), adverse events (6 RCTs; OR, 1.22; 95% CI, .82-1.82; $I^2 = 0\%$), post-ERCP pancreatitis (9 RCTs; OR, 1.47; 95% CI, .60-3.60; $I^2 = 0\%$), or acute cholecystitis (9 RCTs; OR, 1.62; 95% CI, .78-3.36; $I^2 = 0\%$). The type of SEMS did not impact surgical resection in 1 RCT ($P = .99$); however, SEMS were placed at least 2 cm below the hilum in this study.[28] No RCTs compared postsurgical adverse events between cSEMS and uSEMS. None of the results differed in subgroup analyses by type of cSEMS (fully covered vs partially covered).

The cost of cSEMS is higher than uSEMS. Despite this difference in costs, 1 RCT demonstrated that use of cSEMS was more cost-effective than use of uSEMSs ($3901 vs $5129, respectively, for costs of stents and reinterventions; $P = .0072$).[29] Another RCT showed equivalent cost-effectiveness between cSEMS and uSEMS; however, fully covered SEMS minimized interruptions of neoadjuvant chemotherapy because of a lower risk of stent occlusion.[26] No data are available comparing cSEMS and uSEMS on patient values or preferences.

The panel discussed additional considerations. uSEMS often become embedded in the bile duct because of tissue ingrowth and are extremely difficult or impossible to remove endoscopically. For this reason, uSEMS should not be placed for distal biliary obstruction when malignancy has not been confirmed. In addition, when placing uSEMS in patients with resectable or borderline resectable tumors, care should be taken to position the top of the stent well below the hilum to facilitate future biliary dissection and surgical anastomosis. Although the risk of acute cholecystitis has been reported to be higher with cSEMS in observational studies,[30,31] our systematic review and meta-analysis found no difference between uSEMS and cSEMS for this outcome. Until sufficiently powered studies are conducted for this outcome, the top of the SEMS should be placed below the cystic duct orifice, when possible, to prevent mechanical occlusion of the cystic duct.

In summary, in patients with distal malignant biliary obstruction undergoing ERCP, cSEMS have a longer patency than uSEMS, without other differences in desirable or undesirable effects. Considering the low quality of the evidence, the panel made a conditional recommendation in favor of using cSEMS over uSEMS in patients with distal malignant biliary obstruction undergoing ERCP with a metal stent. The panel strongly emphasized that the use of a uSEMS should be avoided if a confirmatory diagnosis of malignancy has not yet been established.

Question 7: In patients with pancreatic cancer–related abdominal pain, is CPN better than medical analgesic therapy alone?

Recommendation 7: In patients with unresectable pancreatic cancer and abdominal pain, the ASGE suggests CPN as an adjunct to medical analgesic therapy.
(Conditional recommendation/low quality of evidence)

We conducted a systematic review and meta-analysis that included 8 RCTs, encompassing 602 patients with unresectable pancreatic cancer and abdominal pain. CPN was delivered percutaneously in 5 studies, endoscopically using EUS in 2 studies, and surgically in 1 study. Outcomes of interest were survival; pain severity by a 10-point visual analog scale (VAS) at 4 weeks, 8 weeks, and 6 months; opioid use by morphine milligram equivalents at 4 weeks and 8 weeks; quality of life, measured on a scale from 0 to 10, at 4 weeks and 8 weeks; constipation; diarrhea; and drowsiness.

Compared with medical analgesic therapy alone, adding CPN decreased pain severity at 4 weeks (5 RCTs; mean difference [MD], –.37 points in VAS; 95% CI, –.65 to –.09; $I^2 = 35\%$) and at 6 months (2 RCTs; MD, –1.2 points in VAS; 95% CI, –1.47 to –.93; $I^2 = 0\%$) and lowered the risk of constipation (5 RCTs; OR, .23; 95% CI, .07-.74; $I^2 = 63\%$). No differences between CPN and medical analgesic therapy were found on mean survival (3 RCTs; MD, .11 months; 95% CI,

–1.13 to 1.35; $I^2 = 0\%$), pain severity at 8 weeks (7 RCTs; MD, –.7 points in VAS; 95% CI, –1.57 to .17; $I^2 = 99\%$), opioids at 4 weeks (5 RCTs; MD, –34.91 morphine milligram equivalents; 95% CI, –79.01 to 9.19; $I^2 = 99\%$), opioids at 8 weeks (5 RCTs; MD, –38.31 morphine milligram equivalents; 95% CI, –93.57 to 16.95; $I^2 = 99\%$), quality of life at 4 weeks (2 RCTs; MD, .57 points; 95% CI, –.43 to 1.57; $I^2 = 0\%$), quality of life at 8 weeks (4 RCTs; MD, .57 points; 95% CI, –.45 to 1.6; $I^2 = 0\%$), diarrhea (4 RCTs; OR, 3.73; 95% CI, .99-14.12; $I^2 = 0\%$), and drowsiness (2 RCTs; OR, .92; 95% CI, .09-9.03; $I^2 = 56\%$). Subgroup analyses by CPN approach (EUS-guided vs percutaneous or surgical) showed similar effects of CPN to the overall results.

Although not evaluated by our meta-analysis, CPN carries a risk profile different from medical management alone. In a systematic review of 16 studies in 867 patients with pancreatic cancer, CPN was associated with spinal cord infarction with paralysis (.2%), transient diarrhea (9%), pain exacerbation (8%), and hypotension (6%).[32] Other undesirable outcomes inherent to the invasive nature of CPN are sedation adverse events and risk of bleeding with needle puncture. No data are available that compare CPN with medical therapy on costs, cost-effectiveness, or patient values and preferences. Our patient representative considered CPN as an attractive intervention that seems to reduce pain severity and constipation.

Given the modest benefit in pain severity and potential undesirable effects with CPN, the panel discussed that analgesic therapy alone might be preferred as the first-line strategy to alleviate abdominal and/or back pain in patients with pancreatic cancer. In view of the low quality of the evidence, the panel made a conditional recommendation and suggested that CPN be used as an adjunct for treatment of pain in patients with unresectable pancreatic cancer. This should be especially considered when abdominal pain is refractory to medical therapy or when the adverse effects of opioids are not well tolerated. The panel recognized that the effects of CPN in patients with resectable or borderline resectable pancreatic cancer are not well known. No direct comparisons have been made between percutaneous and EUS-guided CPN; however, both approaches performed similarly in our meta-analysis. The endoscopic route may be preferred when an upper endoscopy or EUS is being performed for other purposes or when percutaneous CPN is not available.

FUTURE DIRECTIONS

Our systematic literature review highlighted several areas in need of more data to inform the role of endoscopy in the diagnosis and management of solid pancreatic masses. Future studies should address the following:

1. *EUS-TA of solid pancreatic masses.* The role of FNB needles in chronic pancreatitis, autoimmune pancreatitis, and neuroendocrine tumors needs to be better delineated. Although the ASGE suggests using a 22-gauge needle to sample solid pancreatic masses, additional research is needed to define the circumstances in which a different needle caliber may be beneficial. Additional studies need to determine the best sampling technique, optimal number of passes, role of macroscopic on-site evaluation, and specimen handling approach when doing EUS-FNB of pancreatic masses in the absence of ROSE. Special circumstances in which ROSE may be of benefit should be elucidated. The impact of adding elastography or contrast-enhanced EUS to guide TA with EUS-FNB needs to be tested in RCTs. The diagnostic ability of emerging FNB needle designs remains to be proven in RCTs comparing them with Fork-tip or Franseen FNB needles. Future studies of EUS-TA need to include important outcomes such as survival, quality of life, molecular testing, patient perspective, and cost-effectiveness.
2. *ERCP stent placement in distal malignant biliary obstruction.* More data are needed to guide biliary stent selection in patients with a pancreatic mass and unknown histopathologic diagnosis. Whether EUS-FNB with ROSE should be used to guide this decision is unknown. Although metal stents are suggested in this document, the factors that may favor placing plastic stents need to be better understood. Future studies should compare fully covered with partially covered SEMSs and specific cSEMS designs with and without antimigration technology. The risk of acute cholecystitis with different SEMS types and the factors associated with this adverse event need to be better explored in large sufficiently powered studies. Despite emerging data on the role of EUS-guided biliary drainage as a primary modality to treat malignant distal biliary obstruction,[33] ERCP is still the standard of care for this, and large sufficiently powered RCTs are needed to determine when the EUS approach is indicated as first-line treatment.
3. *EUS-guided CPN for management of pain in pancreatic cancer.* Future research is needed to determine the appropriate timing of CPN in the disease trajectory, predictive factors that guide patient selection, best route of administration, and optimal delivery technique. Studies that compare pain relief between CPN with chemotherapy and/or radiation are needed. The risks and benefits of CPN in patients with resectable disease need to be established. Studies are needed that evaluate the cost-effectiveness and patient preferences of different CPN approaches in comparison with other analgesic strategies.
4. *Treatment of pancreatic cancer.* The effects of EUS-guided intratumoral therapy (eg, chemotherapy, immunotherapy, gene transfer) and radiofrequency ablation in patients with pancreatic cancer need to be further investigated in RCTs. Similarly, the benefits of EUS placement of fiducial markers to facilitate radiation therapy need to be better clarified.

SUMMARY AND CONCLUSIONS

These ASGE guidelines use the best available evidence to make recommendations on the role of endoscopy in the diagnosis and management of pancreatic masses. The ASGE recommends using novel or contemporary FNB needles (fork-tip or Franseen designs) and suggests using 22-gauge needles without the routine use of ROSE for EUS-TA of solid pancreatic masses. In the setting of distal malignant biliary obstruction requiring ERCP, the ASGE suggests using metal stents over plastic stents and covered over uncovered metal stents. The ASGE suggests performing CPN as an adjunct to medical analgesic therapy for treating abdominal pain in patients with unresectable pancreatic cancer.

GUIDELINE UPDATE

ASGE guidelines are reviewed for updates approximately every 5 years or in the event that new data may influence a recommendation. Updates follow the same ASGE guideline development process.

DISCLOSURE

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Abbreviations: ASGE, American Society for Gastrointestinal Endoscopy; CI, confidence interval; CPN, celiac plexus neurolysis; cSEMS, covered self-expandable metal stent; EUS-FNB, EUS-guided fine-needle biopsy sampling; EUS-TA, EUS-guided tissue acquisition; FNB, fine-needle biopsy; OR, odds ratio; MD, mean difference; RCT, randomized controlled trial; ROSE, rapid on-site evaluation; SEMS, self-expandable metal stent; uSEMS, uncovered self-expandable metal stent; VAS, visual analog scale.

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