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 management of chronic pancreatitis: summary and recommendations

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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 management of chronic pancreatitis (CP). This document was developed using the Grading of Recommendations Assessment, Development and Evaluation framework. The guideline addresses effectiveness of endoscopic therapies for the management of pain in CP, including celiac plexus block, endoscopic management of pancreatic duct (PD) stones and strictures, and adverse events such as benign biliary strictures (BBSs) and pseudocysts. In patients with painful CP and an obstructed PD, the ASGE suggests surgical evaluation in patients without contraindication to surgery before initiation of endoscopic management. In patients who have contraindications to surgery or who prefer a less-invasive approach, the ASGE suggests an endoscopic approach as the initial treatment over surgery, if complete ductal clearance is likely. When a decision is made to proceed with a celiac plexus block, the ASGE suggests an EUS-guided approach over a percutaneous approach. The ASGE suggests indications for when to consider ERCP alone or with pancreatoscopy and extracorporeal shock wave lithotripsy alone or followed by ERCP for treating obstructing PD stones based on size, location, and radiopacity. For the initial management of PD strictures, the ASGE suggests using a single plastic stent of the largest caliber that is feasible. For symptomatic BBSs caused by CP, the ASGE suggests the use of covered metal stents over multiple plastic stents. For symptomatic pseudocysts, the ASGE suggests endoscopic therapy over surgery. This document clearly outlines the process, analyses, and decision processes 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.*

Chronic pancreatitis (CP) is a progressive and irreversible fibroinflammatory disorder of the pancreas that can result in chronic abdominal pain and exocrine and endocrine insufficiency.[1,2] Morphologically, CP may be characterized by the

development of pancreatic duct (PD) stones and strictures and may be complicated by the development of benign biliary strictures (BBSs) and pseudocysts. Although pain in CP is multifactorial and complex, a subgroup of patients may have pain from obstruction of the PD, with resultant ductal hypertension and pancreatic inflammation, and therefore may benefit from endoscopic therapy.[3]

Although the American Society for Gastrointestinal Endoscopy (ASGE) has provided previous recommendations for endoscopic strategies in benign pancreatic diseases, there has not been a recent guideline specifically addressing the role of endoscopy in the management of CP.[4] Therefore, the ASGE aimed to develop updated evidence-based guidelines for the role of endoscopy in the management of CP. Recommendations made in these guidelines should be used in the context of the individual patient and clinical setting, and as such the ultimate decision regarding the role of endoscopy in the management of CP should be made with consideration of individual patient values, preferences, and availability of local expertise.

## METHODS

This document was prepared by the Standards of Practice Committee of the ASGE and was conceptualized and conducted in accordance with the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) framework.[5] The evidence was presented to a panel of experts representing various stakeholders including pancreatologists, advanced endoscopists, and pancreaticobiliary surgeons. A patient representative was also included. All panel members were required to disclose potential financial and intellectual conflicts of interest in compliance with 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, resources utilization, cost-effectiveness, and health equity.[5,6] The final wording of the recommendations including direction and strength were approved by all members of the panel and the ASGE Governing Board. Consensus among the panel members was used to determine the wording of the recommendation and the direction and strength. The GRADE approach was used to categorize recommendations as strong or conditional; "recommend" was used for strong recommendations and "suggest" for conditional recommendations. Further details of the methodology used for this guideline can be found in the Methodology and Review of Evidence document that accompanies this Summary and Recommendations document, which provides systematic reviews, evidence profile, and results from all meta-analyses.

This guideline addressed clinical questions in the endoscopic management of the following categories using the GRADE format: pain in CP (questions 1 and 2), obstructive PD stones (question 3), PD strictures (question 4), and sequelae of CP (questions 5 and 6). Relevant clinical outcomes included mortality, technical and clinical success, pain relief, reintervention rates, endocrine and exocrine function, and adverse events.

### External review

The guideline was reviewed by the *Gastrointestinal Endoscopy* Editorial Board and ASGE Governing Board and was made available for public comment for 30 days 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 outlined in Table 1.

*Question 1: In patients with painful CP and an obstructed main PD, how does endoscopic therapy compare with surgical management for pain relief?*

**Recommendation 1**

a. In patients with painful CP and an obstructed main PD with no contraindications to surgery, the ASGE suggests surgical evaluation before initiation of endoscopic management.
b. In patients with contraindications to surgery or those who prefer a less-invasive modality, the ASGE suggests endoscopic management as the initial approach.

*(Conditional recommendation/low to moderate quality of evidence)*

### Summary of evidence

We performed a systematic review and meta-analysis of studies in CP patients with main PD obstruction related to stone(s) and/or stricture(s). The search resulted in 6 studies including 4 randomized controlled trials (RCTs).[7-12] We conducted a meta-analysis of RCTs, which included 3 of the 4 RCTs because 1 of the studies was with the same patient population but with a different follow-up period. These studies compared the outcomes of surgical intervention with endotherapy in 199 CP patients with an obstructed main PD. None of these studies included pancreatoscopy with lithotripsy in the endoscopic arm. In most of these studies, patients had pain that was nonresponsive to conservative management.[7-12] Exclusion criteria for these studies were prolonged opioid use, prior surgical or endoscopic intervention, suspected malignancy, poor surgical candidacy, or pregnancy.[7-12]

When comparing endoscopic with surgical approaches for ductal decompression, the RCTs showed that endoscopy

**TABLE 1. Summary of recommendations**

| Grading of Recommendations, Assessment, Development, and Evaluation recommendation | General concepts |
|---|---|
| When considering endoscopic or surgical management in patients with painful CP and obstructed main PD, the ASGE suggests the following:<br>a. In patients with no contraindications to surgery, the ASGE suggests surgical evaluation before initiation of endoscopic management.<br>b. Otherwise, in patients with contraindications to surgery or those who prefer a less-invasive modality, the ASGE suggests endoscopic management as the initial approach.<br>*(Conditional recommendation/low to moderate quality of evidence)* | • A multidisciplinary approach is strongly recommended in evaluating patients who have failed medical treatment for pain management.<br>• Assess availability of an expert endoscopist and a pancreatic surgeon and other ancillary facilities such as lithotripsy. |
| In patients with painful CP in whom a decision is made to proceed with a celiac plexus block, the ASGE suggests an EUS-guided over a percutaneous approach.<br>*(Conditional recommendation/low quality of evidence)* | • Less than 60% of patients get pain relief with an EUS-guided celiac plexus block, and it is nonsustained (<6 mo).<br>• Celiac plexus block can be carefully considered in CP patients nonresponsive to medical therapy or when no endoscopic or surgical options are available (nonobstructive CP).<br>• May be considered in patients who have side effects to opioids or wish to avoid opioids. |
| In patients with painful CP and main PD stones, the ASGE suggests that the management strategy be based on stone size, location, and radiopacity:<br>a. For radiopaque stones >5 mm and in the head, neck, or body of the pancreas, the ASGE suggests ERCP with or without pancreatoscopy or ESWL alone.<br>b. After ESWL and with no spontaneous stone clearance after adequate fragmentation (defined as the presence of fragments <2-3 mm), the ASGE suggests performing ERCP (with or without pancreatoscopy) for stone clearance.<br>c. For radiopaque stones <5 mm, any radiolucent stone, or contraindications to ESWL, the ASGE suggests ERCP with or without pancreatoscopy.<br>*(Conditional recommendation/very low to low quality of evidence)* | • The decision to choose pancreatoscopy or ESWL is largely based on local expertise and availability of these modalities.<br>• Consider ESWL for radiopaque stones >10 mm.<br>• Pancreatoscopy is likely to be difficult in the presence of strictures, with stones upstream from the stricture. |
| In patients with painful CP and main PD strictures, the ASGE suggests the following management strategy:<br>a. ***Number of stents:*** The ASGE suggests placement of single over multiple PSs for the initial treatment of a dominant PD stricture.<br>b. ***Stent diameter:*** The ASGE suggests the placement of the largest possible diameter PS that can be safely deployed in the initial treatment of a dominant PD stricture, while avoiding forceful or traumatic placement, with a gradual upsizing if necessary.<br>c. ***Use of metal stents*:** The ASGE suggests against the routine use of FCSEMSs for patients with persistent or refractory PD strictures who have failed initial stent placement.<br>*(Conditional recommendation /very low quality of evidence)* | • Assess the need for upsizing the stent at 3 monthly follow-up ERCPs after the initial PS placement.<br>• FCSEMSs have significant delayed adverse events and questionable efficacy. |
| The ASGE suggests FCSEMSs over multiple PSs for the treatment of benign biliary strictures complicating CP.<br>*(Conditional recommendation/low to moderate quality of evidence)* | • Treat benign biliary strictures when symptomatic or unresolved after 4 weeks to prevent secondary biliary cirrhosis.<br>• FCSEMSs are especially beneficial over multiple PSs in cases of likely noncompliance or scheduling difficulty, as serious adverse events may occur for PSs left in place for longer durations.<br>• Multiple PS placement may be considered if the biliary stricture is indeterminate or when there is a risk of cystic duct obstruction with a gallbladder in situ. |
| The ASGE suggests endoscopic drainage over surgical drainage of symptomatic pseudocysts in patients with CP.<br>*(Conditional recommendation/low quality of evidence)* | • Avoid a percutaneous approach for pseudocyst drainage as the sole therapy because of the risk of pancreaticocutaneous fistula.<br>• Consider a multidisciplinary approach in cases of altered anatomy or pseudocysts not in proximity of the GI lumen. |

*ASGE,* American Society for Gastrointestinal Endoscopy; *CP*, chronic pancreatitis; *PD*, pancreatic duct; *ESWL*, extracorporeal shock wave lithotripsy; *PS*, plastic stent; *FCSEMS*, fully covered self-expandable metal stent.

was significantly inferior to surgical management in providing any pain relief (3 RCTs: odds ratio [OR], .38; 95% confidence interval [CI], .21-.70; $I^2 = 0.00\%$), complete pain relief (2 RCTs: OR, .44; 95% CI, .23-.87; $I^2 = 0\%$), and technical success (ductal decompression) (2 RCTs: OR, .07; 95% CI, .02-.24; $I^2 = 0\%$) and also had a lower improvement in physical quality of life scores (2 RCTs: mean difference, –3.66; 95% CI, –7.29 to .04; $I^2 = 0\%$).[7-9,12] However, no differences were found in mortality, adverse events, length of hospitalization, impact on endocrine or exocrine function, or improvement in mental quality of life scores. A study of cost-effectiveness showed that the surgical approach was more cost-effective compared with an endoscopic approach in terms of costs per unit decrease in the pain score and gain in quality-adjusted life-years.[13]

## Discussion

In our meta-analysis, only 49 of 199 CP patients (24.6%) had complete pain relief from either surgical or endoscopic ductal decompression. This illustrates the multifactorial nature of pain in CP and the relative ineffectiveness of drainage procedures. Hence, the panel suggested that when patients fail conservative medical treatment, a multidisciplinary discussion should ensue involving medical pancreatologists, pancreatic surgeons, interventional endoscopists, and pain specialists. Despite the superiority of surgical approaches, the panel noted that many patients, and their surgeons, prefer starting with the less-invasive endoscopic route before surgery. Second, many patients may not be optimal surgical candidates because of comorbidities, age considerations, and contraindications to surgery.

Specifically, the panel noted that an endoscopic approach by ERCP may be preferred in patients in whom there is a high likelihood of complete relief of ductal obstruction (stone clearance and/or stricture resolution), such as in patients with uncomplicated obstruction in the head, neck, or body of the pancreas. This is because when complete ductal clearance was achieved by endoscopy, reduction in the pain score was comparable with the surgical group.[12] However, surgery may be considered first when endoscopic treatment is likely to be unsuccessful such as with disease in the tail of the pancreas or dense calcification and stone burden not amenable to endoscopic treatment.[14] Of note, successful surgical or endoscopic outcomes are highly dependent on the availability of an expert pancreatic surgeon or endoscopist, which may be restricted to specialized centers. Although no studies are available that provide guidance on when to consider endoscopic treatment as failed or to inform us on the timing of surgery when endoscopic treatment fails, the panel, based on expert opinion and experience, suggested early consideration of surgery over repeated unsuccessful ERCPs and after shared decision-making between the patient and all providers.

In summary, for patients who are surgical candidates, early surgical evaluation should be considered. For patients who prefer to avoid surgical interventions or those who are not surgical candidates, the ASGE suggests an endoscopic approach first. These recommendations are conditional with a low to moderate quality evidence.

*Question 2: Should an EUS-guided or percutaneous (PC) approach be used in patients with painful CP undergoing celiac plexus block (CPB)?*

**Recommendation 2:** In patients with painful CP in whom a decision is made to proceed with a CPB, the ASGE suggests an EUS-guided over a PC approach.

*(Conditional recommendation/low quality of evidence)*

## Summary of evidence

A systematic review and meta-analysis was performed to address the main outcomes of interest for this clinical question. We identified 2 RCTs that compared EUS-guided CPB (EUS-CPB) and PC-CPB among 74 patients with intractable abdominal pain unresponsive to medical therapy.[15,16] PC-CPB was performed with either fluoroscopic or CT guidance. The studies excluded patients with CP complicated by abscesses, pseudocysts, or biliary strictures. The outcomes of interest included the proportion of patients with pain relief at 1-, 4-, and 12-week intervals; improvement in pain intensity based on the visual analog scale; and adverse effects. CPB was performed using a combination of a local anesthetic with or without a steroid injection.[17] No cost-effective studies were identified.

In the systematic review and meta-analysis of the 2 RCTs, EUS-CPB was more successful than PC-CPB in providing pain relief at 4 weeks (OR, 8.11; 95% CI, 2.77-23.75; $I^2 = 0\%$) and at 12 weeks (OR, 4.33; 95% CI, 1.24-15.08; $I^2 = 0\%$) in patients with CP who had failed medical treatment. Also, the intensity of pain measured by the median visual analog scale score was significantly lower after EUS-CPB compared with fluoroscopic-guided PC-CPB in 1 study and CT-guided PC-CPB in the other study. No differences were seen in adverse events between EUS-CPB and PC-CPB.[15,16] The quality of the evidence among the available studies was low (rated down for risk of bias and imprecision given the low number of events), and no cost-analysis data were identified.

In a systematic review and meta-analysis of 8 single-arm, noncomparative studies of 283 patients with CP, EUS-CPB showed modest pain relief in 59.5% of patients (95% CI, 54.51-64.30).[18] In a subgroup analysis, bilateral injections of the plexus provided better pain relief than unilateral injections. The panel noted that pain relief with CPB is not durable, and most patients return to their baseline pain in less than 6 months.[16] However, patients who benefited from a single CPB injection may benefit from a subsequent injection when pain relief subsided after the first injection.[19] In a large study, nonserious adverse events with CPB

occurred in 1.6% of 220 procedures carried out in 158 patients and included transient hypotension, diarrhea, retroperitoneal abscess, and postprocedural pain.[20]

## Discussion

Pain in CP is frequently severe, and even with high-potency opioids, many patients do not have adequate pain relief. Moreover, patients may experience significant adverse effects from long-term opioid use and are at risk of opioid dependence. EUS-CPB may be superior to PC-CPB because of better localization and targeting of the plexus by EUS.[15,16] No studies have compared CPB with placebo or sham, making the decision on when to use CPB difficult and not evidence-based and questions the efficacy of CPB. However, the panel suggested that CPB could be considered in CP patients with severe ongoing pain nonresponsive to medical therapy (and who have exhausted all other options), in those with nonobstructive small-duct disease (not amenable to endoscopic or surgical therapy decompression), or in patients who have side effects to opioids or prefer to avoid opioids.

Overall, the low-quality evidence suggests that CPB may provide modest and nonsustained pain relief in CP patients with reasonable safety.[21] Based on all considerations, the panel made a conditional recommendation for EUS-CPB over PC-CPB in patients with painful CP in whom a decision is made to proceed with a CPB.

*Question 3: In patients with painful CP and main PD stones, what is the optimal approach in endoscopic management: ERCP alone, ERCP with pancreatoscopy and lithotripsy, or ERCP with extracorporeal shock wave lithotripsy (ESWL)?*

**Recommendation 3:** In patients with painful CP and main PD stones, the ASGE suggests that the management strategy be based on stone size, location, and radiopacity:

a. For radiopaque stones >5 mm and in the head, neck, and body of the pancreas, the ASGE suggests ERCP with or without pancreatoscopy or ESWL alone.
b. For post ESWL and no spontaneous stone clearance after adequate fragmentation (defined as presence of fragments <2-3 mm), the ASGE suggests performing ERCP (with or without pancreatoscopy) for stone clearance.
c. For radiopaque stones <5 mm, any radiolucent stones, or patients with contraindications to ESWL, the ASGE suggests ERCP (with or without pancreatoscopy).

*(Conditional recommendation/very low to low quality of evidence)*

## Summary of evidence

To address the management strategy of PD stones, we evaluated studies comparing ESWL versus pancreatoscopy with electrohydraulic lithotripsy (EHL) and studies comparing ESWL alone versus ESWL followed by ERCP. We systematically reviewed the literature, which yielded 4 original studies (1 RCT and 3 observational studies).[22-25] These studies included adult CP patients with PD stones and abdominal pain. The exclusion criteria for these studies included the presence of a pancreatic fluid collection, serum alkaline phosphatase greater than twice the normal value or cholangitis, age <18 years, pregnancy, or lactation.

**Pancreatoscopy with EHL versus ESWL.** We identified only 1 comparative study that assessed this question. Bick et al[22] compared 18 patients undergoing single-operator pancreatoscopy with EHL with 240 patients who underwent ESWL in a single-center observational cohort study.[22] The median stone size was >5 mm. Compared with ESWL, the number of procedures required was significantly lower in the pancreatoscopy group (1.6 [standard deviation {SD}, .6] vs 3.1 [SD, 1.5], $P < .001$) with a significantly shorter procedural time in the pancreatoscopy group (101.6 minutes [SD, 68] vs 191.8 minutes [SD, 111.6], $P = .001$). No significant differences in the rates of stone clearance (16/18 [88.9%] vs 208/240 [86.7%], $P = 1.0$), improvement in pain (15 [93.8%] vs 182 [82.7%], $P = .43$), and rates of adverse events (1 [5.6%] vs 16 [6.7%], $P = 1.0$) were found for pancreatoscopy compared with ESWL, respectively. Efficiency of stone clearance, defined as ≤2 procedures required for stone clearance, was significantly greater in the pancreatoscopy group (OR, 5.24; 95% CI, 1.3-20.39; $P = .02$). However, pancreatoscopy was less efficient in ductal clearance when stones were >10 mm (OR, .484; 95% CI, .256-.912; $P = .025$). Additionally, based on noncomparative data from a systematic review and meta-analysis of 15 studies, totaling 370 patients, pancreatoscopy with lithotripsy (EHL or laser) had a pooled technical success rate of 88.1% (95% CI, 86.6-92.8), a clinical success rate of 87.1% (95% CI, 86.3-92.7), and an adverse event rate of 12% (95% CI, 8.7-15.5).[26]

**ESWL alone versus ESWL and ERCP combined.** We identified 3 studies (1 RCT and 2 observational studies) that assessed this question.[23-25] When comparing ESWL alone with ESWL and ERCP, both groups had similar success in pain relief.[23,24] Ductal clearance was also similar in 2 studies (RCT included) in both groups[23,24] but was lower in the ESWL alone group in the observational Japanese study by Suzuki et al.[25] No differences were found in adverse events or mortality in both groups, but length of hospital stay was trended to be longer in the combined ESWL and ERCP group (ESWL+ERCP vs ESWL: 8.6 [SD, 16.5] vs 3.1 [SD, 5.3], $P = .1$), albeit not statistically significant. The cost of ESWL alone was significantly lower than ESWL + ERCP ($4092.66 vs $12,939.30, $P < .001$); however, a cost-effective analysis was not performed.[23] Overall, the quality of evidence was found to be moderate to very low (with rating down for imprecision and indirectness for some outcomes).

## Discussion

Removal of stones at endoscopy may relieve obstruction and improve pain.[27] Conventional methods of stone

removal with ERCP alone (with interventions including stricture dilation, stent placement, or stone extraction alone or in combination) are successful in less than 15% of CP patients.[25] Hence, stone extraction by ERCP alone is reserved for smaller stones (<5 mm) or radiolucent stones that cannot be targeted by ESWL and typically located in the head, neck, and body of the pancreas.[25,28]

When considering larger stones (>5 mm) that require lithotripsy, an advantage of pancreatoscopy with lithotripsy over ESWL is that non-radiopaque stones unable to be seen on fluoroscopy can be fragmented under direct vision and the procedure can be combined with ERCP at the same time. However, pancreatoscopy is technically difficult when stones are located upstream from a PD stricture or in the tail of the pancreas. On the other hand, ESWL requires a clear shock wave pathway without interference by bones, calcified vessels, or lung tissue, with most patients requiring ≤3 ESWL sessions for stone clearance.[29] During the panel meeting, we discussed equity and feasibility issues of various modalities, recognizing that ESWL is not as readily available in the United States at all centers, whereas pancreatoscopy is becoming more widely available across the country.

Overall, the panel suggested that when PD stones are radiopaque and <5 mm or radiolucent and located in the head or proximal body of the pancreas, ERCP alone (with or without pancreatoscopy) should be attempted first, given a higher probability of ductal clearance. For radiopaque PD stones >5 mm, either pancreatoscopy with lithotripsy or ESWL can be used depending on local availability. Pancreatoscopy with lithotripsy may be more efficient than ESWL in ductal clearance except when stones are >10 mm. These recommendations are conditional with very low and low quality of evidence.

*Question 4: In patients with painful CP and main PD stricture undergoing ERCP, what is the optimal management strategy for PD stent placement?*

**Recommendation 4:** In patients with painful CP and main PD strictures, the ASGE suggests the following management strategy:

a. *Number of stents:* The ASGE suggests placement of single over multiple plastic stents (PSs) for the initial treatment of a dominant PD stricture.
b. *Stent diameter:* The ASGE suggests the placement of the largest possible diameter PS that can be safely deployed in the initial treatment of a dominant PD stricture, while avoiding forceful or traumatic placement, with a gradual upsizing if necessary.
c. *Use of metal stents:* The ASGE suggests against the routine use of fully covered self-expandable metal stents (FCSEMSs) for patients with a persistent or refractory PD stricture who have failed initial stent placement.

*(Conditional recommendations/very low quality of evidence)*

## Summary of evidence

Three comparative observational cohort studies met the inclusion criteria and compared the utility of single versus multiple PSs, 10F versus 8.5F or smaller PSs, and single PSs versus FCSEMSs.[30-32] The outcomes reported in these studies varied, as discussed below.[30-32]

**Number of stents.** Only 1 observational study by Papalavrentios et al[30] assessed the difference between single and multiple PSs for the initial treatment of a dominant PD stricture. Dominant PD strictures were defined as an upstream dilation of the PD of >6 mm.[33] The study compared 3 groups based on the number of stents used during endoscopic treatments for each patient: single PS (n = 18; only 1 stent used though the entire duration of endoscopic therapies), 1 or 2 PSs (n = 35; starting with 1 stent and increasing to 2 stents during follow-up endoscopy), and 2 PSs (n = 32; starting with 2 stents and remaining at 2 stents throughout endoscopic treatment).[30] A single PS had significantly higher odds of providing pain relief compared with 1 or 2 PSs (OR, 7.5; 95% CI, 1.46-38.70; $P$ = .04) as well as a significantly higher proportion of pain relief than the other groups (1 PS vs 1-2 PSs vs 2 PSs: 88.2% vs 74.2% vs 50%; $P$= .02).[30] However, no significant differences were seen in either mortality or exocrine and endocrine function between the 3 groups. The quality of evidence was very low (based on a single observational study with a low number of events). Based on thses data, the panel made a conditional recommendation for single PS compared with multiple PSs.

**Stent diameter.** When evaluating the size of the PS, Sauer et al[31] compared 10F PSs with ≤8.5F PSs in a single observational cohort study of 169 patients. Patients with smaller PSs had significantly more hospitalizations for abdominal pain per patient (10F vs ≤8.5F PSs: .8 [SD, 2.2] vs 1.5 [SD, 2.40]; $P$ = .0); also, the proportion of patients hospitalized in this group was significantly higher (8 [24%] vs 63 [49%], respectively; $P$ < .001).[31] The quality of evidence was very low (based on a single observational study with a low number of events). Based on the limited data, large PSs may be superior. However, the panel recognized that endoscopists should avoid forceful or traumatic stent placement when attempting to place larger diameter PSs.

**Single PS versus FCSEMSs for persistent PD strictures.** Symptomatic strictures that do not resolve after 3 months or 1 year after stent placement with a single PS are referred to as persistent and refractory strictures, respectively.[32,34] We identified a study by Lee et al[32] that compared a single PS (n = 54) with FCSEMSs (n = 26). Patients with persistent strictures showed no difference between FCSEMSs and a single PS in pain relief (26 [100%] and 52 [96.3%], respectively; $P$ = .32), rate of successful stent placement (100% in both groups), number of ERCPs (PS vs FCSEMS: 3 [interquartile range {IQR}, 1-10] vs 2 [IQR, 1-3]; $P$ = .14), or immediate adverse events. The rate of stricture resolution was significantly higher in the FCSEMS group

(87.0% vs 42.0%, $P < .001$). However, delayed adverse events including spontaneous stent migration (26.9% vs 3.7%, $P = .002$) and de novo strictures (23.1% vs 0%, $P < .001$) were significantly more common in the FCSEMS group. A cost analysis showed no difference between the 2 groups (PS vs FCSEMSs: $1596.9 [SD, 1000.8] vs $1455 [SD, 333.1]; $P = .49$).[32] The quality of evidence was low to very low (based on observational studies with a low number of events).

**Multiple PSs versus FCSEMSs in refractory PD strictures.** In a systematic review and meta-analysis of 13 noncomparative (single-arm) studies, Sofi et al[34] evaluated the efficacy and safety of multiple PSs and FCSEMSs in CP patients with symptomatic PD strictures refractory to treatment after 1 year of stent placement in 298 patients. Both groups had similar improvement in pain after stent placement (FCSEMSs vs multiple PSs: 88% [IQR, 79%-93%] vs 89% [IQR, 70%-96%]; $P = .79$), recurrence of pain after stent removal (FCSEMSs vs multiple PSs: 14.8% [IQR, 8%-26%] vs 11.8% [IQR, 7%-20%]; $P = .48$), recurrence of stricture after stent removal (FCSEMSs vs multiple PSs: 14% [IQR, 8%-26%] vs 11.8% [IQR, 7%-20%]; $P = .48$), and rates of reintervention (FCSEMSs vs multiple PSs: 20.2% [IQR, 13.1%-29.9%] vs 25.4% [IQR, 17.1%-36%]; $P = .31$). However, the FCSEMS group had significantly more adverse events (38.6% vs 14.3%, $P < .0001$) than the multiple PS group, with higher rates of stent migration, biliary obstruction, and pancreatitis. In addition, a recent multicenter, noncomparative (single-arm) study of 67 patients who were treated with FCSEMSs for a distal dominant PD stricture showed pain reduction in only 26% patients, with significant adverse events in approximately one-third of patients (21/67), with stent migration in 48% (n = 31) and secondary strictures in 8% (n = 5) of patients.[35] The quality of the evidence was low to very low (based on observational studies with a low number of events). Given the higher rates of adverse events with FCSEMSs compared with PSs in this patient population, the panel made a conditional recommendation against placement of FCSEMSs. As evidence on this topic evolves, this suggestion may be reconsidered.

## Discussion

Pain relief is common after stent placement, but short- and long-term results vary, and in up to 30% of patients the stricture may not resolve after initial stent placement.[36] Overall, data informing these clinical questions were scarce. However, the panel noted that clinicians often struggle with these important clinical questions and that guidance on these topics is important for the panel and the ASGE to consider. Based on the low-quality evidence presented above, the panel agreed that for the initial treatment of a main PD stricture, a single PS appears to perform better than multiple PSs, using the largest diameter PS that can be safely deployed without forceful placement. The approach eventually adopted may be modified based on the expertise and preference of the endoscopist. However, currently, routine placement of FCSEMSs has no role in initial or secondary treatment of PD strictures given the high rates of adverse events and questionable efficacy.

*Question 5: In patients with CP complicated by BBSs with jaundice and/or elevated alkaline phosphatase for >4 weeks, how do multiple PSs compare with FCSEMSs?*

**Recommendation 5:** The ASGE suggests FCSEMSs over multiple PSs for the treatment of BBSs complicating CP.

*(Conditional recommendation/low to moderate quality of evidence)*

## Summary of evidence

To address this clinical question, we performed a systematic review and meta-analysis of RCTs that compared multiple PSs with FCSEMSs in patients with BBSs with jaundice and/or elevated alkaline phosphatase for >4 weeks. Three RCTs that met the inclusion criteria were identified and compared 259 patients managed with multiple PSs versus FCSEMSs.[37-39] The findings showed no differences between FCSEMSs and multiple PSs in rates of stricture resolution (OR, .59; 95% CI, .19-1.81; $I^2 = 50.6\%$), time to resolution of strictures (multiple PSs vs FCSEMSs: median, 199.5 days [IQR, 95] vs 184 days [IQR, 38 ]; $P = .146$), procedural time (mean difference, 8.26; 95% CI, –6.24 to 22.76]; $I^2 = 83\%$), adverse events (OR, .67; 95% CI, .35-1.30; $I^2 = 0\%$), or mortality. The rates of stricture resolution in all 3 RCTs ranged from 75% to 90% in follow-up. Multiple PS use was associated with more ERCPs (mean difference, 1.42; 95% CI, 1.5-1.70; $I^2 = .00$, $P < .01$),[37,38] and a higher number of stents were used (7.0 ± 4.4 vs 1.3 ± .6, $P < .001$).[38] In most patients in the 3 studies, up to 3 PSs of 8.5F to 10F and FCSEMSs 8 to 10 mm diameter were deployed. No cost data were available in the included RCTs.[37-39] The quality of evidence was moderate to low.

## Discussion

Up to 30% of patients with CP can develop BBSs, which may result in biliary obstruction with associated jaundice, elevation of alkaline phosphatase, cholangitis, and risk of secondary biliary cirrhosis.[40,41] This obstruction may be reversible because of acute inflammation; if persisting beyond 4 weeks, it should be treated to prevent secondary biliary cirrhosis.[42]

Studies showed that FCSEMSs are as efficacious as multiple PSs in the treatment of BBSs in CP patients but require fewer ERCPs. The panel believed that in cases with concerns for noncompliance or difficulty in scheduling multiple procedures, FCSEMSs may be considered over multiple PSs because serious adverse events have been reported in cases of noncompliance when PSs are placed.[43] Multiple PS placement may be considered if the biliary stricture is indeterminate and obstructing the cystic duct is a concern, as in patients with an intact gallbladder

in which there is theoretically a potential risk of causing cholecystitis.

*Question 6: In patients with CP and symptomatic pseudocysts, how does endoscopic drainage compare with surgical drainage?*

**Recommendation 6:** The ASGE suggests endoscopic drainage over surgical drainage of symptomatic pseudocysts in patients with CP.

*(Conditional recommendation/low quality of evidence)*

## Summary of evidence

To address this clinical question, we conducted a systematic review that yielded only 1 RCT.[44] Pseudocysts were diagnosed based on CT criteria, measured ≥6 cm, and were located adjacent to the stomach with symptoms including persistent pancreatic pain, symptomatic gastric outlet obstruction, or bile duct obstruction. The study excluded patients aged <18 years or >80 years, with contraindications to surgery or endoscopic drainage, pregnancy, associated necrosis, and pseudocyst with multilocularity, multiplicity, or distant from the stomach.

Only 20 patients were included in each group, and EUS cystgastrostomy was performed under fluoroscopic guidance. No statistical differences occurred in treatment success (19 [95%] vs 20 [100%], $P = .5$), recurrence of pseudocyst (0 [0%] vs 1 [5%]), adverse events (0 vs 2, $P = .24$), or reintervention rates (1 [5%] vs 1 [5%], $P = .76$) in the endoscopy versus surgical groups, respectively. However, in the endoscopy group, the length of hospital stay was significantly shorter (2 days [IQR, 1 -4] vs 6 days [IQR, 5-9], $P < .001$) and costs notably lower ($7011 [$4171] vs $15,052 [$10,670], $P = .003$). Although physical and mental quality of life scores improved in both groups, the improvement in these scores was significantly lower in the surgical group as compared with the endoscopy group (physical scores, 4.48 points lower [95% CI, –8.23 to –.73; $P = .019$]; mental scores, 4.41 lower [95% CI, –8.26 to –.55; $P = .025$]).[44] The quality of the evidence was low (rated down for imprecision because of a low number of events).

In a systematic review and meta-analysis of 6 studies including 342 patients, Farias et al[45] compared endoscopic versus surgical drainage of pseudocysts of any etiology. Most patients had pseudocysts in the setting of acute pancreatitis. They also reported that the endoscopy group had a significantly shorter length of hospital stay and lower cost compared with the surgical group. No significant differences were found in success rate, drainage-related adverse events, general adverse events, or recurrence between both groups. Endoscopic treatment was found to be more cost-effective than surgical drainage.[46] A PC approach as the sole therapy often can result in an external pancreaticocutaneous fistula and therefore is rarely performed.[47,48] The quality of the evidence was moderate (rated down for indirectness given that the population was not specifically patients with CP).

## Discussion

Although data on these outcomes in CP patients were scarce, many studies have assessed the efficacy of endoscopic versus surgical drainage of pseudocysts in non-CP patients (ie, acute pancreatitis). These data were used as indirect evidence. Pancreatic pseudocysts are less common in CP than in acute pancreatitis but can still develop in up to one-third of CP patients during the course of their disease.[49] Procedural outcomes in endoscopic and surgical drainage of symptomatic pseudocysts in CP patients are similar, but endoscopic management results in a shorter length of hospital stay, lower costs, and better physical and mental quality of life. The data on pseudocyst drainage in CP patients are similar to the more extensive evidence reported in acute pancreatitis patients. Hence, the panel suggested endoscopic drainage over surgical drainage for pseudocysts in CP patients. The panel also discussed that it can be helpful to delineate the underlying pancreatic ductal anatomy either by magnetic resonance of endoscopic imaging before either endoscopic or by surgical treatment of pseudocysts. It should also be noted that self-expanding metal stents have been used for drainage of symptomatic pseudocysts but were not studied in the above-mentioned RCT.[44]

# FUTURE DIRECTIONS

Our systematic literature reviews highlighted several areas in need of more data to inform endoscopic management of CP. Future studies should consider addressing the following:

1. *Endoscopic versus surgical management of painful CP with PD obstruction.* More data are needed on predictors of successful endoscopic and surgical treatment and guidance on selection of patients for both approaches. More data are also required on the timing of surgery when endoscopic attempts fail.
2. *CPB in the treatment of pain in CP.* Although limited data suggest an EUS-guided approach is superior to a PC approach for administering CPB in CP patients, the true efficacy of CPB is unknown. Studies are needed comparing CPB with other treatment modalities (medical, endoscopic, or surgical). Data are also needed to compare CPB with placebo or sham procedures in RCTs to evaluate its true efficacy.
3. *PD stones.* Future studies are needed to accurately identify and select patients who are most appropriate for specific types of treatment (ie, ERCP, pancreatoscopy, lithotripsy, ESWL with and without ERCP) in randomized trials.
4. *PD strictures.* The current evidence on the management of PD strictures with dilation and stents is of very low

quality. Guidance is needed on how to approach symptomatic PD strictures at the initial endoscopy and during subsequent treatment when a particular type of stent placement strategy fails and when the stricture persists or becomes refractory. More data are needed on selection of patients, number of stents to use (single vs multiple), diameter and length of stents, and types of stents (PSs vs FCSEMSs).

5. *Treatment of BBSs in CP.* Although FCSEMSs are equally efficacious compared with multiple PSs, additional information is needed on when to consider multiple PSs or FCSEMSs based on specific patient and stricture characteristics.
6. *Management of symptomatic pseudocysts in CP.* Although there is substantial evidence to recommend endoscopic drainage of pseudocysts over surgical or PC approaches in acute pancreatitis, data on management of pseudocysts in CP patients are extremely limited, with only 1 study of 20 patients.[44] Hence, more data are needed for CP patients with symptomatic pseudocysts. Guidance is also needed on various endoscopic approaches (transpapillary vs transmural) and the use of PSs versus lumen-apposing stents in CP patients.
7. *Screening for pancreas cancer in CP.* Currently, recommendations to screen for pancreatic cancer in nonhereditary CP patients are not available. However, CP is known to increase the risk of malignancy in the pancreas. Morphologic changes of cancer can be difficult to discern on imaging and EUS in the setting of parenchymal and ductal changes seen in CP. Well-designed studies are needed to quantify the risk of cancer and clarify the appropriate modalities for screening.

## SUMMARY AND CONCLUSIONS

This ASGE guideline uses the best available evidence to make recommendations for endoscopic management of CP. As discussed above, data on this topic are very limited, and the evidence is of low quality. Hence, all recommendations are conditional. Within this framework, the ASGE suggests a multidisciplinary approach in the management of CP patients. In patients with painful CP and an obstructed main PD with no contraindications to surgery, the ASGE suggests surgical evaluation in patients before initiating endoscopic management. In patients who have contraindications to surgery and who prefer a less-invasive modality, the ASGE suggests an endoscopic approach as the initial treatment over surgery if complete ductal clearance is likely. The ASGE suggests an EUS guided-approach (over a PC approach) when a decision is made to proceed with a CPB in CP patients. The ASGE suggests indications for the use of ERCP alone, pancreatoscopy (with lithotripsy), and ESWL for obstructing PD stones and use of a single, larger PS for the initial treatment of main PD strictures while avoiding FCSEMSs for treatment of PD strictures. The ASGE also suggests the use of FCSEMSs over multiple PSs for the treatment of symptomatic BBSs and endoscopic therapy over surgery for the treatment of symptomatic pseudocysts in CP patients.

## 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

The following authors disclosed financial relationships: S. G. Sheth: Consultant for Janssen Research & Development, LLC. J. D. Machicado: Consultant for Mauna Kea Technologies, Inc; food and beverage compensation from Mauna Kea Technologies, Inc and Boston Scientific Corporation. J. M. Chalhoub: Travel compensation from Olympus Corporation of the Americas;food and beverage compensation from Boston Scientific Corporation. C. Forsmark: Consultant for Nestle Healthcare Nutrition, Inc. N. C. Thosani: Consultant for Pentax of America, Inc, Boston Scientific Corporation, AbbVie Inc, and Ambu Inc; travel and food and beverage compensation from Pentax of America, Inc, Boston Scientific Corporation, and AbbVie Inc; speaker for AbbVie Inc. N. R. Thiruvengadam: Research support from Boston Scientific Corporation. S. Pawa: Consultant for Boston Scientific Corporation. S. Ngamruengphong: Consultant for Boston Scientific Corporation; food and beverage compensation from Medtronic, Inc, Boston Scientific Corporation, Pentax of America, Inc, and Ambu Inc. N. B. Marya: Consultant for Boston Scientific Corporation; food and beverage compensation from Boston Scientific Corporation and Apollo Endosurgery US Inc. D. R. Kohli: Research support from Olympus Corporation of the Americas. L. L. Fujii-Lau: Food and beverage compensation from Pfizer Inc. and AbbVie Inc. N. Forbes: Consultant for Boston Scientific Corporation, Pentax of America, Inc, AstraZeneca, and Pendopharm Inc; speaker for Pentax of America, Inc and Boston Scientific Corporation; research support from Pentax of America, Inc. S. E. Elhanafi: Food and beverage compensation from Medtronic, Inc, Nestle HealthCare Nutrition Inc, Ambu Inc, Salix Pharmaceuticals, Takeda Pharmaceuticals USA, Inc, and Merit Medical Systems Inc. N. Cosgrove: Consultant for Olympus Corporation of the Americas and Boston Scientific Corporation; food and beverage compensation from Boston Scientific Corporation and Ambu Inc. N. Coelho-Prabhu: Consultant for Boston Scientific Corporation and Alexion Pharma; research support from Cook Endoscopy and FujiFilm; food and beverage compensation from Olympus America Inc and Boston Scientific Corporation. S. K. Amateau: Consultant for Boston Scientific Corporation, Merit Medical, Olympus Corporation of the Americas,

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*Abbreviations: ASGE, American Society for Gastrointestinal Endoscopy; BBS, benign biliary stricture; CI, confidence interval; CP, chronic pancreatitis; CPB, celiac plexus block; EHL, electrohydraulic lithotripsy; ESWL, extracorporeal shock wave lithotripsy; EUS-CPB, EUS-guided celiac plexus block; FCSEMS, fully covered self-expandable metal stent; GRADE, Grading of Recommendations, Assessment, Development, and Evaluation; IQR, interquartile range; OR, odds ratio; PC, percutaneous; PD, pancreatic duct; PS, plastic stent; RCT, randomized controlled trial; SD, standard deviation.*

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