

## GUIDELINE



# American Society for Gastrointestinal Endoscopy guideline on gastrostomy feeding tubes: summary and recommendations

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This document was reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy.

This clinical practice guideline from the American Society for Gastrointestinal Endoscopy (ASGE) provides an evidencebased approach for strategies to manage endoscopically placed gastrostomy tubes. This document was developed using the Grading of Recommendations Assessment, Development and Evaluation framework. The guideline addresses the utility of percutaneous endoscopic gastrostomy (PEG) versus interventional radiology–guided gastrostomy (IR-G), need for withholding antiplatelet and anticoagulant medications before PEG tube placement, appropriate timing to initiate tube feeding after PEG, and selection of the appropriate technique of gastrostomy in patients with malignant dysphagia. In patients needing enteral access, the ASGE suggests PEG as the preferred technique for initial gastrotomy over IR-G. The ASGE recommends that tube feeding can be safely started within 4 hours of gastrostomy. The ASGE suggests that PEG can be performed without withholding antiplatelet medications. The ASGE suggests that the periprocedural management of anticoagulants should be based on a multidisciplinary discussion regarding the risk of bleeding versus cardiovascular events. In patients with malignant dysphagia, either transoral "pull" PEG or direct PEG can be performed for initial enteral access. (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.

Enteral access for long-term nutrition may be required for patients with dysphagia or inadequate intake of food. In such patients with an intact and functional GI tract, a gastrostomy is the preferred means to facilitate enteral nutrition.<sup>1,2</sup> Although the percutaneous insertion of a feeding tube is a safe and effective technique,<sup>3</sup> there are uncertainties regarding the most effective approach for gastrostomy tube placement, managing patients requiring gastrostomy tube placement, and providing guidance for clinical decision-making.

For initial enteral access, either an endoscopic or radiologic technique can be used to perform a gastrostomy. Conventionally, a percutaneous endoscopic gastrostomy (PEG) entails

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visualization of the gastric lumen, and the procedure is performed with the patient under moderate sedation or propofol-based anesthesia without the need for fluoroscopy or contrast. Radiologic techniques typically require minimal sedation of the patient, are performed with fluoroscopy, and require nasogastric tube access and use of iodinated contrast media.<sup>4</sup> The optimal technique and comparative benefits of either technique remain under investigation.

Questions regarding the management of antithrombotic medications routinely come up before performing a gastrostomy, and these medications are often withheld to minimize the risk of bleeding. PEG is categorized as a higher risk procedure for bleeding when patients are on anticoagulants or dual-antiplatelet therapy.<sup>5</sup> Withholding antiplatelet therapy for PEG tube placement is risky in patients with cardiovascular or cerebrovascular comorbidities. More recent data have further clarified the risk and questioned the utility of withholding antiplatelet therapy in patients undergoing PEG.<sup>6</sup> Hence, existing algorithms for the management of antithrombotic therapy need to be re-evaluated.

Initiation of tube feeding is often delayed after PEG tube placement, although data to support this practice are limited. Finally, in a subset of patients with upper GI tract malignancy, there is a risk of implantation metastasis with a gastrostomy. In such patients, guidance is limited on the safest and most appropriate technique for enteral access. Therefore, the aim of this guideline is to provide highquality, clinically relevant, evidence-based recommendations for the management of gastrostomies in patients requiring long-term enteral access.

#### **METHODS**

This document was prepared by the Standards of Practice Committee of the American Society for Gastrointestinal Endoscopy (ASGE) and was conceptualized and conducted according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework.<sup>7-9</sup> Evidence was presented to a panel of experts including an interventional radiologist, nutrition support specialist, and gastroenterologists with expertise in managing gastrostomy feeding tubes. 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. We took into consideration the certainty of the evidence, benefits and harms of different management options, feasibility, patient values and preferences, resource utilization, cost-effectiveness, and health equity in developing these recommendations. The final wording of the recommendations were approved by all members of the panel and the ASGE governing board. Stronger recommendations are stated as "we recommend...," whereas conditional recommendations are indicated by "we suggest...." based on the GRADE framework. Further details of the methodology used for this guideline including systematic reviews, evidence profile, and results from all meta-analyses are presented separately in the accompanying document on methodology and review of evidence.

This guideline addressed the following clinical questions following the population, intervention, comparison, outcome format using the GRADE methodology:

- 1. In patients with normal foregut anatomy needing initial enteral access, is PEG or interventional radiology– guided percutaneous gastrostomy (IR-G) the preferred modality?
- 2. In patients undergoing PEG, should antiplatelet or anticoagulant agents be held before the procedure?
- 3. In patients who undergo PEG tube placement, should tube feeds be initiated early or be intentionally delayed?
- 4. In patients with malignant dysphagia requiring gastrostomy placement, is transoral pull PEG or transcutaneous direct gastrostomy the preferred modality to reduce the risk of implantation metastasis?

#### SUMMARY OF RECOMMENDATIONS

Details of our literature search, data analyses, pooledeffects estimates, evidence profiles, forest plots, and panel deliberation for each outcome can be found in the accompanying document subtitled "Methodology and review of evidence" published in videoGIE. A summary of our final recommendations for management of patients with gastrostomy is listed in Table 1.

Question 1. In patients with normal foregut anatomy needing initial enteral access, is PEG or IR-G the preferred modality?

Recommendation 1. In patients with normal foregut anatomy requiring enteral access, the ASGE suggests PEG over IR-G as the initial approach for gastrostomy.

(Conditional recommendation, low quality of evidence)

#### Summary of the evidence

For this question, a systematic review of published literature comparing PEG and IR-G as the initial intervention for enteral access was performed. Outcomes of interest included all-cause mortality at 30 days, malfunction of feeding tube, colon perforation, peritonitis, technical failure, bleeding, and aspiration. Studies assessing outcomes of percutaneous endoscopic jejunostomy, PEG or IR-G with jejunal extension, and feeding tube exchange through preexisting gastrostomies were excluded.

A recently published high-quality systematic review and meta-analysis that assessed 33 studies comparing outcomes in 275,117 patients who underwent PEG and 192,691 patients who underwent IR-G was identified and updated.<sup>10</sup> While updating that meta-analysis,<sup>10</sup> 2 other studies that met selection criteria were also included.<sup>11,12</sup> The meta-

Recommendation	Best practice advice	Strength of recommendation	Quality of evidence
1. In patients with normal foregut anatomy requiring enteral access, the ASGE suggests PEG over interventional radiology–guided gastrostomy as the initial approach for gastrostomy.	<ul> <li>Transillumination, 1-to-1 indentation, and safe-track needle technique with air aspiration should be performed during PEG to reduce risk of colon perforation.</li> <li>Prophylactic antibiotics (eg, cefazolin) should be administered at the time of initial gastrostomy to reduce risk of infection.</li> </ul>	Conditional	Low
<ul> <li>2a. In patients on antiplatelet drugs, including dual-antiplatelet therapy, who need to undergo PEG tube placement, the ASGE suggests against routine withholding of antiplatelet drugs.</li> <li>2b. In patients on anticoagulants who need to undergo PEG tube placement, the ASGE suggests that the periprocedural management of anticoagulants should be based on a multidisciplinary discussion including the patient, weighing the risk of bleeding vs cardiovascular events.</li> </ul>	<ul> <li>PEG tube placement may be performed while patients are on antiplatelet medications.</li> <li>In patients on antithrombotic medications who have restrictions to blood transfusions (antibodies or religious beliefs) or are at high risk of bleeding, the ASGE suggests that continuation of antiplatelet and anticoagulation medications should be based on a multidisciplinary discussion with the team and patient</li> <li>Tightening the bumper of the PEG tube for 24 hours and then loosening it may be considered to tamponade against potential bleeding. However, data to support the practice are limited, and care should be taken to avoid excessive tightening to minimize the risk of a buried bumper.</li> </ul>	Conditional	Very low
3. In patients who undergo PEG tube placement, the ASGE recommends that PEG tubes may be used for feeding early (within 4 h) over routine delays in initiation.	<ul> <li>In the absence of clinical contraindications, medications may be administered through the PEG tube immediately after placement.</li> <li>Routine measurement of gastric residual volume is not indicated.</li> </ul>	Strong	Moderate (for randomized controlled trials) Low (for all studies)
<ol> <li>In patients with malignant dysphagia requiring gastrostomy tube placement, the ASGE suggests either transoral pull PEG or transcutaneous direct PEG.</li> </ol>	<ul> <li>Patients should be counseled about the risk of implantation metastasis during the informed consent process.</li> <li>The gastrostomy site should be periodically examined to assess for implantation metastasis.</li> </ul>	Conditional	Very low

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analysis also included 1 randomized clinical trial<sup>12</sup> and 3 large, nationwide studies that used administrative databases to identify patients and compare outcomes.<sup>13-15</sup> These 3 studies were excluded from the initial analysis and used as supportive evidence after an initial analysis had been completed.

TABLE 1. Summary of recommendations and best practice advice

When compared with IR-G, PEG was associated with a lower all-cause mortality at 30 days (20 studies<sup>4,16-34</sup>; odds ratio [OR], .57; 95% confidence interval [CI], .37-.87;  $I^2 = 30.3\%$ , P = .01) and lower incidence of tube malfunction (20 studies<sup>11,18-21,23,24,27-32,35-41</sup>; OR, .51; 95% CI, .28-.92;  $I^2 = 84\%$ , P = .02). PEG and IR-G had comparable incidences of significant postprocedural bleeding (15 studies<sup>4,12,18,19,21,24,25,29,32-38</sup>; OR, .8; 95% CI, .31-2.0;  $I^2 = 0$ , P = .59), technical failure (14 studies<sup>4,16,17,24,25,29-31,33,36,38,42-44</sup>; OR, 2.52; 95% CI, .92,6.89;  $I^2 = 61\%$ , P = .06), peristomal infection (21 studies<sup>11,19-21,24-30,32-41</sup>; OR, .92; 95% CI, .65-1.29;  $I^2 = 24.5\%$ , P = .63), and aspiration pneumonia

(9 studies<sup>4,21,25,29,30,32,33,37</sup>, OR, .58; 95% CI, .28-1.21;  $I^2 = 0, P = .11$ ).

Colon perforation and peritonitis are critical but uncommon adverse outcomes and are unlikely to be detected in underpowered, retrospective, single-center studies with small sample sizes. Hence, the panel reviewed the data from the recently published meta-analysis<sup>10</sup> that included 3 studies which used large, nationally representative, administrative databases.<sup>13-15</sup> Compared with IR-G, PEG was associated with lower odds of colon perforation (OR, .6; 95% CI, .49-.75;  $I^2 = 17\%$ , P = .008) and peritonitis (OR, .71; 95% CI, .63-.81;  $I^2 = 0$ , P < .001). Furthermore, when considering the evidence from the administrative databases,<sup>13-15</sup> PEG was associated with lower odds of all-cause 30-day mortality (OR, .73; 95% CI, .58-.93;  $I^2 = 50\%$ , P = .01) and tube malfunction (OR, .56; 95% CI, .33-.95;  $I^2 = 95\%$ , P = .03).

No studies directly assessed cost or cost-effectiveness. No specific concerns were related to equity because IR-G and PEG are both invasive procedures that are frequently performed at large and small community hospitals. Based on the GRADE methodology, the evidence was rated as low quality. Considering the above data and given the lower risk of all-cause mortality and tube malfunction, the panel made a conditional recommendation for PEG compared with IR-G.

#### Discussion

The interventional radiologist on the panel noted that IR-G feeding tubes are typically of a smaller diameter (12F-18F) that predisposes them to tube-related malfunction, including clogging and need for readjustment. The difference in malfunction may also partially be explained by the inflatable balloon system for the internal bolster on the IR-G tube versus the fixed mushroom internal bolster on the PEG tube. Further, the interventional radiologist noted that there has been considerable progress and advancement in the techniques of IR-G including the use of ultrasound guidance to identify structures in the planned needle access tract, use of coned-beam CT fluoroscopy with enhanced needle guidance, "I-guide" technology in challenging colonic interposition cases, and CT-guided gastrostomy tube placement, which may reduce the risk of adverse outcomes and mortality; however, outcomes data for these techniques are currently not available. The patient advocate on the panel also noted their own experience with the need for frequent replacement and higher incidence of tube malfunction with IR-G.

The panel noted that the risk of colon perforation with PEG can be mitigated by using endoscopic techniques to detect the presence of air-containing viscus between the anterior gastric wall and the abdomen. Transillumination, 1-to-1 indentation, and a safe-track needle technique (simultaneous aspiration of air and visualization of the needle within the stomach) must be performed to reduce the risk of colon perforation.<sup>1,45</sup>

To minimize the risk of peristomal infection, current guidelines from the ASGE and the Society of Interventional Radiology recommend that prophylactic antibiotics should be administered at the time of gastrostomy,<sup>46,47</sup> which was supported by this panel. Cefazolin is a frequently used antibiotic because it can be administered as a single intravenous dose and provides adequate broad-spectrum coverage.<sup>48</sup> It is typically administered at the time of the procedure or 30 minutes before the procedure.

Based on the above evidence and panel deliberations, the ASGE suggests PEG over IR-G as the modality of choice for initial enteral access. The panel noted that in institutions where IR-G is frequently performed or PEG is unavailable, IR-G can be considered an appropriate method for enteral access. Question 2. In patients undergoing PEG, should antiplatelet or anticoagulant agents be held before the procedure?

Recommendation 2a. For patients on antiplatelet agents, including dual-antiplatelet therapy, who need to undergo PEG tube placement, the ASGE suggests against routine withholding of antiplatelet agents.

(Conditional recommendation, very low quality of evidence)

Recommendation 2b. In patients on anticoagulants who need to undergo PEG tube placement, the ASGE suggests the periprocedural management of anticoagulants should be based on a multidisciplinary discussion including the patient regarding the risk of bleeding versus cardiovascular events.

(Conditional recommendation, very low quality of evidence)

#### Summary of the evidence

A systematic review of published literature comparing PEG tube placement with or without antithrombotic medications was performed. Outcomes of interest were bleeding, mortality, risk of cardiovascular events, adverse events, blood product transfusions, and cost. Studies assessing outcomes of percutaneous endoscopic jejunostomy, PEG with jejunal extension or IR-G with jejunal extension, feeding tube exchange through pre-existing gastrostomies, or pediatric patients were excluded. Noncomparative studies were also excluded.

Only 1 study was identified that specifically compared outcomes after holding antithrombotic medications or continuing them at the time of feeding tube placement.<sup>49</sup> Because this was insufficient to make conclusions, further supportive evidence was obtained by including studies evaluating patients on any antithrombotic medication in the periprocedural period versus antithrombotic-naive patients. Five retrospective cohort studies were identified, from which patient-level data were extracted on clinically significant bleeding.<sup>6,49-52</sup> No usable data were available on other outcomes of interest, including mortality, risk of cardiovascular events, overall adverse events, transfusions, hospitalization, and cost. Very limited data were available on novel oral anticoagulants, and hence these were not included in the current guideline.

The definition of bleeding varied between different studies. Only 1 study stratified their data specifically on PEG-related bleeding. However, all studies reported "significant bleeding," defined as some variation of requiring endoscopic intervention, transfusion requirements, hemoglobin drop of  $\geq 2$  g/dL, or clinical signs of active bleeding.

The prevalence of bleeding did not vary when comparing patients taking antiplatelet drugs with those not taking antiplatelet drugs. Specifically, compared with patients not on aspirin, those on aspirin did not have a significant increase in bleeding (4 studies<sup>6,50-52</sup>; OR, 1.39; 95% CI, .56-3.44; P = .32). Similarly, patients on clopidogrel did not have an increased rate of bleeding compared with patients not on clopidogrel (4 studies<sup>6,50-52</sup>; OR, 1.26; 95% CI, .18-8.81; P = .72). Data on patients on dual-antiplatelet therapy were also extracted and no increase in bleeding was found, although only 2 studies reported patient-level  $data^{6,50}$  (OR, .75; 95% CI, .16-3.59; P = .25). The rate of bleeding for patients on compared with not on anticoagulation medications (therapeutic heparin or warfarin) also did not differ, although data were available from only 2 studies<sup>6,50</sup> (OR, 1.56; 95% CI, .00-853.51; P = .53).

## Discussion

Although the general practice in many centers is to hold antithrombotic medications, holding these medications is not feasible in some patients (ie, patients with recent ischemic stroke). The data reviewed, despite low quality, showed a very low risk of bleeding if patients continue antithrombotic medications. The panel noted that withholding antithrombotic medications could result in harm, particularly an increased risk of cardiovascular events.<sup>53</sup> Other unintended consequences may include delaying PEG tube placement, longer duration of nasogastric feeds, longer length of hospital stay, and delays in transfer to long-term acute care facilities. Furthermore, the bleeding events that were noted in the studies were non-life-threatening and generally easy to treat. Feedback was also elicited from the patient representative, who preferred bleeding over any risk of stroke or cardiovascular adverse event.

The data were limited given the low number of studies and the low event rates. This is particularly apparent in the wide OR in patients given anticoagulation drugs during their hospitalization, such that imprecision was rated very serious. Based on these data and the panel's deliberation, patients on antiplatelet and anticoagulation medications are treated differently. The ASGE suggests against routine withholding of antiplatelet drugs, including dual-antiplatelet therapy, in patients who need to undergo PEG tube placement. Additionally, the ASGE suggests that the periprocedural management of anticoagulants should be based on a multidisciplinary discussion, which should include the patient and their representatives, regarding the risk of bleeding from continuing antiplatelet and/or anticoagulation medications compared with the risk of cardiovascular adverse events from withholding such medications (cerebrovascular accident, myocardial infarction, pulmonary embolus, etc).

Question 3. In patients who undergo PEG tube placement, should tube feeds be initiated early or be intentionally delayed?

Recommendation 3. In patients who undergo PEG tube placement, the ASGE recommends that PEG tubes may be used for feeding early (within 4 hours) over routine delays in initiation.

(Strong recommendation, low to moderate quality of evidence)

## Summary of the evidence

For this question, a systematic review of the published literature comparing intentionally delayed versus early tube feed initiation after PEG tube placement was performed. Outcomes of interest were all-cause mortality at 30 days, short-term mortality (<72 hours), adverse events, vomiting, aspiration, peristomal leak, wound infection, and PEG site stomatitis. Noncomparative studies and studies assessing outcomes of percutaneous endoscopic jejunostomy, PEG with jejunal extension or IR-G with jejunal extension, feeding tube exchange through pre-existing gastrostomies, or examining pediatric patients were excluded.

We identified 4 randomized controlled trials (RCTs)<sup>54-57</sup> and 4 non–randomized controlled comparative studies<sup>58-61</sup> for a total of 1120 patients. The definitions of early and delayed feeding varied across the studies. For our metaanalysis, we defined the initiation of early tube feed as at or before 4 hours after PEG tube placement and delayed initiation as over 4 hours after PEG tube placement. Outcomes were measured for both the RCTs alone and for the RCTs and non-RCTs combined.

All-cause mortality at 30 days was similar based on 2 RCTs<sup>54,56</sup>: 23.3% for delayed versus 24.6% for early initiation (relative risk [RR], .93; 95% CI, .06-14.00; P = .79,  $I^2 = 0$ %). When we additionally included 3 observational studies, <sup>54,56,59-61</sup> these values were 9.3% versus 12% for delayed versus early initiation (OR, .83; 95% CI, .51-1.35; P = .45,  $I^2 = 0$ %).

Short-term (<72 hours) mortality was also similar between early and delayed feeding in RCTs (6.7% vs 3.3%; RR, 1.78; 95% CI, .03-95.63; P = .31,  $I^2 = 0\%$ )<sup>54,56</sup> and all studies (1.3% vs 1.6% for delayed versus early; OR, 1.06; 95% CI, .24-4.8; P = .94,  $I^2 = 8\%$ ).<sup>54,56,59</sup> Four RCTs<sup>54-57</sup> showed no difference in the overall adverse event rate (12.4% vs 12.4%; RR, 1.02; 95% CI, .23-4.47; P = .96,  $I^2 = 25\%$ ). This was also true when combining observational studies<sup>54-61</sup> (15.4% vs 18.4% for delayed versus early feeding; OR, .97; 95% CI, .69-1.35; P = .85,  $I^2 = 0\%$ ).

Regarding specific adverse events, there was no difference in vomiting in either the RCT data<sup>54,56</sup> (8.3% vs 6.6%; RR, 1.30; 95% CI, .00-1819.1; P = .72,  $I^2 = 0\%$ ) or for all studies combined<sup>54,55,57,59,60</sup> (6.6% vs 4.6% delayed vs early feeding; OR, 1.42; 95% CI, .73-2.77; P = .3,  $I^2 =$ 0%). Only 4 aspiration events were reported for all studies,55-57,59-61 all of which occurred in the delayed feeding group (.8% vs 0%; OR, 4.53; 95% CI, .73-28.06;  $P = .1, I^2 = 0\%$ ). Although more peristomal leaks were noted in the early feeding group for all studies<sup>54,56,58-61</sup> (2.8% vs 1%), this difference was small and not statistically significant (OR, .5; 95% CI, .16-1.59; P = .24,  $I^2 = 3\%$ ). Rates of wound infection were also similar at 6% versus 4.2% (RR, 1.34; 95% CI, .0-304,188; P = .81,  $I^2 = .8\%$ ) for the RCTs alone<sup>56,57</sup> and 3.0% versus 3.3% for delayed versus early feeding (OR, 1.04; 95% CI, .46-2.34; P = .93,  $I^2 = 0\%$ ) for combined studies.<sup>56-61</sup> A nonsignificant increase in stomatitis rates was noted for the early versus delayed feeding groups (4.9% vs 0%; RR, .26; 95% CI, .01-9.04; P = .8,  $I^2 = .0\%$ ) when including only the RCTs<sup>54,56</sup>; however, no difference was seen for the combined studies<sup>54,56,58,59,61</sup> (1.9% delayed vs 1.4% early; OR, .9; 95% CI, .15-5.51;  $P = .10, I^2 = 49\%$ ).

#### Discussion

There is a misconception that delayed initiation of tube feeds allows the stoma site to heal before tube feed initiation. However, the stoma site likely takes at least several weeks to heal completely.<sup>61</sup> Another concern with early tube feed initiation has been that gastric wall puncture during PEG tube placement may transiently decrease gastric motility, resulting in increased gastric residual volume.<sup>54</sup> Although several studies included in our analysis reported gastric residual volume as an outcome, gastric residual volume measurement and definition of high gastric residuals are not standardized and vary between studies. Routine measurement of gastric residuals is also of unclear clinical significance and may lead to unnecessary tube feed discontinuation.<sup>62-65</sup> Additionally, the omission of gastric residual monitoring results in increased enteral nutrition provision with reduced prokinetic use and GI adverse events.<sup>66</sup> Based on the available evidence, the panel agreed that routine gastric residual measurement is not indicated.

No studies compared cost-effectiveness, time to reach goal tube feed rate, or length of hospital stay. However, earlier tube feed initiation may theoretically allow patients to reach goal rates more quickly, resulting in decreased hospitalization length and reduced healthcare cost. The panel noted that the difference in nutritional status is likely clinically insignificant between early versus delayed tube feed initiation, although no studies reported this. Our patient advocate emphasized a desire to have tube feeding initiated as soon as possible to not delay or interrupt nutrition therapy and was reassured that there were no increased adverse events noted for earlier tube feed initiation. The expert panel also noted a theoretical benefit of reducing the risk of ileus with earlier tube feed.

Overall, the evidence was of moderate quality. Given the lack of significant difference in outcomes between the early and delayed feeding groups, the theoretical benefits of earlier tube feed initiation, and the patient value assessment, the panel made a recommendation for early (within 4 hours) versus intentionally delayed tube feed initiation after PEG tube placement. The panel noted that initiation of early tube feeding after PEG tube placement may not be clinically appropriate in certain situations, including severe ileus, obstruction, or bowel ischemia. Early initiation of tube feeding may not always be feasible because of logistic delays. The panel noted that in most cases, medications may be given immediately through the PEG tube after placement, unless there are contraindications to enteral medications.

Question 4. In patients with malignant dysphagia requiring gastrostomy placement, is transoral pull PEG or transcutaneous direct gastrostomy the preferred modality to reduce the risk of implantation metastasis?

Recommendation 4. In patients with malignant dysphagia requiring gastrostomy placement, the ASGE suggests either a transoral pull PEG or transcutaneous direct PEG or IR-G.

(Conditional recommendation, very low quality of evidence)

### Summary of the evidence

For this question, a systematic review of the published literature was performed. Outcomes of interest included the incidence of implantation metastasis and comparative success of direct PEG versus other modalities. A systematic review and meta-analysis from Siu et al<sup>67</sup> was reviewed. This meta-analysis was updated, and case reports were excluded from our final analysis. No studies directly compared transcutaneous direct PEG with transoral pull PEG in patients with malignant dysphagia. The incidence of implantation metastasis based on 11 observational retrospective studies<sup>11,23,68-76</sup> was .6% with transoral pull PEG versus .07% with direct gastrostomy (transcutaneous direct PEG and IR-G) (OR, 3.34; 95% CI, .36-30.70; P = .52,  $I^2 = 0$ ).

The quality of evidence was rated down because of the retrospective study design of the source studies, publication bias, small sample sizes, and imprecision because of a very low incidence of implantation metastasis. Further, 1 study had an outsized impact on the forest plot because of a relatively higher incidence of metastasis within a small cohort.<sup>11</sup> These data were considered outliers and led to further down-rating of the quality of evidence.

Because a transcutaneous direct PEG obviates the transoral passage of the feeding tube, it has historically been considered to have a lower risk of implantation metastasis in patients with malignant dysphagia. A transcutaneous direct PEG can also be performed using a narrow-caliber or ultraslim gastroscope<sup>77</sup> in patients with esophageal cancer with luminal stenosis or complex strictures. Hence, it is considered an attractive alternative to a conventional pull PEG or an IR-G, although the 5F catheters used for IR-G are also often able to navigate tight malignant strictures.

One study compared transcutaneous direct PEG and IR-G in patients unable to undergo a transoral pull PEG. This single-center, nonrandomized study noted comparable technical success between transcutaneous direct PEG and IR-G.<sup>4</sup> However, the all-cause 30-day mortality rate was 15.6% (7/45) in IR-G compared with 0 for transcutaneous direct PEG. The only serious adverse outcome, a perforation of the colon, was noted with IR-G. Procedure times were shorter and dosage of sedatives higher with transcutaneous direct PEG compared with IR-G

No studies assessed cost and cost-effectiveness. In view of the inconsistency, imprecision, small sample sizes, and retrospective study design of the source studies, the evidence was rated down to very low quality.

## Discussion

In addition to concerns with the quality of the data, we noted that mechanical translocation of malignant cells during transoral passage of the gastrostomy tube is not the only putative etiology of implantation metastasis. Available literature also suggests hematogenous spread of malignant cells leading to implantation metastasis.<sup>78</sup> Implantation metastasis has also been reported with transcutaneous direct PEG as well as IR-G even though there is no transoral passage of the feeding tube.<sup>79,80</sup>

Further, the panel expressed significant concerns regarding the inequitable access to IR gastrostomy and transcutaneous direct PEG because most centers preferentially perform pull PEG.<sup>81</sup> In many centers, the expertise to perform transcutaneous direct PEG is not available, and IR-G may be associated with adverse outcomes. Hence, although the use of transcutaneous direct PEG may be advisable, it is not mandatory, and the panel refrained from making a recommendation against use of transoral pull PEG in patients with aerodigestive malignancies despite such recommendations made by other gastroenterological societies.<sup>82,83</sup>

The risk of implantation metastasis should be discussed with the patient during the informed consent process.<sup>84</sup> In centers where IR-G or transcutaneous direct PEG is available, these options should be offered. Further, the site of the gastrostomy should be periodically assessed for implantation metastasis during physical examination. Finally, better-quality studies examining implantation metastasis are needed to better delineate the risk of this outcome.

## **FUTURE DIRECTIONS**

Our systematic literature review highlighted several areas in need of more data to inform the role of endoscopy in the management of PEG tubes. Future studies should address the following:

- 1. Optimal gastrostomy technique for altered foregut anatomy. Gastrostomy tubes can be placed surgically, fluoroscopically, or endoscopically.<sup>1,14</sup> Further, endoscopic techniques include direct, push, and pull PEG. Although some comparative data exist, high-quality studies are needed to guide selection techniques that are tailored to specific clinical scenarios such as surgically altered foregut anatomy.
- 2. *Selection of type of feeding tube.* Feeding tubes come in various designs and sizes. These include standard-profile and low-profile tubes, tubes with bumper or balloon retention systems, and tubes with varying number of ports, including a dedicated port for medications. Studies examining the relative benefits and harms of the different types of tubes are needed to select the appropriate feeding tube tailored to specific patient needs.
- 3. *Protocols for exchange of feeding tube*. Feeding tubes are often placed for long-term access and hence require periodic exchange. Evidence-based recommendations are not available because of a lack of high-quality studies that can define the protocols for scheduled exchanges of feeding tubes.
- 4. Safety of PEG tubes in patients with ascites. A subset of patients needing enteral access have ascites, which could be because of portal hypertension, peritoneal metastasis from abdominal and pelvic malignancies, or poor nutritional status. Adverse events include bacterial peritonitis, failure of tract maturation, and consequent leakage of peritoneal fluid in the event of PEG removal. Although some data suggest a higher incidence of adverse events in hospitalized patients with ascites,<sup>85,86</sup> other studies suggest gastrostomy tubes for venting are safe in patients with malignant ascites.<sup>87,88</sup> Although PEG tube placement may be safe in malignant ascites especially after a therapeutic paracentesis, risks are higher with portal hypertension associated with cirrhosis. High-quality studies are needed to define the best practices and selection protocols in patients with ascites needing a PEG tube.
- 5. Assessment of risk of implantation metastasis. As noted above, there is a low but finite risk of implantation metastasis associated with PEG tubes, including the pull technique.<sup>67</sup> Although there are suggestions to avoid pull PEG in patients with foregut malignancies,<sup>82,83</sup> better studies are needed to understand the risk of implantation metastasis and efficacy of endoscopic techniques to mitigate this risk.
- 6. *Managing long-term adverse events*. Potential postprocedure adverse events include leaking around the gastrostomy tube, cellulitis, persistent gastrocutaneous

fistula after removal of the feeding tube, or pain at the gastrostomy site. Research is needed to find algorithmic solutions to these common long-term issues.

7. *Developing an algorithm for gastric, gastro-jejunal, or jejunal access.* Subsets of patients may benefit from postpyloric feeding, with or without concurrent gastric access. These include patients with malignant gastric outlet obstruction or selected patients with medication-refractory gastroparesis. Comparing clinical outcomes and assessing best practices to identify patients who would benefit from a transgastric jejunal access versus direct jejunal access need to be undertaken.

#### SUMMARY AND CONCLUSIONS

These ASGE guidelines use the best available evidence to make recommendations on the management of PEG tubes. In patients needing enteral access, the ASGE suggests PEG as the initial intervention while continuing antiplatelet medications and recommends starting tube feeding within 4 hours of placement. Management of anticoagulant medications should be individualized as part of a shared medical decision-making based on a multidisciplinary discussion regarding the risk of bleeding versus cardiovascular events. In patients with malignant dysphagia, either transoral pull PEG or direct PEG can be performed for initial enteral access.

### **GUIDELINE UPDATE**

ASGE guidelines are reviewed for updates approximately every 5 years or if 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; Cl, confidence interval; GRADE, Grading of Recommendations Assessment, Development and Evaluation; IR-G, interventional radiology–guided gastrostomy; OR, odds ratio'; RCT, randomized controlled trial; RR, relative risk.

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