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Quality Indicator Development for the Approach to Ineffective Esophageal Motility: a Modified Delphi Study

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Abstract

Goals: Develop Quality Indicators for Ineffective esophageal motility (IEM).

Background: IEM is identified in up to 20% of patients undergoing esophageal high-resolution manometry (HRM) based on the Chicago Classification. The clinical significance of this pattern is not established and management remains challenging.

Study: Using RAND/UCLA Appropriateness Methods, we employed a modified-Delphi approach for quality indicator statement development. Quality indicators were proposed based on prior literature. Experts independently and blindly scored proposed quality statements on importance, scientific acceptability, usability, and feasibility in a three-round iterative process.

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Results: All 10 of the invited esophageal experts in the management of esophageal diseases invited to participate rated 12 proposed quality indicator statements. In round one, 7 quality indicators were rated with mixed agreement, on majority of categories. Statements were modified based on panel suggestion, modified further following round two's virtual discussion, and in round three voting identified 2 quality indicators with comprehensive agreement, 4 with partial agreement, and 1 without any agreement. The panel agreed on the concept of determining if IEM is clinically relevant to the patient's presentation and managing GERD rather than the IEM pattern; they disagreed in all four domains on the use of promotility agents in IEM; and had mixed agreement the value of a finding of IEM during anti-reflux surgical planning.

Conclusion: Using a robust methodology, two IEM quality indicators were identified. These quality indicators can track performance when physicians identify this manometric pattern on HRM. This study further highlights the challenges met with IEM, and the need for additional research to better understand the clinical importance of this manometric pattern.

Keywords

Gastrointestinal Motility; Quality Indicators; Esophageal Diseases; Evidence Practice Gaps; Gastroesophageal reflux

Introduction:

Ineffective esophageal motility (IEM), as based on the Chicago Classification version 4.0, is a manometric pattern defined as a normal median IRP with >70% ineffective swallows or 50% failed peristalsis.¹ This manometric pattern represents swallows with a low amplitude and is an indirect way to describe the "ineffectiveness" of a swallow. IEM poses a challenge when identified as it has been reported in as many as 20% of patients undergoing high resolution manometry (HRM) and is the most common abnormality identified on HRM – often in those without any clinical symptoms.^{2,3} While clinical implications and treatment options are well established for the major motility disorders such as achalasia, the treatment of IEM remains less well known.

Clinical symptoms associated with IEM can include heartburn (reported in as high as 49% of patients with IEM) and dysphagia; globus, atypical chest pain, nausea, and chronic cough.⁴ Further, interstitial lung disease and COPD have also been reported.⁵ Prior studies suggested that patients with IEM in particular have higher mean total acid esophageal exposure time and total reflux events compared to those with normal motility, and that these patients may be more likely to have erosive esophagitis or Barrett's esophagus on endoscopy.⁵⁻⁷ Reflux can contribute to IEM, but IEM can also contribute to poor clearance of reflux. In addition, higher reflux symptom burden as based on the GerdQ has been associated with higher rates of hypomotility patterns (IEM, absent contractility, fragmented peristalsis) on HRM.⁸ In patients who have reflux symptoms and the manometric pattern of IEM, management emphasis is directed at GERD. Indeed, IEM may represent a clinically incidental manometric pattern in asymptomatic patients who have this finding on HRM, and thus definitive therapy need not be pursued.⁹

Nonetheless, the overall clinical significance of IEM remains unclear and global treatment recommendations remain challenging as a result. To date, there is a limited framework guiding gastroenterologists in their management when IEM is identified. Therefore, we aim to establish quality indicators to optimize the care of patients with IEM.

Materials & Methods:

To develop IEM-specific quality indicators, we applied the RAND/University of California, Los Angeles Delphi Appropriateness Method (RAM) through a modified three-round Delphi technique among invited academic gastroenterologists with expertise in esophageal motility disease (Figure 1). This study was approved by the Stanford University Institutional Review Board (IRB). Neither patients nor the public were involved in the design or dissemination of this research, due to the nature of this project seeking a consensus among experts in the field.

Expert panel recruitment

To develop consensus for quality indicator development, we invited experts from tertiary care settings with experience in management of esophageal disease, particularly dysmotility and gastroesophageal reflux disease (GERD). The expert panel were recruited by direct email invitations from the primary investigators (AK, PK, DL, FO), the majority of whom are experts and co-authors of the Chicago Classification v4.0.¹ To maximize generalizability of the proposed quality indicators, members were recruited if proficient in English language and, if working within international, academic health systems similar to our current United States health system. While not inclusive of all recognized experts in this field, this number of experts is consistent with similar projects,^{10,11} is pragmatic, and within the range across a large number of projects aimed at identifying quality indicators. All experts recruited accepted the invitation and were enrolled into round one of the study.

Compilation of potential quality indicators

Potential IEM quality indicators were identified by the primary investigators through an extensive literature review and assessment of symposium statements. The literature review was challenged by the lack of established guidelines or systematic reviews with meta-analysis on the topic, therefore this included assessment of all available observational studies as well. Candidate indicators consisted of initial evaluation, manometric findings, management, and follow up. By intent, the primary investigators proposed indicators that contained both specific and general quality indicators, to spark discussion among the experts. Final quality indicators were established based on modifications suggested by the experts through each three rounds of voting.

Analyzing quality indicators for validity

Analysis of the quality indicators were performed using standard scoring definitions applied for quality indicator development.⁶⁻⁸ The primary investigators were not themselves voting members of the panel. For each proposed quality indicators, the panelists independently voted through a survey link on Qualtrics (Provo, UT) and responses were collated. For each proposed quality indicator, a distinct score for each of four separate categories were

collected. The panelists voted applying a 9-point Likert scale, where a score of 1 = “definitely not valid”, 5 = “uncertain”, and 9 = “definitely valid”. The four categories in which each indicator was scored were: *importance, scientific acceptability, usability, and feasibility*.

Proposed quality indicators were scored based on degree of agreement within the same three-point range (i.e., 1–3, 4–6, or 7–9). For a quality indicator to be accepted, all 4 categories for that individual indicator (e.g., importance, scientific acceptability, usability and also feasibility) had to reach 80% agreement in the ranking range between 7–9.^{6–8}

Round 1: Initial ranking of IEM quality indicators

We applied a well-established RAND/UCLA Delphi technique organized by the primary investigators.¹² This was an iterative process, applying one virtual round bounded by two-voting rounds. In round one, panel experts received an invitation with specific instructions to complete the round. Ranking was completed independently and electronically through Qualtrics (Provo, UT). Prior to voting, each expert received detailed definitions of the four categories (importance, scientific acceptability, usability, and feasibility) to ensure each rater was interpreting the category similarly. Since ranking occurred electronically through Qualtrics (Provo, UT), panelists could access the survey on any personal electronic device (i.e., cell phone, computer) and complete on multiple sittings.

Panelists received approximately two-weeks to complete round one, in which each panelist independently rated the proposed quality indicators applying the 9-point Likert scale. While completing round one, we designed the ranking process to additionally provide each expert to suggest word modifications to improve potential validity. Responses were de-identified. Summary statistics were calculated for each proposed quality indicator assessing for level of agreement, in which we defined agreement by 80% falling in the ranking of 7–9, within all four categories.

Round 2: Video conference discussion

Following the initial ranking round, we invited experts to participate in a real-time, virtual discussion hosted by Zoom Video Communications (San Jose, CA). Prior to the meeting, panelists received a de-identified overall group rating, to indicate proposed quality indicators that might have reached agreement and those that might be discarded due to low agreement. Experts did not vote during this round; instead, this round functioned as a platform to open discussion regarding word modification on indicators with mixed-agreement, defined as an indicator where one of four categories reached 80% within rankings of 7–9, but not all four categories. Experts who did not attend the video conference (83%) were provided an opportunity to discuss these indicators, to provide suggested modifications to wording and sentence structure, which would then be incorporated into the final round. The majority who did not attend contributed via email correspondence.

Round 3: Final ranking of IEM quality indicators

Following round two discussion, proposed quality indicators were modified by non-voting members (AK, PK, DL, FO) based on the expert suggestions. In the final round, experts

independently re-scored the indicators meeting mixed-agreement electronically through Qualtrics (Provo, UT).

Results

Through an extensive review of the literature, we identified 12 potential quality indicators for approaching IEM when identified on HRM. Our expert panel was composed by physicians from North America (n=6) and Europe (n=4), and all experts accepted our invitation to participate in a three-round RAND/UCLA Appropriateness Method (modified Delphi). In round one, there was zero (0%) consensus agreement on validity of the 12 proposed indicators. A consensus of low scores was identified among 5 (41.7%) statements which were completely removed. Experts rated 7 (58.3%) quality indicators with mixed-agreement (<80% agreement across all four categories). The indicators with mixed agreement covered topics pertaining to the definition of IEM as a diagnosis, the role of the care team when manometry patterns are consistent with IEM, as well as the importance of the IEM in surgical management.

These 7 indicators were then modified based on panel suggestion and placed on the agenda to discuss in *round two* video conference portion of this iterative process. Panelists provided suggestions on word modification of proposed quality indicators rated with mixed-agreement. For example, the first statement rated with mixed-agreement included “High resolution esophageal manometry reveals >70% ineffective swallow sequences (DCI<450 mmHg cm s) with normal LES relaxation on HRM, THEN the manometric pattern is consistent with IEM” and reached complete agreement under the category of “feasibility.” Panelists discussed the statements not reaching consensus, and suggested modifications to the quality indicator statements. Additional comments from those unable to attend the virtual discussion were read aloud by the primary investigators. The discussion primarily surrounded the topic of IEM as a “manometric pattern” and not a true “diagnosis.” Following completion of round two, the proposed quality indicators were modified based on expert discussion and re-rated in *round three*.

In total, after completing a three-round modified Delphi method, the expert panel agreed with a consensus on 2 quality indicators statements out of the initial 12 proposed (Table 1). These statements related to determining if IEM was clinically relevant based on the patient’s clinical presentation, particularly in the setting of GERD – rather than focusing on IEM as a clinical entity. Further, the panel disagreed in the use of promotility agents, such as prucalopride, in management of IEM, and met with mixed-agreement on the relevance of IEM with contractile reserve prior to anti-reflux surgery.

Discussion

Quality indicators can provide a framework to identify care practices that are associated with desired clinical outcomes as well as generate a rubric for measuring, and ultimately improving, healthcare delivery. In the context of IEM, the evolving definition and limited high-quality data present a challenge to develop more concrete quality measures, which pre-specify populations of interest and are commonly used for inclusion in quality payment

programs. As a result, quality indicators are a useful conceptual framework on which to measure variation in care and establish future quality measures. In this study, we systematically evaluated and eventually developed comprehensive quality indicators for gastroenterologists related to IEM.

The advent of HRM has greatly facilitated our understanding of pathophysiological states of the esophagus while the hierarchical diagnostic algorithms of the Chicago Classification have greatly improved diagnostic outcomes.¹ In addition to the iterative development of Chicago Classification, the European society of Neurogastroenterology and Motility have also put together recommending to address the heterogeneity on how manometric studies are completed, including subtle differences in preprocedural preparation, technique of catheter placements, test interpretation and management, has been examined by various societal and expert panels.¹³ There is now more agreement regarding manometric patterns and the associated clinical implications, natural history of disease, and preferred treatments. This is most relevant in but less clear for IEM. However, IEM is a substantially more common finding on HRM but paradoxically has fewer discrete management strategies. As a result, patient outcomes are impacted by treatment choices, suggesting a need for standardized approaches emphasizing quality. By using a modified RAND/UCLA Delphi process, in which the expert panel focused on importance, scientific acceptability, usability and feasibility among proposed quality indicators, there was independent partial agreement on 7 IEM quality indicators spanning the domains of diagnosis, communication and care coordination, and medical and surgical management. Of those; 2 IEM quality indicators reached high validity. While only a small fraction of indicators reached agreement, this conclusion illustrates fundamental best practices as well as highlighting ongoing needs for the field.

IEM was coined in 1997 by Leite et al.¹⁴, standardized in 2001¹⁵ and eventually refined seven years later.¹⁶ The manometric pattern is characterized by hypo-contractility and frequently associated with incomplete bolus transit on impedance measurement. The salient manometric patterns have evolved from reliance on peristaltic breaks to the recent emphasis on the distal contractile integral (DCI). There are now two thresholds based on severity of hypo-contractility, including both weak and failed swallows under the manometric pattern.

While IEM is the most commonly seen manometric pattern (20–58% regardless of symptoms),^{17,18} its significance remains uncertain. Particularly, as DCI changes do not equate to alteration in radiographic bolus clearance. Recent data show that with increasing ineffective swallows patients are more likely to have dysphagia,¹⁹ and affirmed the thresholds in CC4.0, but patients may also be asymptomatic. Associated symptoms have included dysphagia, heartburn, odynophagia and regurgitation. IEM is commonly found in the evaluation of gastroesophageal reflux disease (GERD). When present, IEM can effect surgical planning regarding the type of anti-reflux operation performed, and also has implications for outcomes in the context of an anti-reflux surgery.^{20–22} Causality is still debatable and invariable most patients have multiple contributing etiologies to their symptoms, including a tight or slipped fundoplication, or recurrent hernia.²³ Potential other associated etiologies for IEM include rapid food intake, vagal hyperreactivity, enteric smooth muscle neuropathy and advanced age.¹⁷ This in part has generated significant

differences in diagnosis and management choices. Thus, this poses a need to evaluate quality indicators given the heterogeneity in presentation. Indicators frequently describe the clinical concepts involved and perspective from which measurement occurs, but rarely designate the method for measurement (*e.g.*, the data source(s) to be used), specify precise population criteria, or include instructions for how the measure is to be used.

Manometry only provides an indirect measurement of pressure and does not assess luminal diameter, anatomical variations, or bolus retention. Incorporating other studies including a timed barium esophagram and functional lumen impedance planimetry would further improve diagnostic correlation with symptoms and outcomes.²⁴ One of the challenges in over-reliance on the Chicago Classification is the assumption that manometric patterns are a diagnosis of a disease state, which may hold true in achalasia but is inaccurate for IEM. A common recurrent theme discussed by the experts in our study was the emphasis of labelling IEM as a manometric pattern rather than a diagnosis. This likely explains why the indicators focusing on diagnosis had a greater agreement in the usability and feasibility relative to importance and scientific acceptability. As with many disease states in which the diagnostic modalities are rapidly expanding, our ability to phenotype disease states is lagging. We suspect that future subdivisions of IEM maybe able to generate a longer list of quality indicators with greater agreement.

In regards to management, experts agreed that treatment in IEM should be focused on the symptom and etiologic association when identified. This is particularly relevant in the absence of high-quality evidence demonstrating the ability of medical or surgical interventions to restore esophageal smooth muscle contractile vigor and/or coordination. Prior unsuccessful pharmacologic agents have included cholinergic agonists, acetylcholinesterase inhibitors, dopamine antagonist, motility receptor agonists, and serotonin-4 agonists. Some of the agents with preliminary efficacy, notably cisparide and tegaserod, have now been taken off market due to cardiovascular adverse events. While the effect of buspirone on the lower esophageal sphincter is consistent, its effect on esophageal body contraction trended without significance. These effects have not been demonstrated to translate into clinical improvement.²⁵ More recently, prucalopride has been found to decrease esophageal acid exposure in addition to accelerating gastric emptying.²⁶

The natural history of IEM is heterogenous. Most experts, including our panelists, feel that IEM may carry a predictive role in the development of dysphagia post-fundoplication. There is an interest but lack of standardization in manometric provocation, which makes developing a relevant quality indicator challenging. In round two some of the experts argued that IEM alone should not be a sole determinant of type of anti-reflux procedure pursued. The experts also agreed that although counseling on the risk of post-operative dysphagia is important, it need not fall upon a single provider; rather a multi-disciplinary approach should be pursued when managing patients with this heterogeneous manometric pattern.

The authors also felt that focusing the discussion on the appropriate confirmatory and complementary diagnostic testing for GERD and subsequent management were not within the scope of this project. There was an acknowledgment of the multitude of efforts working on phenotypic diagnosis and management of this broad disease state.

While there are obvious strengths to having an expert panel provide their opinion regarding candidate indicators, these were generated by a comprehensive but not systematic review of the literature. Second, the expert panel provided their input but did not help in the generation of these concepts. While including international experts is a strength of this study, an acknowledged limitation is the lack of an in-person meeting. Nonetheless, the contributions of a global panel should help to generalize our findings. Additionally, the expert panel comprised of gastroenterologists practicing within tertiary care academic referral centers, did not include foregut surgeons or gastroenterologists working within a community setting. Therefore, proposed indicators may be subject to external selection bias and may not be generalizable. Finally, the selection of experts from the Chicago Classification panel may be a source of bias, but interestingly their disagreement across candidate statements highlights the lack of consensus in the field. Moreover, many of the authors have published other recommendations as part of other collective groups such as ESNM. Additional studies that would incorporate a multitude of specialties, primarily foregut surgeons, would further strength the clinical applicability of the outcomes. They would also likely allow for refinement of indicators pertaining to the communication of the clinical applicability of results. We recognize our singular perspective in facilitating the navigation of symptomatic patients through the myriad of further diagnostic and management steps associated with the finding of a manometric pattern of IEM.

In conclusion, an expert panel identified 2 quality indicators of comprehensive validity in the diagnosis and management of IEM. We anticipate validating these indicators in multicenter study as we have done with other indicators in the pasts. Future studies, including both retrospective evaluations of past care delivery and prospective tracking of performance, will be needed to evaluate for quality gaps in IEM management.

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IEM Quality Indicator Development

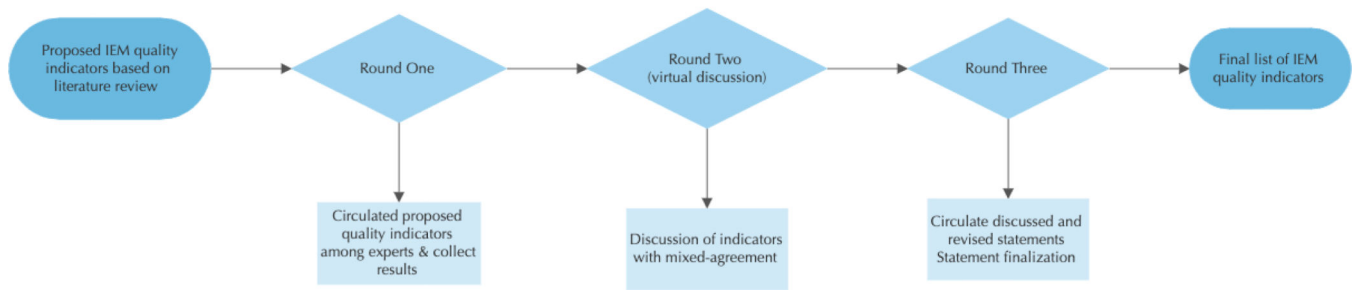


Figure 1.
Study Overview

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Table 1.

Proportion of proposed quality indicators rated with high validity following a three-round modified Delphi method.

Statements	Proportion Agreement (%) with high validity			
	Importance	Scientific Acceptability	Usability	Feasibility
IF a high-resolution esophageal manometry reveals >70% ineffective swallow sequences then the manometric pattern is consistent with IEM.	70	70	90	100
IF a high-resolution esophageal manometry reveals \geq 50% failed swallows and <100% failed swallow sequences with normal LES relaxation on HRM, THEN a patient should be diagnosed with IEM.	60	60	90	100
IF a patient has between 50–70% ineffective swallow sequences (DCI<450 mmHg cm s) with normal LES relaxation on HRM, THEN consider provocative HRM maneuvers (e.g., multiple rapid swallows). [†]	40	30	40	60
IF a patient's high resolution esophageal manometry reveals IEM, THEN a member of the care team should assess if the manometric pattern is clinically relevant.	90	80	80	90
IF a patient's high resolution esophageal manometry reveals IEM, THEN a member of the care team should communicate the clinical relevance of this manometric pattern to the patient.	80	70	60	90
IF a patient is classified with IEM on high resolution esophageal manometry, THEN a member of the care team should consider evaluating for gastroesophageal reflux disease. [†]	50	30	50	60
IF a patient is suspected to have a systemic smooth muscle disorder and classified with IEM on high resolution esophageal manometry, THEN consider additional work up. [†]	50	40	50	50
IF a patient has gastroesophageal reflux disease (GERD) and a manometric pattern of IEM, THEN control of GERD is the main approach to patient management.	90	80	90	100
IF a patient is diagnosed with clinical ineffective esophageal motility, THEN conventional prokinetic agents (e.g., metoclopramide, domperidone) should not be recommended. [†]	60	60	70	70
IF a patient is diagnosed with clinical ineffective esophageal motility, THEN Prucalopride can be considered in patients with GERD. [†]	20	10	30	60
IF a patient with a manometric pattern of IEM and contractile reserve on pre-operative high resolution esophageal manometry is being considered for anti-reflux surgery, THEN surgical management should not differ from a patient without IEM.	40	50	60	60
IF a patient with a manometric pattern of IEM and absent contractile reserve on pre-operative high resolution esophageal manometry is being considered for anti-reflux surgery, THEN the care team should discuss the increased risks of post-operative dysphagia.	70	60	70	80

[†] Indicator did not meet criteria to proceed into second round