QUALITY INDICATORS FOR GI ENDOSCOPIC PROCEDURES

Development of quality indicators for endoscopic eradication therapies in Barrett's esophagus: the TREAT-BE (Treatment with Resection and Endoscopic Ablation Techniques for Barrett's Esophagus) Consortium

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Barrett's esophagus (BE) is the only identifiable precursor to esophageal adenocarcinoma (EAC), a malignancy that is associated with an increasing incidence and a dismal 5-year survival rate of 15% to 20%.[1-3] BE is characterized by the replacement of normal squamous epithelium of the distal esophagus with metaplastic intestinal-type columnar epithelium.[4,5] The presumed step-wise progression of BE to invasive EAC through the histopathologic stages of low-grade dysplasia (LGD), high-grade dysplasia (HGD), and intramucosal EAC provides opportunities to halt the progression and decrease the incidence of BE-related EAC.[6-10] Endoscopic eradication therapy (EET) in BE patients at increased risk of progression to invasive EAC (intramucosal EAC, HGD, and LGD) is a strategy that has been investigated extensively for cancer prevention, with the ultimate goal of reducing morbidity and mortality.

The effectiveness and safety of EET in eradicating BE-related neoplasia and maintaining remission, as demonstrated in randomized controlled trials, large observational studies, and population-based studies, has revolutionized the management of these patients and avoids the morbidity and mortality associated with esophagectomy.[11-21] Population-based studies report comparable outcomes after EET and esophagectomy in the management of HGD and mucosal EAC.[22] In addition, this practice is now endorsed by multiple recent GI society guidelines and consensus documents.[4,23-25]

EET is used increasingly not only at academic and tertiary-care centers but also among community practices.[15] Although available data support the increasing use of EET in patients with BE-related neoplasia, quality indicators in the field of EET are not well-defined. There is currently a lack of guidance with regard to quality indicators for EET such as the role of an expert pathologist, advanced endoscopic imaging, benchmark rates of complete eradication of intestinal metaplasia (CE-IM), and the number of treatment sessions necessary to achieve this endpoint in clinical practice. In addition, significant variability in endoscopic practices and lack of concordance with published guidelines is well-described both at a tertiary-care and community levels.[26] Although recent guidelines,[4,5,24] consensus documents,[25] and the American Society for Gastrointestinal Endoscopy (ASGE)/American College of Gastroenterology (ACG) Task Force on Quality in Endoscopy documents[27-29] provide excellent direction as to best practices for care of patients with BE, there is a need for formal development of quality indicators for EET in the management of patients with BE-related neoplasia.

The objective of this study was to use a methodologically rigorous process to develop valid quality indicators for EET in the management of patients with BE-related neoplasia. Defining quality indicators has the potential to optimize the management of BE-related neoplasia by increasing high-quality care.

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METHODS

RAND/University of California, Los Angeles Appropriateness Method

The RAND/University of California, Los Angeles Appropriateness Methodology[30] (RAM) was used to develop quality indicators for EET in patients with BE-related neoplasia. In the RAM, the concept of appropriateness refers to the relative weight of the benefits and harms of an intervention. An appropriate indicator is one in which the expected health benefit exceeds the expected negative consequences by a sufficiently wide margin exclusive of costs.[30] This is a modified Delphi method[25] that, unlike the original Delphi, provides panelists with the opportunity to discuss their judgments between rating rounds in a face-to-face meeting to discuss their answers, similar to the method of the National Institute of Health Consensus Conferences. This methodology is applicable when randomized controlled trials are not available or cannot provide evidence at a level of detail sufficient to apply to the wide range of patients seen in everyday clinical practice.[30] It is a well-described methodology for the development of quality indicators and has been applied across a broad range of disease processes and procedures within gastroenterology (upper endoscopy, colonoscopy, GERD, esophageal manometry) and non-GI conditions (vascular interventions, orthopedic surgeries, surgical oncology, among others).[31-41]

Study design and methodology

The study design used to develop quality indicators for EET in BE-related neoplasia is highlighted in this section and Figure 1.

Recruitment of the expert panel. An international multidisciplinary panel of experts (gastroenterologists, a pathologists, epidemiologist, RAM methodologist, and a statistician) was recruited. The main selection criteria in the nomination process included a history of peer-reviewed publications in the field of BE and EET as well as diversity of geography and practice setting. RAM experts suggest that expert panels can be of any size that permits sufficient diversity (a minimum of 7) while ensuring that all have a chance to participate.[30]

Round 0 meeting: face-to-face meeting to discuss study objectives and methodology. This was a face-to-face meeting of invited expert panelists (Digestive Disease Week, May 16-19, 2015, Washington, DC). During this meeting, the panel was oriented to RAM and discussed the study objectives, population, diagnostic parameters, and management strategies. This facilitated the rating process and improved the efficiency of the panel process by building confidence in the methodology and creating a positive environment for future work.[30]

Compilation of potential quality metrics. After review of available guidelines, consensus documents, and relevant published literature, panel members were randomly assigned to 1 of 3 working groups that developed potential quality indicators in the before, during, and post–procedure categories. To do this, panel members provided potential quality indicators, conference calls were held to discuss and vet the proposed quality indicators, and a list was created of potential quality indicators for initial ranking.

Round 1: Initial ranking of potential quality metrics. All panel members independently ranked the potential quality indicators generated by the 3 working groups. The list of potential quality indicators was sent as a link to a REDCap database (Appendix 1, available online at www.giejournal.org) with specific instructions for ranking via e-mail (Appendix 2). Instructions highlighted that the purpose of the proposed quality indicators was to assist practitioners with quality improvement. Panel members were instructed that the indicators were intended to be measured and reported at the practice level and need not apply to a specific patient but rather to the overall care of patients with BE. An indicator was considered appropriate and/or valid if adherence to the indicator was deemed critical to providing quality care to patients with BE exclusive of cost or feasibility. As per the RAM protocol, it was emphasized that the panel members should not consider cost implications or the feasibility of implementing the indicator in their rankings. The indicator should have applied to the average patient presenting to the average physician at an average facility. Where appropriate, panelists suggested a benchmark threshold for satisfying specific metrics. Each indicator was ranked on a 9-point interval scale in which a score of 1 to 3 was signified as inappropriate, 4 to 6 was of uncertain appropriateness, and 7 to 9 was deemed appropriate. The panelists also had the opportunity to provide comments regarding each proposed quality indicator and suggest modifications.

Search strategy and systematic review of literature. A medical librarian performed a comprehensive literature search of Ovid Medline (Ovid MEDLINE in-process and other non-indexed citations, Ovid MEDLINE) Daily and Ovid MEDLINE 1946 to present), Embase (via Embase.com), and the Cochrane Database of Systematic Reviews/Cochrane Register of controlled trials (via Wiley Online Library). Publication dates were limited to 1990 through August 12, 2015, and the search was limited to English language articles. Medline records were excluded from the Embase search results before export to an EndNote Library (Clarivate Analytics, Philadelphia, Penn). The primary concept of BE along with 30 other dimensions of interventions and outcomes, their associated synonyms, and MeSH/Emtree controlled vocabulary were searched. The 30 dimensions were "ORed" together to create a single large set that was then "ANDed" with the BE set. The full search strategy for Ovid Medline can be found in the online

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