

Is routine preoperative esophagogastroduodenoscopy prior to bariatric surgery mandatory? protocol for a systematic review and meta-analysis

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ABSTRACT

Introduction: Routine preoperative esophagogastroduodenoscopy (p-EGD) prior to bariatric surgery (BS) is currently widely undertaken, and hence an important issue with many clinical and financial repercussions. Yet, the true extent of why p-EGD is routinely undertaken for all bariatric patients remains not well understood.

Methods and analysis: To address this, we will undertake a systematic review and meta-analysis of routine p-EGD prior to BS from around the world. This protocol describes the methodological approach to be adopted and outlines the search strategies and eligibility criteria that will be employed to identify and select studies, and the way by which data from the selected studies will be extracted for analysis. PubMed, Cochrane Central Register of Controlled Trials (CENTRAL), WHO International Clinical Trials Registry Platform, Cochrane Library, MEDLINE, Scopus, clinicaltrials.gov and Google scholar will be searched from 01 January 2000 to 30 April 2019 for original studies written in English that provided prevalence estimates of the outcomes of routine p-EGD prior to BS. STROBE criteria will assess the methodological quality of the selected studies. The use of fixed or random effects model will depend on the results of statistical tests for heterogeneity. Publication bias will be visually estimated by assessing funnel plots. Pooled estimates will be calculated. This protocol conforms to the Preferred Reporting Items for Systematic reviews and Meta-Analysis (PRISMA) guidelines and has been submitted for registration at the PROSPERO International Prospective Register of systematic reviews. No ethical clearance is required for this study. This review will be published in a peer-reviewed journal and will be presented at various national and international conferences.

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1. Introduction

There are much deliberations about the value and advantage of routine preoperative esophagogastroduodenoscopy (p-EGD) screening of patients undergoing bariatric surgery (BS) [1,2]. The European and Italian recommendations advocate the use of presurgery upper gastrointestinal endoscopy together with multiple biopsies in the work-up of patients; in contrast, the American Society for Metabolic & Bariatric Surgery (ASMBS) only recommends it in selected cases with symptomatic gastric disease [3–5]. The question of routine p-EGD has many clinical repercussions and considerable financial impact [1].

Some evidence supports routine p-EGD among BS patients, advocating that EGD is convenient, easy and safe [6–8]; and EGD findings may influence the management of patients [9] or detect asymptomatic benign or pre/malignant lesions. Some authors endorse that all bariatric patients have p-EGD [10]. For some procedures, p-EGD findings might influence the operative procedure [7,11]. Others challenged whether routine p-EGD should be conducted for all patients undergoing e.g., laparoscopic sleeve gastrectomy (LSG) [12].

Some authors support p-EGD in BS patients with upper GIT symptoms [3,13,14]. Others reported that routine p-EGD screening might need more rationalization for asymptomatic patients [2]. Only 2% of asymptomatic patients had any abnormal finding detected at EGD, none of which affected their treatment plan [15].

Opinions are divided as to whether p-EGD should be undertaken for all BS patients. One view is that the “intuitive reasons

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to continue p-EGD screening of BS patients include endoscopic findings that optimize medical management for the healing of their BS in a substantial proportion of patients and/or the endoscopic findings in at least a few patients that alter or delay the surgery itself" (p. 712) [16]. An alternative view recommended that standard p-EGD in BS is not indicated, as many patients are screened in order to discover clinically significant abnormalities [17]. Hence the question: "We do not screen the general population for those minor EGD findings; so why should we do it on people planned for bariatric surgery?" (p. 414) [14]. Similarly, a comment on 'Is esophagogastroduodenoscopy before Roux-en-Y gastric bypass or sleeve gastrectomy mandatory?' concluded that p-EGD had no value in prediction or prevention of postoperative complications [18].

1.1. Rationale

The inconsistency in the literature represents a gap in knowledge as to whether routine p-EGD is justified for all BS patients. These considerations inspired the current proposal. The proposed systematic review and meta-analysis will be first to assess the yield of p-EGD findings in terms of four patient groups [6], in order to gauge justifications as to whether p-EGD should be routine for all BS patients. EGD carries risks to patients, as well as legal risks [19]. Hence, in addition to the p-EGD 'yield' in discovering/ excluding pathologies, the appropriate gauging of whether routine p-EGD is justified for all BS patients needs to also consider several parameters. These include: adverse effects of routine p-EGD; skill level of the EGD personnel; missing or over-diagnoses of lesions; availability and cost of alternative (non-invasive) diagnostic methods to discover upper GIT pathology, and the costs of routine p-EGD [1,20–26]. A related point is the changes that could occur to any missed pathology across time: i.e. initially before and then subsequent to BS in terms of the histological patterns of cellular alterations after gastric surgeries [27,28].

In view of the knowledge that p-EGD findings add, balanced against the potential adverse effects of routine p-EGD and other parameters highlighted above, the rationale for whether or not routine p-EGD should be undertaken prior to BS needs to be clear. Findings from this systematic review and meta-analysis will provide valuable insights into if and why routine p-EGD should/ should not be mandatory. The goal of this proposal is to present a wide-ranging synthesis of prevailing studies on routine p-EGD in BS. It will synthesize, across the selected studies, using Sharaf et al.'s classification [6], better estimates of the benefits to various groups of patients or otherwise, thus contributing more clarity into the dis/advantages that routine p-EGD prior to BS bestows. Such understanding will assist informed decision making related to this wide-spread practice. Given the potential importance of such a systematic review and meta-analysis, this protocol is a description of the research objectives as well as the methodological and analytical approaches that will be utilized to identify, appraise, and synthesize the relevant studies.

2. Objectives

In order to assess the significance of routine p-EGD screening in BS patients, the specific objectives are to:

- Conduct a systematic review of the literature in order to identify all relevant articles on the topic;
- Employ Sharaf et al.'s classification [6] of predetermined criteria to categorize the p-EGD findings of each article into the four groups;
- Compute the yield of p-EGD findings of each article in terms of the four groups of Sharaf et al.'s classification [6]; and,

- Pool and synthesize the findings to make informed judgments about whether p-EGD should be routinely undertaken for all BS patients or otherwise.

2.1. Review questions

The systematic review and meta-analysis will seek to address the following main research questions: (1) What are the justification as to whether p-EGD should be routinely undertaken for all BMS patients?; and, (2) What are the prevalence of Helicobacter Pylori infection, patients with hiatal hernia, and patients with symptoms?

3. Methods

This review protocol has been submitted to the PROSPERO International Prospective Register of systematic reviews (www.crd.york.ac.uk/PROSPERO) (ID:157596, registration pending). The protocol is reported according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses Protocol (PRISMA-P) [29,30].

3.1. Eligibility criteria

This protocol will identify studies on routine p-EGD prior to BS published from 01 January 2000 to 30 April 2019 in all settings. All studies meeting the eligibility criteria will be selected for extended review and synthesis. Where several publications report the same study, the report that furnishes the greatest amount of data will be included in the meta-analysis. There will be no constraints on the type of BS procedure undertaken in the eligibility criteria, hence capitalizing on many studies that address the outcomes of routine p-EGD prior to BS. The inclusion/ exclusion criteria are based on whether a study provided information on the association between p-EGD and post-operative outcomes among BS patients. Therefore, even studies with smaller sample sizes will also included in the initial evaluation.

3.1.1. Inclusion criteria and study selection

Study design: (1) Original studies. Fig. 1 shows the flow diagram that will be used for the study selection process for the systematic review.

Language: (2) Published articles in English language.

Time Period: (3) Original studies published from 01 January 2000 through 30th April 2019.

Interventions: (4) Published articles that assessed "Esophagogastroduodenoscopy" and "bariatric surgery", and provided prevalence estimates of the outcomes of routine p-EGD prior to BS.

Participants: (5) Published articles enrolling patients of any age, gender, and ethnicity.

3.1.2. Exclusion criteria

(1) Articles other than original studies such as commentaries, letters to the editor, reviews, conference proceedings, opinion papers, case reports.

(2) Studies that did not include outcomes or comparisons.

3.2. Information sources

We will employ a search strategy to discover and attain both published and unpublished studies using bibliographic databases and grey literature. The search strategy stemmed from scrutinizing prevailing reviews of the outcomes of routine p-EGD prior to all types of BS, in order to identify the appropriate bibliographic data-

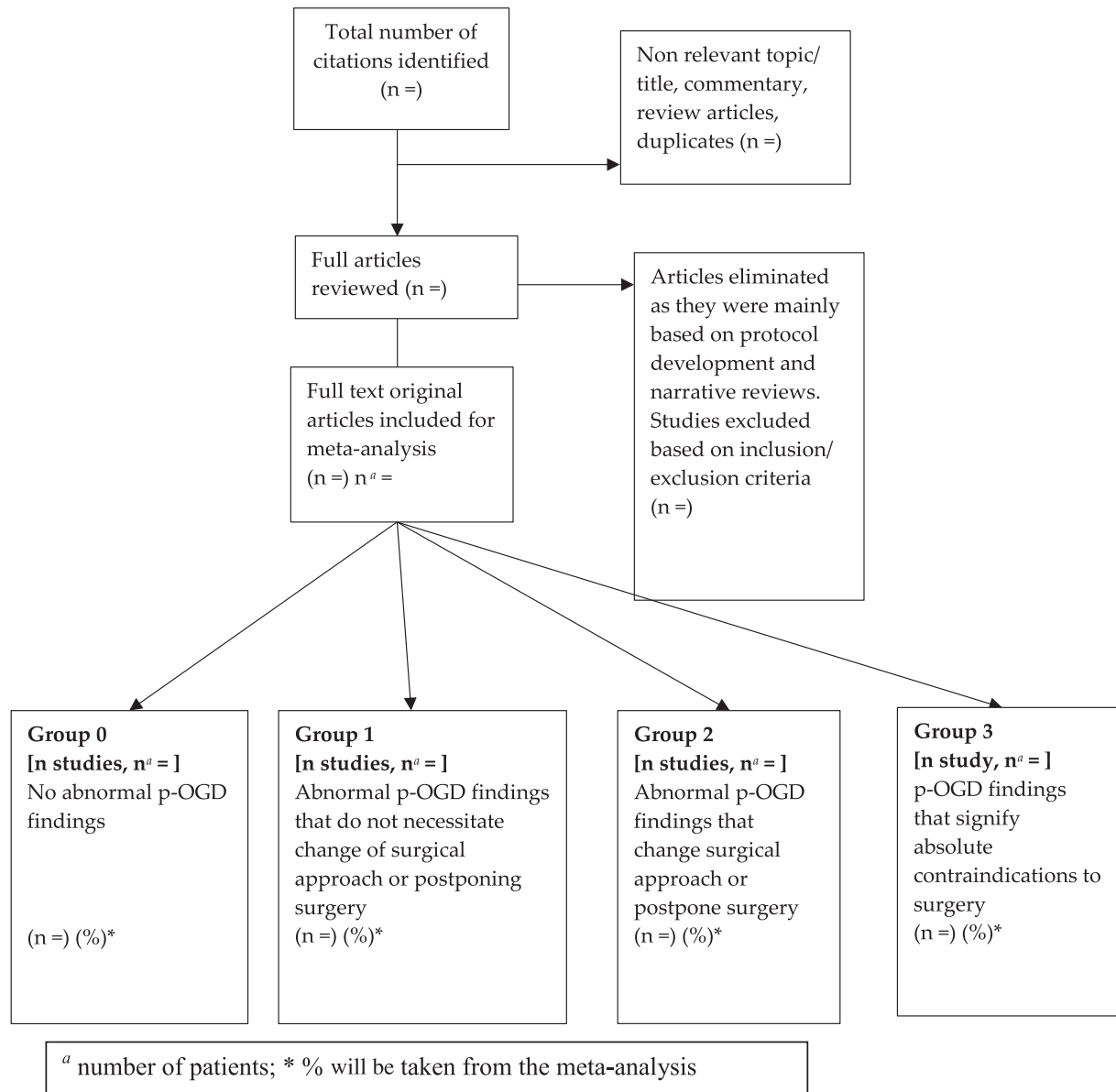


Fig. 1. Flow diagram of study selection process for the systematic review.

bases and search terms. Additional search terms were included in consultation with an information specialist (librarian) at our institution with experience in systematic reviews.

3.3. Literature searches

We will adapt the same search strategy for each database. A systematic review will be carried out using PubMed, Cochrane Central Register of Controlled Trials (CENTRAL), WHO International Clinical Trials Registry Platform, Cochrane Library, MEDLINE, Scopus, clinicaltrials.gov and Google scholar electronic databases. We used the keywords “bariatric surgery” “Esophagogastroduodenoscopy”; “preoperative” [in Title/Abstract]. The medical subject headings (MeSH) terms used were bariatric surgery [All Fields] AND (“Esophagogastroduodenoscopy”[MeSH Terms]; bariatric surgery [All Fields] AND (“preoperative AND Esophagogastroduodenoscopy” [MeSH Terms]; bariatric surgery [All Fields] AND (“preoperative” AND Esophagogastroduodenoscopy” [MeSH Terms]. Additional searches were conducted using reference lists of studies and review articles for a selection of relevant articles. The references of all

included articles or relevant reviews will be cross-checked. Grey literature searches will be undertaken employing the above keywords in Google. Search results of the first 20 pages of Google will be assessed and scrutinized for eligibility.

3.4. Finding research Evidence: Three-step search strategy

This protocol will meticulously search for outcomes of routine p-EGD prior to BS. In order to achieve this task, the protocol utilizes a three-step search strategy incorporating academic bibliographies and internet searches:

Step 1: studies will be detected applying the predefined search strategy and bibliographic databases (see above) to systematically discover studies published from 01 January 2000 to 30th April 2019 that reported the outcomes of routine p-EGD prior to BS.

Step 2: screening will be conducted on the reference lists of the retrieved articles, dissertations, and other studies on the outcomes of routine p-EGD prior to BS for relevant research premised on the defined eligibility criteria.

Step 3: searching will be performed of web-based platforms for studies using the above keywords in specialized journals, Google search for grey literature, as well as using other global libraries for scientific literature.

3.5. Study records

3.5.1. Data management

Citations retrieved from the bibliographic databases will be imported into Endnote in order to oversee and delete duplicate records. Studies retrieved from reference lists of retrieved articles and Google search will be entered into an Excel spreadsheet for identification and removal of duplicates and screening.

3.5.2. Data extraction

The titles of the research articles obtained from the initial database searches will be screened and relevant papers will be selected. Then the abstracts and full texts will be reviewed according to the inclusion criteria for final selection. Three members of the research team will independently review the studies based on the exclusion and inclusion criteria. Initially, titles of the studies identified from the search will be assessed for inclusion. Titles approved by authors will progress to abstract screening. If three researchers reject a study at this stage, it will be excluded from the review. Then, full text articles will be screened for eligibility. Only those studies approved by the three researchers will be included. Agreement between the researchers on the quality of the articles will be calculated. All disagreements will be resolved by consensus among the researchers. The reasons for exclusion will be noted.

3.5.3. Categorization of the extracted p-EGD findings

In order to gauge the value of routine p-EGD screening in BS, the review will employ Sharaf et al.'s classification [6] of predetermined criteria to categorize p-EGD findings into 4 groups:

Group 0: no abnormal p-EGD findings, i.e., normal.

Group 1: abnormal p-EGD findings that do not necessitate changing the surgical approach or postponing surgery (e.g., mild esophagitis, gastritis and/or duodenitis, esophageal web).

Group 2: abnormal p-EGD findings that change the surgical approach or postpone surgery (e.g., mucosal/ submucosal mass lesions, ulcers, severe erosive esophagitis, gastritis, and/or duodenitis, Barrett's esophagus, Bezoar, hiatal hernia, peptic stricture, Zenker's or esophageal diverticula, arteriovenous malformations).

Group 3: p-EGD findings that signify absolute contraindications to surgery (e.g., upper gastrointestinal cancers and varices).

3.5.4. Data items to be extracted

We will extract several main categories of data: (1) (Author/s) names; (2) Year of publication; (3) Type of bariatric procedure undertaken; (4) Study design; (5) Sample or type of sampling; (6) Period of data collection; (7) Country where research was undertaken; (8) Number of patients in the study (sample size); (9) Sex of the patients enrolled in the study; (10) Mean age of patients enrolled in the study; (11) Number of patients in Group 0 of Sharaf et al.'s classification [6]; (12) Number of patients in Group 1 of Sharaf et al.'s classification [6]; (13) Number of patients in Group 2 of Sharaf et al.'s classification [6]; (14) Number of patients in Group 3 of Sharaf et al.'s classification [6]; (15) Number of patients with *Helicobacter Pylori*; (16) Number of patients with hiatal hernia; (17) Number of patients with symptoms; and, (18) Whether STROBE appraisal was undertaken for the given study.

4. Outcomes

4.1. Primary outcomes

This protocol has one primary outcome, which will contribute to understanding the value of routine p-EGD screening in BS. To achieve this outcome, we will employ predetermined criteria to categorize the p-EGD findings of the selected studies into four groups [6]. Such categorization will enable informed judgements to be undertaken in terms of whether routine p-EGD prior to BS should be mandatory or otherwise.

4.2. Secondary outcomes

Where available, secondary outcomes for this review will include estimates, based on p-EGD findings, for sub-groups such as those with *Helicobacter Pylori* infection, patients with hiatal hernia, and patients with symptoms.

5. Assessment of methodological quality

An assessment of risk of bias will be incorporated into the analysis. We will appraise the quality of the studies that will be included in the meta-analysis, in order to evaluate the strength of the body of evidence on the estimates. Methodological quality of the selected studies will be assessed using five STROBE criteria from the checklist (study design, setting, participants, data sources/ measurement, study size). The STROBE criteria are most relevant in the assessment of the methodological quality of observational studies. This appraisal will adhere to the same practice of the data collection process where disagreements will be settled by discussion between the reviewers or with a third reviewer. As the systematic review is based on the secondary research of published literature, the quality of the included studies determines the quality level and reliability of the final findings.

6. Data analysis and synthesis

Data will be synthesized in two phases. Phase 1 will answer the first question 'What are the justifications as to whether p-EGD should be routinely undertaken for all BMS patients or otherwise?' In this phase, we will provide a descriptive overview and analysis of the characteristics of the selected studies; and using predetermined criteria [6], we will categorize the p-EGD findings of the selected studies into four groups.

Although the strength of metaanalysis is related to the number of studies included in the analysis, research that examined the characteristics of metanalyses across disciplines found that the median number of studies included in metaanalysis was three [31]. Prevalences will be calculated for categorical variables (with 95% confidence intervals). The decision to select either fixed effect or random effects model will depend on the results of statistical tests for heterogeneity. Data heterogeneity will be assessed using the Cochrane Q homogeneity test (significance set at $p < 0.10$). If studies are statistically homogeneous, fixed effect model will be selected. A random effects model will be used when studies are statistically heterogeneous. The Higgin's I^2 test will assess the ratio of true heterogeneity to the total variation in observed effects.

In order to measure the proportion of the observed variance that reflects true effect sizes rather than sampling error, we will use Higgins (I^2) statistic, reported as a percentage [32]. A rough guide to interpretation of I^2 test is 0–25%: might not be important; 25–50%: may represent moderate heterogeneity; 50–75%: may represent substantial heterogeneity; and > 75%: considerable heterogeneity. Publication bias will be visually estimated by assessing funnel plots. Pooled estimates will be calculated using

R 3.5.1 software. The quality of this systematic review is foreseen to be high, having a high level of compliance with AMSTAR2 [33].

7. Ethics and dissemination plans

This systematic review and meta-analysis will analyse and synthesize data from existing published and unpublished studies. These studies are available in the public domain, ethics approval is not required. The results from this protocol will be published in peer-reviewed journals. Findings will also be presented at conferences and shared with relevant centres and institutions. We plan to update the review over time as seen appropriate.

8. Guarantor of the review

Walid El Ansari

9. PROSPERO number

ID:157596 Is Routine Preoperative Esophagogastroduodenoscopy Prior to Laparoscopic Sleeve Gastrectomy Mandatory? A Systematic Review and Meta-analysis. Submitted on 14/11/2019. Approval pending.

10. Registration of research studies

1. Name of the registry: research registry
2. Unique Identifying number or registration ID: researchregistry5513
3. Hyperlink to the registration: <https://www.researchregistry.com/browse-the-registry#home/registrationdetails/5e9720a327b6d700150ee098/>

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Author contributions

WEA: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Writing - original draft, Writing - review & editing. **AE:** Data curation, Formal analysis, Methodology, Resources, Supervision, Validation, Visualization, Writing - review & editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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