Title:

Dietary Interventions for Gastroparesis in Pediatric and Adult populations: A PRISMA-protocol

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INTRODUCTION

Gastroparesis (**GP**) is a delay in gastric emptying of fluids or solids in the absence of a mechanical obstruction[1]. Both adult and pediatric patients with GP typically develop symptoms such as early satiety, anorexia, bloating, abdominal pain, nausea, and vomiting, among others[1]. The first-line treatment for GP for pediatric and adult patients is dietary intervention. Dietary management research studies for patients with GP are primarily from the adult literature, but a publication that organizes the data into clear and concise guidelines is lacking; in pediatrics, the need is even greater. Hence, we aim to conduct a systematic review of the literature assessing the effect of dietary interventions carried out in adults and pediatric patients with GP to attempt to identify concrete recommendations using an evidence-based medicine framework.

OBJECTIVES

To assess the efficacy and effectiveness of dietary interventions on clinical outcomes in patients with GP. Clinical outcomes in GP will be a) reduction in gastroparesis-specific patient-reported scores/outcomes (e.g., Gastroparesis Cardinal Symptom Index), b) general scoring symptoms (e.g., SF-36), c) re-admissions, hospitalization length-of-stay, d) improved emptying time on gastric scintigraphy

METHODS

Eligibility criteria:

P: patients with gastroparesis:

- Gastroparesis diagnosis will be defined by delayed gastric emptying (greater than 60% gastric retention at the 2-hr mark or greater than 10% retention at the 4-hr mark) on gastric scintigraphy[2].

I: various dietary interventions

C: not applicable

O: improvement of gastroparesis symptoms such as nausea, abdominal pain, bloating, and early satiety, decreased hospital stay or decreased admissions if noted

Evaluated outcomes
Reduction in gastroparesis-specific patient-reported scores/outcomes (Gastroparesis Cardinal Symptom index, PAGI-SYM)
Reduction in general scoring symptoms (e.g., SF-36, measures of quality-of-life)
Reduction in re-admissions, hospitalizations, length of stay
Improved emptying time on gastric scintigraphy

Design:

We will include randomized control trials and cohort studies published in the database from the time of the consensus definition of gastroparesis based on gastric scintigraphy (3/1/2008) to 8/1/2020. We will not include abstracts presented at scientific meetings due to a lack of complete and detailed information.

Information Sources:

We will use PubMed and EMBASE as well as references from publications found for randomized controlled trials and cohort studies investigating diets for GP.

Search Strategy

All studies addressing dietary interventions and GP will be reviewed. The search strategy will include utilizing free text and MeSH database of PubMed or EMTREE in EMBASE.

The following terms will be used, adapted to each database: gastroparesis, diet or dietary intervention, randomized control trial, cohort, cohort study. The bibliographic section of relevant articles also will be searched to find additional articles that fit the search criteria.

Study Records:

Data Management and selection process: Using a COVIDENCE database, two reviewers will independently review abstracts of studies from the PUBMED and EMBASE search results. Each abstract will be graded as eligible/maybe eligible/not eligible based on the previously described aims. Studies that are “may be eligible” and studies in which the reviewers disagree upon will be reviewed by a third, independent reviewer. The inclusion criteria are as follows:

1. Human subjects diagnosed with any subtype of GP
2. Studies on dietary interventions in patients with GP evaluating their symptoms
3. Studies on dietary interventions in patients with GP evaluating their rate of gastric emptying
4. Studies on dietary interventions in patients with GP evaluating their quality of life
5. Studies on dietary interventions in patients with GP evaluating metrics of hospitalizations

Data collection process:

Pertinent information will be collected using the COVIDENCE software. Pertinent, extracted data will be collected based on the desired outcomes. In studies that show various scales of assessment, the primary outcome measures will be extracted.

Outcomes and Prioritization**:**

Primary outcomes: After starting a new diet in patients with GP - symptom improvement or symptom resolution, improved general scoring symptoms including quality of life, reduction of emptying time during gastric scintigraphy

Secondary outcomes: Reduction in re-admissions, hospitalizations, and length of stay

Risk of bias will be assessed by independent reviewers

The cohort studies will be assessed for risk of bias by the Newcastle-Ottawa scale (attached). The randomized control trials and cohort studies will be assessed by the representativeness of their cohort, comparability of cohorts, and time to survey. Randomized controlled trial studies will be graded using the GRADE approach using GRADE Pro GDT as high, moderate, low, and very low based on their certainty and a 1-9 importance scale based on the certainty of evidence and the importance, respectively. Based on the GRADE Handbook, the scale of importance for the evaluated articles will be based on whether the data is critical, important, but not critical, and of limited importance. Grades of 1 are considered the least important and grades of 9 are considered critical[3].

Table 1: Representation of importance scale to be used for the articles, from the GRADE Handbook[3].

rating scale:								
1	2	3	4	5	6	7	8	9
of **least** importance								of **most** importance
of limited importance for making a decision (not included in evidence profile)			important, but not critical for making a decision (included in evidence profile)			Critical for making a decision (included in evidence profile)		

Data Synthesis

We intend to perform a quantitative summary of the data with a meta-analysis. Depending on the outcome, we will use quantitative summary estimates (e.g., standardized mean difference with 95% Confidence Intervals, 95%CI) or dichotomous outcomes (e.g., odds ratio and 95%CI). We plan at this time to use the random-effects model but also evaluate with the fixed-effects meta-analysis approach to assess the different dietary interventions being analyzed. We will assess statistical heterogeneity by quantifying the variation using I^2 . If statistical heterogeneity is found, we plan, *a priori*, to conduct the following sensitivity analysis based on the following clinical variables:

a. By underlying etiology of GP: diabetes, surgically-induced, idiopathic

b. Use of medication and when the medication was started

c. Methods used to show improvement: surveys vs gastric scintigraphy studies

d. Country of origin

e. Referral center- vs. community-based

We plan on performing meta-regression to understand the influence of such variables on the overall estimates. Publication bias will be addressed using a funnel plot

Proposed timelines

Item	Resident/faculty	Due by
Paper review and data Collection	Debra and Tanya	10/15/2020
Data Synthesis	Debra	11/15/2020
Abstract synthesis	Debra, Dr. Shulman, and Dr. Hernaez	11/30/2020 (DDW 2021 abstract deadline is 12/3/2020)
Manuscript preparation	All	01/30/2021
Submission	Debra	03/30/2021

Bibliography:

1. Islam, Saleem. “Gastroparesis in Children.” *Current Opinion in Pediatrics*, vol. 27, no. 3, 2015, pp. 377–382., doi:10.1097/mop.0000000000000216.
2. Abell, T. L., et al. “Consensus Recommendations for Gastric Emptying Scintigraphy: A Joint Report of the American Neurogastroenterology and Motility Society and the Society of Nuclear Medicine.” *Journal of Nuclear Medicine Technology*, vol. 36, no. 1, 2008, pp. 44–54., doi:10.2967/jnmt.107.048116.
3. Schünemann, Holger, et al. *GRADE Handbook*, Oct. 2013, gdt.gradepro.org/app/handbook/handbook.html#h.pq7g5y80zfhj.