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🌐 Testing the effect of changes in emotional distress on post-esophagectomy outcomes

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We use this protocol and it's working

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Abstract

This study aims to investigate the impact of changes in preoperative emotional distress on postoperative outcomes in esophageal cancer patients undergoing esophagectomy. This is a retrospective study, using data collected by McGill University's Division of Thoracic Surgery. We will assess emotional distress at diagnosis and immediately prior to surgery using the Functional Assessment of Cancer Therapy-Esophageal (FACT-E) Emotional Well-Being subscale. We will categorize changes in emotional distress as 'improved' or 'unimproved' and analyze their association with postoperative length of hospital stay, complications, and 30-day readmission rates. This research seeks to determine whether preoperative psychological interventions could enhance surgical recovery and reduce healthcare utilization.

Attachments



[FACT-E Scoring.pdf](#)

76KB



[FACT-E_ENG.pdf](#)

54KB

Description

- 1 This study aims to investigate the impact of changes in preoperative emotional distress on postoperative outcomes in esophageal cancer patients undergoing esophagectomy. This is a retrospective study, using data collected by McGill University's Division of Thoracic Surgery. We will assess emotional distress at diagnosis and immediately prior to surgery using the Functional Assessment of Cancer Therapy Esophageal (FACT-E) Emotional Well-Being (EWB) subscale. We will categorize changes in emotional distress as 'improved' or 'unimproved' and analyze their association with postoperative length of hospital stay, complications, and 30-day readmission rates. This research seeks to determine whether preoperative psychological interventions could enhance surgical recovery and reduce healthcare utilization.

Hypotheses

- 2
 - 2.1 Participants exhibiting improvements in their EWB subscale scores are hypothesized to experience a significantly lower incidence of postoperative complications following esophagectomy compared to those without such improvements.
 - 2.2 Participants exhibiting improvements in their EWB subscale scores are hypothesized to have a significantly shorter hospital length of stay after esophagectomy compared to those without such improvements.
 - 2.3 Participants exhibiting improvements in their EWB subscale scores are hypothesized to have a significantly lower rate of 30-day readmissions following esophagectomy compared to those without such improvements.

Study Design

- 3 This study uses a retrospective cohort design, an observational approach that examines existing data to explore the relationship between preoperative emotional distress and postoperative outcomes in esophageal cancer patients undergoing esophagectomy. In this design, participants are selected based on their exposure status—in this case, changes in emotional well-being—and are followed over time to assess the occurrence of specific outcomes.

Explanation of Existing Data

- 4 In this retrospective cohort study, data were sourced from the McGill University Esophageal and Gastric Data- and Bio-Bank, which prospectively collects clinical and

psychosocial information from patients diagnosed with esophageal cancer at the McGill University Health Centre (MUHC). The data collection process adheres to standardized protocols to ensure consistency and reliability.

- 5 We have implemented several measures to ensure that the research team remains unaware of any patterns or summary statistics in the data prior to analysis, thereby minimizing potential bias:

- 5.1 Data Access Restriction: Access to the dataset has been strictly limited to a designated data manager who is not involved in the analysis or interpretation of the study. This individual is responsible for data entry and extraction.
- 5.2 Blinded Data Preparation: The data manager has anonymized the dataset by removing all personally identifiable information and has assigned random identifiers to each participant.
- 5.3 Predefined Analysis Plan: Prior to accessing the data, the research team developed a comprehensive analysis plan detailing the hypotheses, variables of interest, statistical methods, and criteria for significance.

- 6 Data collection process

- 6.1 Patient Recruitment and Consent:
- * Population: Patients diagnosed with esophageal cancer at the McGill University Division of Thoracic Surgery are approached for participation.
 - * Consent: Informed consent is obtained from each patient, allowing for the collection and use of their clinical data for research purposes.
- 6.2 Data Acquisition:
- * Clinical Data: Information such as demographic details, medical history, diagnostic findings, treatment plans, and surgical outcomes are abstracted from the electronic medical record system.
 - * Patient-Reported Data: Patients complete the FACT-E questionnaire at two time points: upon diagnosis and immediately prior to surgery. The EWB subscale of the FACT-E is used to assess emotional distress levels.

- 7 Inclusion / exclusion criteria

- 7.1 Inclusion Criteria:
- * Patients aged 18 years or older.
 - * Histologically confirmed diagnosis of esophageal cancer.
 - * Underwent esophagectomy as part of their treatment plan.
 - * Completed the FACT-E questionnaire at both specified time points (diagnosis and pre-surgery).



- 7.2 Exclusion Criteria:
- * Did not provide informed consent.
 - * Underwent emergency esophagectomy procedures.
 - * Insufficient data availability for analysis.

Sample Size

- 8 In this retrospective study, all eligible patients from the McGill University Esophageal and Gastric Data- and Bio-Bank who meet the inclusion criteria will be included. This approach ensures that the study is comprehensive and leverages the full extent of available data.

Variables

- 9 Measured variables

- 9.1 Change in EWB: Assessed using the Emotional Well-Being subscale of the FACT-E questionnaire. The EWB subscale comprises six items, each rated on a 5-point Likert scale ranging from 0 ("Not at all") to 4 ("Very much"), with higher scores indicating better emotional well-being. The total EWB score ranges from 0 to 24. Changes in EWB are calculated by subtracting the pre-operative score from the baseline (diagnosis) score. Patients are categorized as:
- * Improved: An increase in EWB score from diagnosis to pre-surgery.
 - * Unimproved: No change or a decrease in EWB score between diagnosis and pre-surgery.

- 10 Outcome variables

- 10.1 Postoperative Complications:
Definition: Any adverse medical events occurring within 30 days post-esophagectomy.

Measurement: Calculated as a dichotomous variable: 0 for no complications, 1 for any complications documented in the medical record.

- 10.2 Hospital Length of Stay (LOS):
Definition: The duration, in days, from the date of esophagectomy to the date of discharge.

Measurement: Calculated as a continuous variable documented in the medical record.

- 10.3 30-Day Readmissions:

Definition: Unplanned hospital admissions occurring within 30 days after discharge from the initial esophagectomy hospitalization.

Measurement: Calculated as a dichotomous variable: 0 for no readmission, 1 for any readmission documented in the medical record.

11 Covariates

11.1 Demographic Factors:

Age: Patient's age at the time of diagnosis, measured in years.

Sex: Biological sex of the patient (Male/Female).

11.2 Clinical Factors:

Cancer Stage: Determined according to the American Joint Committee on Cancer (AJCC) staging system at the time of diagnosis.

Neoadjuvant Therapy: Receipt of chemotherapy and/or radiation therapy prior to surgery, recorded as Yes/No

12 Indices

In this study, the EWB scores will be derived from the FACT-E. The EWB subscale comprises six items, each rated on a 5-point Likert scale ranging from 0 ("Not at all") to 4 ("Very much"). To calculate the EWB score at each time point (diagnosis and pre-surgery), the following steps are undertaken:

12.1 Reverse Scoring: Certain items are reverse-scored to ensure that higher scores consistently reflect better emotional well-being. Specifically:

- * Item 2: "I am satisfied with how I am coping with my illness."
- * Item 4: "I feel nervous."
- * Item 5: "I worry about dying."
- * Item 6: "I worry that my condition will get worse."

For these items, responses are transformed as follows:

- * 0 becomes 4
- * 1 becomes 3
- * 2 remains 2
- * 3 becomes 1
- * 4 becomes 0

12.2 Summation: After reverse scoring the specified items, all six item scores are summed to obtain the total EWB score for each time point. The possible range for the EWB score is 0 to 24, with higher scores indicating better emotional well-being.

- 12.3 Change Calculation: Changes in EWB are calculated by subtracting the pre-operative score from the diagnosis score:

$$\text{Change in EWB} = \text{EWB}_{\text{pre-operative}} - \text{EWB}_{\text{diagnosis}}$$

Statistical Analyses

13 Hypothesis testing

- 13.1 Association Between Changes in Emotional Well-Being and Postoperative Complications
Statistical Model: Multivariate Logistic Regression

Model Specification:

- * Dependent Variable: Occurrence of postoperative complications (dichotomous outcome: Yes/No)
- * Independent Variable: Change in EWB score (categorical: Improved vs. Unimproved)
- * Covariates: Age, sex, cancer stage, and neoadjuvant therapy

Interpretation: The coefficient will indicate the odds ratio of experiencing postoperative complications for patients with improved EWB scores compared to those without improvement, adjusting for other covariates.

- 13.2 Association Between Changes in Emotional Well-Being and Hospital Length of Stay (LOS)
Statistical Model: Multivariate Linear Regression

Model Specification:

- * Dependent Variable: Hospital LOS (continuous variable: number of days)
- * Independent Variable: Change in EWB score (categorical: Improved vs. Unimproved)
- * Covariates: Age, sex, cancer stage, neoadjuvant therapy, and occurrence of postoperative complications

Interpretation: The coefficient will represent the mean difference in hospital LOS between patients with improved versus unimproved EWB scores, controlling for other factors.

- 13.3 Association Between Changes in Emotional Well-Being and 30-Day Readmissions
Statistical Model: Multivariate Logistic Regression

Model Specification:

- * Dependent Variable: 30-day readmission status (binary outcome: Yes/No)
- * Independent Variable: Change in EWB score (categorical: Improved vs. Unimproved)

* Covariates: Age, sex, cancer stage, neoadjuvant therapy, occurrence of postoperative complications, and hospital LOS

Interpretation: The coefficient β_1 will reflect the odds ratio of 30-day readmission for patients with improved EWB scores compared to those without improvement, after adjusting for other variables.

14 Missing data

14.1 Initial Assessment:

Extent and Patterns: We will quantify the amount of missing data for each variable and examine patterns to determine if data are missing completely at random (MCAR), at random (MAR), or not at random (MNAR).

Comparison Analyses: Baseline characteristics of participants with complete data will be compared to those with missing data to assess potential biases.

14.2 Handling Missing Data:

Multiple Imputation (MI): Given its robustness and ability to handle different types of data, MI will be employed to address missing values. The imputation model will include all variables used in the analysis and outcome measures. We will perform multiple imputations (e.g., 20-50) to ensure stability and accuracy of the estimates.

Sensitivity Analyses: To assess the robustness of our findings, analyses will be repeated using complete-case analysis (excluding cases with missing data) and compared to the MI results.

14.3 Reporting:

Transparency: The extent of missing data, methods used for imputation, and any assumptions made will be clearly reported.

Impact Assessment: We will discuss how missing data and the chosen handling methods may influence the study results and interpretations.

15 Exploratory analyses

15.1 Interaction Effects: To explore whether the association between EWB changes and outcomes varies by subgroups (e.g., different cancer stages or surgical approaches), interaction terms between EWB change status and these variables will be included in the models.

15.2 Subgroup Analyses: Separate analyses may be conducted within specific subgroups, such as patients receiving neoadjuvant therapy versus those who did not, to assess the



consistency of associations across different patient populations.

- 15.3 Post-Hoc Tests: If significant interactions or main effects are found, post-hoc pairwise comparisons will be performed with appropriate adjustments (e.g., Bonferroni correction) to control for multiple testing.