

Biometry 726  
Fall 2010  
GEE Project  
Due Tuesday 30 November 2010

A gastroenterologist has asked you to assist in a study of factors associated with persistent gastro-esophageal reflux disease (GERD). Specifically, she is interested in better understanding those reflux episode characteristics associated with symptomatic reflux episodes among patients who are on twice-daily acid suppressive therapy. Reflux episode data were collected from adult subjects (18 years of age or older) over a 24-hour period using a combined multichannel intraluminal impedance and pH (MII-pH) testing catheter inserted transnasally through the esophagus and into the stomach. Impedance monitoring allows characterization of the physical composition of the refluxate as liquid, gas, or mixed, while pH informs on the refluxate's acidity based on predefined pH criteria. Prior to reflux monitoring, patients were queried about typical and atypical GERD symptoms. During monitoring, subjects wore an external transmitter and pushed preprogrammed buttons on a data logger whenever they experienced symptoms. A reflux episode was considered temporally associated with a symptom if the patient recorded a symptom within 5 minutes after a reflux episode.

The following patient- and episode-level characteristics are contained in the data set `reflux.csv`, available on the class website.

1. **ptid** Unique patient ID
2. **symptomatic** Indicator of symptomatic reflux episode. 1 = symptomatic, 0 = asymptomatic.
3. **age** Patient age (years)
4. **gender** Patient gender. 1 = male, 2 = female.
5. **cleartime** Refluxate clearance time (sec). The elapsed time between refluxate entry into the distal esophagus and refluxate exit at 5 cm above the lower esophageal sphincter (LES) (see Figure 1).
6. **extent** Refluxate esophageal extent coded as 1 if the refluxate was detected at 15 cm or greater above the LES (i.e., proximal reflux), and 0 if refluxate was not detected at 15 cm or more above the LES (i.e., distal reflux).
7. **composition** Refluxate composition (gas episodes are excluded from the analysis). 1 = liquid, 2 = mixed (gas + liquid).
8. **deltaph** Change in pH = refluxate pH at entry into the distal esophagus - refluxate pH at maximum proximal extent (nadir pH)
9. **acidity** Refluxate acidity. 1 = non-acid (nadir pH  $\geq$  4), 2 = acid (nadir pH  $<$  4).
10. **position** Patient position at time of episode. 1 = upright, 2 = supine.

These variables represent those factors believed by the investigator to be most clinically relevant, and include factors that may act as confounders. Additionally, the investigator suspects the relationship between the symptomatic status of a reflux episode and the refluxate's

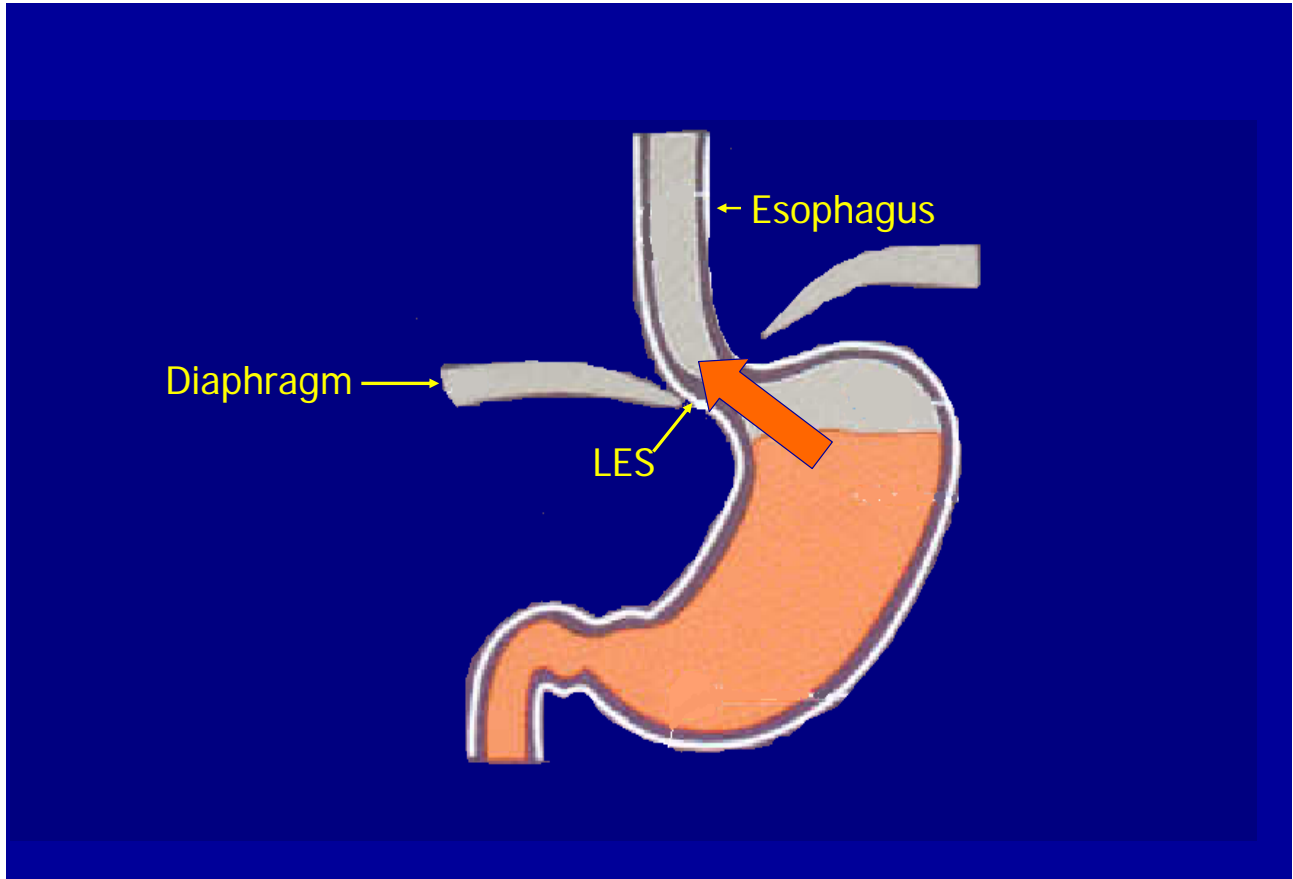


Figure 1: Diagram indicating location of lower esophageal sphincter.

acidity may differ depending on the refluxate's esophageal extent and also on the refluxate's clearance time.

Perform an appropriate data analysis to address the investigator's aim. You should write a report in the form of a paper with introduction, materials and methods, results and discussion sections. The paper may not exceed 8 pages in length. An additional document is provided on the class website providing the rubric detailing how your work will be evaluated.