

# Recorded Lower Esophageal Pressures as a Function of Electronic Sleeve Placement and Location of Gastric Pressure Measurement in Patients With Hiatal Hernia

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#### **Background/Aims**

In high-resolution manometry lower esophageal sphincter pressure (LESP) is measured relative to intragastric pressure, however Gastric Marker<sup>TM</sup> (GM) location used to determine resting LESP is not well established with hiatal hernia (HH). We test the hypothesis that measured resting LESP varies with HH based on GM location.

#### Methods

Subjects with HH  $\geq$  2 cm were included. The eSleeve<sup>TM</sup> was adjusted to span only the LES, excluding the crural diaphragm (CD). Resting LESP was determined by placing the GM below and above the CD (in the position yielding the highest resting LESP). Resting pressure across the lower esophageal sphincter (LES) to CD and pressure in the HH relative to subdiaphragmatic intragastric pressure were also measured.

#### Results

HH  $\geq$  2 cm was present in 98 patients (mean length 2.7 cm). LESP decreased when GM was moved from below the CD into the HH: respiratory minimum LESP 7.5  $\pm$  1.1 to 3.6  $\pm$  0.9 mmHg; P < 0.001, mean LESP 17.7  $\pm$  1.3 to 13.7  $\pm$  1.1 mmHg; P < 0.001. When the eSleeve encompassed the LES and CD, the respiratory minimum pressure was 12.2  $\pm$  0.9 mmHg and mean pressure was 23.9  $\pm$  1.0 mmHg pressure (P < 0.001 for both). Pressure in the hernia pouch was greater than intragastric pressure: respiratory minimum 3.0  $\pm$  0.7 mmHg and mean 9.0  $\pm$  0.8 mmHg (P < 0.001 for both). pH studies showed a trend toward an association between abnormal distal esophagus acid exposure and lower resting LESP.

#### **Conclusions**

GM placement in the HH produces lower resting LESPs. This may provide a more physiologic representation of LESP in HH. (J Neurogastroenterol Motil 2013;19:479-484)

# **Key Words**

Catheters; Esophagus; Gastroesophageal reflux; Hernia, hiatal; Manometry

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## Introduction

Esophageal manometry is used in the evaluation of gastroesophageal reflux disease (GERD) to localize the lower esophageal sphincter (LES) for pH probe placement, and to evaluate of esophageal motor function prior to anti-reflux procedures. The diagnostic capability of manometry has been greatly enhanced by the use of high-resolution manometry (HRM). HRM catheters consist of numerous closely spaced pressure sensors that allow simultaneous recording of pressure from the pharynx to the stomach. Advanced software programs transform the pressure data into topographical plots that give a detailed spatial and temporal representation of esophageal motor. Standard values are provided in the literature to aid the analysis process. 2

Although there have been significant advances in the technical aspects of esophageal manometry, it is still an evolving tool with some associated limitations. One possible limitation is the accurate determination of resting lower esophageal sphincter pressure (LESP) in the setting of a hiatal hernia (HH). The convention is to measure resting LESP relative to intragastric pressure. However, from where in the stomach gastric pressure should be measured is not well defined in the literature and might be confusing. This is particularly true when a HH is present: should resting LESP be measured in the HH pouch or below the crural diaphragm (CD)? With modern HRM systems, positioning a tool called the Gastric Marker<sup>TM</sup> (Sierra Scientific Instruments, Culver City, CA, USA) can be used to choose the intragastric sensor used to calculate resting LESP. Therefore, resting LESP can be determined relative to gastric pressure in the HH pouch or in the stomach below the CD. We long thought that the measured value for resting LESP might depend upon in which of these locations the Gastric Marker is positioned. If this is so, quantifying resting LESP relative to intragastric pressure below the CD might not give a clear picture of LES function in the presence of a HH. The accuracy of these measurements is paramount as these values help determine the choice of therapy in patients with impairment of esophageal motor function, such as GERD.

In this study, we compare resting LESPs determined as a function of intragastric pressure measured in the HH or below the CD. We also aim to correlate intraesophageal pH exposure with these values.

## Materials and Methods

# Subjects

Consecutive patients presenting to a tertiary care medical center for HRM were eligible for inclusion in the study. Manometry studies demonstrating hiatal hernia  $\geq 2$  cm (measured manually from distal border of LES to proximal border of the CD) were included in the study. Subjects without HH or with HH < 2 cm were excluded from the study. Available data from esophageal pH testing were recorded. The Institutional Review Board approved this study.

# High-resolution Manometry

Manometric recordings of esophageal motor function were acquired with the Manoscan<sup>TM</sup> manometry system (Sierra Scientific Instruments, Culver City, CA, USA). All subjects presented to the GI Motility Laboratory for HRM after a minimum 8-hour fast. Medications known to affect esophageal motor function were discontinued 5 days prior to HRM. A solid-state manometry catheter with 36 circumferential pressure transducers spaced at 1-cm intervals on center was used for the manometry (Sierra Scientific Instruments). A Manoshield<sup>TM</sup> (Sierra Scientific Instruments) was threaded over the catheter for sanitary protection. The catheter was calibrated from 0 to 300 mmHg using externally applied pressure immediately prior to use. It was then inserted transnasally into the esophagus with distal channels located in the stomach as identified by positive pressure deflection with deep inspiration. The catheter was then positioned to incorporate visualization of the upper esophageal sphincter (UES) and LES in the field of view. This allowed simultaneous recording of pressure from the hypopharynx to the proximal stomach.

Patients were placed in a 15° semi-recumbent position and allowed to accommodate to the catheter. Once comfortable, a 30 second recording was made with the patient at rest and not swallowing. This interval was delineated as the Landmark Frame TM (Sierra Scientific Instruments). It was during this Landmark Frame that resting LESP was determined. Following this recording of pressures at rest, the subjects were given 5-mL, room temperature water swallows in a sequence of 10 swallows. Water swallows were given 30 seconds apart. Double swallows and swallows including pressure artifacts associated with coughing or belching were not counted in the 10 swallows.

# Data Analysis

Manometric recordings of esophageal motor function were evaluated with the Manoview TM software (Sierra Scientific Instruments). Resting pressures were assessed within the 30 seconds Landmark Frame during which the patients did not swallow. A software algorithm resident in the Manoview software package called the electronic sleeve or eSleeve TM (Sierra Scientific Instruments) uses HRM pressure data to mimic a Dent sleeve. The default length of the eSleeve is 6 cm, but it can be adjusted to encompass varying numbers of contiguous pressure sensors. During the Landmark Frame, the Manoview software calculates respiratory minimum and mean LESPs relative to intragastric pressure. Manual positioning of a tool call the Gastric Marker TM (Sierra Scientific Instruments) allows us to

choose the intragastric sensor used to calculate resting LESP.

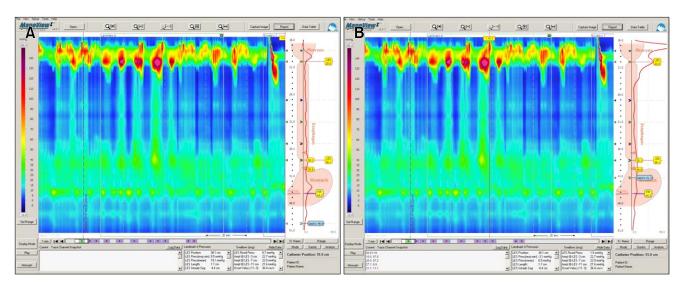
The eSleeve was first adjusted and positioned to span just the LES, excluding the CD. The esophagogastric junction (EGJ) in normal anatomy is a composite of tonic LES contraction and cylindrical CD contraction with inspiration. Because an inclusion criteria of the study is the presence of HH of 2 cm or more, the CD component is not included in this measurement. Therefore, LES pressure measurement in this study is defined as the pressure provided by tonic LES contraction alone and should be the same as EGJ pressure. Respiratory minimum and mean LESPs were determined relative to pressure in the HH pouch or in the stomach below the CD. This was done by placing the Gastric Marker above the CD or within the HH. The location of the Gastric Marker was standardized by choosing the position which yielded the highest resting LESP within each of these zones (Fig.

Table. Pressure Profiles in Different Measurement Zones

	Pressure profiles			
	Minimum (mmHg)	P-value	Mean (mmHg)	P-value
Resting LESP when GM is located in the stomach	$7.5 \pm 1.1$	-	$17.7 \pm 1.3$	-
Resting LESP when GM is located in the hernia sac	$3.6 \pm 0.9$	< 0.001	$13.7 \pm 1.1$	< 0.001
Resting pressure of high pressure zone	$12.2 \pm 0.9$	-	$23.9 \pm 1.0$	-
Resting pressure in hernia sac	$3.0 \pm 0.7$	-	$9.0 \pm 0.8$	-

In reference to lower esophageal sphincter pressure (LESP) with intragastric pressure (IGP) landmark below the crural diaphragm (CD), LESP with IGP landmark above the CD and pressure within the hernia sac were significantly lower while the minimum and mean pressures in the pressure zone spanning from the proximal LES to distal CD were significantly higher.

Values are presented as mean  $\pm$  SE.



**Figure 1.** Gastric Marker placement below (A) and above (B) the crural diaphragm in hiatal hernia. The Gastric Marker placement is denoted by the blue marker on the right side of the image. Note that the zone within the hernia in this case is greener, denoting higher pressure.

1). For instance, the location of the Gastric Marker for traditional measurement of the LESP and measurement of the high pressure zone spanning from the CD to the LES was chosen based on the position within the non-hernia stomach which provided the highest value measurement within these pressure zones. For measurement within the hernia sac, the Gastric Marker was positioned at the location within this zone which provided the highest LESP. The eSleeve was then adjusted to span from the proximal boundary of the LES to the distal boundary of the CD in order to provide an assessment of resting pressure across the entire high-pressure zone (LES, HH and CD). Finally, the eSleeve was adjusted from the distal boundary of LES to proximal boundary of CD so that resting pressure in the HH pouch could be measured.

# pH Studies

The electronic medical records of all subjects included in the study were reviewed for data from 24 or 48-hour pH studies. Time pH < 4 in the proximal and lower esophagus were recorded. Abnormal acid exposure was defined as time with pH < 4 greater 5% or 1% of the study duration in the distal or proximal esophagus, respectively. The number of reflux episodes in the distal and proximal esophagus, respectively, was also recorded.

# Statistical Methods

Comparisons of continuous data were made by paired t test using appropriate statistical software. A P-value of < 0.05 was considered significant. Continuous data were expressed as a mean  $\pm$  standard error of mean (SEM). Regression statistics using a linear analysis were utilized to assess relationships with percent total acid exposure in the distal esophagus.

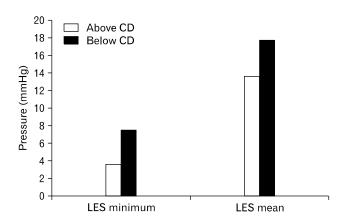
## Results

# Subjects

HRM studies of 98 consecutive subjects with hiatal hernia  $\geq$  2 cm were analyzed. Mean hiatal hernia length was 2.7  $\pm$  0.1 cm.

## **Pressure Profiles**

Respiratory minimum LESP was 7.5  $\pm$  1.1 mmHg when the Gastric Marker was positioned below the CD, and 3.6  $\pm$  0.9 mmHg when placed in the HH (P < 0.001) (Table and Fig. 2).



**Figure 2.** Comparison of placement of Gastric Marker above and below crural diaphragm (CD) in hiatal hernia. Lower esophageal sphincter (LES) minimum and mean pressure were both significantly lower (P < 0.001) with placement of the Gastric Marker above than below the CD.

Mean resting LESP was 17.7  $\pm$  1.3 mmHg with the Gastric Marker below the CD, and dropped to 13.7  $\pm$  1.1 mmHg when it was moved into the HH pouch (P < 0.001). When the eSleeve was adjusted to span the LES, HH and CD and the Gastric Marker was positioned below the CD, respiratory minimum pressure rose to 12.2  $\pm$  0.9 mmHg, and mean resting pressure to 23.9  $\pm$  1.0 mmHg. Relative to intragastric pressure below the CD, respiratory minimum pressure within the HH was 3.0  $\pm$  0.7 mmHg and mean pressure was 9.0  $\pm$  0.8 mmHg: both lower than resting LESPs, but higher than subdiaphragmatic intragastric pressure (Table).

## Distal Esophageal Acid Exposure

We evaluated data from 24-hour ambulatory intraesophageal pH studies in those subjects (n = 36) who had this study performed at our medical center. Those subjects with abnormal distal esophagus acid exposure had lower minimum (3.1  $\pm$  2.4 vs. 8.1  $\pm$  2.7 mmHg, P = 0.085) and mean (12.8  $\pm$  3.1 vs. 19.3  $\pm$  3.2 mmHg, P = 0.084) LESP with Gastric Marker below the CD. With Gastric Marker above CD, subjects with increased acid exposure also had lower measured minimum (-0.1  $\pm$  2.5 vs. 2.5  $\pm$  1.7 mmHg, P = 0.242) and mean (9.7  $\pm$  2.6 vs. 13.6  $\pm$  2.3 mmHg, P = 0.135) LESP, although these differences did not reach statistical significance. Linear regression analysis did not reveal a statistically significant association between increased acid exposure (percent time pH was below 4 in the distal esophagus) and any of the pressure zones evaluated (Gastric Marker below CD, Gastric Marker above CD, pressure zone across LES

to CD, or pressure zone within HH). In other words, neither placement of Gastric Marker below or above the CD provided LES pressures which correlated well with increased distal esophagus acid exposure.

# **Discussion**

We evaluated how positioning the Gastric Marker and eSleeve during the analysis of HRM of 98 subjects with HH might alter reported values for resting LESP. Respiratory minimum and mean LESP reported by Manoview algorithms varied significantly as a function of where and how these tools were positioned. When the Gastric Marker was moved from its subdiaphragmatic position into the HH, reported respiratory minimum and mean pressures dropped significantly. This indicates that in our patients resting pressures in the HH are greater than in the subdiaphragmatic stomach (Fig. 1). Here, the green hue within the HH, represents higher pressure than the more blue color below the CD. This is supported by our observation that pressure measured in the HH by the eSleeve is greater than subdiaphragmatic intragastric pressure. While we did not directly address this question, this observation suggests that the pressure gradient across the LES may be greater with a HH than when the stomach is normally positioned below the CD. In the presence of a HH, calculating resting LES pressures relative to HH pressure might be more physiologically relevant than calculating them relative to subdiaphragmatic intragastric pressure. This is because the gastric pressure adjacent to the LES is that within the

Sparse data are available regarding assessment of HH with HRM.<sup>1,4-7</sup> Crural CD function is an independent predictor of GERD and LES-CD separation is associated with GERD.<sup>5</sup> The presence of HH may be a pivotal contributor to compromised LES function.<sup>6</sup> In our regression analysis of 36 subjects with available pH studies, there was a trend between increased distal esophagus acid exposure and lower resting LESPs with Gastric Marker placed either below or above the CD, but these differences did not reach statistical significance in either case.

A previous report suggests that CD function may augment the barrier at the EGJ and the loss of this function is reflected by this increase in acid exposure in the distal esophagus. HH has been showed to alter dynamic responsiveness of LESP by spatially separating pressure components of the LES and extrinsic esophageal compression within the hernia canal and shape of the EGJ has been shown to correlate with grade of esophagitis. The severity of HH may also influence susceptibility to reflux. In a HRM comparison of type I (separation but still some overlap between LES and CD) and type II (LES and CD completely separated) HH, reflux events were twice as likely to occur with the latter EGJ spatial configuration. <sup>10</sup> These data are corroborated by the increase in minimum and mean pressure we appreciated with the eSleeve spanning from the LES to the CD (12.2  $\pm$  0.9 mmHg) compared to traditional measurement including the boundaries of the LES only (7.5  $\pm$  1.1, P < 0.001).

Furthermore, the CD may play a role in the etiology of dysphagia in patients with HH. Subjects with HH and dysphagia have higher residual CD pressure and intrabolus pressure compared to subjects with HH and GERD. This suggests that HH alters pressure dynamics at the EGJ and may lead to functional obstruction. It is conceivable that not only the CD but the high pressure zone created between the LES and CD in patients with HH may create functional obstruction and dysphagia.

In summary, we demonstrated lower minimum and mean LESP in subjects with HH ( $\geq 2$  cm) with Gastric Marker measured within the HH compared to traditional measurement below the CD. This difference may be explained by the demonstration of higher pressure within the hernia sac compared to the zone below the CD. This novel measurement technique may provide a more physiologic representation of the pressure profile across the LES in patients with HH and further investigation is necessary to validate this measurement.

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