


# Reference high-resolution manometry values after magnetic sphincter augmentation

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## Abstract

**Background:** Magnetic sphincter augmentation (MSA) is an innovative antireflux procedure that can improve lower esophageal sphincter (LES) competency and reduce symptoms of gastroesophageal reflux disease (GERD). Some patients report postoperative dysphagia. To date, no studies have described reference high-resolution manometry (HRM) values after MSA implantation.

**Methods:** High-resolution manometry was performed in patients free of dysphagia after MSA with or without concurrent crura repair. Reference values for all parameters of the Chicago Classification were defined as those between the 5th and 95th percentiles. The contribution of concurrent crura repair to LES competency and to reference values was also analyzed.

**Key Results:** Eighty-four patients met the study inclusion criteria. The upper limit of normality for integrated relaxation pressure (IRP) and intrabolus pressure (IBP) was 20.2 mmHg and 30.3 mmHg, respectively. Both variables were higher after MSA compared to normative Chicago Classification v3.0 values. The Distal Contractile Integral upper limit was in the range of normality. Patients undergoing crura repair had a significantly higher IRP ( $p = 0.0378$ ) and lower GERDQ-A scores ( $p = 0.0374$ ) and Reflux Symptom Index ( $p = 0.0030$ ) compared to those who underwent MSA device implantation alone.

**Conclusion & Inferences:** This study provides HRM reference values for patients undergoing successful MSA implantation. Crural repair appears to be a key component of LES augmentation and is associated with improved clinical outcomes.

## KEYWORDS

Chicago Classification, crural repair, high-resolution manometry, integrated relaxation pressure, intrabolus pressure, magnetic sphincter augmentation, normative values

## Key Points

- This study aimed to provide reference high-resolution manometry values for all parameters of the Chicago Classification after magnetic sphincter augmentation.
- The upper limit of normality for integrated relaxation pressure and intrabolus pressure was higher after magnetic sphincter augmentation compared to normative Chicago v3.0 values.

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Patients in whom crura repair was part of the surgical procedure had a significantly higher integrated relaxation pressure and better control of reflux symptoms.

- Results of the present study provide clues for interpretation of postoperative symptoms.

## 1 | INTRODUCTION

Laparoscopic Nissen and Toupet funduplications are the most commonly used antireflux surgical procedures to re-establish competence of the esophagogastric junction (EGJ) in patients with gastroesophageal reflux disease (GERD).<sup>1</sup> Both operations are effective in reducing symptoms associated with abnormal esophageal acid exposure.<sup>2</sup> Magnetic sphincter augmentation (MSA) is a novel laparoscopic procedure designed to augment the barrier function of the lower esophageal sphincter (LES). It has been shown that MSA can reduce GERD symptoms and improve patients' quality of life up to 12 years of follow-up.<sup>3</sup>

Similar to what occurs after fundoplication, a proportion of patients receiving MSA complain of postoperative dysphagia which may be associated with elevated LES residual pressure on conventional manometry.<sup>4</sup> Ayazi et al.<sup>5</sup> demonstrated an increased intrabolus pressure (IBP) on high-resolution manometry (HRM) in patients with good clinical outcome after MSA. However, post-MSA threshold values have not been established yet. The aim of the present study was to describe HRM features of patients after MSA implantation and to define reference values.

## 2 | METHODS

A retrospective, observational cohort study was conducted at our tertiary care hospital and referral center for esophageal surgery. After Institutional Review Board approval, the prospectively collected antireflux surgery database was reviewed to identify all individuals who received MSA (Linx Reflux Management System, Ethicon, Johnson & Johnson).

Inclusion criteria were age between 18 and 65 years, MSA implant with or without concurrent crura repair, HRM performed pre- and postoperatively, and minimum 6-month postoperative follow-up. Exclusion criteria were the presence of major motility disorders at preoperative HRM or persistent postoperative dysphagia, defined as Functional Outcome Swallowing Scale (FOSS) score > 1.<sup>6</sup>

### 2.1 | Preoperative assessment and surgical procedure

Symptoms were assessed using the GERD Health Related Quality of Life (HRQL) score,<sup>7</sup> the GERD Questionnaire (GERDQ),<sup>8</sup> and the Reflux Symptom Index (RSI).<sup>9</sup> Preoperative investigations included upper gastrointestinal endoscopy, barium swallow study, and 24-h esophageal pH-impedance study.

Patients underwent laparoscopic MSA implantation under general anesthesia, as previously described.<sup>10,11</sup> The gastroesophageal junction was exposed, and the distal esophagus was encircled. A full mediastinal dissection with posterior crural repair was routinely performed if a hiatus hernia > 3 cm was identified. The esophagus was measured with a dedicated sizing instrument, and the appropriate MSA device was inserted through a tunnel made between the posterior vagus nerve and the esophageal wall and was locked anteriorly.

### 2.2 | Postoperative assessment

Patients were assessed with GERD-HRQL, RSI, GERDQ, and FOSS questionnaires. Barium swallow study and upper gastrointestinal endoscopy were routinely performed between 6 and 12 months after surgery. HRM was offered to patients who signed an informed consent.

### 2.3 | Technique of HRM

A solid-state catheter with 36 pressure channels spaced at 1-cm intervals (Medtronic) was used. The test was conducted in semi-recumbent position after 6 h of fasting. The catheter was positioned transnasally, and 5 min of adaptation period were observed. Basal esophageal and gastric pressure were recorded during 30 s without swallowing. LES characteristics were recorded: total and intra-abdominal length, basal pressure, and esophago-gastric junction contractile integral (EGJ-CI). The latter, a measure of the contractility of the EGJ, was calculated enclosing the upper and lower margins of the EGJ in the DCI tool box for three consecutive respiratory cycles, and the threshold isobaric contour (IBC) was set at 2 mm Hg above gastric pressure. The DCI tool in mmHg s cm was then divided by the duration of the three respiratory cycles (in s) yielding EGJ-CI units of mmHg cm.<sup>12</sup> The study protocol included 10 consecutive swallows of 5 ml of water administered every 30 s to measure the integrated relaxation pressure (IRP), the distal esophageal amplitude (DEA), the distal contractile integral (DCI), the intrabolus pressure (IBP), and the distal latency (DL). Finally, multiple rapid swallows (MRS) were performed with five consecutive swallows of 2 ml of water at <4-second intervals, to define deglutitive inhibition and the contractile response following the final swallow of the sequence. A ratio of MRS-DCI to mean DCI > 1 indicated the presence of contractile reserve.<sup>13</sup> Data were analyzed using ManoView 3.0 (Given Imaging, Medtronic). The references for normal range were the Chicago Classification 3.0 criteria.<sup>14</sup>

## 2.4 | Statistical analysis

Descriptive data are expressed as counts (percentages) for categorical data and as mean  $\pm$  standard deviation (SD) and median

**TABLE 1** Baseline patient demographic, clinical, and manometric characteristics. Continuous values expressed as median (IQR)

	N = 84
Sex, females (%)	27 (32.1)
Age, years	51 (15.9)
BMI, kg/m <sup>2</sup>	26.1 (5.3)
Disease duration, years	7 (10)
PPI responders (%)	56 (71.8)
Years of therapy	4 (8)
Hiatal hernia, n (%)	64 (76.1)
Number of MSA beads	13.9 (1.1)
Time from intervention, months	13 (22.5)
Pre-op manometric variables	
LES length, cm	1.85 (0.7)
Intra-abdominal LES length, cm	0.0 (1.0)
LES basal pressure, mmHg	22.9 (17.6)
IRP, mmHg	6.9 (6.9)
EGJ-CI, mmHg cm	24.2 (27.2)
IBP, mmHg	9.8 (8.1)
DCI, mmHg cm s	957 (834)

Abbreviations: BMI, Body Mass Index; DCI, Distal Contractile Integral; EGJ-CI, Esophagogastric Junction Contractile Integral; IBP, Intrabolus Pressure; IQR, Interquartile Range; IRP, Integrated Relaxation Pressure; LES, Lower Esophageal Sphincter; MSA, Magnetic Sphincter Augmentation; PPI, Proton-Pump Inhibitors.

(interquartile range, IQR) for continuous variables. Reference values were considered between the 5th and 95th percentiles.

Mann-Whitney-Wilcoxon test was used to verify statistically significant differences among groups. To compare categorical data, Fisher's exact test or chi-square test was used, as appropriate. All *p* values are two-tailed and considered significant if  $<0.05$ . Statistical analyses were done with SAS software, version 9.4 (SAS Institute, Inc.).

## 3 | RESULTS

During the study period, 105 patients underwent MSA with or without crural repair. All were offered postoperative HRM, but 10 of them declined, eight had undergone HRM after endoscopic dilation for persistent dysphagia, and only three had untreated persistent dysphagia. Therefore, 84 patients were considered eligible for inclusion in the study. The median time from intervention to postoperative HRM was 13 months (22.5). The median IRP and IBP values were 6.9 (IQR 6.9) and 9.8 (IQR 8.1) mmHg, respectively. The full demographic and baseline characteristics are reported in Table 1.

### 3.1 | Postoperative esophagogastric junction features

A type I or type II EGJ morphology was observed in 68 (80.9%) and 16 (19.0%) patients, respectively. Table 2 shows the full mean ( $\pm$ SD), median, and reference values of HRM metrics after MSA compared to the Chicago Classification (CC) v3.0. Mean LES length was  $2.4 \pm 0.7$  cm, and the mean intra-abdominal LES length was  $1.1 \pm 1$  cm. Both parameters significantly increased after MSA

**TABLE 2** Reference manometric values after MSA device placement in the patient population

	Mean	SD	Median	Reference values		Chicago classification
				5th percentile	95th percentile	
UES basal pressure (mmHg)	89.9	49.8	77.6	36.1	190.1	34–104
UES residual pressure (mmHg)	2.6	7.6	1.2	−6.7	14.3	<12
LES length (cm)	2.4	0.7	2.2	1.5	3.8	2.7–4.8
Intra-abdominal LES length (cm)	1.1	1.0	1.0	0.0	2.9	n.a
LES basal pressure (mmHg)	24.3	11.2	23.0	7.0	42.0	13–43
EGJ-CI (mmHg cm)	59.2	24.7	55.2	23.6	97.4	
IRP (mmHg)	11.2	5.4	10.5	3.7	20.2	<15
IBP (mmHg)	16.5	7.6	17.0	4.1	30.3	<17
DCI (mmHg cm s)	1587.0	1245.1	1309.0	190.8	3710.8	500–5000
MRS-DCI (mmHg cm s)	2614.1	2307.1	1975.0	387.0	8875.0	n.a.
MRS ratio	1.5	1.6	1.2	0.1	3.4	
Distal Latency (s)	6.8	1.5	6.6	5.4	8.8	>4.5

Abbreviations: DCI, Distal Contractile Integral; EGJ-CI, Esophagogastric Junction Contractile Integral; IBP, Intrabolus Pressure; IRP, Integrated Relaxation Pressure; LES, Lower Esophageal Sphincter; MRS, Multiple Repeated Swallows; SD, Standard Deviation; UES, Upper Esophageal Sphincter.

TABLE 3 Demographic and clinical characteristics of patients who underwent MSA device placement with or without crural repair

	No crural repair (N = 31)	Crural repair (N = 53)	p value
Sex, females (%)	10 (32.3)	17 (32.1)	1.000
Age at intervention, years	46.1 (11.9)	52.7 (11.5)	0.0098
BMI, kg/m <sup>2</sup>	25.2 (3.2)	26.8 (4.3)	0.1294
Disease duration, years	8.3 (7.1)	11.0 (9.9)	0.3383
Pre-op GERD-HRQL score	19.6 (6.6)	19.4 (6.9)	0.8967
Pre-op hiatal hernia (%)	9 (29)	53 (100)	<0.0001
PPI responders (%)	22 (73.3)	34 (70.83)	1.000
Years of therapy	6.3 (6)	7.6 (8.1)	0.9913
Number of MSA beads	14.5 (1)	14.9 (1.1)	0.1004
Duration of intervention, minutes	64.8 (31.8)	78.6 (36.7)	0.0232
Post-op hiatal hernia (%)	5 (16.1)	14 (26.4)	0.2790
Post-op GERD-HRQL score	5.4 (6.6)	3.4 (5.7)	0.0611
Post-op GERDQ-A score	3.1 (3)	1.4 (2.4)	0.0030
Post-op GERDQ-B score	0.8 (1.3)	0.4 (1)	0.2154
Post-op RSI	6 (6.6)	3.7 (6.5)	0.0374

Note: Continuous variables are expressed as mean (SD).

Abbreviations: BMI, Body Mass Index; GERD-HRQL, Health Related Quality of Life; GERDQ, GERD Questionnaire; MSA, Magnetic Sphincter Augmentation; PPI, Proton-Pump Inhibitors; RSI, Reflux Symptom Index; SD, Standard Deviation.

implantation ( $p = 0.004$  and  $p = 0.029$ , respectively). The upper limit of LES basal pressure was 42 mmHg. The mean IRP value was  $11.2 \pm 5.4$  mmHg, and the upper limit of normality (95th percentile) was 20.2 mmHg, higher than the upper normative values. The 95th percentile of IBP was 30.3 mmHg. Comparison with preoperative values was significant for both variables ( $p < 0.001$ ).

### 3.2 | Postoperative esophageal body motility parameters

As shown in Table 2, the DCI was found within the limits of the CC v3.0 in all patients, as the mean value was  $1587 \pm 1245.1$  mmHg s cm and the upper normal limit was 3710.8 mmHg s cm. The normal values of DCI after multiple repeated swallows were between 387 and 8875 mmHg s cm, with a mean peristaltic reserve (ratio of MRS-DCI to mean DCI) of  $1.5 \pm 1.6$ . The mean DEA was  $84 \pm 41.5$  mmHg, ranging between 31.6 and 167.7 mmHg. All patients had a value of DL  $> 4.5$  s, as reported in the CC, going from a minimum of 4.8 up to 16.6 s, and the mean value was  $6.8 \pm 1.5$  s.

### 3.3 | Reference manometric values in patients undergoing MSA plus crural repair

Compared to the no crural repair group, patients undergoing MSA and concurrent crural repair were older at intervention, had a greater incidence of hiatal hernia, required a longer operative time, and had better clinical outcomes with lower mean scores at GERDQ-A and RSI questionnaire (Table 3).

A comparative analysis of manometric variables in patients with and without crural repair is reported in Table 4. While total LES length was comparable in the two groups, patients who underwent crural repair had a shorter intra-abdominal LES length, although reference values varied between 0 and 2.6 cm in both cases. Individuals with crural repair had a significantly higher IRP compared to patients who underwent MSA device implantation alone. Moreover, in the crural repair group, the 95th percentile of IBP was greater than the normative value of CC v3.0 (31.5 mmHg vs. 17 mmHg) (Figure 1).

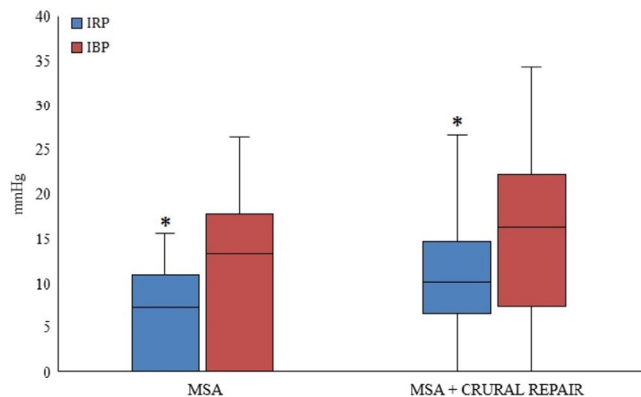
## 4 | DISCUSSION

This is the first study reporting comprehensive HRM reference values in patients undergoing laparoscopic MSA for GERD. Normative values as established by the Chicago Classification were obtained from patients without previous esophageal surgery and are now routinely used to define motility disorders. As it has been done for patients undergoing Nissen and Toupet funduplications,<sup>15</sup> assessment of reference postoperative HRM metrics after MSA is crucial to clarify the physiological effect of a new antireflux surgical technique and to identify pathological values that may correlate with postoperative dysphagia. In particular, IRP is a key variable for diagnosing EGJ outflow obstruction (EGJOO) and achalasia in patients with dysphagia.<sup>16</sup> In the present study, the IRP reference value after MSA implant was 20.2 mmHg, which is higher than the reference value of the CC v3.0 (15 mmHg). Despite a diagnosis of EGJOO could have been applied to 23.8% of our patients, none of them reported dysphagia. Our hypothesis, as described in a previous study,<sup>17</sup> is that

TABLE 4 Manometric variables in patients who underwent MSA device placement with or without crural repair

	No crural repair (n = 31)					Crural repair (n = 53)					p value
	Mean	SD	Median	5th percentile	95th percentile	Mean	SD	Median	5th percentile	95th percentile	
LES length (cm)	2.3	0.8	2.0	1.4	3.3	2.4	0.7	2.3	1.6	3.8	0.3580
Intra-abdominal LES length (cm)	1.3	1.1	1.4	0.0	2.5	0.9	1.0	0.5	0.0	2.6	0.0432
DEA (mmHg)	86.3	48.0	78.3	32.1	179.2	82.7	37.6	72.4	37.0	139.5	0.9004
MRS-DCI (mmHg s cm)	3004.4	2881.9	2416.0	342.6	9197.8	2383.1	1883.4	1678.0	631.6	5634	0.7059
DCI (mmHg s cm)	1772.3	1607.4	1500.0	132.8	3241.6	1478.7	975.5	1191.6	458.7	3514.5	0.8239
MRS ratio	1.3	1.1	1.1	0.1	3.4	1.7	1.8	1.4	0.1	2.9	0.2000
LES basal pressure (mmHg)	22.9	13.0	21.4	6.6	42	25.1	10.1	23.7	12.4	47.1	0.2906
IRP (mmHg)	9.5	5.5	10.3	2.2	15.4	12.2	5.1	11.6	6.1	20.1	0.0378
UES basal pressure (mmHg)	93.1	48.4	84.7	36.1	190.1	88.0	51.0	76.9	41.0	183.5	0.5104
UES residual pressure (mmHg)	0.2	6.2	0.2	-5.5	8.4	4.0	8.1	2.5	-2.5	15.9	0.0258
IBP (mmHg)	15.7	8.0	16.0	0.5	25.4	17.0	7.3	17.4	7.2	31.5	0.4897
Distal Latency (s)	7.0	1.2	6.9	5.7	8.7	6.7	1.7	6.5	5.5	8.8	0.0842
EGJ-CI	52.8	16.1	53.4	28.9	72.8	61.4	26.9	58.1	30.2	100.6	0.6661

Abbreviations: DCI, Distal Contractile Integral; DEA, Distal Esophageal Amplitude; EGJ-CI, Esophago-gastric Junction Contractile Integral; IBP, Intrabolus Pressure; IRP, Integrated Relaxation Pressure; LES, Lower Esophageal Sphincter; MRS, Multiple Repeated Swallows; UES, Upper Esophageal Sphincter.



**FIGURE 1** Integrated relaxation pressure and intrabolus pressure in patients without and with concomitant crural repair. IBP, Intrabolus Pressure; IRP, Integrated Relaxation Pressure; MSA, Magnetic Sphincter Augmentation. \* $p$  value = 0.03.

increased LES resistance may induce a change in the motility pattern of the esophageal body. We also found that reference IBP values were higher in operated patients, with the upper limit of normality being 30.3 mmHg compared to 17 mmHg of the CC v3.0. This result was not unexpected since IBP represents the force exerted on a bolus during esophageal peristalsis, and its elevation is an indirect sign of relative esophageal obstruction.<sup>18</sup> This is consistent with the findings of other investigators who reported a 95th percentile value of 30.4 mmHg in a series of 43 patients.<sup>5</sup> In our opinion, IRP is a more standardized parameter for EGJ resistance, while the clinical significance of IBP has to be defined yet, and its automatic measurement has been omitted in the latest version of the ManoView analysis software.

A multicenter study by Weijenborg et al.<sup>15</sup> reported reference HRM values at an average of 3 months after Nissen and Toupet funduplications in 40 patients. Crural repair was not mentioned as part of the operative procedure. IRP was higher after Nissen and the upper limit of normal (95th percentile) was higher compared to the CCv3.0 (24.4 mmHg), while the upper normal limit of IRP after Toupet was the same as reported in the CCv3.0 (15 mmHg). Interestingly, the IRP value after MSA in our patients was intermediate between the complete and the partial funduplications.

An increased resistance of EGJ in MSA patients can be explained by the magnetic force and the fibrotic reaction around the device.<sup>5</sup> We further explored the potential contribution of crura repair in addition to MSA implant. In our series, patients who received MSA combined with crura repair had a higher IRP and a DCI in the range of CC v3.0. The results of the present study confirm that crura repair plays a crucial role in sphincter augmentation.<sup>19,20</sup> Moreover, although all patients in the study had excellent results after surgery, those who underwent crural repair had superior outcomes on most scores. The shorter postoperative intra-abdominal LES length in the crural repair group may be due to patient selection bias or inaccurate measurement of LES length.<sup>21</sup>

The reproducibility of LES length measurement may be influenced by inter-observer and technology variability in different

laboratories. Recently, Rogers et al.<sup>22</sup> published normative EGJ metrics in a large cohort of healthy volunteers. Taking into account only the Medtronic group, that is, the same technology used in our laboratory, the median EGJ-CI and LES length were 37 mmHg cm and 3.7 cm, respectively. In our study, the median postoperative EGJ-CI was 55.2 mmHg cm and the LES length was 2.2 cm, indicating restoration of the antireflux barrier after MSA.

Our study emphasizes the need of a detailed pre- and postoperative pathophysiologic study of patients who undergo antireflux surgery. Also, we reported a set of values that may be useful to assess efficacy of MSA and to select patients who may benefit from endoscopic dilation.

Dysphagia is the most common adverse event after MSA implant, and HRM cutoff values may help to select patients for endoscopic dilation. It has been shown that early dilation (within 6 months after surgery) should be avoided. In fact, during the last decade, adequate dietary exercise and change in sizing protocol and dilation strategy have decreased the long-term dysphagia rate in these patients.<sup>23</sup> Unfortunately, we were unable to include in the present study a number of patients with persistent dysphagia in whom HRM was performed after endoscopic dilatation, thereby precluding any reasonable comparison with the asymptomatic patients.

Limitations of the present study are the retrospective design and the absence of a control group of patients with dysphagia that could have provided a more robust set of cutoff values. Further studies are needed to compare normal values of these patients to the manometric values of patients with postoperative dysphagia.

## 5 | CONCLUSIONS

We reported HRM reference values in patients who underwent successful laparoscopic MSA device implantation for GERD. The crural repair is a key component of the resistive force at the EGJ and may account for the increased IRP after surgery.

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### DISCLOSURE

None declared.

### AUTHOR CONTRIBUTIONS

SS, DF, and LB designed the research study. SS, DF, CGR, MS, and VL collected the data. VM and CGR analyzed the data. LB, SS, DF, and CGR wrote the manuscript. All authors reviewed the final version of the manuscript.

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