Increase of lower esophageal sphincter pressure after osteopathic intervention on the diaphragm in patients with gastroesophageal reflux

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SUMMARY. The treatment of gastroesophageal reflux disease may be clinical or surgical. The clinical consists basically of the use of drugs; however, there are new techniques to complement this treatment, osteopathic intervention in the diaphragmatic muscle is one these. The objective of the study is to compare pressure values in the examination of esophageal manometry of the lower esophageal sphincter (LES) before and immediately after osteopathic intervention in the diaphragm muscle. Thirty-eight patients with gastroesophageal reflux disease – 16 submitted to sham technique and 22 submitted osteopathic technique – were randomly selected. The average respiratory pressure (ARP) and the maximum expiratory pressure (MEP) of the LES were measured by manometry before and after osteopathic technique at the point of highest pressure. Statistical analysis was performed using the Student’s t-test and Mann–Whitney, and magnitude of the technique proposed was measured using the Cohen’s index. Statistically significant difference in the osteopathic technique was found in three out of four in relation to the group of patients who performed the sham technique for the following measures of LES pressure: ARP with $P = 0.027$. The MEP had no statistical difference ($P = 0.146$). The values of Cohen $d$ for the same measures were: ARP with $d = 0.80$ and MEP $d = 0.52$. Osteopathic manipulative technique produces a positive increment in the LES region soon after its performance.

KEY WORDS: gastroesophageal reflux, lower esophageal sphincter, osteopathic manipulation, treatment.

INTRODUCTION

Gastroesophageal reflux disease (GERD), although not considered a severe illness, 1 is one of the most common disorders of the gastrointestinal system. 2 It has a great medical-social importance, with a high and growing prevalence. It is the cause of various esophageal symptoms 3–7 and extraesophageal symptoms, 8, 9 having a negative impact on quality of life 10, 11 with reflex on the economy of the society. 12, 13

The LES and the crural diaphragm represent the intrinsic and extrinsic sphincters, respectively. They are anatomically overlaid and anchored one to the other through the phrenoesophageal ligament. 14 During contraction of the crural diaphragm, an increase of the LES pressure occurs, 15 contributing to a three- to four-fold growth of the pressure in the
gastroesophageal junction (GEJ) region. In addition, both the LES and the diaphragm relax during a short period of time to allow passage of the food bolus during esophageal peristalsis.

Investigation using high-resolution manometry reviewed the diaphragmatic function in patients with and without gastroesophageal reflux (GER) and evidenced a diaphragmatic deficient function in patients with GER, as shown by the reduced increase of the inspiratory pressure of the GEJ.

Nevertheless, the inspiratory muscles, including the diaphragm, are morphologically and functionally skeleton muscles and therefore should respond to training just like the gait muscles, if submitted to an appropriate stimulus. It has already been demonstrated that the diaphragm increases its thickness when a resistance is applied against it during weight-lifting training. Downey et al. reported an 8–12% increase in the diaphragm thickness during contraction after muscular inspiratory post-training for 4 weeks.

Within this background and considering other studies that have shown good results with the osteopathic manipulative treatment in visceral dysfunctions, the study of this kind of therapeutic approach has shown to be important to be added to the GERD conservative treatments and maybe, avoid surgery.

Many authors have shown the fundamental importance of the diaphragm within the GEJ structures, with an important role in the sphincter mechanism against reflux. Therefore, we shall use the lower esophageal sphincter (LES) manometric study to review the immediate repercussion of the diaphragmatic stretching technique widely used by osteopaths to obtain equilibrium of the diaphragm functions in the mechanism against GER compared with the placebo technique.

MATERIALS AND METHODS

Patients

All patients above 18 years old, regardless of gender, referred to the Laboratory of Digestive Motility Investigation of the Gastroenterology Service of Hospital das Clinicas of the University of São Paulo School of Medicine to undergo an esophageal manometric examination, who were released with a GERD diagnostic, were randomly screened and invited to participate in the study.

Studied groups

Patients were randomly allocated to two groups: group O (osteopathy) undergoing the diaphragm stretching technique, which included 22 individuals, and group P (placebo – control) who went through the placebo technique and included 16 patients.

Diaphragm stretching technique

The diaphragm stretching technique has been performed by only one of the investigators, who was not in charge of data collection nor interpretation of the manometry measurements. The protocol includes the technique suggested by Coster and Pollaris modified as follows: the position of the patient laying back (supine) with the legs bent and the feet against the bed. A total of eight deep respiratory maneuvers were performed in two steps: first step – four deep respirations, in which the inspiration and expiration movements are exacerbated by the investigator through manual contact on the lower rim of the last ribs; second step: four deep respirations, in which, during the expiratory phase, the investigator will sustain the ribs grid using the same contact to avoid the descent of the thoracic cage during the expiratory phase. During the performance of the technique, the investigator would encourage and coordinate deep breathing of the patients through voice command.

Sham technique

The sham technique was performed by the same investigator who performed the diaphragm stretching techniques. Patient lying back with the legs bent and feet against the bed. The investigator maintained one hand in contact on the patient’s sternum and the other hand on the abdomen, next to the gastric region. The patient had to produce the same eight deep breathings, during which the same voice commands of the diaphragm technique were given; however, the investigator’s hands only maintain a physical contact with the patient without exerting any pressure, or putting any incentive or restriction to the movements of the thoracic cage.

Esophageal manometry

The esophageal manometry exam was performed by a specialized physician using the device Alacer Multiplex BP 108 (Alacer Biomedica®, São Paulo, Brazil). The manometric exam was performed normally by the dedicated physician who, after reaching the gastric cavity, coordinated so that the probe was pulled each 0.5 cm throughout the extension of the LES. The objective was to obtain a more faithful characterization of all its extension and pressure characteristics. After the end of the esophageal body manometric exam, the probe was reintroduced in the patient’s stomach, and the technique was performed by the osteopathologist in charge. After 20 seconds, the probe was pulled again each 0.5 cm throughout the extension of the LES, and the data were immediately recorded after performing the diaphragm stretch or sham techniques.
Selection of the points studied

After the end of the exam, the physician measured the average respiratory pressure (ARP) and maximum expiratory pressure (MEP) and chose the highest point (HP) and the mean between all points before and immediately after the osteopathic intervention or application of the placebo technique. In case of dispute as to which would be the best method to measure the LES, excluding the diaphragm pressure force.

Statistical analysis

Before analyzing the data was performed transformations of each variable in order to facilitate calculations and understanding of the problem. We chose to change based on differences in values as follows: The variables ARP from the HP pre-intervention and postintervention of the group O gave rise to the variable ‘Difference (pré-pós) of ARP (HP) of the group O,’ the variables ARP from the HP pre-intervention, and postintervention of the group P gave rise to the variable ‘Difference (pré-pós) of ARP (HP) of the group P,’ and so on. Then, analyze the data to find possible differences between the responses of two groups are summarized in comparing these new variables and determine whether they are statistically different.

The next step was to analyze the distribution of each group of new variables to correctly define which the best test to use is. For this, it took several Quantile-Quantile (QQ) plots more specifically, normal QQ plots. Non-parametric tests (Mann–Whitney) were adopted for those variables that did not comply with the homogeneity criteria of the variance and/or normal distribution. For all other variables, the Student’s t-test was except for the comparison of the proportion of men and women in each group, for which an exact Fisher test with 95% significance level was used. In addition to the inferential analysis, as a way to quantify the magnitude of the difference observed among two groups, the magnitude of the effect was determined (‘effect size’: Cohen $d$), a rate that measures the magnitude of the effect of the proposed technique. The $d$ values for small, medium, and large magnitude effects are 0.2, 0.5, and 0.8, respectively, and the medium and large values are considered as having clinical importance.

RESULTS

A total of 38 patients were assessed, of which 25 were of the female gender (65.7%). The mean age, weight, height, and body mass index (BMI) of the group O (osteopathy) was 49.5 years of age, 67.3 kg, 1.61 m, and BMI 25.72, respectively. And that of the placebo group (group P) was 50.5 years of age, 61.8 kg, 1.62 m, and BMI 23.52. The two groups were not different as far as age, weight, BMI, and height are concerned (tests $t_P > 0.21$), as well as with regard to the gender distribution (Table 1).

Variables of the LES pressure

In Table 2, we analyzed variables of the LES pressure in each group before and after the procedures. All $P$-values were greater than 0.05; however, the null hypothesis cannot be rejected. In other words, all LES pressure variables may be seen as normally distributed and parametric ($t$-Student) being the tests suited to the task of group comparison.

ARP and MEP mean values

A summary of the mean values of ARP and MEP is shown in Table 3.

## Table 1  Gender, age, and body mass index variation

<table>
<thead>
<tr>
<th>Variable</th>
<th>Placebo group</th>
<th>Osteopathy group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>16</td>
<td>22</td>
</tr>
<tr>
<td>Women/men</td>
<td>09/07</td>
<td>16/06</td>
</tr>
<tr>
<td>Mean body mass index*</td>
<td>23.52</td>
<td>25.72</td>
</tr>
<tr>
<td>Mean age (years)*</td>
<td>50.5 ± 16.21</td>
<td>49.4 ± 15.01</td>
</tr>
</tbody>
</table>

* $P > 0.21$.

## Table 2  Variables of the LES pressure: at the point of maximum pressure (ARP and MEP pre-intervention and postintervention)

<table>
<thead>
<tr>
<th>Statistical analysis</th>
<th>Osteopathy group</th>
<th>Placebo group</th>
<th>ARP – pre</th>
<th>ARP – post</th>
<th>MEP – pre</th>
<th>MEP – post</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>20.04</td>
<td>25.74</td>
<td>21.87</td>
<td>22.14</td>
<td>12.03</td>
<td>16.88</td>
</tr>
<tr>
<td>Standard deviation</td>
<td>8.07</td>
<td>15.29</td>
<td>9.70</td>
<td>18.25</td>
<td>5.76</td>
<td>12.90</td>
</tr>
<tr>
<td>Kolmogorov–Smirnov Z</td>
<td>0.622</td>
<td>0.913</td>
<td>0.655</td>
<td>0.927</td>
<td>0.831</td>
<td>0.923</td>
</tr>
<tr>
<td>$P$-value</td>
<td>0.834</td>
<td>0.376</td>
<td>0.784</td>
<td>0.357</td>
<td>0.495</td>
<td>0.362</td>
</tr>
</tbody>
</table>

ARP, average respiratory pressure; LES, lower esophageal sphincter; MEP, maximum expiratory pressure; post, postintervention; pre, pre-intervention.

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The values of $d$ for small, medium, and large magnitude are, respectively, 0.2, 0.5, and 0.8, and the medium and large values are considered as having clinical relevance.\textsuperscript{28} The values of Cohen $d$ for these measurements were: $ARP - d = 0.80$ and $MEP - d = 0.52$. This demonstrates that the difference of the measurement of $ARP$ between the groups is of high magnitude, considered clinically relevant by Cohen\textsuperscript{28} (Table 3).

### Difference (pre–post) of ARP (HP) between groups O and P

Both variables arise from normal distributions. In this case, the Student’s $t$-test was used to compare the two groups with regard to this variable. The mean difference of the ARP (HP) in the group O was $1.84 \pm 5.20$ standard deviation (SD) and the mean of the difference of ARP (HP) in the group P was $-3.61 \pm 8.05$ SD ($P = 0.027$). In reviewing each group mean and considering that these are variables related to the difference between two other values (pre–post), it may be stated that in the group O, the value of ARP postintervention is generally greater than the ARP value postintervention in the group P (Table 4).

### Difference (pre–post) of ARP (mean between all points) between groups O and P

The Mann–Whitney test was used to compare the two groups with regard to this variable. The median difference of ARP ($mean between all points$) in group P was $-1.85$ ($P = 0.0066$).

### Difference (pre–post) of MEP (HP) between groups O and P

Both variables arise from normal distributions. In this case, the Student’s $t$-test was used to compare the two groups with regard to this variable. The mean of the difference of MEP (HP) in the group O was $2.53 \pm 4.75$ SD and of group P $-1.36 \pm 9.48$ SD ($P = 0.146$). Given the high value of $P (>0.05)$, we cannot say that the groups differed in terms of variable MEP (HP). Although the means are very different, the high SD value in group P also implies a large variation, which may be why no differences were found between the groups in this analysis (Table 4).

### Difference (pre–post) of MEP (mean between all points) between groups O and P

The Mann–Whitney test was used to compare the two groups with regard to this variable. The median difference of MEP ($mean between all points$) in group O was 3.70, and the median difference of ARP ($mean between all points$) in group P was $-0.82$ ($P = 0.0493$). Analyzing the value of $P (<0.05)$, we can say that the differences in groups are statistically significant between them. Looking again, their median can be seen that group O has higher values than group P after the intervention (Table 4).

### Table 3 ARP and MEP values pre-intervention and postintervention in the groups placebo and osteopathic for the mean values

<table>
<thead>
<tr>
<th>Variable</th>
<th>Placebo group</th>
<th>Osteopathy group</th>
<th>Cohen values ($d$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average respiratory pressure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(mmHg) Pre</td>
<td>25.74 ± 15.28</td>
<td>20.03 ± 8.07</td>
<td>0.80</td>
</tr>
<tr>
<td>(mmHg) Post</td>
<td>22.13 ± 18.24</td>
<td>21.87 ± 9.70</td>
<td></td>
</tr>
<tr>
<td>Maximum expiratory pressure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(mmHg) Pre</td>
<td>16.87 ± 12.89</td>
<td>12.03 ± 5.76</td>
<td>0.52</td>
</tr>
<tr>
<td>(mmHg) Post</td>
<td>15.51 ± 18.03</td>
<td>14.56 ± 8.12</td>
<td></td>
</tr>
</tbody>
</table>

ARP, average respiratory pressure; MEP, maximum expiratory pressure; post, postintervention; pre, pre-intervention; SD, standard deviation.

### Table 4 Difference (pre–post) of ARP and difference (pre–post) of MEP values for mean and median values in the placebo and osteopathic groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Placebo group ($n = 16$)</th>
<th>Osteopathy group ($n = 22$)</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difference (pre–post) of ARP (mmHg)</td>
<td>Mean −3.61 ± 8.05 SD</td>
<td>1.84 ± 5.20 SD</td>
<td>0.027</td>
</tr>
<tr>
<td></td>
<td>Median −1.85</td>
<td>3.70</td>
<td>0.0066</td>
</tr>
<tr>
<td>Difference (pre–post) of MEP (mmHg)</td>
<td>Mean −1.36 ± 9.48 SD</td>
<td>2.53 ± 4.75 SD</td>
<td>0.146</td>
</tr>
<tr>
<td></td>
<td>Median −0.82</td>
<td>2.69</td>
<td>0.0493</td>
</tr>
</tbody>
</table>

ARP, average respiratory pressure; MEP, maximum expiratory pressure; post, postintervention; pre, pre-intervention; SD, standard deviation.
DISCUSSION

The assumption of this study was that the diaphragm stretching maneuver largely used by osteopaths to obtain the functional equilibrium of this muscle fosters increase of the LES pressure immediately after performing the maneuver, as a consequence of an increased strengthening of the diaphragm muscle. Among the major findings is the observed LES increased pressure in patients who underwent the osteopathic technique when compared with the placebo technique for all the measurements investigated.

Another interesting outcome was the response with regard to the effect size that demonstrated the clinical relevance in connection with the majority of the variables reviewed.

Our results demonstrated that there was an increase of 9–27% of the LES pressure in patients who performed the osteopathic maneuvers, while in the group of patients who did not perform the maneuvers, a reduction of that pressure was observed (Table 5). These results are quite close to those of other investigators, who indicated that during the contraction of the crural diaphragm, an increase of the LES pressure occurs, contributing for a three- to four-fold increase in the pressure in the GEJ region, as well as an increase from 8% to 12% in the diaphragm thickness during muscular inspiratory post-training contraction for 4 weeks; this is different from our study that showed an increase of the LES pressure.

Our data are of extreme clinical importance and of high practical relevance because in the assessment by the LES esophageal manometry, we assessed the regions of the LES having greater pressure either by ARP or MEP, and not the average of all the sphincter assessment. In addition to supporting the beliefs of the osteopathic community and what they observe clinically, nevertheless, we cannot say that a complete osteopathic treatment has been conducted for the diaphragm or even for the GEJ; this characterizes our osteopathic treatment has been conducted for the diaphragm stretching technique often report an improvement in areas such as heartburn and reflux, which corresponds with the values of large and medium clinical effect (according to Cohen’s statistic) achieved in the study variables.

CONCLUSION

The osteopathic manipulative technique used to produce the diaphragm functional equilibrium causes a positive increment, statistically significant, in the LES region soon after it is performed.

Acknowledgments

We wish to thank the Gastroenterology Discipline of University of São Paulo School of Medicine and the Escuela de Osteopatia de Madrid for the support and encouragement of the study conducted.

References


Table 5 Difference between the values ARP (HP) and MEP (HP) postintervention in relation to pre-intervention values in the groups placebo and osteopathic (%)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Placebo group</th>
<th>Osteopathy group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n = 16)</td>
<td>(n = 22)</td>
</tr>
<tr>
<td>ARP (mmHg) post/pre</td>
<td>14.02% reduction</td>
<td>9.18% increase</td>
</tr>
<tr>
<td>MEP (mmHg) post/pre</td>
<td>8.06% reduction</td>
<td>21.03% increase</td>
</tr>
</tbody>
</table>

ARP, average respiratory pressure; HP, highest point; MEP, maximum expiratory pressure; post, postintervention; pre, pre-intervention.

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