

# Qualitative Evaluation of Osteopathic Manipulative Therapy in a Patient With Gastroesophageal Reflux Disease: A Brief Report

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## Abstract

**Context:** Gastroesophageal reflux disease (GERD) is a chronic condition that affects a growing number of people and is currently among the most common disorders seen in clinical practice.

**Objective:** To develop a protocol for the management of GERD with osteopathic manipulative therapy (OMTh) applied to the diaphragm and esophagus, and to evaluate the protocol's effectiveness using the quality of life scale (QS-GERD) for the disease.

**Methods:** In this single-blinded prospective study, an OMTh protocol focusing on the diaphragm and esophagus was applied to a single patient, who had received a diagnosis of GERD 4 years previously. Outcomes were measured using the QS-GERD, which has a total possible score ranging from 0 to 45 (the lower the score, the better the quality of life) and a level of satisfaction from very satisfied to incapacitated. The OMTh protocol was applied at 3 sessions (initial session, second session 1 week after the first, and third session 2 weeks after the second), and the patient completed the QS-GERD 4 times (before the first session, before the third session, and 2 and 4 weeks after the third session).

**Results:** The OMTh protocol was administered without adverse events, and the patient reported positive outcomes after the third session. The QS-GERD showed a score improvement from 13 of 45 to 4 of 45.

**Conclusion:** The results in the present report show that OMTh applied to the diaphragm and esophagus may improve symptoms of GERD and should be added to the somatovisceral approach to the care of patients with this condition.

Gastroesophageal reflux disease (GERD) is a chronic condition that affects a growing number of subjects, and it is 1 of the most prevalent diseases in clinical practice.<sup>1</sup> In the United States it was estimated that 14% to 20% of adults are affected, based on self-reported symptoms.<sup>2</sup> Sandler et al<sup>3</sup> found that GERD had the highest annual direct costs of all gastrointestinal diseases, at \$9.3 billion.

Heartburn is the most predominant esophageal symptom of GERD, and bronchospasm and chronic cough are the most common extraesophageal symptoms.<sup>4</sup> Gastroesophageal reflux disease compromises patient quality of life by requiring modification of the patients' eating habits and resulting in changes in sleep patterns as a result of its various recurrent or lasting symptoms that in the long term may limit daily activities.<sup>5</sup> Furthermore, its multifactorial nature prevents the complete description of the mechanical, chemical, physiopathologic, and functional factors that predispose patients to the disease.<sup>1,6</sup>

In the present report, we describe the anatomic and physiologic characteristics of GERD, review the history of osteopathic manipulative therapy (OMTh) as it relates to GERD, relate the usefulness of quality of life surveys in patients with such conditions, and present our prospective study of OMTh for a patient with GERD.

## Anatomic and Physiologic Characteristics

The esophagogastric junction (EGJ) is a complex valvular structure that prevents reflux, is composed of the intrinsic lower esophageal sphincter (LES), is situated within the diaphragmatic hiatus, and is surrounded by the crural diaphragm (CD), which provides additional sphincteric compression.<sup>7</sup> It is the main barrier against gastroesophageal reflux, and its function has been attributed to intrinsic LES pressure, extrinsic compression of the LES by the CD, the intraabdominal location of the LES, integrity of the phrenoesophageal ligament, and maintenance of the acute angle between the esophagus and stomach, promoting a “flap valve” function. The association of its constituent parts and their ability to maintain a high-pressure zone or a closed luminal segment in the region separating the stomach from the esophagus plays a major role in the overall function of the EGJ.<sup>8,9</sup>

The LES smooth muscle is innervated by vagal pre-ganglionic efferents, which provide both excitatory and inhibitory innervation to the LES. The sympathetic efferents originate in spinal segments T6 through T10, and they may not exert a major direct effect on LES contraction or relaxation. They are likely primarily nociceptive and potentially a modulator of LES relaxation induced by the vagus nerve. Thus, the vagus nerve is the prime mediator of LES reflexes.<sup>7</sup>

The CD surrounds the esophagus with a loop-shaped muscle, forming an extrinsic sphincter around the esophagus: the crural sling.<sup>10</sup> Basseur et al<sup>11</sup> observed that the lower esophageal sphincter is composed of 2 components, 1 proximal and 1 distal. They separated and quantified these components and identified 2 pressure peaks: 1 upper peak overlapped and displaced rigidly with the crural sling, and 1 lower peak that likely reflects the gastric sling or clasp muscle fibers at the EGJ.<sup>11</sup>

Moreover, Shafik et al<sup>10</sup> observed that the crural sling seems to affect esophageal occlusion not only by direct compression but also by “kinking” the esophagus.

Pandolfino et al<sup>12</sup> suggested that the compromised CD function, indicated by diminished inspiratory augmentation of EGJ pressure found on high-resolution manometry results, is an independent predictor of GERD. They also stated that the radial dimensions or distensibility of the hiatal canal or the thickness and elasticity of the CD itself may be important factors in maintaining CD function.

The works of Kwiatek et al<sup>7,13</sup> showed that the inspiratory component of EGJ pressure is the pressure signature of the CD, and that the pressure oscillations at the EGJ high-pressure zone are proportional to the force of diaphragmatic contraction, whether voluntary or not. This finding corroborates the reports of Pandolfino et al,<sup>12</sup> Basseur et al,<sup>11</sup> and Shafik et al.<sup>10</sup>

## Osteopathic Manipulative Medicine

When standard or surgical medical therapies do not produce the desired outcome or do result in adverse effects, patients may turn to complementary or alternative treatments. In the United States, the overall expenditure for complementary and alternative medicine is in the tens of billions of dollars per year.<sup>14</sup> Osteopathic manipulative treatment (OMT) and OMTh, which are considered by some to be a complementary or alternative medicine, are based on concepts and unique approaches that enable the self-healing and self-regulating process within the body.<sup>15</sup>

According to Lossing,<sup>16</sup> the viscera are connected to the musculoskeletal system by connective tissue forming functional chains that connect all of the anatomic elements from head to toe. Because the functional component cannot be recognized with laboratory or radiologic tests, the only way to recognize it is to treat it. Generally, 1 to 3 treatment sessions will reveal whether an osteopathic approach is helpful and cost effective.<sup>16</sup>

Manual therapy techniques such as high-velocity, low-amplitude maneuvers and spinal mobilizations have received much attention in the literature. The same cannot be said for visceral manipulation because there is a lack of published research on the topic and because the current model of visceral manipulation is mostly drawn from textbooks and clinical experience.<sup>17</sup>

Unfortunately, as stated by Steele et al,<sup>18</sup> several issues compromise the efficacy of OMT studies, such as subject recruitment and retention. Even the use of standardized protocols is subject to variations among practitioners. In addition, OMT application cannot always be quantified, especially when treating visceral dysfunctions.<sup>18</sup>

We conducted a literature review and found that OMT affects gastrointestinal diseases. For example, Branyon<sup>19</sup> and Mirocha and Parker,<sup>20</sup> reported successful management of GERD and successful management of functional dyspepsia, respectively, using OMT. The study by Smilowicz<sup>21</sup> on gastritis associated OMT with antibiotic resistance to *Helicobacter pylori*, and the study by da Silva et al<sup>22</sup> reported increased LES pressure after diaphragm intervention. However, we found no studies investigating the effects of techniques particular to the diaphragm and esophagus in GERD. The OMT protocol we describe in the present study was thus focused on the diaphragm and esophagus to verify the outcomes of a direct approach based on anatomophysiologic studies.<sup>8-12,27-29</sup>

### Quality of Life Instruments

The interest in measuring quality of life related to health status has increased significantly in recent years, and its scope has expanded to encompass other dimensions, such as global health status, cognitive competence, establishment of satisfying relationships, and appreciation of housework such as cleaning, washing, and caring for the children, as well as opportunities to travel and experience new surroundings. Likewise, the impact of chronic diseases on the biopsychosocial functioning of individuals and their influence on the complex interaction between behavior and health has become the focus of many researchers. In this context, GERD stands out for its high prevalence, chronicity, recurrence, and high costs related to diagnosis and treatment.<sup>23,24</sup>

Quality of life instruments related to health have been valuable in measuring this outcome from the perspective of the patient, whether generic or specific. Generic questionnaires are used by the general population and are applicable to a variety of health states, conditions, or diseases.<sup>25,26</sup> Therefore, because the use of quality of life instruments might provide reliable measures with minimal patient bias, we used a quality of life instrument to quantify outcomes from the present prospective report.<sup>6</sup>

### Methods

#### Patient

A 55-year-old white man with a 4-year history of heartburn and hoarseness was interviewed and recruited from the osteopathy outpatient clinic for an 8-week-long study. According to the patient, the symptoms were related to emotional distress; alcohol, corn, coffee, fat, milk, and chocolate ingestion; and prolonged fasting—but were not related to any drug intake. The patient denied fever, abdominal pain, vomiting, hematemesis, dysphagia, constipation, diarrhea, hemochezia, weight loss, dysuria, hematuria, or melena.

He underwent an esophagogastroduodenoscopy in 2009, after which the gastroenterologist diagnosed GERD. His physician prescribed pantoprazole sodium (40 mg/d for 6 months and then 20 mg/d for another 6 months). He became asymptomatic and stopped taking the medication; he remained asymptomatic for almost 1 year. When the symptoms returned, he returned to his gastroenterologist, who prescribed pantoprazole (20 mg on demand). He denied seeking additional treatment or testing of his symptoms.

His past medical history included sinusitis, prediabetes, and hypercholesterolemia. He had been in 3 car accidents with no major injuries or need of surgery. His medical history revealed surgery for phimosis in 1977 and vasectomy in 1989. His medications were pantoprazole as needed, metformin hydrochloride, and simvastatin.

Relevant family history revealed his father had hypertension, diabetes mellitus, and a gastric ulcer and died of a heart attack. His mother had osteoarthritis and hypertension. The patient could not provide further information about other relatives. His social history was negative for tobacco, alcohol, and recreational drug use.

At his most recent presentation before initiating the OMTh protocol, his blood pressure was 120/75 mm Hg and his pulse was 72 beats per minute. Physical examination revealed a healthy-appearing man, 5 feet 9 inches tall, and weighing 178 lb. His abdomen was mildly tender at the epigastric zone, and borborygmus was present.

Osteopathic examination revealed tissue congestion in the epigastric zone; the cervical region of the spine revealed the C4 vertebra was extended, rotated left, and sidebent left; the thoracic region of the spine showed the T6 vertebra was extended, rotated right, and sidebent right; the T1-T4 group was flexed, rotated right, and sidebent right, and hypomobility was present in the right diaphragmatic cupula; and in the lumbar spine, L3 was extended, rotated left, and sidebent left. The remainder of the physical examination was normal or unrelated to the patient's GERD.

Results from a repeated esophagogastroduodenoscopy showed mild antrum gastritis and esophageal reflux. Tissue biopsy results were negative for *H pylori*, and the esophageal pH test was normal. The study lasted a total of 8 weeks. The patient was not asked to cease his medication, and he was advised to maintain his dietary routine. He signed an informed consent to participate in the study.

### Survey Instrument

To qualitatively evaluate the effect of osteopathic techniques on the diaphragm and esophagus, the patient came to the outpatient clinic and a practitioner (who was blinded to the OMTh provided by another practitioner) administered the quality of life scale for GERD (QS-GERD). The scale comprised 9 questions regarding GERD symptoms (*Figure 1*); response options ranged from 0 to 5 points per question, with available answers ranging from “no symptoms” to “symptoms are incapacitating—unable to do daily activities.” The 10th question addressed the patient's level of satisfaction with his condition according to the following options: very satisfied, satisfied, neutral, dissatisfied, very dissatisfied, and incapacitated. We administered the survey 4 times: (1) before the first OMTh session, (2) before the third OMTh session, (3) 2 weeks after the third OMTh session, and (4) 4 weeks after the third OMTh session.

| Symptoms <sup>a</sup>                                         |
|---------------------------------------------------------------|
| 1. How bad is the heartburn?                                  |
| 2. Heartburn when lying down?                                 |
| 3. Heartburn when standing up?                                |
| 4. Heartburn after meals?                                     |
| 5. Does heartburn change your diet?                           |
| 6. Does heartburn wake you from sleep?                        |
| 7. Do you have difficulty swallowing?                         |
| 8. Do you have pain with swallowing?                          |
| 9. If you take medications, does this affect your daily life? |
| Satisfaction <sup>b</sup>                                     |
| 10. How satisfied are you with your present condition?        |

Figure 1.

Quality of Life Scale—Gastroesophageal Reflux Disease. <sup>a</sup> Patient responded according to a 6-point scale, as follows: 0, no symptoms; 1, symptoms noticeable, but not bothersome; 2, symptoms noticeable and bothersome, but not every day; 3, symptoms bothersome every day; 4, symptoms affect daily activities; 5, symptoms are incapacitating. Total score could range from 0 (best quality of life) to 45 (worst quality of life). <sup>b</sup> Response

options for satisfaction level were as follows: very satisfied, satisfied, neutral, dissatisfied, very dissatisfied, and incapacitated.

The total score could range from 0 to 45 points; the higher the score, the poorer the quality of life associated with the patient's level of satisfaction. According to Velanovich et al.,<sup>6</sup> patients who were satisfied with their condition had a median score of 5, and patients who were not satisfied had a median score of 26.

### OMTh Protocol

Once it was apparent that there was no reasonable evidence in the scientific literature that direct OMT or OMTh techniques could manage GERD, we developed the following protocol using the textbooks by Quef<sup>30</sup> and Camirand.<sup>31</sup>

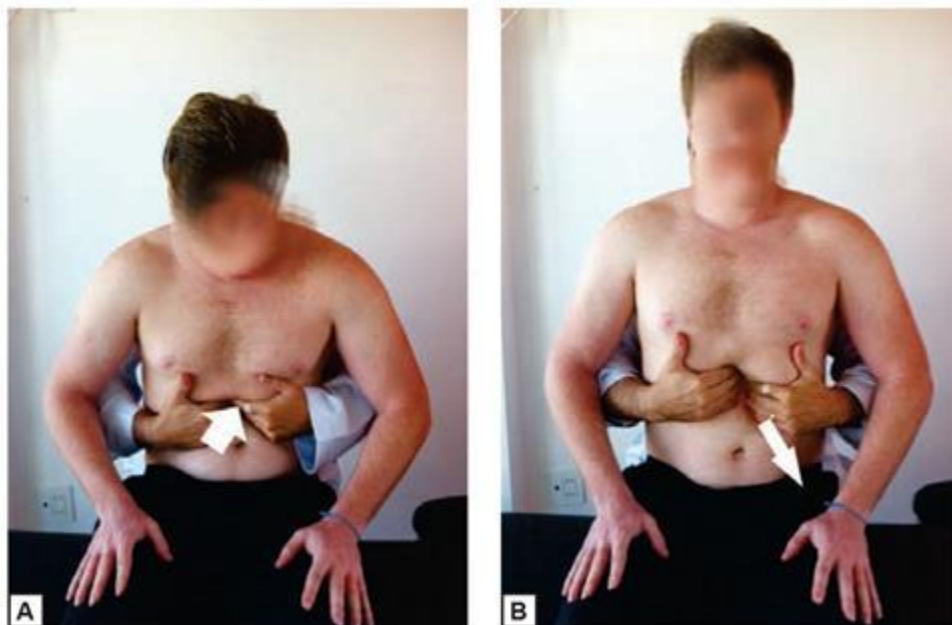
The protocol was executed in 3 sessions and consisted of 4 techniques: hiatal hernia reduction, pillars of the diaphragm normalization, sphincter normalization by recoil, and balancing of the diaphragms. The protocol was applied at the initial session, 1 week after the initial session, and 2 weeks after the second session.

### Hiatal Hernia Reduction

The objective of hiatal hernia reduction<sup>30</sup> is to reduce the spasm of the smooth muscle at the EGJ. The patient is seated on the examination table with the thoracic spine in a slightly kyphotic position. The practitioner stands behind the patient. The practitioner passes his arms under the patient's arms and supports the patient's back with his sternum at the height of thoracic vertebrae T4 through T8. The practitioner places the tips of his second through fourth fingers of both hands at the epigastric zone, pointing up and to the left. When the patient exhales, the practitioner exerts a force toward the left iliac fossa on the tissues under his fingers and asks the patient to straighten his back and to keep his head flexed while the practitioner increases the support of his sternum against the patient's back. During the patient's inspiration, the practitioner slightly relaxes his pressure and resumes the maneuver in the following expiration (*Figure 2*). The technique was applied 3 or 4 times.

Figure 2.

Hiatal hernia reduction technique. (A) The practitioner places the tips of his second through fourth fingers of both hands at the epigastric zone, pointing up and to the left. (B) When the patient exhales, the practitioner exerts a force toward the left iliac fossa on the tissues under his fingers and asks the patient to straighten his back and to keep his head flexed while the practitioner increases the support of his sternum against the patient's back. During the patient's inspiration, the practitioner slightly relaxes his pressure and resumes the maneuver in the following expiration.





On the basis of anatomicophysiology, this technique should reduce the smooth muscle spasm by acting on the vagal mechanoreceptors through a theoretical esophageal distention promoted by the maneuver, eliciting muscle relaxation.<sup>7,32</sup>

### Pillars of the Diaphragm Normalization

The objective of the pillars of the diaphragm normalization technique<sup>31</sup> is to relax the tension of the pillars of the diaphragm. The patient is in a supine position with the lower limbs flexed (to relax the abdominal wall and to facilitate the maneuver). The practitioner stands on the side to be treated. One hand of the practitioner is positioned posterior and perpendicular to the axis of the spine and with the fingers hooking the spinous processes (index finger in thoracic vertebra T12) and lumbar vertebrae (middle finger in L1, ring finger in L2, and little finger in L3). The other hand approaches the chondrocostal arc with the fingers pointing laterally and the thumb reaching the diaphragmatic cupula (under the chondrocostal arc). The anterior-placed hand takes the chondrocostal arc laterally while the thumb deepens beneath the arc, putting the diaphragmatic cupula in tension. The other hand stabilizes the spinous processes so they do not rotate. The practitioner holds the tension until he feels the tissues relax (*Figure 3*).

Figure 3.

Pillars of the diaphragm normalization technique. One hand of the practitioner is positioned posterior and perpendicular to the axis of the spine and with the fingers hooking the spinous processes and lumbar vertebrae. The other hand approaches the chondrocostal arc with the fingers pointing laterally and the thumb reaching the diaphragmatic cupula. The anterior-placed hand takes the chondrocostal arc laterally while the thumb deepens beneath the arc, putting the diaphragmatic cupula in tension. The other hand stabilizes the spinous processes so they do not rotate. The practitioner holds the tension until he feels the tissues relax.



The pillars of the diaphragm are muscle bundles attached to the first 3 lumbar vertebrae on the right side and to the first 2 vertebrae on the left side. They proceed superiorly and anteriorly, forming muscular arms that

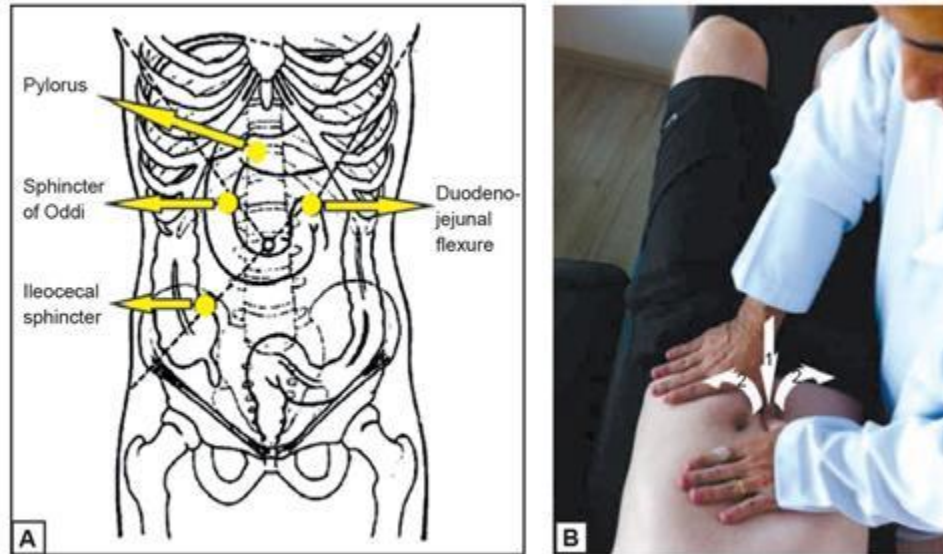
surround the esophageal opening and insert in the central tendon of the diaphragm.<sup>27</sup> Their relaxation should improve the mechanical relation between LES and CD, thus promoting their proper functioning.

### Sphincter Normalization by Recoil

The objective of the sphincter normalization by recoil technique<sup>30</sup> is to relax the smooth muscle of the sphincters or areas considered as such. They are the ileocecal valve, the duodenojejunal junction, the sphincter of Oddi, and the pylorus. The patient is in the supine position, with knees flexed and upper limbs along the body. The practitioner stands on the right side of the patient, facing the area to be treated. The practitioner places his thumbs crossed over the area to be treated and presses progressively posteriorly during the patient's expiration. When the zone's distensibility limit is reached, the practitioner exerts a slight pressure and a sudden release of great speed occurs (*Figure 4*). The duration of the technique is dependent on the tissues' distensibility.

Figure 4.

Sphincter normalization by recoil technique. (A) Illustration of the location of sphincters. (B) The practitioner places his thumbs crossed over the area to be treated and presses progressively posteriorly during the patient's expiration. When the zone's distensibility limit is reached, the practitioner exerts a slight pressure and a sudden release of great speed occurs.



### Balancing of Diaphragms

The objective of the balancing of diaphragms technique<sup>30</sup> is to restore the fluidic and harmonic function between the diaphragms. The patient is in the supine position, and the upper and lower limbs are relaxed. The practitioner sits next to the patient. In procedure 1, the pelvic diaphragm, 1 hand is under the sacrum and the other hand is just above the pubic bone; in procedure 2, the thoracoabdominal diaphragm, 1 hand is under the vertebrae T12 through L2 zone, and the other hand is on the epigastric area; in procedure 3, the cervicothoracic diaphragm, 1 hand is under vertebrae T1 through T3 and the other hand is on the manubrium. For each of the 3 diaphragms, the practitioner perceives the tissues and, if necessary, induces the normalization according to the tissue's motility.

The perception of tissue normalization could be felt like a loosening of the tissues or a movement synchronization between the hands, but that is personal perception of the technique; it might vary among practitioners on the basis of the practitioner's experience and sensibility.

## Results

When the patient answered the fourth questionnaire, he reported an improvement of the symptoms when drinking cold and/or sparkling beverages, wine, or beer. He also reported an improvement in his eating habits except for products with lactose, which still produced heartburn when ingested.

Osteopathic examination, which occurred after the patient completed the fourth questionnaire, showed an improvement of the tissue congestion on the epigastric zone and of the hypomobility of the right diaphragmatic cupula. Vertebrae T1 through T4, T6, and L3 showed no improvements. Those areas received no treatment; we only examined the areas to determine whether there were any changes, but we did not expect any changes.

The first time the patient answered the questionnaire, it resulted in a score of 13 of 45 and a “dissatisfied” level of satisfaction. The results of the second questionnaire revealed no improvement, and the third and fourth questionnaires showed reasonable improvement of his quality of life (score of 5 of 45 and 4 of 45, respectively) and level of “satisfaction” (*Table*).

Table.

Patient Self-Reported Scores and Satisfaction Levels on the QS-GERD Before and After OMTh

| Survey Administration     | Score <sup>a</sup> | Level of Satisfaction <sup>b</sup> |
|---------------------------|--------------------|------------------------------------|
| Before first OMTh session | 13                 | Dissatisfied                       |
| Before third OMTh session | 12                 | Dissatisfied                       |
| 2 wk after third session  | 5                  | Satisfied                          |
| 4 wk after third session  | 4                  | Satisfied                          |

<sup>a</sup>Total score could range from 0 (best quality of life) to 45 (worst quality of life).

<sup>b</sup>Response options for satisfaction level were as follows: very satisfied, satisfied, neutral, dissatisfied, very dissatisfied, and incapacitated.

**Abbreviations:** QS-GERD, quality of life scale for gastroesophageal reflux disease; OMTh, osteopathic manipulative therapy.

## Comment

The results of the present study show reasonable improvement in the quality of life according to the patient's perspective. However, no improvement was observed on the fifth question, “Does heartburn change your diet?” which was the only question to maintain a high score.

The use of a quality of life instrument might provide us the patient's perspective of the disease, the patient's level of satisfaction, and the quantification of the impact of the disease in the patient's life, rendering the instrument a valuable measure in clinical practice. The scores obtained in this study are in accordance with the results of Velanovich et al.<sup>6</sup>

present study proposes a novel case study. We are aware of no model that exists in OMT or OMTh with visceral manipulation to discuss these results in the context of managing GERD. The osteopathic techniques adopted here were chosen on the basis of anatomophysiologic studies, which revealed the role played by the diaphragm and the esophagus in maintaining the anti reflux barrier<sup>8-12,27-29</sup> to verify—other than the viscerosomatic reflex at the thoracic or cervical spine<sup>19-21</sup>—whether the techniques used on the diaphragm and esophagus could result in positive outcomes when treating patients with GERD.

There are several limitations to the current study, such as the selection of certain information over other elements, the inadequacy of language in explaining the richness and complexity of the clinical observation of a disease, and the risk of reducing the subject to what is only observed.<sup>33,34</sup> In addition, despite the positive outcomes found in this work and in other studies, the use of a single case is not enough to provide strong



evidence to support OMTh as an adjuvant therapy for GERD or other gastrointestinal diseases. Thus, clinical relevance, efficacy, and the impact of this study cannot be ascertained, and no extrapolation of these findings in relation to the various manifestations of GERD can be made.

## Conclusion

The present study provided an opportunity to assess the effects of OMTh on the diaphragm and esophagus in a patient with GERD and the use of a qualitative instrument to assess the intervention. The outcomes indicate the possible use of a direct approach, which should be taken into consideration when treating patients with GERD.

A randomized controlled trial with a larger sample size and a standardized OMT protocol should be conducted to understand the mechanism and use of OMT and OMTh in GERD and other gastrointestinal diseases.

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