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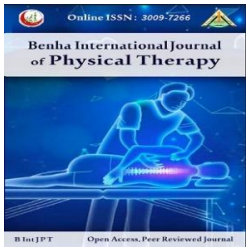

Original research

Effect of manual diaphragmatic activation on diaphragm function in patients with gastroesophageal reflux disease.

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Abstract

Background: In gastroesophageal reflux disease (GERD), opposite to traditional medications which do not target the pathophysiological mechanism of GERD, manual diaphragmatic activation maneuver (MDAM) directly corrects the pathophysiological mechanism of GERD, as it strengthens/augments the anti-reflux barrier. **Purpose:** This study aimed to investigate the effect of MDAM on GERD patients' diaphragmatic excursion (DE), diaphragmatic thickness fraction (DTF), and 19-item Pittsburgh sleep quality index (PSQI). **Methods:** Thirty GERD sufferers were randomly assigned into two 15-patient groups, the MDAM group (study group) and the control group. Both GERD groups received for-GERD-designed medical routine/care for 2 months. A 30-minute manual diaphragmatic activation maneuver was applied to the MDAM group only three times per week for 2 months. For all GERD patients in both groups, DE, DTF, and PSQI were the outcomes of this randomized GERD trial. **Results:** All outcomes (DE, DTF, and PSQI) of this GERD trial significantly improved in both GERD groups. The percent of change in GERD patients' DE, DTF, and PSQI of the MDAM group was 8.65, 19.56, and 60.40%, respectively, and that in the GERD group that received only GERD routine medical care was 2.43, 5.80, and 34.82%, respectively. **Conclusions:** manual diaphragmatic activation maneuvers improve GERD in DE, DTF, and PSQI more than the other group who received only traditional medical care.

Keywords: Diaphragm function, Manual diaphragm release; Gastro esophageal reflux disease.

Introduction

A common upper gastrointestinal disorder called gastroesophageal reflux disease (GERD) is characterized by frequent complaints of acid regurgitation and/or heartburn.[1] In comparison to men, women had considerably greater prevalence of GERD (29.5 vs. 15.4%). Subjects with ages ranging from 15 to 24 years old report the lowest prevalence of GERD (7.5%), while subjects aged ≥ 75 years had a massive rate of GERD (28.4%).[2]

Proton pump inhibitors (PPIs) are well-known medications that are approved for GERD-designed pharmacological choice when it comes to treating GERD patients. PPI users with GERD are typically at risk for various pulmonary, vascular, and digestive dysfunctions in addition to the recurrence of GERD-associated symptoms after stopping PPI use. [3]

The failure of patients to adhere to GERD PPIs, untreated GERD negatively affects sufferers' ability to execute their everyday tasks, hence GERD patients' quality of life is negatively affected.[1] Thus, it's mandatory to look into alternative, secure, complementary therapies for GERD.[3]

Recently breathing retraining exercises are well-known physiotherapeutic alternative techniques that are documented to lessen GERD-related acid reflux, lower perception of GERD-induced heartburn, and maximize the effectiveness of GERG-treating PPIs.[4]

Manual diaphragmatic activation maneuver (MDAM) – a myofascial release intervention (MFRI) that directly stretches patients' diaphragmatic muscle fibers - is one of the common breathing retraining techniques used in physical therapy. In GERD, opposite to PPIs which do not target the pathophysiological mechanism of GERD, MDAM directly corrects the pathophysiological mechanism of reflux, as it strengthens the anti-reflux barrier and/or promotes clearance of esophageal refluxate, hence symptoms of GERD improve.[5] This study aimed to investigate the efficacy of MDAM in GERD patients.

Methods

Design

A randomized-controlled trial.

Settings

The random recruitment of thirty GERD sufferers was from Benha University Hospital's outpatient clinic for internal disorders. GERD participants of this study were managed during the period from September to December 2023.

Ethics

GERD sufferers were enrolled after the institutionally based approval was granted (GERD protocol was approved by the Ethics Committee/Board of Cairo University's Faculty of Physical Therapy; Ethical Agreement P.T.REC/012/004790 Egypt). Helsinki standards, values, principles, and philosophy for conducting medical/clinical trials on humans were followed. The consent of this GERD trial was signed by all GERD sufferers. Clinical Trials.gov Identifier: NCT06268548

Inclusion criteria

Participants who were previously diagnosed with GERD were enrolled. The diagnosis was based on gastroenterologist endoscopic study. The enrolled GERD participants' ages ranged from 20-50 years old. Male and female GERD patients who did not reject the manual contact were enrolled.

Exclusion criteria

The protocol of this GERD study was designed to exclude patients with previous endoscopic studies that have proven the presence of hiatal hernia, old/recent erosive esophagitis, and old/recent surgeries at the lower esophageal sphincter. Also, besides GERD patients who previously received MDAM, our designed GERD protocol excluded patients with other gastrointestinal disorders, systemic/metabolic disease, local abdominal open wounds, congenital/acquired immune disorders, neoplastic masses/tumors, any type of allergy, pregnancy, psychiatric/mental irregularities, leukemia, trunk surgeries (spinal, thoracic, and abdominal surgeries), neuromuscular/neurological dysfunctions, hypersensitivity of the skin, previous vertebral or rib cages injuries/fractures, aneurysm/hemophilia, acute/chronic localized abdominal soft tissue inflammations, corticosteroid therapies, radiotherapies or chemotherapies, respiratory diseases, trunk dermatological disorders preventing the application of MDAM, and anticoagulant therapies.

Randomization

Names of GERD sufferers were entered on the computer that developed a computerized list. This list divided GERD sufferers into two 15-patient groups, the MDAM group (study group) and the control group. Both GERD groups received for-GERD-designed medical care for 2 months. 30 - minute manual diaphragmatic activation maneuver was applied to the MDAM group only thrice weekly for 2 months.

The procedure of manual diaphragmatic activation maneuver

The patient with GERD was encouraged to lie in a crock line position, or 90-degree hip flexion and 90-degree knee flexion. While keeping this position, the physical therapist asked them to rest the patient's legs on blocks. Then, the patient performed a 5-minute diaphragmatic breathing exercise.

Then, the diaphragmatic transverse plane was used. A bimanual transverse contact was conducted on the patient's diaphragmatic region (this region is opposite to T12–L1 and the patient's xiphoid appendix). By the above-mentioned bilateral transverse contact, a tridimensional pressure was performed. During this by-hand pressure, a 5-minute fascial movement was maintained.

After 5-minute MDAM, a 5-minute diaphragmatic breathing exercise was done which was followed by another a myofascial release intervention (MFRI) called diaphragm stretching technique (DST), applied for 5 minutes. The maneuver of DST contained two steps. During the first step of DST, the physical therapist stood at the head of the patient, then placed his hands at the patient's lower ribs and the physical therapist exaggerated the patient's down movement of the diaphragm while the patient taking four successive deep breaths. During the second step of DST, the physical therapist stood at the head of the patient, and then placed his hands at the patient's lower ribs, during the patient's four successive deep breaths, the physical therapist hands were synchronized during patient's inspiratory movement while sustaining the patient's rib gird to inhibit its descension by hold for 5 seconds, then followed by stretching it in a simultaneous lateral and cranial directions during the patient's expiration.[6]

After DST, the physical therapist ended the session performed for every patient with a 5-minute diaphragmatic breathing exercise. The patient was encouraged to learn self-release to performed it as home program.

Ultrasonography of the diaphragm:

Diaphragmatic Ultrasonography was done by pulmonologist in chest department, Benha university hospitals for all patients before and after manual diaphragmatic activation maneuver using GE LOGIQ P5 Ultrasound Machine using both low-frequency convex and high frequency linear transducers for assessment of diaphragmatic thickness and excursion.

Patients were examined in semi-recumbent position. Right hemi diaphragm was evaluated by B-mode and M-mode ultrasound as it was easily visualized through the large acoustic window of the liver, while visualization of the left diaphragm was more difficult because of the smaller window of the spleen, so we chose to examine the right one.

Diaphragmatic thickness (TD) was measured at zone of apposition, diaphragmatic excursion was assessed using B and M mode with the lower frequency curvilinear probe placed subcostal parallel to the intercostal space between the midclavicular and anterior axillary lines, anterior subcostal view. The DTF was calculated as percentage from the following formula: (Thickness at end inspiration (TLC) - Thickness at end expiration (RV)) X 100 / Thickness at end of expiration.[7]

Outcomes

The patients with GERD diaphragmatic excursion (DE) and diaphragmatic fractional thickness (DTF) were assessed under a Pulmonologist by (GE LOGIQ P5 Ultrasound Machine). Also, the patients with GERD 19-item Pittsburgh sleep quality index (PSQI) an indicator for patients' good or bad sleeping quality was assessed.

Statistical analysis

The statistician performed/executed GERD patients' data analysis using the Shapiro-Wilk test to check patients' data normality. The unpaired test compared patients' demographics before initiating assigned interventions (for GERD-designed routine medical care alone or combined with MDAM).

Patients' sex distribution between GERD groups was checked/tested via a Chi-square test. Levenes test, a statistical test/examination used for assessing the homogeneity of variances between GERD groups was also used by the statistician of this GERD study. Also, the effect of applied GERD interventions (for GERD-designed routine medical care alone or combined with MDAM) on GERD patients' DE, DTF, and PSQI. Utilizing the Bonferroni correction model, post-hoc statistical analytic tests were the by-statistician used tests for the GERD study's subsequent multiple comparisons. The by-statistician used statistical

program was SPSS 25. For all patients' data, the p-value significance of the above-mentioned statistical tests was examined at a level below than 0.05.

Results

GERD subjects' demographic data: Before initiating the assigned interventions (for GERD-designed routine medical care alone or combined with MDAM), no significant difference was mentioned as shown in (Table 1) during the between-group comparison of GERD sufferers' age, GERD sufferers' body weight/mass, GERD sufferers' height, and GERD sufferers' sex distribution. value/test; BMI: body mass i

Table 1: Patients' demographics data

	MDAM group	**Control GERD group**			
	Mean ± SD	**Mean ± SD**	**MD**	**t- value**	**p-value**
Age (year)	36.13 ± 9.61	34.80 ± 7.89	1.33	0.42	0.68
Weight (kg)	75.93 ± 13.02	72.60 ± 12.91	3.33	0.70	0.48
Height (cm)	169.47 ± 7.68	167.13 ± 8.14	2.34	0.81	0.43
BMI (kg/m^2)	26.32 ± 3.43	25.77 ± 2.48	0.55	0.49	0.63
Sex, n (%)					
GERD Females	8 (53%)	9 (60%)		($\chi^2 = 0.13$)	0.71
GERD Males	7 (47%)	6 (40%)			

SD: Standard deviation; **MDAM:** Manual diaphragmatic activation maneuver; **MD:** Mean difference; **GERD:** Gastroesophageal reflux disease; **χ^2:** Chi squared

Effect of GERD interventions on GERD patients' DE, DTF and PSQI:

Treatment and time's significant interaction/matching effects (F = 32.97, p = 0.001) were confirmed/detected by the used statistical test, mixed MANOVA. Away from this detected interaction, a separate significant effect of the applied GERD treatment (F = 3.24, p = 0.03) and the time (F = 196.43, p = 0.001) was also confirmed.

Within-group comparison:

The pre-to post-comparison executed/performed within every GERD group confirmed that both GERD groups' outcomes (GERD patients' DE, DTF and PSQI) significantly improved **(Table 2)**. To be noted/mentioned here, the percent of change in GERD patients' DE, DTF, and PSQI of the MDAM group was 8.65, 19.56, and 60.40%, respectively, and that in the GERD group that received for-GERD routine medical care was 2.43, 5.80, and 34.82%, respectively.

Between-group comparison:

Before starting GERD-designed routine medical care alone or combined with MDAM, between-group comparison of outcomes (GERD patients' DE, PSQI, and DTF) did not significantly differ **(Table 2)**. The post-comparison executed/performed between GERD groups confirmed that outcomes (GERD patients' DE, PSQI, and DTF) were significantly improved in the direction of the GERD group received the for-GERD combined managements/interventions (for-GERD routine medical care combined with MDAM) **(Table 2)**.

Discussion

According to this GERD study, patients' DE, DTF, and PSQI significantly improved when a 2-month MDAM was added to routine GERD medical care. The mechanism of MDAM in improving patients' DE and DTF may be explained by the anatomical interconnection between the diaphragm muscle and esophagus.

Table 2. Mean ± SD of GERD patients' DE, DTF, and PSQI (pre and post-levels in both GERD groups).

	Pre-treatment value	**Post-treatment value**			
	(Mean ± SD)	**(Mean ± SD)**	**(MD)**	**(% of change)**	**(p value)**
DE (cm)					
Study group	4.97 ± 0.38	5.40 ± 0.37	-0.43	8.65	0.001
Control group	4.94 ± 0.34	5.06 ± 0.36	-0.12	2.43	0.001
MD	0.03	0.34			
	p = 0.79	***p = 0.01***			
DTF (%)					
Study group	57.17 ± 7.95	68.35 ± 7.53	-11.18	19.56	0.001
Control group	57.73 ± 8.28	61.08 ± 7.83	-3.35	5.80	0.02
MD	-0.56	7.27			
	p = 0.85	***p = 0.01***			
PSQI					
Study group	7.07 ± 1.75	2.80 ± 1.15	4.27	60.40	0.001
Control group	7.87 ± 1.81	5.13 ± 1.25	2.74	34.82	0.001
MD	-0.8	-2.33			
	p = 0.28	***p = 0.001***			

PSQI: Pittsburgh Sleep Quality Index; **SD**: Standard deviation; **DE**: Diaphragmatic excursion; **MD**: Mean difference; **DFT:** Diaphragmatic thickness fraction; **GERD**: Gastroesophageal reflux disease

The costal and crural portions of the patients' thoracic diaphragm are attached to the subject's ribs and the vertebral column, respectively. This unique anatomical origin and insertion of costal and crural portions of the diaphragm makes the subject's esophagus tied up or rounded by the diaphragm's left and right crura, forming a canal where the subject's esophagus enters his/her abdomen.

While the inner fibers of the diaphragm-formed canal are orientated/directed obliquely, the outside fibers of the diaphragm-formed canal are oriented from cranial to caudal direction. During voluntary/involuntary contractions, the crural components of the diaphragm act as an extrinsic sphincter. This diaphragm-induced sphincter acts as a clamp around the subject's lower esophageal sphincter. This diaphragm-induced clamping effect on the lower esophageal sphincter prevents gastric contents from refluxing into the subject's esophagus.[4] As a skeletal muscle, the diaphragm can be somewhat controlled voluntarily.

Breathing exercises and or myofascial release interventions increase muscular strength and force of the diaphragm that decreases, inhibits, or prevents gastric contents from refluxing into the subject's esophagus. Thus, GERD sufferers' psychological complaints (overall stress, anxiety, and depression) improve after using breathing exercises and or myofascial release interventions, hence patients' sleep problems and sleep quality improve.[5]

Through breathing exercises and or myofascial release interventions that strengthen the anti-reflex barrier, patients usually report less frequency of GERD-related symptoms/signs, less consumption of Proton pump inhibitors (PPIs), and good quality of life.[6]

Since the goal of a myofascial release intervention (MFRI) is typically to release myofascial restrictions or limitations and rearrange collagen fibers, aiding to augment the proprioceptive mechanism of soft tissues, including the diaphragm. All of these MFRI-

induced effects augment the contractile capacity of the diaphragm and enhance the easiness of its movement, hence the increased force production from contraction of the diaphragm lowers the refluxing of gastric acids into the esophagus and decreases the frequency of GERD-related symptoms.[6]

In agreement with the current study, MFRI applied on patients' diaphragm for 4 weeks significantly decreased their GERD-related symptoms, lowered the rate of their consumption of PPIs, and improved their quality of life.[6]

Further, breathing retraining in the form of regular abdominal breathing applied on 100 patients significantly decreased the frequency and severity of their GERD-related symptoms, lowered the rate of their consumption of GERD medications, lowered the score of Pittsburgh Sleep Quality Index (PSQI), and improved their GERD-related quality of life .[8]

Following the brief period application of one session of MFRI in GERD patients, another GERD study published in 2013 reported an immediate improvement in the pressure around GERD patients' lower esophageal sphincter (the pressure was measured objectively by an esophageal manometry) .[9]

In agreement with the current study, the manual osteopathic therapy which resembled our MFRI in some aspects such as the application of the technique on GERD patients' epigastric area) significantly improved GERD patients' symptoms.[10]

In agreement with the current study, as a part of 1-month inspiratory muscle training, the during-training synchronized pressure by GERD patients' fingertips with inspiration and expiration significantly improved patients' GERD-related symptoms and quality of life (to be noted, patients' fingertips were placed few centimeters away from the patients' last costal arch bilaterally).[11]

In addition to the enhancement in patients' quality of life, incorporating breathing exercises in the medical treatment of GERD significantly lowered GERD patients' use of PPIs .[12] and frequency/severity of GERD symptoms.[12]

This current study shows objective improvements in diaphragm thickness and excursion against the limitation in the previous study by Newberry & Lynch, first off, it was hard to determine whether there had been any modifications to the refluxate or EGJ's strength because we didn't employ any objective methods, such as diaphragm ultrasonography, to analyze potential changes at the EGJ. Second, because the pressure and sensitivity characteristics employed in clinical interventions involving manual therapies cannot be unified, it is exceedingly difficult to standardize their application. In this way, one study constraint is the application of manual treatment itself.[13]

Limitations

There are two main limiting factors for this study: Small sample size was the basic limitation of this GERD study and lack of follow up period for patients in this GERD study.

Conclusion

The results of this GERD study demonstrated that patients in the group that received combined traditional medical treatment with manual diaphragm release had a considerably higher improvement in DE, DFT, and PSQI than patients in the other group that received only traditional medical care.

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Conflict of interests

The authors report no conflict of interest.

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