Acta Otorrinolaringol Esp. 2019;xxx(xx):xxx-xxx

Acta Otorrinolaringológica Española

www.elsevier.es/otorrino

ORIGINAL ARTICLE

Modified inspiratory muscle training (m-IMT) as promising treatment for gastro-oesophageal reflux disease (GERD)

Antonio Moffa[a,*], Giuseppe Oliveto[b], Francesco Di Matteo[c], Peter Baptista[d], Alicia Cárdenas[a], Michele Cassano[a], Manuele Casale[b]

[a] *Unit of Otolaryngology, University of Foggia, Foggia, Italy*
[b] *Unit of Otolaryngology, University Campus Bio-Medico, Rome, Italy*
[c] *Unit of Gastroenterology, University Campus Bio-Medico, Rome, Italy*
[d] *Unit of Otolaryngology, University of Navarra, Campus Universitario, Pamplona, Spain*

Received 6 November 2018; accepted 20 January 2019

KEYWORDS
Gastro-oesophageal reflux disease;
Inspiratory muscle training;
Lower oesophageal sphincter;
Acid exposure;
Myofunctional therapy

Abstract
Background: Gastro-oesophageal reflux disease (GERD) is one of the most common diseases, but is still a challenge to cure. Different medical treatments are used, first of all Proton pump inhibitors (PPIs), however these are sometimes ineffective and long-term intake can lead to underestimated complications. Recently, some studies investigated the role of inspiratory muscle training (IMT) in the medical treatment of GERD. It seems that IMT is able to increase the pressure generated by the lower oesophageal sphincter (LES), reduce spontaneous releases of LES, acid exposure, use of PPIs, and improve symptoms and quality of life for GERD patients.
Objective: The aim of this study was to evaluate the effectiveness of IMT in association with myofunctional therapy exercises of swallowing set by Daniel Garliner (m-IMT) on the symptoms of patients with non-erosive gastro-oesophageal reflux disease (NERD).
Methods: Twenty-one adult patients with NERD were enrolled from May to December 2017 and performed m-IMT over a period of 4 weeks. Before and after treatment, all the patients completed the following questionnaires: GERD oesophageal symptomatology (GERDQ), extra-oesophageal GERD symptomatology (RSI), quality of life (GERD-Health Related Quality of Life Questionnaire (GERD-HRQL), and underwent laryngeal endoscopy.
Results: Nineteen patients completed m-IMT. GERDQ (from 8.36 ± 3.94 to 1.7 ± 3.41; $p < .05$), RSI (from to 21.68 ± 10.26 to 6.93 ± 8.37; $p < .05$) and GERDHRQL (from 25.68 ± 16.03 to 8.4 ± 11.06; $p < .05$) the questionnaire scores significantly reduced after treatment. In addition, the laryngeal endoscopy score greatly improved (from 14.24 ± 4.15 to 7.4 ± 1.77; $p < .05$).

* Corresponding author.
E-mail address: moffa.antonio1@gmail.com (A. Moffa).

https://doi.org/10.1016/j.otorri.2019.01.003

Conclusions: m-IMT is a low cost therapy without side effects. It could be useful in association with PPI or alone for selected GERD cases and for mild NERD forms, in association with diet. Further studies are required to prove the effects of m-IMT on GERD symptoms and decide the best treatment schedule.

PALABRAS CLAVE
Enfermedad por reflujo gastroesofágico;
Entrenamiento muscular inspiratorio;
Esfínter esofágico inferior;
Exposición a ácidos;
Terapia miofuncional

Entrenamiento de músculos inspiratorios modificado como tratamiento prometedor de la enfermedad por reflujo gastroesofágico

Resumen
Introducción: La enfermedad por reflujo gastroesofágico (ERGE) es una de las enfermedades más comunes, pero sigue siendo un desafío para curar. Se utilizan diferentes tratamientos médicos, en primer lugar los inhibidores de la bomba de protones (IBP), sin embargo, en ocasiones son ineficaces y una ingesta a largo plazo puede llevar a complicaciones subestimadas. Recientemente, algunos estudios investigaron el papel del entrenamiento muscular inspiratorio (IMT) en el tratamiento médico de la ERGE. Parece que el IMT es capaz de aumentar la presión generada por el esfínter esofágico inferior (LES), reducir las liberaciones espontáneas del LES, la exposición al ácido, el uso de IBP, y mejorar los síntomas y la calidad de vida en pacientes con ERGE.
Objetivo: El objetivo de este estudio es evaluar la efectividad de la IMT en asociación con los ejercicios de terapia miofuncional de tragar de Daniel Garliner (m-IMT) en los síntomas de los pacientes con ERGE no erosivo (NERGE).
Métodos: Veintiún pacientes adultos con ERGE se inscribieron de mayo a diciembre de 2017 y realizaron un período de 4 semanas de m-IMT. Antes y después del tratamiento todos los pacientes completaron los siguientes cuestionarios: sintomatología esofágica de ERGE, sintomatología de ERGE extraesofágica (RSI), calidad de vida (cuestionario de calidad de vida relacionada con la salud [ERGE-HRQL]) y endoscopia laríngea.
Resultados: Diecinueve pacientes completaron m-IMT. GERDQ (desde $8{,}36 \pm 3{,}94$ a $1{,}7 \pm 3{,}41$; $p < 0{,}05$), RSI (desde hasta $21{,}68 \pm 10{,}26$ hasta $6{,}93 \pm 8{,}37$; $p < 0{,}05$) y ERGE-HRQL (desde $25{,}68 \pm 16{,}03$ hasta $8{,}4 \pm 11{,}06$; $p < 0{,}05$), las puntuaciones se redujeron significativamente después del tratamiento. Además, la puntuación de la endoscopia laríngea mejoró enormemente (de $14{,}24 \pm 4{,}15$ a $7{,}4 \pm 1{,}77$; $p < 0{,}05$).
Conclusiones: m-IMT es una terapia de bajo costo sin efectos secundarios. Podría ser útil en asociación con IBP o solo en casos seleccionados de ERGE y en formas NERGE leves, en asociación con la dieta. Se requieren estudios adicionales para probar los efectos de m-IMT en los síntomas de ERGE y establecer el mejor programa de tratamiento.

Introduction

Gastroesophageal reflux disease (GERD) is one of the most common diseases in the Western world, with a prevalence of 18.1–27.8% in North America, and 8.8–25.9% in Europe. It is caused by an imbalance between the injurious factors, represented by the components of the gastric juice, and the defensive factors that constitute the anti-reflux barrier. The anti-reflux barrier can be distinguished anatomically in intrinsic component, lower esophageal sphincter (LES), and an extrinsic component, crural fibers of the diaphragm that compress, ab extrinsic, the LES. Reduced efficiency of this barrier can predispose to reflux.[1]

GERD clinical manifestations are classified as esophageal and extraesophageal symptoms.[2] The most common, or cardinal, symptoms are heartburn and regurgitation, but frequently patients report extra-esophageal symptoms such as chronic cough, pharyngodynia, hoarseness, dysphonia, dysphagia and globus pharyngeus.[3]

Numerous therapeutic approaches have been proposed from a suitable diet regimen to antireflux surgery. Currently the proton pump inhibitors (PPIs) play a pivotal role in the management of GERD. PPIs block the gastric H,K-ATPase, inhibiting gastric acid secretion, leading to a reduction of the harmful effect on the esophageal mucosa during reflux episodes. Nevertheless, in some patients with visceral

Please cite this article in press as: Moffa A, et al. Modified inspiratory muscle training (m-IMT) as promising treatment for gastro-oesophageal reflux disease (GERD). Acta Otorrinolaringol Esp. 2019. https://doi.org/10.1016/j.otorri.2019.01.003

hypersensitivity, the symptoms are also triggered by basic refluxes, in some even by the simple gas, so the PPI are ineffective.[4] Also, a long-term intake of PPI can lead to several and underestimated complications.

Evidence has recently emerged in the scientific literature that point to a potential use of inspiratory muscle training (IMT) on the GERD symptoms.[5] Crural diaphragm fibers surrounding the esophageal musculature are one of the fundamental components of the anti-reflux barrier and these actively contract during inspiration. IMT could train the crural fibers, therefore positively influencing the anti-reflux barrier. Indeed it seems that it is able to increase the pressure generated by LES,[6] reduce spontaneous releases of LES acid exposure, GERD symptoms, the use of PPIs [7],and improve Quality of life. However, there are very few studies in literature about IMT effects, with small patient populations, not homogeneous and with different rehabilitation exercise.

The aim of this study is to evaluate the effect of diaphragmatic respiratory training in association with myofunctional therapy exercises of swallowing set by Daniel Garliner (m-IMT) on the GERD symptoms, with standardized questionnaires and laryngoscopic findings.

Materials and methods

Twenty-two adult patients with NERD, not yet in pharmacological therapy (mean age 54.9 ± 11.18, M:F, 6:16) were enrolled from May to December 2017.

Patients with erosive esophagitis, hiatal hernia, previously undergoing anti-reflux surgery and comorbidity diseases that prevent m-IMT execution, were excluded.

Based on these criteria, twenty-one patients were enrolled (mean age 55.8 ± 11.29, M:F, 5:16) and, after informed consent, complete a 4 weeks period of m-IMT according to protocol developed, focusing on the diaphragmatic respiration and on physiological deglutition.

m-IMT schedule

Every patient included in the study must repeat m-IMT schedule twice a day before lunch and dinner for a total of 4 weeks. M-IMT schedule takes about 30 min. They will only be effective if they are carried out correctly, without haste. The exercises must be performed every day. If you experience dizziness during exercise, stop whatever you are doing and rest.

m-IMT schedule is composed of 4 different exercises:

Exercise number 1: Supine position. Inhale slowly from the nose thinking of making a minimum supply. Suspend the breath for about 3 s. Exhale from the nose by performing an expiratory act as long as possible and avoiding a state of contraction of the abdominal muscles.[8]
Exercise number 2: Repeat exercise number 1 after positioning the fingertips few centimeters away from the last costal arch. Apply constant pressure inwards and upwards during the expiratory phase. Check the tension status of the abdominal and cervical muscles. Try to keep the physiological curves of the spine as much as possible.
Exercise number 3: Repeat exercise number 2, expiring from the mouth with maximum mandibular destabilization keeping the tongue well laid on the oral floor.
Exercise number 4: Sitting position. Bring the lingual apex on the retro-incisal papilla. Keeping lips open, perform swallowing acts for 3 min.[9]

Check for the correct chin-breast alignment. Ensure that the correct and constant contact of the lingual apex and the retro-incisal papilla are maintained during the swallowing act.

Invite the patient to perform the same exercise daily with liquid bolus until solid consistencies are obtained, in order to automate a correct deglutitory scheme.

Before and after treatment, all patients completed standardized anamnestic evaluation for GERD esophageal symptomatology (GERDQ questionnaire), extra-esophageal GERD symptomatology (Table 1), quality of life (GERD-Health Related Quality of Life Questionnaire (GERD-HRQL questionnaire) and physician evaluated laryngeal endoscopy standardized by reflux finding score (Table 2).

After the first treatment session, two patients could not continue the exercises, so nineteen patients (mean age 54.9 ± 14.24, M:F, 4:15) completed the sessions.

Table 1 RSI questionnaire.

Within the last month, how did the following problem affect you? Circle the appropriate response	0 = No problem 5 = Severe problem					
1. Hoarseness or a problem with your voice	0	1	2	3	4	5
2. Clearing your throat	0	1	2	3	4	5
3. Excess throat mucus or postnasal drip	0	1	2	3	4	5
4. Difficulty swallowing food, liquids, or pills	0	1	2	3	4	5
5. Coughing after your ate or after lying down	0	1	2	3	4	5
6. Breathing difficulties or choking episodes	0	1	2	3	4	5
7. Troublesome or annoying cough	0	1	2	3	4	5
8. Sensations of something sticking in your throat or a lump in your throat	0	1	2	3	4	5
9. Heartburn, chest pain, indigestion, or stomach acid coming up	0	1	2	3	4	5

Please cite this article in press as: Moffa A, et al. Modified inspiratory muscle training (m-IMT) as promising treatment for gastro-oesophageal reflux disease (GERD). Acta Otorrinolaringol Esp. 2019. https://doi.org/10.1016/j.otorri.2019.01.003

Table 2 RFS score.

Subglottic edema	0 = absent		2 = present	
Ventricular obliteration	2 = partial		4 = complete	
Erythema/hyperemia	2 = arytenoids only		4 = diffuse	
Vocal fold edema	1 = mild	2 = moderate	3 = severe	4 = polypoid
Diffuse laryngeal edema	1 = mild	2 = moderate	3 = severe	4 = obstructing
Posterior commissure hypertrophy	1 = mild	2 = moderate	3 = severe	4 = obstructing
Granuloma/granulation tissue	0 = absent		2 = present	
Thick endolaryngeal mucus	0 = absent		2 = present	

Statistic analysis

The collected data were expressed as mean and standard deviation and analyzed using Student's *t*-test. *P* values of less than 0.05 were regarded as ''statistically significant''. No side effects were observed during the study. The study protocol was approved by the ethics committee of the University Campus Bio-Medico, Rome, Italy; written informed consent was obtained from all patients.

Results

Nineteen patients with NERD completed our proposed rehabilitation treatment.

After 4-weeks treatment, GERDQ questionnaire score about common symptoms, significantly improved (score before treatment: 8.36 ± 3.94; after treatment: 1.7 ± 3.41; $p < 0.05$).

Also RSI questionnaire score about extra-esophageal GERD symptomatology, was significantly better after treatment (score before treatment: 21.68 ± 10.26; after treatment: 6.93 ± 8.37; $p < 0.05$).

GERDHRQL questionnaire score evaluating quality of life, was significantly greater after m-IMT (score before treatment: 25.68 ± 16.03; after treatment: 8.4 ± 11.06; $p < 0.05$).

At last, there was a significant improvement in the laryngoscopic finding (RFS score before treatment: 14.24 ± 4.15; after treatment: 7.4 ± 1.77; $p < 0.05$).

Discussion

GERD is a common disease that is expensive to diagnose and treat.[10] PPIs are the most effective agents in the first-line and maintenance treatment, but they are not always effective and a chronic consumption have been linked to an increased risk of several conditions such as hip fractures, community acquired pneumonia, diarrhea, gastrinoma, and drug interactions.[11]

In recent years, lifestyle modifications and non-pharmacological treatment have gained considerable attention and frequently are recommended as supportive measure but not been well studied. Among, there is the breathing training better known as IMT.

To our knowledge, this is the first study to analyze the efficacy of IMT in combination with myofunctional swallowing therapy exercises set by D. Garliner.

We conducted a comprehensive assessment of the GERD patients, evaluating the esophageal and extra esophageal symptoms with common clinical questionnaire GERDQ, GERDHRQL and RSI. In addition, we assessed laryngeal objectivity with RSF, using fibrolaringoscopy, a parameter not analyzed by other studies in the literature.

The main results of this study show that IMT with myofunctional therapy exercises of swallowing, reduced GERD symptoms and improved laryngoscopic findings.

We have noticed a significantly improvement not only for the common symptoms of the disease such as heartburn and regurgitation, but also for the atypical symptoms like cronic cough, pharyngodynia, hoarseness, dysphonia, dysphagia and globus pharyngeusas, confirmed by RSI questionnaire score and laryngeal objectivity.

Recently, a systematic review analyzed the effects of IMT on the GERD symptoms and concluded that the breathing training given its safety, cost effectiveness and lack of collateral effects, could play a crucial role in the management of mild GERD.[10] Particularly Eherer et al. observed that abdominal breathing exercises improved quality of life and reduced acid exposure to the esophagus and use of PPIs.[12] De Miranda Chaves et al. showed that respiratory physiotherapy can increase the pressure of LES.[11] Da Silva et al.[12] noted that the modified osteopathic techniques for diaphragmatic stretching, increased mean respiratory pressure. Finally Nobre et al. found that inspiratory muscle training reduce the transient LES releases and improve GERD symptoms.[13]

The breathing exercises could train the crural diaphragm, therefore, positively influencing the anti-reflux barrier. Inspiratory muscles, including crural diaphragm fibers, are morphologically and functionally skeletal muscles and, should respond to training in the same way as any locomotor muscle.[13]

Also myofunctional reeducation on swallowing with a focus on eliminating tongue and orofacial muscle hypotonia, could reinforced the physiological deglutitory scheme and optimize the pressure exerted on the LES.[14]

IMT has been well described in respiratory diseases. Indeed, despite most of such children having pathological reflux, those with marked adenotonsillar hypertrophy and severe obstructive sleep apnea syndrome tended to have less esophageal acid exposure.[15]

Finally, IMT is a physical exercise that improve autonomic function, particularly vagal tone, similarly to regular physical training. It would drive a new and healthier balance in autonomic nervous system activity that could be associated with a better esophagogastric junction motor function comprising both enhancement of the pressure generated by the smooth muscle component of LES and the

Please cite this article in press as: Moffa A, et al. Modified inspiratory muscle training (m-IMT) as promising treatment for gastro-oesophageal reflux disease (GERD). Acta Otorrinolaringol Esp. 2019. https://doi.org/10.1016/j.otorri.2019.01.003

decrease in the rate of Transient lower esophageal sphincter relaxation.[14]

Extra-esophageal GERD symptomatology and laryngeal endoscopy signs are linked to failure of physiological barriers. Among these, there is not only the LES but also upper esophageal sphincter (UES). It is usually closed except while swallowing and the most contracted zone corresponds to the cricopharyngeal muscle. Because cricopharyngeal muscle, is anatomically positioned between the vertebrae posteriorly and the cricoid cartilage anteriorly, its intraluminal pressure can be enhanced by external pressure applied perpendicularly to the cricoid cartilage. Shaker et al.[16] made a simple UES assist device composed by an elastic band and a cushion in order to apply 20–30 mm Hg cricoid pressure significantly. The authors observed that this technique increases the UES intraluminal pressure and prevents Laryngopharyngeal reflux (LPR). The utility of cricoid pressure has been previously recognized in several other settings for example in acute life-threatening situations to prevent aspiration of gastric content and during ventilatory assistance of cardiopulmonary resuscitation to prevent air-induced gastric distention. However, it is necessary to specify some other exercise such as isotonic/isometric head raising developed by Shaker which improve swallowing, increasing the anteroposterior diameter and cross-sectional area of UES but indirectly causes an increase in LPR.[17]

This non-pharmacological intervention proposed may represent a promising option for the treatment of PPI-refractory GERD patients and could help in reducing the annual PPI needed intake in responder GERD patients.

In the future, this study could be improved with another treatment group performing different exercises, and it might be useful to evaluate esophageal pH monitoring and manometry. In addition, it may be useful to combine exercises and techniques that act simultaneously on both the LES and UES.

A reasonable multidisciplinary approach would be to consider in GERD patients: gastroenterologist, ENT, phoniatrist, physiatrist, physiotherapist and speech therapist are necessary to complete an accurate valuation.

Acknowledgements

The authors reported no conflict of interest and no funding has been received for this work.

References

1. Kahrilas PJ, Lee TJ. Pathophysiology of gastroesophageal reflux disease. Thorac Surg Clin. 2005;15:323–33.
2. Campagnolo AM, Priston J, Thoen RH, Medeiros T, Assunção AR, Laryngopharyngeal reflux: diagnosis treatment and latest research. Int Arch Otorhinolaryngol. 2014;18:91–184.
3. Ahuja V, Yencha MW, Lassen LF, Ahuja V. Head and neck manifestations of gastroesophageal reflux disease. Am Fam Physician. 1999;60:873–80.
4. Scarpellini E, Ang D, Pauwels A, De Santis A, Vanuytsel T, Tack J. Management of refractory typical GERD symptoms. Nat Rev Gastroenterol Hepatol. 2016;13:281–94.
5. Casale M, Sabatino L, Moffa A, Capuano F, Luccarelli V, Vitali M, et al. Breathing training on lower esophageal sphincter as a complementary treatment of gastroesophageal reflux disease (GERD): a systematic review. Eur Rev Med Pharmacol Sci. 2016;20:4547–52.
6. Carvalho de Miranda Chaves R, Suesada M, Polise F, de Sá CC, Navarro-Rodriguez T. Respiratory physiotherapy can increase lower esophageal sphincter pressure in, GERD patients. Respir Med. 2012;106:1794–9.
7. Nobre e Souza MÂ, Lima MJ, Martins GB, Nobre RA, Souza MH, de Oliveira RB, et al. Inspiratory muscle training improves antireflux barrier in GERD patients. AJP Gastrointest Liver Physiol. 2013;305:G862–7.
8. Méal G, Anatomy trains: myofascial meridians for manual and movement therapists. Clin Chiropr. 2003.
9. Garliner D. Myofunctional therapy. Gen Dent. 1976;24:30–40.
10. Richter JE. Gastrooesophageal reflux disease. Best Pract Res Clin Gastroenterol. 2007;21:609e31.
11. Rohof WO, Bennink RJ, de Ruigh AA, Hirsch DP, Zwinderman AH, Boeckxstaens GE. Effect of azithromycin on acid reflux, hiatus hernia and proximal acid pocket in the postprandial period. Gut. 2012;61:1670–7.
12. Eherer AJ, Netolitzky F, Högenauer C, Puschnig G, Hinterleitner TA, Scheidl S, et al. Positive effect of abdominal breathing exercise on gastroesophageal reflux disease: a randomized, controlled study. Am J Gastroenterol. 2012;107:372–8.
13. Enright SJ, Unnithan VB, Heward C, Withnall L, Davies DH. Effect of high-intensity inspiratory muscle training on lung volumes, diaphragm thickness and exercise capacity in subjects who are healthy. Phys Ther Mar. 2006;86:345e54.
14. Levy WC, Cerqueira MD, Harp GD, Johannessen KA, Abrass IB, Schwartz RS, et al. Effect of endurance exercise training on heart rate variability at rest in healthy young and older men. Am J Cardiol. 1998;82:1236–41.
15. Noronha AC, de Bruin VM, Nobre e Souza MA, de Freitas MR, Araújo Rde P, Mota RM, et al. Gastroesophageal reflux and obstructive sleep apnea in childhood. Int J Pediatr Otorhinolaryngol. 2009;73:383–9.
16. Shaker R, Babaei A, Naini SR. Prevention of esophagopharyngeal reflux by augmenting the upper esophageal sphincter pressure barrier. Laryngoscope. 2014;124:74–2268.
17. Shaker R, Kern M, Bardan E, Taylor A, Stewart ET, Hoffman RG, et al. Augmentation of deglutitive upper esophageal sphincter opening in the elderly by exercise. Am J Physiol. 1997;272:G1518–22.

Please cite this article in press as: Moffa A, et al. Modified inspiratory muscle training (m-IMT) as promising treatment for gastro-oesophageal reflux disease (GERD). Acta Otorrinolaringol Esp. 2019. https://doi.org/10.1016/j.otorri.2019.01.003