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Effectiveness of preoperative inspiratory muscle training using the Threshold IMT in patients undergoing esophageal surgery: a randomized clinical trial

Eficácia do treinamento muscular inspiratório pré-operatório utilizando o Threshold IMT em pacientes submetidos à cirurgia esofágica: um ensaio clínico randomizado

Fernanda Maria Rodrigues da Cunha[1], Marisa de Carvalho Borges[2], Fabiana Alves Carvalho[3], Márcia Souza Volpe[4], Virmondes Rodrigues Júnior[5], Eduardo Crema[6]

[1]Corresponding author. Federal University of Triângulo Mineiro. Uberaba, Minas Gerais, Brazil. ORCID: 0000-0003-0539-3985. femariacunha@yahoo.com.br
[2]Federal University of Triângulo Mineiro. Uberaba, Minas Gerais, Brazil. ORCID: 0000-0001-5823-2996. marisaborges.uftm@gmail.com
[3]Pio XII Foundation. Barretos, São Paulo, Brazil. ORCID: 0000-0002-4014-3327. fac.fisio@gmail.com
[4]Federal University of São Paulo. São Paulo, São Paulo, Brazil. ORCID: 0000-0003-1179-6254. marciasvolpe@gmail.com
[5]Federal University of Triângulo Mineiro. Uberaba, Minas Gerais, Brazil. ORCID: 0000-0001-8706-4223. virmondes.rodrigues@uftm.edu.br
[6]Federal University of Triângulo Mineiro. Uberaba, Minas Gerais, Brazil. ORCID: 0000-0002-6688-0819. cremauftm@mednet.com.br

RESUMO | INTRODUÇÃO: O treinamento muscular inspiratório (TMI) no pré-operatório pode evitar complicações pulmonares no pós-operatório (CPPO) em pacientes submetidos a esofagectomia. **OBJETIVO:** Avaliar a eficácia do TMI que foi realizado no período pré-operatório e seus benefícios no período pós-operatório, através da avaliação da pressão inspiratória máxima (PImáx), da pressão expiratória máxima (PEmáx), da ventilação voluntária máxima (VVM) e do pico de fluxo expiratório (PFE) e os benefícios do mesmo no pós-operatório. **MATERIAIS E MÉTODOS:** Foi realizado um ensaio clínico, randomizado, que foi realizado pela disciplina de Cirurgia do Aparelho Digestivo do Hospital das Clínicas da Universidade Federal do Triângulo Mineiro. Foram incluídos 26 pacientes em: Grupo Controle (GC: n=12) e Grupo Intervenção (GI: n=14). O GI realizou TMI por no mínimo 2 semanas. As avaliações foram realizadas no pré e pós-operatório. **RESULTADOS:** Houve aumento da PImáx (p=0,006), da PEmáx (p=0,005) e do VVM (0,042) no GI, após o TMI realizado no pré-operatório em relação ao GC. Na avaliação do PFE não foi observada aumento após o TMI no GI em relação ao GC (p=0,63). Na alta hospitalar houve queda das variáveis avaliadas em ambos os grupos e no 30°PO ocorreu recuperação em relação aos valores iniciais. Quanto a ocorrência de CPPO não houve diferença significativa entre os grupos. **CONCLUSÃO:** O TMI realizado em nosso estudo melhorou a força muscular inspiratória, expiratória e a função ventilatória no pré-operatório, porém não resultou em melhor evolução no pós-operatório de pacientes submetidos a esofagectomia.

PALAVRAS-CHAVE: Fisioterapia. Terapia respiratória. Esofagectomia.

ABSTRACT | INTRODUCTION: Preoperative inspiratory muscle training (IMT) can prevent postoperative pulmonary complications in patients undergoing esophagectomy. **OBJECTIVE:** To evaluate the effectiveness of preoperative IMT and its postoperative benefits by assessing maximal inspiratory pressure (MIP), maximal expiratory pressure (MEP), maximal voluntary ventilation (MVV), and peak expiratory flow (PEF). **MATERIALS AND METHODS:** A randomized clinical trial was conducted by the Digestive Tract Surgery Service, University Hospital of the Federal University of Triângulo Mineiro. Twenty-six patients were included: control group (CG, n=12) and intervention group (IG, n=14). Patients of IG underwent IMT for at least 2 weeks. Assessments were performed before and after surgery. **RESULTS:** There was an increase of MIP (p=0.006), MEP (p=0.005) and MVV (0.042) in IG after preoperative IMT compared to CG. Evaluation of PEF revealed no increase in IG after IMT compared to CG (p=0.63). A decrease in the variables analyzed was observed in both group at discharge and the variables had returned to baseline values on postoperative day 30. There was no significant difference in the frequency of postoperative pulmonary complications between groups. **CONCLUSION:** The IMT applied in our study improved preoperative inspiratory and expiratory muscle strength and ventilatory function but did not result in better postoperative evolution of patients undergoing esophagectomy.

KEYWORDS: Physiotherapy. Respiratory therapy. Esophagectomy.

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Introduction

Chagasic megaesophagus is a gastrointestinal abnormality characterized by the destruction or absence of intramural nerve plexuses of the esophagus and is the most common esophageal disorder in Brazil[1]. The causes of esophageal cancer are still unknown, but studies indicate some risk factors related to its incidence, such as tobacco, alcohol and the consumption of hot beverages[2]. The main symptom of esophageal cancer is dysphagia or swallowing difficulties. First, the patient has difficulty swallowing solid foods, then pasty foods and, finally, liquids. Consequently, most patients lose weight and are often anemic and dehydrated[3].

Surgery is the most common procedure used to treat chagasic megaesophagus in patients with grade III and IV involvement, as well as in patients with esophageal cancer. However, although esophagectomy is the therapeutic procedure with the best outcomes in these patients, postoperative pulmonary complications may occur due to pulmonary disturbances that can reduce lung volume and capacity, with a decrease in chest expandability and respiratory muscle dysfunction[4].

The importance of preoperative respiratory physiotherapy has increased considerably in an attempt to prepare the patient for surgery and for the postoperative period. Adequate preparation of these patients should result in a postoperative period without intercurrences or severe complications[5]. Inspiratory muscle training (IMT) has been recommended as a tool to increase inspiratory muscle strength because of its effects on the cardiovascular and respiratory systems, improving oxygen uptake, dyspnea, functional capacity, and quality of life[6].

In view of the importance of the integrity of respiratory muscle strength to reduce the risk of postoperative pulmonary complications, the aim of the present study was to evaluate the effectiveness of preoperative IMT using the Threshold IMT and its postoperative benefits in patients undergoing esophagectomy by assessing maximal inspiratory pressure (MIP), maximal expiratory pressure (MEP), maximal voluntary ventilation (MVV), and peak expiratory flow (PEF).

Methods

A randomized clinical trial with a parallel group design was conducted by the Digestive Tract Surgery Service, University Hospital of the Federal University of Triângulo Mineiro (UFTM). The data were collected between January 2011 and December 2013 at the Maria da Glória Outpatient Clinic of UFTM. After receiving detailed information about the objectives of the study, the data of each patient were recorded on an assessment chart and each patient provided free written informed consent.

The participants were chosen randomly according to the following inclusion criteria: diagnosis of megaesophagus grade III and IV, diagnosis of resectable esophageal cancer, and age older than 18 years. Exclusion criteria were undergoing surgery within a period of less than 2 weeks after initial assessment, incomprehension, and non-adherence to the proposed treatment.

Sealed opaque envelopes were used for treatment allocation. Two groups were formed by drawing lots using these envelopes that were opened sequentially (containing 30 letters “C” and “I”, i.e., “control” and “intervention”), divided according to stratification and numbered sequentially. The generation of the list of simple randomization and allocation in sealed envelopes were performed by a health professional who did not participate in the clinical follow-up of the patients. The envelopes were opened by a collaborative researcher who did not participate in the study or patient follow-up after the patient had signed the consent form during the outpatient visit. All participants in the study were taught to perform the respiratory exercises (diaphragmatic and in three times) and upper and lower limb exercises combined with breathing, but only patients of the intervention group (IG) underwent preoperative IMT using the Threshold IMT. The participants were assigned to the interventions by two researchers of the study.

Thirty patients were initially randomized but four were excluded from the study because of non-adherence to the treatment, including 3 (25%) patients of the control group (CG) and one (7.1%) of IG.

Thus, 26 male patients, who would be submitted to esophagectomy through a laparoscopic access, participated in the study. Twelve (46.1%) were randomized to CG and 14 (53.9%) to IG. Regarding diagnosis, 6 (50%) patients in CG had cancer and 6 (50%) had megaesophagus. In IG, 7 (50%) patients had cancer and 7 (50%) had megaesophagus.

The evaluator of the primary clinical outcomes was blind to patient allocation and the treatment performed. However, the physiotherapists, physicians and patients were not blind to the treatment.

The MIP, MEP, MVV, and PEF were evaluated at the following time points: first and second preoperative assessment, discharge, and postoperative day 30.

The study was analyzed and approved by the Ethics Committee of UFTM (Approval No. 1823).

First Preoperative Physiotherapy Assessment (1st Pre)

During anamnesis, personal data, diagnosis, history of current and past diseases, history of smoking and presence of comorbidities, including lung and heart disease, were collected. Physical examination consisting of anthropometric measurements (body weight height, and body mass index - BMI) was performed, and MIP, MEP, MVV, and PEF were evaluated.

Second Preoperative Physiotherapy Assessment (2nd Pre)

The second physiotherapy assessment was performed 48 h before the surgical procedure and consisted of the measurement of MIP, MEP, MVV, and PEF.

Hospital Discharge and Postoperative Day 30

The MIP, MEP, MVV and PEF were measured at discharge and on postoperative day 30.

Measurement of Maximal Respiratory Pressures

The technique used to evaluate respiratory muscle strength was based on the measurement of maximal respiratory pressures. For this measurement, the patient was sitting with the nostrils clamped with a nose clip. The respiratory pressures were obtained using a duly calibrated analog manovacuometer ranging from -300 to +300 cmH2O (GeRar, São Paulo, SP, Brazil). The measurement of MIP was started from the residual volume and MEP from total lung capacity as recommended by Neder et al.[7].

At least three measurements of each variable were obtained, with a resting interval of approximately 1 minute between maneuvers. The maneuver was only considered valid if the pressure was sustained for at least 2 seconds. If the highest value was obtained in the third maneuver, the measurement was repeated until the same or a lower value was found, with a variation less than 10% between measurements.

The highest values found during the measurement of each variable were considered the MIP and MEP, given that they were not obtained in the last maneuver. These measurements were obtained weekly in the outpatient clinic.

Maximal Voluntary Ventilation

The MVV was performed using a duly calibrated ventilometer (Wright®, British Oxygen Company, London, England). The patient was instructed to inspire and expire a volume greater than the tidal volume at a constant and regular rhythm for 10 seconds. The volume obtained was extrapolated to 1 minute for the calculation of MVV in L/min. The maneuver was repeated three times and the highest value was considered. Using MVV, the largest air volume that the individual can mobilize through maximum voluntary effort over one minute provides a nonspecific measure of ventilatory function.

Peak Expiratory Flow

The PEF was measured with a duly calibrated Master Screen-Pneumo spirometer (Jaeger®) at HC-UFTM. The test was performed using the criteria recommended by the Guidelines for Pulmonary Function Tests of the Brazilian Society of Pneumology and Phthisiology. The reference values of Pereira et al.[8] were used.

Control Group

The patients of CG were taught to perform the breathing exercises (diaphragmatic and in three times) and upper and lower limb exercises combined with breathing. The volunteers were asked to perform 10 repetitions of each breathing and limb exercise, 5 times per week. In addition, they received instructions about the importance of pre- and postoperative physiotherapy and were encouraged to remain active within their physical limits. The patients were given written instructions in the form of explanatory leaflets about the exercises that should be performed at home and were asked to record on the exercise leaflet if they had performed the exercises and if they felt any type of discomfort during their execution.

After the first preoperative assessment, the patients were asked to perform these exercises at home according to the instructions and to return to the outpatient clinic once a week until the day of hospital admission. During the weekly return, the responsible researcher verified that the exercises were being performed correctly and the instructions were reinforced.

Intervention Group

Patients of IG received the same instructions as those of CG but IMT was added. The Threshold IMT (Philips Respironics, NJ, USA) was used for this training at a load of 60% MIP, 3 sets of 12 repetitions, 5 times per week for at least 2 weeks. The load was adjusted weekly in order to maintain it at 60% MIP in the case of an increase in this parameter. In addition to the exercise leaflets, the patients received a Threshold IMT provided by HC-UFTM to perform the proposed treatment at home. The patients of this group were also instructed after the first assessment to perform the exercises at home and to return to the outpatient clinic once a week until the day of hospital admission. The researcher who accompanied the patients of both groups during the preoperative period was always the same.

During the preoperative period, patients of CG and IG performed the exercises between the first (1^{st} Pre) and second (2^{nd} Pre) assessment, i.e., 48 h before the surgical procedure.

Statistical Analysis

The Kolmogorov-Smirnov test was used to determine whether the data were normally distributed. Parametric data were compared by the Student t-test and nonparametric data by the Wilcoxon test. Correlations were evaluated using Pearson and Spearman correlation coefficients. The differences were considered significant when $p < 0.05$. Statistical analysis was performed using the Microsoft Excel 2010, GraphPad Prism 5.0, and SPSS 16.0 programs.

Results

Thirty patients were initially randomized but four were excluded from the study because of non-adherence to the treatment, including 3 (25%) patients of CG and one (7.1%) of IG. Thus, 26 male patients, who would be submitted to esophagectomy through a laparoscopic access, participated in the study. Twelve (46.1%) patients were randomized to CG and 14 (53.9%) to IG.

The age and BMI of the patients are shown in Table 1, and risk factors are described in Table 2. Table 3 shows the MIP, MEP, MVV and PEF of patients in CG and IG (submitted to IMT).

Table 1. Age and BMI of patients in the control (CG) and intervention (IG) groups obtained in the first preoperative assessment (1st Pre)

Variables	CG (n=12)	IG (n=14)	p
Age (years)	53.41 ± 10.8	53.71 ± 11.6	0.94
BMI (kg/m^2)	22.6 ± 3.7	24.38 ± 5.0	0.32

Continuous variables are reported as mean ± standard deviation.
BMI: body mass index.

Table 2. Risk factors of patients in the control (CG) and intervention (IG) groups obtained in the first preoperative assessment (1st Pre)

Risk factors	CG (n=12)	IG (n=14)	p
History of smoking, n (%)			0.50
Non-smoker	4 (40.0)	3 (21.5)	
Former smoker	2 (10.0)	6 (42.8)	
Smoker	6 (50.0)	5 (35.7)	
Alcohol consumption, n (%)	3 (30.0)	4 (28.5)	0.83

Table 3. Maximal inspiratory and expiratory pressures, maximal voluntary ventilation and peak expiratory flow in patients of the two groups evaluated in the first and second physiotherapy assessment, at discharge, and on postoperative day 30

	Group	1st Pre	2nd Pre	Discharge	PO30
MIP	p	0.18	0.006	0.78	0.28
	CG	-75.0 ± 32.0	-75.8 ± 32.8	- 59.5± 27.8	-80.8 ± 34.7
	IG	-92.8 ± 34.0	-109.2 ± 24.6	- 57.1 ± 16.3	-92.8 ± 20.9
MEP	p	0.178	0.005	0.37	0.23
	CG	96.6 ± 29.6	95.4 ± 29.0	75.8± 27.4	99.1 ± 24.2
	IG	112.1 ± 27.2	127.8± 25.1	86.0±29.7	113.5 ± 33.6
MVV (L/min)	p	0.898	0.042	0.595	0.668
	CG	75.64±11.02	75.96±11.0	63.06±10.41	77.30±8.82
	IG	76.28±13.89	85.67±9.3	65.81±14.82	79.17±12.44
PEF (L/sec)	p	0.68	0.63	0.58	0.883
	CG	381.66±160.84	386.66±159.5	5.81±3.32	383.33±157
	IG	405.0±127	413.57±122.51	5.21±2.23	390.71±91.52

Continuous variables are reported as mean ± standard deviation. p<0.05.
Pre: preoperative; PO30: postoperative day 30; MIP: maximal inspiratory pressure; MEP: maximal expiratory pressur
MVV: maximal voluntary ventilation, PEF: peak expiratory flow.

Discussion

The reduction in respiratory muscle strength after surgical procedures has been associated with decreased functional capacity and contributes to delayed recovery of lung function and loss of fitness, which can persist for many weeks. Respiratory repercussions also cause alterations in respiratory muscle strength, as well as changes in lung volume and capacity, alveolar dysfunction, central respiratory depression, and mechanical disturbances of chest function[9-10].

In the present study, a significant increase of MIP and MEP was observed in the group undergoing preoperative IMT, but this increase of muscle strength did not result in satisfactory MIP or MEP values during the postoperative period nor did it influence the recovery of the patients. These results might be explained by the important nutritional deficit of these patients. A training period longer than that employed in this study would be necessary to obtain a more effective gain in respiratory muscle strength[11]. In the study of Morano et al.[12], the load was increased progressively until reaching 60% MIP. However, the training performed probably has not interfered negatively with the results obtained since high-intensity IMT seems to be more effective than low-intensity training.

In the present study, all patients received written instructions (explanatory leaflets) about the exercises to be performed at home after the first preoperative assessment. In addition to the exercise leaflets, patients of IG received a Threshold IMT to perform the proposed treatment at home. The fact that the patients performed the exercises at home without professional monitoring to prove their correct daily use may have favored the occurrence of unsatisfactory postoperative results.

The MVV reflects the degree of cooperation and voluntary effort of the patient, airway patency, and the capacity of the diaphragm and of the other respiratory muscles to expand the lungs during increased demand for a given period of time[13]. In the present study, a significant difference in MVV was observed in patients of IG after preoperative IMT when compared to CG. The positive effects of IMT on pulmonary ventilation have been demonstrated in 30 patients submitted to preoperative training at 40% MIP, five times per day. Although preoperative IMT had no apparent clinical benefits, it significantly increased ventilatory function demonstrated by an increase in forced vital capacity and MVV[14].

The PEF can be used as a measure of airway patency and coughing effectiveness. In addition, impaired coughing ability can lead to the accumulation of pulmonary secretions, which can increase the risk of postoperative pulmonary complications[15]. The reduction in PEF indicates interference with respiratory mechanics through a decrease in muscle strength and in the range of motion secondary to surgical trauma. No significant difference in PEF was observed in the patients of IG after IMT when compared to CG. Our results agree with those reported by Rodrigues da Cunha et al.[16] who found no difference in pulmonary function between the first and second assessment in either group, indicating that preoperative IMT for 2 weeks does not alter these variables.

In the present study, pain may have been another relevant factor that influenced the unsatisfactory postoperative results. Although we did not evaluate this parameter, pain is an important indicator to estimate physical and psychological losses as well as functional recovery of patients since prolonged painful stimuli cause suffering and affect the capacity to cough, breathe and move properly[17].

Malnutrition has important clinical consequences for the respiratory muscles of patients with esophageal disorders, including muscle weakness, respiratory insufficiency, decreased effort tolerance, difficulty weaning from mechanical ventilation, and postoperative complications[18]. In the present study, no significant difference was observed between the two groups in the occurrence of the pulmonary complications evaluated. Hulzebos et al.[19] demonstrated that submitting high-risk patients scheduled for elective myocardial revascularization surgery to intensive IMT with a linear load device at 30% MIP significantly reduced the risk of pulmonary complications. It is worth mentioning that these are surgeries with different approaches in terms of the surgical approach and clinical representation.

Limitations of the present study include the small number of participants and the fact that the exercises were performed at home without professional monitoring to prove their correct and daily use.

Conclusions

The protocol used in our study applying the TMI improved inspiratory and expiratory muscle strength and ventilatory function during the preoperative period, but these results were not satisfactory to improve the postoperative evolution of the patients. Further studies addressing the importance of supervision by a professional, nutritional support as well as the time, frequency and load that would be most effective for preoperative IMT in patients with esophageal disorders are necessary in order to contribute to more satisfactory outcomes after IMT, with benefits that reaffirm the importance of this therapeutic intervention during the preoperative period for preventing pulmonary complications after esophagectomy.

Acknoledgements

Study carried out at the University Hospital of the Federal University of Triângulo Mineiro (HC-UFTM), Uberaba (MG), Brazil.

Author contributions

Rodrigues da Cunha FMR participated in the conception of the project, the writing of the article and the critical review of its intellectual content. Borges MC participated in the writing of the article, analysis and interpretation of data and critical review of its intellectual content. Carvalho FA participated in data analysis and interpretation, project design and critical review of its intellectual content. Volpe MS participated in the project design and critical review of its intellectual content. Rodrigues Júnior V performed the statistical analysis of the results and performed the analysis and interpretation of the data. Crema E performed the critical analysis of the content, participated in the design of the project and performed the surgical procedures.

Competing interests

No financial, legal or political competing interests with third parties (government, commercial, private foundation, etc.) were disclosed for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.).

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