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Effect of inspiratory muscle training on patients undergoing bariatric surgery: a systematic review

Efeito do treinamento muscular inspiratório em pacientes submetidos à cirurgia bariátrica: uma revisão sistemática

Resultados del entrenamiento muscular inspiratorio en pacientes sometidos a la cirugía bariátrica: revisión sistemática

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ABSTRACT | Studies have shown that among the various techniques that involve chest physical therapy, the inspiratory muscle training (IMT) is essential in the recovery of lung function and in preventing respiratory complications. However, the effect of IMT on patients undergoing bariatric surgery is still inconclusive. The aim of this study was to systematically review randomized and controlled trials that assessed the effect of IMT compared with sham IMT, standard physical therapy (breathing exercises and early ambulation) or no intervention in the lung function on patients undergoing bariatric surgery. The search was conducted in PubMed/MEDLINE, Cochrane, TRIP, PEDro and Scopus databases with no publication year or language limits, following the preferred reporting items for systematic reviews and meta-analyses (PRISMA) statement. Two reviewers independently selected the studies, extracted the data, and assessed the risk of bias. From 2,184 potentially eligible studies, two studies were included. Bias risk criteria were adapted and divided into nine main areas using the Cochrane Handbook. This review included 62 participants, being 30 allocated to receive Threshold® IMT device, but in different periods: preoperative and postoperative. IMT promoted increased maximal inspiratory pressure (MIP) in relation to standard physical therapy, but no significant differences were found in maximal expiratory pressure (MEP). The studies showed low and unclear bias risk. IMT seems to be the most effective treatment in comparison with standard physical therapy alone in pre- or postoperative period. However, there is no solid evidence for clinical decision-making.

Keywords | Breathing Exercises; Bariatric Surgery; Clinical Trial, Review.

RESUMO | Estudos têm demonstrado que, dentre as diversas técnicas que envolvem a fisioterapia respiratória, o treinamento muscular inspiratório (TMI) é essencial na recuperação da função pulmonar e na prevenção de complicações respiratórias. Porém, o efeito do TMI em pacientes submetidos à cirurgia bariátrica ainda é inconclusivo. O objetivo deste estudo foi revisar sistematicamente ensaios clínicos randomizados que avaliaram o efeito do TMI em comparação a TMI sham, fisioterapia convencional (exercícios respiratórios e deambulação precoce) ou nenhuma intervenção na função pulmonar em pacientes submetidos à cirurgia bariátrica. A estratégia de busca foi realizada nas bases de dados PubMed / MEDLINE, Cochrane, TRIP, PEDro e Scopus sem restrição de ano de publicação ou de idioma, conforme a recomendação PRISMA. Dois revisores selecionaram os estudos, extraíram os dados e avaliaram o risco de viés de forma independente. Dos 2.184 estudos potencialmente elegíveis, 2 foram incluídos. O critério do risco de viés foi adaptado e dividido em 9 áreas usando o Handbook da Cochrane. Esta revisão incluiu 62 participantes, sendo 30 alocados para receber dispositivo Threshold® TMI, mas em diferentes períodos, pré-operatório e pós-operatório.

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O TMI promoveu aumento da pressão inspiratória máxima (PIM) em relação à fisioterapia convencional, mas não foram encontradas diferenças significativas na pressão expiratória máxima (PEM). Os estudos apresentaram baixo e incerto risco de viés. O TMI parece ser o tratamento mais eficaz em comparação à fisioterapia convencional isolada tanto no pré quanto no pós-operatório. No entanto, não há nenhuma evidência sólida para a tomada de decisões clínicas.
Descritores | Exercícios Respiratórios; Cirurgia Bariátrica; Ensaio Clínico, Revisão.

RESUMEN | Investigaciones comprobaron que, entre las varias técnicas relacionadas a la fisioterapia respiratoria, el entrenamiento muscular inspiratorio (TMI) es fundamental para la recuperación de la función pulmonar y en la prevención de complicaciones respiratorias. Pero poco se sabe sobre los resultados del TMI en pacientes sometidos a la cirugía bariátrica. El propósito de este estudio es revisar sistemáticamente los estudios clínicos aleatorios que evaluaron los resultados del TMI comparado al TMI sham, fisioterapia convencional (ejercicios respiratorios y deambulación precoz) o ninguna intervención en la función pulmonar en pacientes sometidos a la cirugía bariátrica. Se buscó textos en las bases de datos PubMed / MEDLINE, Cochrane, TRIP, PEDro y Scopus, sin restricción de fecha de publicación ni de idioma según recomienda la PRISMA. Dos revisores eligieron los estudios, recolectaron datos y evaluaron el riesgo de sesgo de forma independiente. De los 2.184 estudios probablemente elegidos, se excluyeron dos. Se adaptó el criterio de riesgo de sesgo y lo dividió en nueve áreas empleando el Manual de Cochrane. En esta revisión participaron 62 personas, siendo 30 de ellas elegidas para recibir el dispositivo Threshold® TMI, pero en momentos distintos, en el preoperatorio y el posoperatorio. A pesar de que el TMI aumentó la presión inspiratoria máxima (PIM) en relación a la fisioterapia convencional, en la presión espiratoria máxima (PEM) no se encontraron diferencias significativas. Los estudios presentaron bajo e incierto riesgo de sesgo. El TMI puede ser el tratamiento más eficaz en comparación con la fisioterapia convencional aislada tanto en el preoperatorio como en el posoperatorio. Pero no se encontraron evidencias concretas en la toma de decisiones clínicas.
Palabras clave | Ejercicios Respiratorios; Cirugía Bariátrica; Ensayo Clínico; Revisión.

INTRODUCTION

Obesity is a severe health problem worldwide[1,2] and can be considered as the epidemy of XXI century[3]. It is characterized by excessive fat accumulation on adipose tissue caused by an imbalance between energy intake and energy expenditure, contributing to several chronic diseases such as dyslipidemia, diabetes[4], hypertension, coronary heart disease[5], obstructive sleep apnea syndrome[6] and also increased mortality[7]. Despite the greater governmental and public health attention over the last decades on dietary and exercise interventions, the proportion of obese population has increased every year[8].

Morbid or severe obese patients frequently develop alterations in body mechanisms, especially in the respiratory system, including interference in the respiratory function, decreased pulmonary volumes and capacities[9–13] mechanical compression of the diaphragm, lungs and of the chest cavity[14], reduced compliance and increased pulmonary resistance[10,15,16] besides reduced respiratory muscle strength[10,17,18]. Thus, due to chest and abdomen fat excess, the morbid obesity has effects on lung function, which leads to a mechanical disadvantage and influences the strength of respiratory muscles[17]. Furthermore, it can reduce respiratory well-being, even in the absence of specific respiratory disease, and may exaggerate the effects of existing airway disease[19].

Some studies have shown the relationship between morbid obesity and reduced respiratory muscle strength[17,20], but there is no consensus on this condition. In addition, patients undergoing gastroplasty showed a reduction in lung volumes and pulmonary capacities, and also in respiratory muscle strength in the first and third day after surgery[12]. Therefore, the analysis of respiratory muscle strength parameters becomes relevant in individuals with morbid obesity and candidates for surgery, considering that through this it is possible to determine the degree of muscle strength impairment and, if necessary, to indicate respiratory muscle training[17].

The treatment with bariatric surgery for these patients is more effective than compared with non-surgical interventions[21]. Even though the innumerous benefits of the surgical procedure, such as the reduction of body weight and improvement of quality of life[22], important clinical and functional effects are triggered by the surgery on the pulmonary function[23], increasing existing respiratory changes in this profile of patients.

In this sense, among the various techniques that involve chest physical therapy, the inspiratory muscle training (IMT) is essential in the recovery of lung function and in preventing respiratory complications[24–27].

Randomized controlled trials have shown the effects of IMT on the inspiratory muscle strength and endurance in several diseases and demonstrated that this technique provides improvement in the peak oxygen consumption, quality of life and dyspnea[24,25], and also reduces postoperative atelectasis, pneumonia and length of hospital stay[28]. Moreover, the use of IMT in patients undergoing bariatric surgery has been investigated in recent studies[18,26,27], but the real effect of IMT in this population profile is still inconclusive. A recent systematic review observed postoperative outcomes following preoperative IMT in patients undergoing cardiothoracic or upper abdominal surgery and demonstrated that preoperative IMT significantly improves respiratory function in the early postoperative period, halving the risk of pulmonary complications[29]. Therefore, systematic reviews specifically related to bariatric surgery may provide a more accurate perspective on the current evidence concerning the effects of preoperative and postoperative IMT on lung function in patients undergoing bariatric surgery.

The aim of this study was to systematically review randomized controlled trials that assessed the effect of IMT compared with sham IMT, standard physical therapy (breathing exercise and early ambulation) or no intervention on the lung function in patients undergoing bariatric surgery. The research question was as follows: Is the use of IMT more effective than sham IMT, standard physical therapy or no intervention in the improving of the lung function in patients undergoing bariatric surgery?

METHODOLOGY

This systematic review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement[30] and recorded in International Prospective Register of Systematic Review (PROSPERO) – CRD42016038810.

Search Strategy and Selection Criteria

A comprehensive literature search was undertaken through PubMed/MEDLINE, Cochrane Central Register of Controlled Trials (CENTRAL), TRIP, Physiotherapy Evidence Database (PEDro) and Scopus databases to identify literature up to August 2016, which evaluated the effect of the IMT on the lung function in patients undergoing bariatric surgery. In order to retrieve all relevant papers, two reviewers (ATD and TDS) screened the reference lists of the included papers and their related reviews. The search was conducted with no publication year or language limits. The subject search used a combination of controlled vocabulary and text words based on the search strategy for the PubMed/MEDLINE database as follows:

((((((“Gastric Bypass”[Mesh] OR “Bypass, Gastric” OR “Roux-en-Y Gastric Bypass” OR “Bypass, Roux-en-Y Gastric” OR “Gastric Bypass, Roux-en-Y” OR “Roux en Y Gastric Bypass” OR “Greenville Gastric Bypass” OR “Gastric Bypass, Greenville” OR “Gastroileal Bypass” OR “Bypass, Gastroileal” OR “Gastrojejunostomy” OR “Gastrojejunostomies” OR “gastroplasty”))) OR ((“Bariatric Surgery”[Mesh] OR “Surgeries, Bariatric” OR “Surgery’, Bariatric” OR “Bariatric Surgical Procedures” OR “Bariatric Surgical Procedure” OR “Procedure, Bariatric Surgical” OR “Procedures, Bariatric Surgical” OR “Surgical Procedure, Bariatric” OR “Surgical Procedures, Bariatric” OR “Bariatric Surgeries” OR “Metabolic Surgery” OR “Metabolic Surgeries” OR “Surgeries, Metabolic” OR “Surgery, Metabolic” OR “Stomach Stapling” OR “Stapling, Stomach”))) AND ((“physiotherapy*” OR “respiratory physiotherapy” OR “chest physiotherapy” OR “respiratory physical therapy” OR “chest physical therapy”))) OR ((“Breathing Exercises”[Mesh] OR “Exercise, Breathing” OR “Respiratory Muscle Training” OR “Muscle Training, Respiratory” OR “Training, Respiratory Muscle” OR “inspiratory muscle training”))) AND (((((clinical[Title/Abstract] AND trial[Title/Abstract]) OR clinical trials as topic[MeSH Terms] OR clinical trial[Publication Type] OR random*[Title/Abstract] OR random allocation[MeSH Terms] OR therapeutic use[MeSH Subheading]))))). A sensitive search strategy was adapted for the other databases.

To reduce publication bias, unpublished documents were pursued through Clinical Trials (website). The results of the searches of various databases were cross-checked in order to locate and eliminate duplicates. The same reviewers (ATD and TDS) independently assessed the identified publications and selected them by title and abstract based on the following inclusion criteria: randomized controlled trials (RCTs) that used IMT as a preoperative or a postoperative treatment method in obese adult patients undergoing bariatric surgery. When only a relevant title without a listed abstract was available, a full copy of the article was assessed for evaluation. The reviewers were previously trained and calibrated for articles selection.

The final decision about inclusion was made based on the full-text article of the potentially relevant studies in accordance with exclusion criteria: (1) did not present a proper control group (sham IMT, standard physical therapy or no intervention); (2) did not include obese adults with age ≥18 years; (3) had non-random allocation of subjects; (4) IMT associated with other respiratory technique; (5) absence of similar follow-up for subjects of both groups evaluated in the same way; and (6) did not assess lung function as outcome.

Data extraction

A protocol for data extraction was defined. Two reviewers (ATD and TDS) independently collected the data of the eligible studies. For each study the following data were systematically extracted: publication details (author, year and country), study methodology (outcomes assessed, sample characterization and size, type of bariatric surgery, description of the intervention and comparison groups) and outcome information (mean and standard deviations).

Assessment of bias risk

Bias risk in included studies (Kappa = 1.00) was assessed using the specific study-design-related risk of bias assessment forms (Cochrane Handbook for Systematic Reviews of Interventions 5.0.1)[31]. The criteria were adapted and divided into nine main domains related to randomization; allocation concealment; blinding of operator(s), subjects and examiner(s); sample calculation; differential losses between groups; selective reporting; and balance of groups. The evaluation of the studies was performed by rating each of the study criteria as "yes" (low bias risk), "no" (high bias risk) or "unclear" (no information or uncertainty over the potential for bias).

RESULTS

The search strategy identified 2,184 potentially relevant records, excluding duplicates. After screening titles and abstracts, we retrieved three full-text articles for more detailed information. One study was excluded because it associated IMT with incentive spirometry. Finally, two studies met the inclusion criteria and were considered in this systematic review. Flow diagram summarizes the process of studies selection and the reasons for exclusions (Figure 1).

The main characteristics of the articles included in the systematic review are summarized in Table 1. Both included studies were published in English in 2011, and were developed in Brazil. This review included 62 participants, of which 30 were allocated to receive Threshold® IMT device, but at different periods, preoperative[26] and postoperative[18]. The IMT group was compared with standard physiotherapy. Only patients presenting body mass index (BMI) between 35 and 60 kg/m^2 were included in the studies and all were undergoing the same surgery Roux-en-Y gastric bypass.

Pulmonary function was measured using a calibrated manovacuometer (± 300cmH_2O), which evaluated maximal inspiratory pressure (MIP) and maximal expiratory pressure (MEP), and by conventional spirometry, which had different parameters analyzed in each study. Spirometry parameters evaluated in both studies were forced vital capacity (FVC) and forced expiratory volume in 1 s (FEV_1). Moreover, different outcomes were investigated as diaphragmatic excursion[26] and respiratory muscle endurance[18].

Different protocols of IMT were used in the included studies. The type of training load used in the preoperative period was 30% of MIP as initial charge with an increase in each supervised session[26], while in the postoperative period the training load was 40% of MIP. The number of training sessions was also varied. In one study, the IMT was performed for 2-4 weeks prior to surgery, consisting of a daily session with duration of 25 min, six times a week (two sessions supervised and four unsupervised)[26]. In the other study[18], the training was conducted from the 2nd postoperative day to the 30th day, involving two training sessions of 20 min each during the period of hospitalization and 30 min once a day in the physical therapy clinic after discharge.

In both studies, IMT promoted increased MIP in relation to control group, but no significant differences were found in maximal MEP[18,26]. The preoperative IMT significantly increased the inspiratory muscle strength and attenuated the negative postoperative effects. There was a decrease of 28% in the IMT group, whereas it was 47% in the control group during postoperative period. The IMT protocol in the 30th postoperative day promoted an increase of 13% on MIP and the mean muscular endurance was significantly higher than in the preoperative value. Conversely, MIP of the control group had a reduction of 8% and muscular endurance did not show substantial changes.

The diaphragmatic excursion did not demonstrate any significant change with the preoperative training[26]. However, progressive improvement of the muscular endurance was found when IMT was applied in preoperative period[18].

Considering the lung volumes and capacities, only the expiratory reserve volume (ERV) remained stable, and the others showed similar reduction in the postoperative period in both groups[26]. A faster recovery in the IMT group was observed on the 7th postoperative day in the spirometric parameters (FEV_1, PEF and FEF 25-75%) while that occured only in the 14th postoperative day for control group[18].

The two studies showed low[15] and unclear[24] risk of bias. Results are described in Table 2, according to the parameters considered in the analysis.

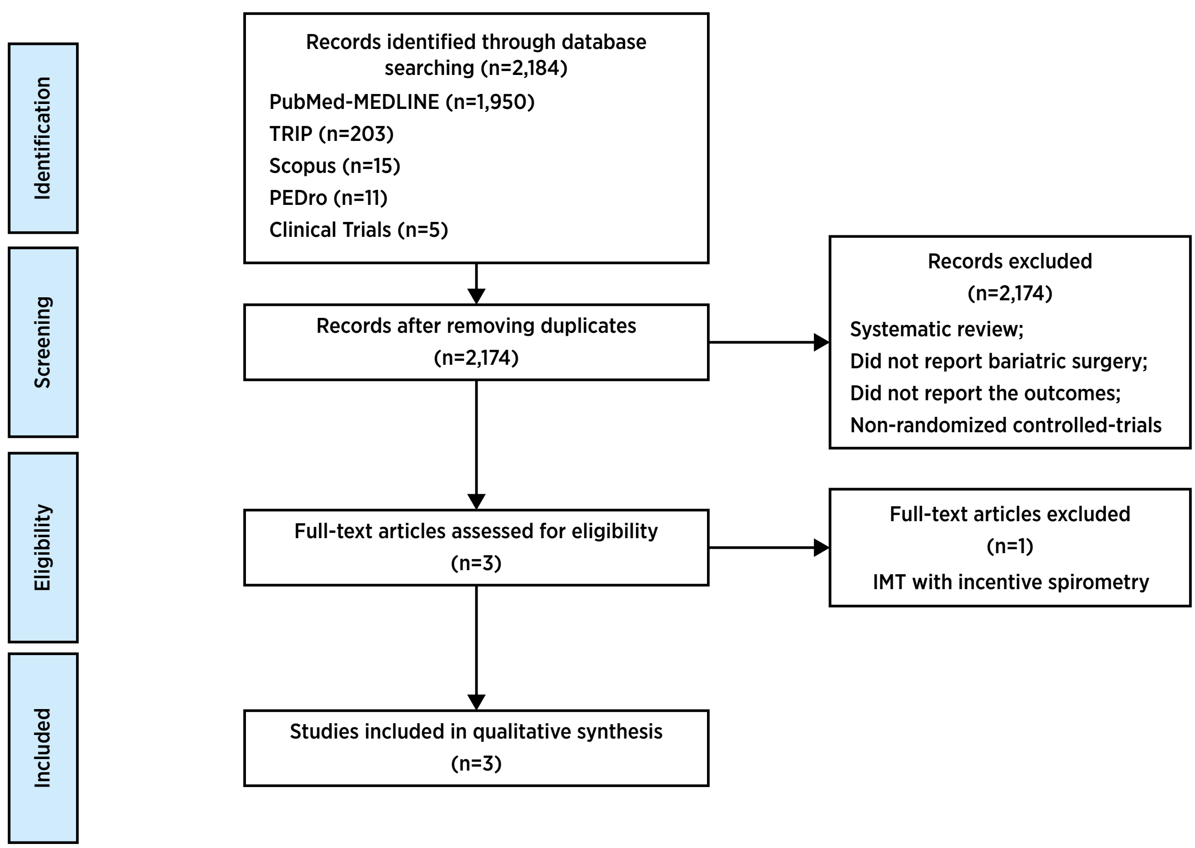

Figure 1. Flow diagram

Table 1. Characteristics of the studies included in the systematic review

Author - Year- Country	Outcomes	Participants	Surgical data	Intervention
Barbalho- Moulim et al.[24] 2011, Brazil	– Respiratory muscle strength; – Lung volumes; and diaphragmatic excursion.	– Mean age (years): CG: 34.8±9.47; GI: 36.13±8.12 – Gender woman: CG: 17; IG: 15 – BMI (Kg/m^2): CG: 42.10±2,98; IG: 41.55±4.74 – Comorbidities: CG: Hypertension (n=7), Diabetes mellitus (n=3) Dyslipidemia (n=2) IG: Hypertension (n=9), Diabetes mellitus (n=3) Dyslipidemia (n=2)	– Type of surgery: Open Roux-en-Y gastric bypass – Duration of anesthesia (min) CG: 176.47±23.89; IG: 185.33±28.06 Hospital stay (days): CG: 2.11±0.33; IG: 2±0	CG: – Preoperative: no intervention; – Postoperative: standard physical therapy (diaphragmatic breathing, incentive spirometry, assisted cough, circulatory exercises and early ambulation). IG: – Preoperative: training consisted of one daily session that lasted 15 min, six times per week. The initial load was calculated at 30% MIP, recalculated after a new measure of this variable at each visit to the physical therapist. – Postoperative: standard physical therapy. Period: Preoperative assessment **(T1)**; Intervention **(T2)** training was performed 2-4 weeks before the surgery; Postoperative assessment **(T3)** Evaluated on the first postoperative day.
Casali, et al.[15] 2011, Brazil	– Respiratory muscle strength and endurance	– Mean age (years): CG: 35.1±10.7; IG: 37.6±10.9 – Gender: CG: 11 woman - 4 men; IG: 11 woman - 4 men. – Initial BMI (Kg/m^2): CG: 43.6±3.9; IG: 42.8±4.2 – Final BMI (Kg/m^2): CG: 39.7±3.7; IG: 37.8±4.6	– Type of surgery: Open Roux-en-Y gastric bypass surgery – Duration of anesthesia (min) CG: 272.7±22.9; IG:278.3±20.5 – Hospital stay (days): CG: 5.3±0.5; IG: 5.4±0.5	CG: – Postoperative: Standard physical therapy (diaphragmatic breathing, sustained maximal inspiration, and timely inhaling of air in three steps and early deambulation). The load was adjusted to zero (sham). IG: – Postoperative: Standard physical therapy. Threshold device to two 20-min training sections during their hospital stay. The patients also performed for 30 min/day, from the 2nd until 30th postoperative day. The load was 40% MIP.

Abbreviations: T1: preoperative; T2: after intervention; T3: postoperative; CG: control group; IG: intervention group

Table 2. Extraction of data on the results

Author	Sample	Significant Results
Barbalho- Moulim et al.[24], Brazil	CG: 17 IG: 15	All values of respiratory muscle strength, lung volumes and diaphragmatic excursion decreased significantly after surgery compared with preoperative ($p<0.05$). In relation MIP (cmH_2O): IG T1: 93.33±23.80; T2: 120.00±20.35; T3: 63.34±21.60 (Difference between T1 and T2: increase of 33%) (Difference between T1 and T3: decrease of 28%) CG T1: 92.94±18.63; T2: 91.76±20.38; T3: 48.82±19.32 (Difference between T1 and T2: decrease of 1%) (Difference between T1 and T3: decrease of 47%) Spirometry measurements – decrease in both groups in postoperative period.
Casali, et al.[15] 2011, Brazil	CG: 15 IG: 15	CG: MIP control group had a reduction of 8% (112.9±25.1 cmH_2O). Muscular endurance, the CG did not show substantial changes. Spirometry measurements - there were significant reductions of all variables, but not FEV1/FVC. Returned to levels similar to preoperative values only at the 14th PO day. IG: MIP was increased by 13% at the 30th PO in the trained group (130.6±22.9 cmH_2O). The mean muscular endurance of IG at 30th PO day was significantly higher than the preoperative value (61.5±39.6 s vs. 114.9±55.2 s). IG reached significantly higher mean MIP values than CG in the days 14 and 30 following surgery. Spirometry measurements - there were significant reductions of all variables, but not FEV_1/FVC. IG group had an earlier recovery of spirometric parameters, with measurements of FEV_1, PEF, and FEF25–75% compared with preoperative levels at the 7th PO day.

Abbreviations: T1: preoperative; T2: after intervention; T3: postoperative; CG: control group; IG: intervention group

DISCUSSION

To our knowledge, this is the first systematic review that assessed the effect of the use of IMT in the improving of the lung function in patients undergoing bariatric surgery. Two randomized controlled trials[18,26] that compared IMT with standard physical therapy were included in this systematic review.

There was a trend of better performance of the IMT in the improving of lung function in patients undergoing bariatric surgery, mainly in the MIP. However, the effect of IMT on lung volumes, diaphragmatic excursion[26], and some parameters on spirometry were uncertain[18] and further investigation is required.

The literature has demonstrated that inspiratory muscle function is inversely related to BMI[32,33]. This correlation is a result of fat tissue excess that favors a mechanical compression of the diaphragm, lungs and chest cavity, resulting in limitation of lung mechanics, which triggers a reduction in respiratory system compliance, increasing of the breathwork, O_2 consumption and also energy expenditure of breath[34]. Thus, obese patients undergoing bariatric surgery have deleterious effects on the respiratory system[19].

IMT is an effective intervention that attenuates inspiratory muscle weakness[24] and it is associated with a reduction of postoperative complications[28]. In this sense, we believe that IMT associated with the standard physical therapy is more effective than isolated standard physical therapy. One of the most important goals of the treatment of patients undergoing surgery is the prevention of pulmonary complications in the postoperative period[35]. Thus, the standard physical therapy is routinely used because of the numerous benefits that it provides. In the study of Casali et al.[18], all patients underwent early ambulation and breathing exercises (diaphragmatic breathing, maximum sustained inspiration, fractionated inspiration in three times). The study conducted by Barbalho-Moulim et al.[26] only reports that all patients daily underwent to respiratory therapy and that it was standardized, but does not describe the techniques that were used. It would be relevant to report that different techniques and resources could influence in our results.

In relation to the training protocols used in both studies, we can notice that they are in line with reports of the literature, that suggest the daily use of low to moderate intensity loading (30-60% MIP)[36], while high-intensity loads have been used on alternate days[37,38]. However, in one study[26] the initial load was calculated at 30% MIP, and recalculated after new measurement at each visit to the physical therapist, while in the other[18], the load was adjusted to 40% MIP without increasing.

Although the period of protocols of application were different (pre- and postoperative periods) in the studies, we could notice that IMT significantly improved MIP compared with the control group. In both studies[15,24], patients submitted to IMT used lower inspiratory load. Despite the significant improvement, we believe that the increased IMT intensity could result in greater gains in the assessed outcomes, since one of the basic properties of muscle training is periodic changes in the nature of the training stimulus[39,40].

The limitation of the diaphragmatic mobility and costal movement can be observed in obese subjects due to structural changes present in the thoracic-abdominal area affecting the proper mechanical ventilation. In this context, the evaluation of diaphragmatic mobility becomes important in obese patients. In one of the included studies in this systematic review[26], the mensuration of diaphragmatic mobility was evaluated by chest X-ray. Nonetheless, even with the development of inspiratory muscle strength, no significant changes were observed in this outcome. It is possible that the method of measurement used (chest X-ray) in the included study[26] had not been sensitive enough to detect changes as gold standard method (fluoroscopy)[41].

Morbidly obese patients show an increased risk of hypoxemia during the postoperative period[42], which can cause higher incidence of postoperative pulmonary complications and increased length of hospital stay, which reflects in higher healthcare costs. As reported in the included studies[18,26] despite the strength gains generated by IMT, there were no significant differences in length of hospital stay when compared with individuals who did not undergo training. In addition, the study that used the IMT preoperatively showed no differences between the groups regarding postoperative pulmonary complications. Thus, these results can influence on decision-making regarding the use of IMT, once this procedure has a high cost. However, studies investigating the cost-effectiveness are necessary because they make possible the guidance of professional's choice.

Several tools for the assessment of study quality have been developed. These tools take several forms such as checklists[43], scales[44], and domain-based assessments[31]. In weighing the strengths and limitations of these approaches, some researchers consider the domain-based approach to be the most comprehensive[45]. In this systematic review, study quality was assessed using nine domain-based criteria, and most items (55.6%) were classified as showing a low risk of bias, considering important parameters suggested by the CONSORT guidelines such as randomization and differential losses between groups. Unclear risk of bias was found for selective reporting in both studies. The sample size was similar in both studies; however, the calculation of the sample size was described only by one study[26].

Therefore, it is important to highlight that overall findings should be interpreted with caution because the systematic review had some limitations. The small number of included studies even using proper and broad search, and the assessment of the outcome in different moments did not enable undertaking the meta-analysis. Consensus on the IMT protocol remains lacking. It is likely that the findings may have been influenced by the publication bias, as negative or similar results were probably not published or were published in low impact factor journals. A lack of reliable studies investigating the outcome of interest can also explain the absence of evidence concerning this topic, considering the difficulties of developing clinical trials with this sample in the hospital environment.

Based on these aspects, there is a need for further randomized controlled clinical investigations comparing IMT with sham IMT, standard physical therapy (breathing exercise and early ambulation) or no intervention on the lung function in patients undergoing bariatric surgery, using standardized methodology for evaluating the success of the treatments to confirm or reject the trend of superiority of IMT that was observed in the current review. Moreover, future studies should consider other relevant outcomes such as functional capacity, postoperative pulmonary complications and quality of life.

Table 3. Quality and risk bias of the included studies

Study	Randomization	Allocation concealment	Blinding of operator(s)	Blinding of subjects	Blinding of examiner(s)	Sample calculation	Differential losses between groups	Selective reporting	Balance of groups
Barbalho-Moulim et al.[24]	Yes	Yes	Unclear	Unclear	Unclear	Yes	Yes	Unclear	No
Casali et al.[15]	Yes	Unclear	Yes	Yes	Yes	No	Yes	Unclear	Yes

"Yes" (low bias risk), "no" (high bias risk) or "unclear" (no information or uncertainty over the potential for bias).

CONCLUSION

The IMT increased maximal inspiratory pressure in patients undergoing bariatric surgery in pre- or postoperative period, showing that IMT seems to be the most effective treatment in comparison with standard physical therapy alone. However, there is no solid evidence for clinical decision-making.

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