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EFEITO DO TREINAMENTO MUSCULAR INSPIRATÓRIO NA PREVENÇÃO E TRATAMENTO DE COMPLICAÇÕES EM PACIENTES HOSPITALIZADOS

DISSERTAÇÃO DE MESTRADO

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Dissertação apresentada ao Programa de Pós-graduação em Medicina e Saúde, da Faculdade de Medicina da Bahia, Universidade Federal da Bahia, como requisito para a obtenção do grau de Mestre em Medicina e Saúde.

Orientador: Profº. Drº Mansueto Gomes Neto.

Salvador

2015

DEDICATÓRIA

Dedico está conquista a minha família e amigos que serviram como escada para que tudo fosse possível. À vocês, meu muito obrigado

SUMÁRIO

LISTAS DE ABREVIATURAS E SIGLAS

ECR	Ensaio clínico randomizado
IB	Indice de Barthel
IC95%	Intervalo de confiança de 95%
PEDRO	*Physiotherapy Evidence Database*
PIMAX	Pressão inspiratória máxima
RR	Risco relativo
SDRA	Síndrome da deficiência respiratória aguda
TMI	Treinamento muscular inspiratório
VM	Ventilação mecânica

1. RESUMO EM PORTUGUÊS E INGLÊS

RESUMO

Objetivo: Investigar a eficácia e segurança do treinamento muscular inspiratório (TMI) na prevenção e tratamento de complicações em pacientes com hospitalização prolongada. **Métodos**: Esse trabalho foi realizado em duas etapas. A primeira se deu através de uma revisão sistemática acerca da carga, freqüência e periodicidade da treinamento muscular inspiratório em atletas, população pioneira no emprego dessa terapia nos moldes da presente dissertação. A etapa seguinte, consistiu em um ensaio clínico randomizado, triplo cego, comparando TMI associada a fisioterapia com grupo SHAM para TMI e fisioterapia. Antes e após a intervenção, as seguintes mensurações foram realizadas: Força muscular respiratória e periférica, funcionalidade através do índice de Barthel (IB), tempo de internamento hospitalar e óbito. Todos os participantes incluídos foram submetidos a um protocolo de TMI com intensidade de 50% da pressão inspiratória máxima (Pimax), duas vezes ao dia por 4 semanas a partir da sua inclusão no estudo, e acompanhado a ocorrência dos desfechos até alta hospitalar. Durante as sessões de TMI os fisioterapeutas notificaram a ocorrência de evento adverso. **Resultados:** A revisão sistemática demonstrou que os protocolos de aplicação do TMI são semelhantes, adotando carga moderada e freqüência elevada. Sua aplicação melhora a capacidade muscular respiratória, além de incrementar a tolerância do atleta ao exercício. A avaliação da escala *Physiotherapy Evidence Database (*PEDro) demonstrou que os estudos da área apresenta rigor metodológico baixo. Sobre o ensaio clinico randomizado (ECR), foram admitidos 293 pacientes durante período de estudo, destes 54 completaram o protocolo, 26 no grupo TMI e 28 no SHAM. TMI comparado a SHAM resultou em beneficio significativo na força muscular respiratória e funcionalidade e tempo de internamento hospitalar ($p<0,05$). O grupo TMI apresentou menor estadia hospitalar em comparação com o grupo SHAM (35,3 ± 2,7

dias em relação a 41,8 ± 3,5 dias, com p< 0,01). O grupo TMI comparado ao grupo SHAM, foi fator de proteção para intubação (RR= 0,36 IC95% 0,27-0,97), fraqueza muscular (RR= 0,36 IC95% 0,19-0,98) e óbito intra-hospitalar (RR= 0,15 IC95% 0,02-0,79) com p<0,05. **Conclusão:** A adição do TMI à fisioterapia foi segura e resultou em beneficio na força muscular inspiratória, funcionalidade e tempo de internamento hospitalar. O TMI foi fator de proteção para mortalidade, intubação traqueal e fraqueza muscular intra hospitalar.

Registro do Trial : NCT02459444. Registrado em 19 de Maio 2015.

Palavras-chave: Exercícios respiratórios. Músculos respiratórios. Fisioterapia, Reabilitação física.

ABSTRACT

Objective: Investigate the efficacy and safety of inspiratory muscle training (IMT) in the prevention and treatment of complications in patients experiencing prolonged ward hospitalization. **Methods:** This study is made in two stages. The first was through a systematic review about the load, frequency and frequency of IMR in athletes, population pioneered the use of this therapy along the lines of this dissertation. The next step consisted of a randomized clinical trial, triple blind, comparing TMI associated with physiotherapy with SHAM group TMI and physiotherapy. Before and after the intervention, the following measurements were performed: peripheral and respiratory muscle strength, functionality through the IB, hospital stay and death. All participants included underwent a TMI protocol with intensity of 50% of MIP, twice daily for 4 weeks from its inclusion in the study, and accompanied by the occurrence of hospital outcomes. During the TMI sessions physiotherapists notified the occurrence of adverse events. **Results:** A systematic review showed that TMI's application protocols are quite similar, adopting moderate load and high frequency. Its application improves respiratory muscle strength, as well as enhancing tolerance

athlete to exercise. The evaluation of the PEDro scale studies showed that the area has a low methodological rigor. About RCT, 293 patients were admitted during the study period, 54 of these completed the protocol, 26 in the IMT group and 28 in SHAM. TMI compared to SHAM resulted in significant benefit in respiratory muscle strength and functionality and hospital stay ($p < 0.05$). TMI group had shorter hospital stay compared with SHAM group (35.3 ± 2.7 days versus 41.8 ± 3.5 days, $p < 0.01$). The IMT group compared to SHAM group, it was a protective factor for intubation (RR = 0.36 95% CI 0.27 to 0.97), muscle weakness (RR = 0.36 95% CI 0.19 to 0.98) and in-hospital death (RR = 0.15 95% CI 0.02 to 0.79) with $p < 0.05$. **Conclusion:** The addition of TMI to physical therapy was safe and resulted in benefit in inspiratory muscle strength, functionality and hospital stay. The TMI was a protective factor for death, intubation and hospital intra muscular weakness.

Trial registration: NCT02459444. Registered 19 May 2015.

Keywords: Respiratory Muscles, Breathing Exercises, Muscle Weakness, Hospitalization, Length of Stay, Mortality.

2. INTRODUÇÃO

O declínio funcional é um dos principais desfechos negativos durante e após a internação hospitalar em pacientes críticos. Pacientes que desenvolveram a síndrome do desconforto respiratório agudo (SDRA), por exemplo, mantém graus de limitação funcional e incapacidade para realizar atividades laborais mesmo após cinco anos da hospitalização. A sarcopenia, a polineuropatia do paciente crítico e fraqueza muscular periférica e respiratória são justificativas para essa incapacidade física, por vezes duradoura.

A fraqueza muscular inspiratória é uma complicação frequente do internamento hospitalar prolongado. O mesmo, expõe o sistema respiratório a desequilíbrio entre a demanda ventilatória e sua capacidade em manter a homeostasia do sistema. O comprometimento da troca gasosa proporcionada por esse desequilíbrio por vezes irá convergir com a necessidade do suporte da ventilação mecânica (VM) e a dependência da mesma, se o fator causal da deficiência não for adequadamente tratada. É conhecido que o tempo de internamento hospitalar prolongado, maior que oito dias, é fator independente para aumento da morbimortalidade em pacientes hospitalizados.

Entretanto, esse descondicionamento muscular respiratório pode ser subclínico até o desenvolvimento da falência respiratória. O treinamento muscular inspiratório (TMI) é uma modalidade terapêutica consagrada no ganho da Pimax em diversas populações. A aplicação através de dispositivos que impõem carga aos músculos inspiratórios por um sistema com mola, conhecido como resistor de carga linear é a modalidade mais referida na literatura, vista a fácil reprodutibilidade da terapia, seu baixo custo e a possibilidade em individualizar a carga adequada a cada indivíduo ou objetivo terapêutico.

O TMI adotando cargas elevadas, maior que 50% da pressão inspiratória máxima (Pimax), tem apresentado resultados promissores na função ventilatória e tolerância ao exercício. Sua aplicação foi primeiramente descrito em atletas, observando ganhos significativos na musculatura respiratória, como tam-

bém no desempenho em atividades físicas e esportivas. O racional teórico mais aceito, na atualidade para justificar o ganho à distância, proporcionado pelo TMI, é o da vasoconstricção periférica reflexa, pela privação de oxigênio durante exercícios de grande intensidade, conhecido como metaboreflexo. Segundo esta hipótese, o condicionamento da musculatura respiratória, aumentaria a tolerância ao fator desencadeante, retardando o aparecimento do reflexo, que limita o fluxo sanguíneo destinado aos músculos apendiculares, reduzindo o desempenho físico, poucos instantes após resposta vascular.

O tecido muscular é extremamente sensível a mudanças de demanda físicas, sendo controlada por um complexo sistema auto regulação na produção e degradação proteica. O paciente hospitalizado pode apresentar mudanças adaptativas no tecido muscular durante seu internamento. Estudos prévios demonstram que restrição prolongada ao leito, hipomobilidade, uso de ventilação mecânica controlada, por períodos maiores ou iguais a doze horas, induz proteólise diafragmática. Além disso, mediadores de proteólise chamados *Calpain*, são liberados na presença de respostas inflamatórias sistêmica comum após períodos prolongados de imobilidade. O mesmo é responsável pela ativação da cascata de degradação das proteínas de actina e miosina. Por sua vez, a protease conhecida como *Caspase-3* é ativada por doenças metabólicas sistêmicas, à exemplo das descompensações na diabetes mellitus.

Pacientes com idade maior que 65 anos, presença de duas ou mais comorbidades, sepse, doenças hepáticas, pulmonar e/ou renal, malignidade, VM, uso de vasopressor, terapia de diálise renal tem risco aumentado para internamento hospitalar prolongado e mortalidade no ambiente hospitalar. O desfecho tempo de internamento e seu impacto em complicações e na mortalidade, tem sido cada vez mais encorajados, devido ao efeito devastador do internamento hospitalar prolongado para os pacientes críticos. A mobilização precoce do paciente para fora do leito, tem demonstrado resultados significativos na redução de dano proporcionado pela hospitalização prolongada.

A despeito das evidências supracitadas, o emprego do TMI no ambiente hospitalar, na maioria das vezes é resguardada a reabilitação de deficiências musculares graves, com repercussões funcionais e sistêmicas já instaladas. Por sua vez, são escassas as evidencias do emprego precoce dessa terapêuti-

ca em pacientes hospitalizados, assim como seus benefícios potenciais e a segurança da aplicação dessa técnica em ambiente hospitalar.

Diante da ausência de ensaio clínico randomizado (ECR) aplicando o TMI precocemente em pacientes com internamento hospitalar prolongado, esse trabalho demandou uma revisão sistemática da literatura, possibilitando avaliação do método empregado em atletas. Visto que, para a realização do presente ECR, fez-se necessário compreender melhor os parâmetros de aplicação do método: intensidade; frequência; periodicidade de aplicação. Bem como, levantar possíveis eventos adversos para estabelecer critérios de segurança para aplicação nos pacientes hospitalizados.

3. OBJETIVOS

3.1 GERAL

Investigar a eficácia e segurança do treinamento muscular inspiratório na prevenção e tratamento de complicações em pacientes com hospitalização prolongada.

3.2 ESPECIFICO

Analisar a intensidade, freqüência e periodicidade do TMI, com resistor de carga linear em atletas e inferir seu impacto ventilatório e físico nesta população;

Mensurar o efeito do treinamento inspiratório na pressão inspiratória máxima, força muscular periférica e capacidade funcional de pacientes hospitalizados.

4. ARTIGO DE REVISÃO

4.1. ARTIGO 1

Número de submissão: S0008186

USE OF POWERBREATHE® IN INSPIRATORY MUSCLE TRAINING FOR ATHLETES: SYSTEMATIC REVIEW

UTILIZAÇÃO DO POWERBREATHE® NO TREINAMENTO MUSCULAR INSPIRATÓRIO POR ATLETAS: REVISÃO SISTEMÁTICA

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Abstract

Introduction: Inspiratory muscle training (IMT) has been used as part of athletic training. It is beneficial due to an increase in respiratory capacity, and can be related to the optimization of exercise tolerance. There are a growing number of publications on the subject, however the methodological rigor of these publications is still unknown. **Objective:** To perform a systematic literature review in order to analyze the effects of Powerbreathe® on inspiratory muscle training by athletes. **Materials and methods:** Original scientific studies published in English, from 2000 to 2015, were included. Their typology was classified. The literature search was performed in the Lilacs, Medline, Pubmed, and Scielo databases using the following keywords: inspiratory muscle training, athletes, and Sports medicine (in English), "treinamento muscular inspiratório", "atleta", "medicina esportiva" (in Portuguese). **Results and discussion:** Inspiratory muscle training with specific linear resistance has been used in some athletic training, and its results are promising. However, its application is still recent and generally supported by experiments with limited population and which do not properly define the confounding factors for the results. **Conclusion:** The state of the art suggests that IMT is useful as a respiratory therapy supporting the training of athletes for some specific sports. However, there is a scarcity of studies of high methodological quality, thus requiring further experiments on the subject.

Keywords: Breathing exercises. Respiratory muscles. Athletes. Sports medicine. Motor activity.

Resumo

Introdução: O treinamento muscular inspiratório (TMI) vem sendo utilizado como coadjuvante na preparação do atleta. Seu benefício viria no aumento da capacidade respiratória, podendo estar relacionado com a otimização da tolerância ao exercício. É crescente o número de publicações sobre o assunto, contudo o rigor metodológico destas publicações ainda é desconhecido. **Objetivo:** Realizar uma revisão sistemática da literatura, a fim de analisar os efeitos do Powerbreathe® no treinamento muscular inspiratório por atletas. **Materiais e métodos:** Foram incluídos estudos científicos originais, classificada na sua tipologia, no idioma inglês, publicados entre 2000 e 2015. A busca dos artigos foi realizada nas bases de dados: Lilacs; Medline; Pubmed; Scielo, utilizando os seguintes descritores: treinamento muscular inspiratório, atleta, medicina esportiva (em português), "*inspiratory muscle trainaing*", "*athletes*" e "*Sports medicine*" (em inglês). **Resultados e discussão:** O treinamento muscular inspiratório com resistor linear específico tem sido utilizado na preparação de algumas modalidades esportivas, seus resultados são promissores. Porém, sua aplicação ainda é recente, e em geral embasada por experimentos com população limitada e sem delimitar adequadamente os fatores de confusão para os resultados encontrados. **Conclusão:** O estado da arte sugere que o TMI é útil como terapêutica respiratória coadjuvante à preparação do atleta de algumas modalidades esportivas específicas. Contudo, escassez na literatura de estudos com alta qualidade metodológica, demanda maiores experimentos sobre o tema.

Palavras-chave: Exercícios respiratórios. Músculos respiratórios. Atletas. Medicina esportiva. Atividade física.

Introduction

High-performance athletic training includes numerous variables, all of which have a significant influence on final performance in the sport. (1,2) Physical training is crucial for optimization of exercise performance, either to gain strength and power, or to prevent musculoskeletal injuries. (3,4) Cardiovascular conditioning focuses on maximizing perfusion capacity, thereby preventing lactic acidosis, which knowingly compromises performance. (4,5) However, a forgotten facet is respiratory training. (6,7) Its benefits are associated with a greater supply of oxygen to the tissues, thereby providing a differentiated physical performance. (8-16)

The respiratory system and its regulatory centers control the levels of oxygen (O_2) and carbon dioxide (CO_2), which is released at higher levels in bursts of activity or activity sustained for a long period. (17-19) Recent studies suggest that the inspiratory muscles can interfere in the performance of physical exercise in athletes, precisely because in physically stressful conditions, when the production of free radicals exceeds elimination capacity, a reflex sympathetic reaction of peripheral vasoconstriction would be triggered, leading to early fatigue in skeletal muscles and dramatically reducing performance in this activity. Conditioned muscles, on the other hand, have an increased tolerance, thereby slowing reflex activation. (19-21)

Inspiratory muscle training (IMT) is a therapeutic modality that overcomes resistance against muscles responsible for expanding the rib cage. This effort must be controlled, specific and repeated at regular intervals. Its application has been demonstrated as a viable strategy for optimizing the respiratory capacity, (22-28) thereby allowing this person to always expand his/her physical tolerance to adverse situations during practice. (29-36)

Powerbreathe® is one of the existing linear load resistor models on the market, which generates resistance via a spring-loaded system or an electronic valve. The basic difference between this tool and the others is its ability to offer the largest load during the therapy, and to adapt inspiratory resistance to the pressure x lung volume curve, (13,37) which could generate load stabilization along the breath, by providing a feeling of comfort to the patient. Up until now this concept has a physiological basis.

Currently, a growing amount of evidence on the use of IMT associated with various sports has been published. (22,29-36) However it is necessary to systematically

analyze the methodological rigor of these experiments in order to delimit the real benefit of IMT in athletic training. In addition, knowledge about this therapeutic resource - its indication, dosage and benefits - is still not familiar to most of the scientific community. Thus, the aim of this study is to perform a systematic review of the literature in order to analyze the effects of Powerbreathe® on inspiratory muscle training by athletes.

Materials and methods

This study was a systematic literature review on the use of inspiratory muscle training, using a specific linear resistor by athletes. The study was performed from October of 2013 to March of 2014.

Inclusion criteria

Original scientific studies were included, classified according to their typology as descriptive, experimental or causal-comparative; published between 2000-2015; inspiratory muscle training with Powerbreathe® was a dependent variable in different protocols; athletic training was a dependent variable; various sports were included in their sample; had no athletes using another respiratory therapy in the studies; had a sample characterized by a group combination therapy with sports or an equivalent practice; was clear regarding the samples and the different analyses performed.

Search strategy

Initially these descriptors were established: inspiratory muscle training, athlete, sports medicine, when in the vernacular and in English language, “inspiratory muscle training”, “athletes” and “Sports medicine” (in English), available in Descriptors of Health Sciences (DeCS) and the Medical Subject Headings (MeSH). In order to maximize the search, synonyms were adapted, as well as the related words used in the retrieved papers found previously.

By respecting the operational differences of each database, when possible, we decided to search in the primary fields "Title" or "Keywords" using "or" and "and" as

connectors and the term "athletes" as a limitation. The survey was performed in the following databases: Lilacs, Medline, Pubmed, Scielo.

Selection criteria

Developed by the Physiotherapy Evidence Database, the PEDro scale is a tool that quantifies the methodological quality of randomized clinical trials (RCT), or quasi-randomized studies. It has external validity (criterion 1, not considered), internal validity criteria (2-9, considered) and if there is sufficient statistical analysis in the results of the experiment, this should be considered (criteria 10 and 11) (38-40). Thus, the criteria are classified dichotomously as "satisfied" or "not satisfied", and can have a maximum degree of methodological requirement, reaching a total of ten points.

Although this scale was adopted as a selection tool for this systematic review, considering the inability to blind those responsible for the intervention and the athletes who participated in experiments with IMT, the chosen cutoff point was > 3 (39).

The PEDro scale was also used as a tool for selecting non-experimental studies accepted according to the inclusion criteria. However, these studies needed to meet criteria 1, 10 and 11, at a minimum, to legitimize their potential generalization and interpretation of results (38,40).

The articles identified in the search strategy were evaluated independently and in a blinded fashion by two researchers (BRVNJ and TBG), strictly observing the inclusion criteria. The article selection was initiated using the key words, followed by the article selection according to the titles, which would focus on inspiratory muscle training in association with sports practice. In the next stage, the abstracts of the pre-selected articles were read and studies were included that satisfied the inclusion criteria described above.

Finally, due to the established cutoff point for the selection criteria, the most experienced researcher in this particular topic independently analyzed the experiments.

Results

Eight hundred thirty-six articles were found using the descriptors. After reading the titles, 36 articles remained on the use of the selected linear resistor in athletes. After methodological examination, eight articles were selected that met the established inclusion criteria; two were excluded because they had a PEDro score ≤ 3. Six clinical trials were included in this systematic review. Figure 1 shows the flowchart for article selection.

Study characteristics and quality

The evaluation of methodological quality using the PEDro scale had a mean score of 4.5. (4-5) Table 1 shows details on the methodological and quality evaluation of the studies. Only one study used a third group with IMT association with expiratory muscle training (EMT) in this review (29), and one article was performed outside the United Kingdom (UK). (36) The low quality identified by the PEDro scale signals to the need for further studies with greater methodological rigor.

Eligibility and randomization were implemented in all studies; however, only three of them clearly stipulated how randomization was performed. The therapists were not blinded in any article. Table 2 expresses the intervention protocols applied in each study, as well as the IMT program duration. This table also demonstrates that biking was the sport in 50% of studies, followed by rowing (33.3%), and swimming (16.6% of the studies).

Characteristics of the population included in the studies

The studies used a population of young adults, with a mean age of 22.9±2.8 years. There was gender balance in the studies; three studies included only male athletes, two included male athletes, and *Kilding et al.* (36) included athletes of both genders.

Inspiratory muscle training intervention program

The included articles had a standardized frequency of IMT. All studies used an inspiratory load of approximately 50% of maximal inspiratory pressure (MIP), one series of 30 breaths, repeated twice daily. At the same time, this uniformity did not extend to the time taken to perform the IMT protocols, with a period ranging from four to 11 weeks of training. Four studies, equivalent to 66.6% of the articles, adopted six weeks of IMT associated with sports training.

Measured outcomes

The article search addressing association of concomitant sports training to an IMT protocol suggests benefits to lung capacity, mainly expressed by the improvement of MIP, present in 62.5% of the articles. In addition, referred gains of associated training included reduced perceived exertion during sports practice, measured by the Borg scale. One study (31) found a statistically significant increase in the maximum volume of oxygen ($MaxVO_2$). The improved sports performance in regard to timed activity can also be related to the combination of therapeutic modalities. (Table 3)

Discussion

The use of IMT using a specific linear resistor showed benefits for respiratory capacity. In addition, the reviewed studies suggested that the association between IMT and specific athletic physical training could improve physical performance, when compared to a control group.

The exposure of inspiratory muscles to a training program with controlled and individualized load, repeated regularly, provides gain in sarcomeres, increasing muscle volume and its ability to generate strength. This information is still empirical, based on muscle physiology. However, in line with this reasoning, this review with athletes submitted to IMT led to an improvement in MIP compared to the placebo group, with a gain of between 17-28% in the baseline studies. The heterogeneity between the time taken for the training protocol is a plausible explanation for this variability in the final MIP.

The IMT protocol was useful when comparing the training of athletes in different sports. Swimming, rowing and cycling were the sports that were associated with respiratory training. In these experiments, there was a strong association between the associated program and the improvement in physical performance during the test against the clock. It should be noted that all six studies had small populations, with less than 20 athletes, which is insufficient to rule out possible confounding factors. Studies were found that used IMT with soccer, running and tennis amateurs. (22,34) However, they did not include the aim of this review.

The athletes treated with IMT with a linear load device had a minimized variability of heart rate (HR), respiratory rate (RR) and feeling of dyspnea, as reported by the Borg scale (20,31). These findings suggest that this treatment could improve tolerance during sports practice. *Romer et al.* (31), in studies with cyclists, improved Max-VO_2 following an associated program for six weeks, as compared to a placebo.

Sheel et al. (19), in 2001, reported that inspiratory muscle fatigue activated a sympathetic reflex reaction of peripheral vasoconstriction, which would precipitate limb muscle fatigue during physical activity. This condition was known as metaboreflex. *McConnell and Lomax* (21), in a clinical trial using different IMT protocols associating lower limb (LL) exercises, observed early lower limb fatigue in the group exposed to severe respiratory muscle overload (greater than 70% of MIP). After the TMI protocol, the duration of fatigue with LL physical activity significantly increased.

All six studies included in this systematic review performed intervention protocols with thirty breaths under inspiratory resistance, equivalent to 56% of the MIP, repeated twice, seven days a week. This standardization facilitates comparison between studies and enables the adoption of this protocol in future studies.

Volianitis et al. (30) found an improvement in the six-minute all-out effort test with a rowing ergometer, in a study with rowers. The IMT program associated with ergometry found an improvement of 3.5±1.2% in the distance covered in kilometers in the intervention group, compared with a 1.6±1.0% gain in the placebo group, $p<0.05$. The study by *Griffiths and McConnell* (29), using the same submaximal testing to assess gain between IMT and IMT/EMT groups, found that the IMT group had a mean improvement of 16.2 m in the final distance in kilometers, with $p=0.02$. The benefit was

not evidenced for the IMT/EMT group. The alternating between IMT and EMT, associated with the small sample per group, are the main factors that could explain the lack of gain in the IMT/EMT group.

Of the six studies selected for this systematic review, five were performed in the UK, the place in which Powerbreathe® was created. Only the study by Kilding et al. (36) was performed in New Zealand. This observation could support the small propagation of scientific knowledge about the benefits of IMT for athletes. With regard to the choice of this linear resistor device for this population, it should be noted that the initial MIP of the population under study was 103±7cmH2O. This magnitude, considered high compared to the mean of the general population, would impair the use of other resistors available on the market, since in most cases they have maximum inspiratory load lower than what is therapeutic for this MIP.

With regard to the stratification with the PEDro scale, low methodological rigor was observed, with mean scores between 4 and 5. The similarity between the methods used probably is related to the fact that most of the studies were performed by the same group. Future studies are needed with larger populations that seek to blind investigators and athletes about the performed intervention. Of the eight studies selected as eligible for the review, two were excluded because they had a PEDro score ≤3. This criterion aimed to ensure the quality of evidence analyzed in this review.

Table 3 shows benefits of IMT using linear resistor for athletes. *Kilding et al.*[8] (36) found a reduced swim time for 100m ($p=0.05$) and 200 m ($p=0.032$) after IMT. *Volianitis et al.* (30), in studies with rowers, found an improvement in the 500m rowing time (reduction of 36' 69" in the IMT group *versus* a reduction of 11' 8" in the placebo group, with $p<0.05$). *Romer et al.,* in a study with cyclists, also evidenced an improved duration of 20km and 40km time-trials ($p=0.025$ and 0.0009, respectively). This evidence is encouraging, and explains the need for further studies with larger populations and other sports. Only then will there be consensus for a recommendation to include IMT using a linear resistor in athletic training programs.

Conclusion

This systematic review has shown that the association between IMT and sports training favors the increase in MIP of athletes, but there is also a relationship with the improved performance in timed tests. The identified studies had a low methodological rigor, with small populations, and without the elimination of possible confounding factors. The IMT practice can be used in athletic training. However, it is necessary to eliminate gaps regarding the duration of the protocol, the sports for which it is beneficial, and studies that blind the population exposed to the intervention, thereby enabling elimination of psychological factors associated with the best final performance.

The state of the art suggests that IMT is useful as an associated therapeutic resource in training for some specific sports. However, further studies with larger populations are necessary, which delineate the confounding factors and utilize greater methodological rigor.

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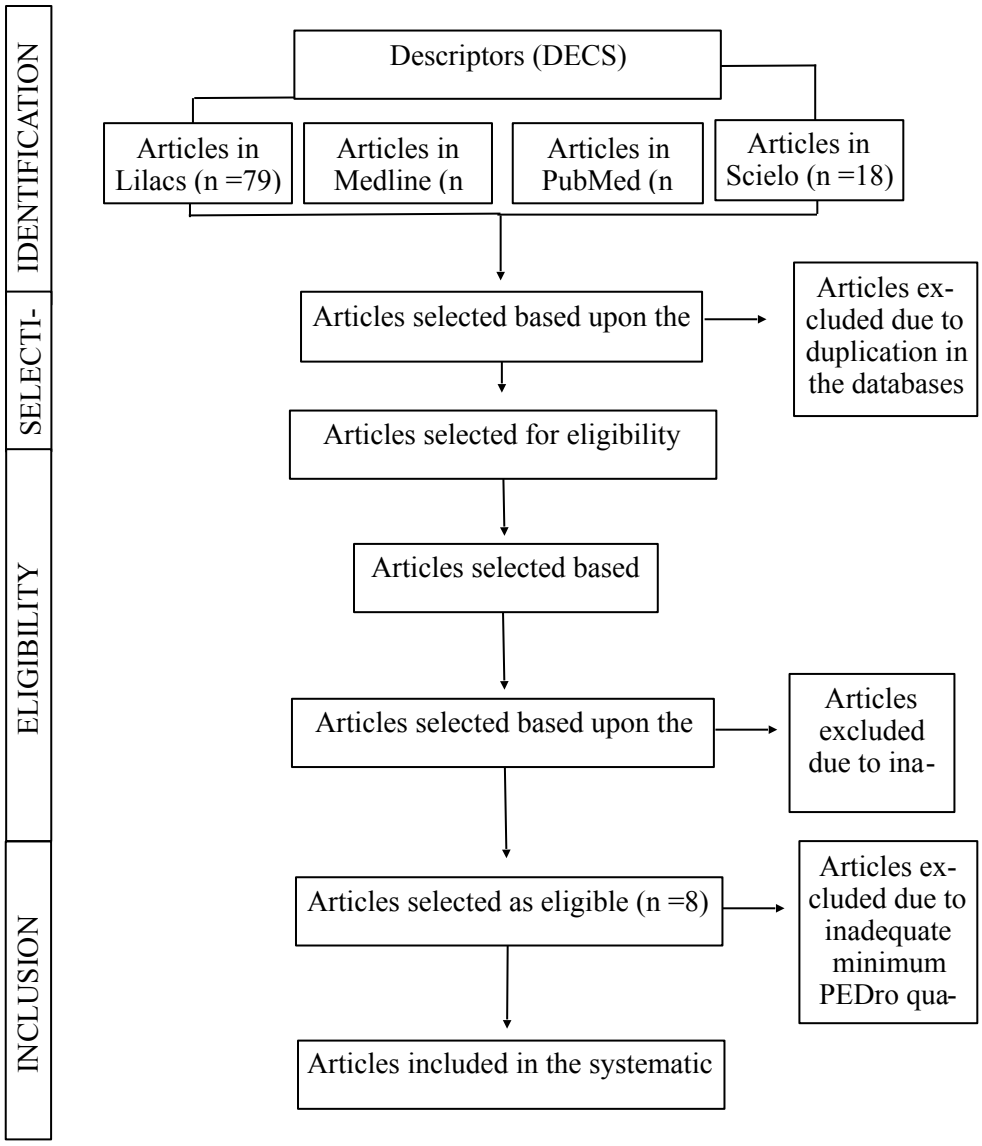

Figure 1: Flowchart of the article selection steps in the systematic review.

Table 1: Stratification of IMT studies in the athlete through the PEDro

Author	Study design	Locality	Program	PEDro scale
Volianitis et al. (30)	Randomized clinical trial	Wolverhampton, UK	IMT with Powerbreathe® + Rowing training	04/10
Romer et al. (31)	Randomized clinical trial	Brunel, UK	IMT with Powerbreathe® + Cycle ergometer training	05/10
Romer and McConnell. (32)	Randomized clinical trial	Brunel, UK	IMT with Powerbreathe® + Cycle ergometer training	05/10
Griffiths and McConnell (29)	Randomized clinical trial	Brunel, UK	EMT vs IMT / EMT + Rowing ergometer training	05/10
Johnson et al. (35)	Randomized clinical trial	Nottingham, UK	IMT with Powerbreathe® + Cycle ergometer training	04/10
Kilding et al. (36)	Randomized clinical trial	Auckland, New Zealand	IMT with Powerbreathe® + Swimming Training	04/10

Scale.PEDro *(Physiotherapy Evidence Database), available in* http://www.pedro.fhs.usyd.edu.au. (38-40)

Table 2: Inspiratory muscle training protocols (TMI) and association with the sport.

Author (year)	Sport	Sample	Application protocol	Training time
Volianitis et al. (30)	Rowing	14	Load 50% of MIP, 30 repetitions, 2 times a day.	11 weeks
Romer et al. (31)	Cycling	16	Load 50% of MIP, 30 repetitions, 2 times a day.	06 weeks
Romer and McConnell. (32)	Cycling	16	Load 50% of MIP, 30 repetitions, 2 times a day.	06 weeks
Griffiths and McConnell (29)	Rowing	17	Load 50% of MIP, 30 repetitions, 2 times a day.	04 weeks
Johnson et al. (35)	Cycling	18	Load 50% of MIP, 30 repetitions, 2 times a day.	06 weeks
Kilding et al. (36)	Swimming	16	Load 50% of MIP, 30 repetitions, 2 times a day.	06 weeks

IMT = Respiratory Muscle Training; MIP = maximal inspiratory pressure

Table 3: Benefits of Inspiratory muscle training (IMT) with *Powerbreathe*® in association with sports training.

Author	Study design	Population	Intervention	Results
Volianitis et al. (30)	Randomized clinical trial	14 athletes	IMT group: 30 repetitions, twice daily, load of 50% MIP; Placebo group: 60 breaths once daily, load of 15% MIP.	IMT group increased respiratory muscle strength to 44 ± 25 cm H_20 (45.3 ± 29.7%) compared with only 6 ± 11cm H_2O (5.3 ± 9.8%) in the placebo group ($P<0.05$, between groups). The distance walked in the 6-minute maximum effort test was 3.5 ± 1.2% compared to 1.6 ± 1.0% in the placebo group ($p<0.05$). The 5000m time decreased to 36 ± 9s in the intervention group compared to only 11 ± 8s in the placebo group ($P<0.05$). The group resistance was improved from a deficit in IMP of 11.2 ± 4.3% to only 3.0 ± 1.6% ($p<0.05$), before and after intervention.
Romer et al. (31)	Randomized clinical trial	16 athletes	IMT group: 30 repetitions, twice daily for six weeks, load of 50% MIP; Placebo group: 60 cycles once daily load of 25% MIP for six weeks	An improvement of respiratory function, with significant increase in MIP (28 ± 7%), $MaxVO_2$ (17 ± 4%), Max W (49 ± 16%) in the intervention group ($p<0.01$), a reduction of 8±1.2% in lactate values, without statistical significance. A reduction in the perception of respiratory and peripheral effort in the IMT group compared to the placebo (Borg: 16 ± 4% and 18 ± 4%, $P<0.01$), respectively

Romer and McConnell. (32)	Randomized clinical trial	16 athletes	IMT group: 30 repetitions, twice a day for six weeks, load of 50% MIP; Placebo group: Load of 25% MIP for six weeks	Improvement in the inspiratory muscle function in IMT group ($p \leq 0.05$); improvement in the simulated clock test to 20 and 40 km (66 ± 30" and 115 ± 38" faster, respectively, p=0.025 and 0.009).
Griffiths and McConnell (29)	Randomized clinical trial	17 athletes	IMT group (four weeks): 30 repetitions, twice daily for four weeks, load of 50% MIP; IMT/EMT group: individual training of IMT or EMT for four weeks, the following two weeks combining IMT/EMT: 30 repetitions, twice daily, load of 50% IMT/EMT;	IMT group had an increase of 26% in MIP ($P<0.001$) and an improvement in performance during ergometric rowing exercise for six minutes of 16.2 meters (p=0.02). IMT/EMT group showed no statistically significant gain for the variables of interest.
Johnson et al. (35)	Clinical trial	18 athletes	IMT group: 30 repetitions, twice daily for six weeks, load of 50% MIP; Placebo group: 30 repetitions, twice daily for six weeks, no load;	The MIP increased by 17.1 ± 12.2% for the IMT group ($p<0.01$) and was accompanied by a reduction of 2.66 ± 2.51% of the time taken to go 25km ($p<0$ 05), and there were no changes compared to group placebo. There was an improvement in physical endurance during cycling in the IMT group (18.3 ± 15.1%, $p <0.05$).

Kilding et al. (36)	Clinical trial	16 athletes	IMT group: 30 repetitions, twice daily for six weeks, load of 50% MIP; Placebo group: 60 breaths daily, load of 15% MIP for six weeks	A substantial reduction in swimming times in 100m (1.7 ± 1.4%, $p<0.05$), 200m (1.5 ± 1.0%, $p=0.02$), and 400m showed no significance, with a change of 0.6 ± 1.2% ($p=0.363$).

HR = Heart rate; IMT= Respiratory muscle training; MIP: Maximum inspiratory pressure; MEP: Maximum expiratory pressure; $PETCO_2$ = pressure of end-tidal carbon dioxide; EMT= Expiratory muscle training; TV= Tidal volume; VFC = Vital functional capacity.

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5. ARTIGO ORIGINAL

5.1. ARTIGO 2

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INSPIRATORY MUSCLE TRAINING IN A HOSPITAL ENVIRONMENT: STUDY PROTOCOL FOR A RANDOMIZED CONTROLLED TRIAL

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INTRODUCTION:

Respiratory muscle deconditioning frequently occurs in patients confined to bed and long stay in hospital (≥8 days)[1-2]. Respiratory muscle weakness causes reduction in ventilatory reserve and leads to dependence on mechanical ventilation (MV), thereby increasing the risk of ventilator-associated pneumonia and morbimortality in hospitalized patients[1-6].

Inspiratory muscle training (IMT) is a known strategy for reconditioning of respiratory muscle, providing optimization of lung capacity and consequently, physical improvement[7,8]. The positive impact of IMT on maximum inspiratory pressure (MIP) has been reported in studies with individuals using MV and during cardiopulmonary rehabilitation programs[9-12], for the treatment of established incapacities[8-13].

IMT is based on three pillars: overload imposed on the muscle; specificity of the training; reversibility of the muscle atrophy. Linear load resistors are the types of equipment most used for IMT. They have the advantage of being capable of maintaining the level of therapeutic resistance in the airway during inspiration. Moreover, the load grading allows training to be specified for the capacity suited to the user. Studies have demonstrated that IMT increases endurance and muscle strength[6,7], produce gains in lung volumes and capacities[8], reduces the feeling of dyspnea[13,14] and may improve tolerance to exercise[6,7,9,14]. These benefits may contribute to performing activities of daily living (ADLs)[15].

Prolonged hospitalization diminishes functional capacity, may impact negatively on the time of stay in hospital, rate of endotracheal intubation and increase in morbimortality. There is a body of evidence that supports the positive effects of IMT in patients with chronic-degenerative diseases treated by rehabili-

tation services[8,13,14], however, there is a scarcity of studies that have tested the use of IMT in hospitalized patients with an acute condition, in a hospital environment,[9-11] nevertheless, its results are promising.

METHODS AND ANALYSIS

Study Methodology

The aim of this study was to evaluate the efficacy of IMT, with a linear charge resistor, for reduction in the hospital rate of intubation and mortality. Furthermore, the present study will measure the impact of this training on MIP, peripheral muscle strength and functional capacity of hospitalized patients. Lastly, the objective of the research is to demonstrate the safety of the application of this technique in patients hospitalized for a long period of time.

Study Design

This study protocol proposes a triple blind (patient-evaluator-analyst), randomized clinical trial, comparing standard ITM and physical therapy, with a SHAM Group for standard IMT and physical therapy. This study will be conducted in accordance with the recommendations of the Consolidated Standards of Reporting Trials (CONSORT)[16] in order to guarantee the methodological transparency and strictness of the study.

The trial will be conducted in the Hospital Geral Roberto Santos, located in Salvador, Bahia, Brazil. The study will be conducted with all the patients hospitalized in the infirmary on admission to hospital, provided they fulfill the pre-established inclusion criteria.

Sample Size

Before the study began, a pilot study was conducted to evaluate the therapeutic feasibility of the protocol. With a view to reducing the drop-out rate during follow-up, a 4-week duration of the IMT protocol was established. Assuming a drop-out rate of 10%, the desired sample size for this study would be up to 50 individuals, with 25 participants in each group. A sample size calculation was made with GPower® Software, considering a statistical power of 80% in the detection of a difference of 15 cmH_2O in MIP, between the IMT and Placebo groups, with alpha of 5% and standard deviation of 05 cmH_2O[6,9].

Inclusion Criteria

Patients in the age-range between 18 and 65 years, hospitalized in the infirmary of the hospital where the study will be conducted.

Exclusion Criteria

Patients with cognitive impairment making them unable to perform respiratory training; uncontrolled cardiac arrhythmia; circulatory shock; acute ischemic heart diseases; acute respiratory insufficiency, characterized by arterial oxygen tension (PaO_2) lower than 60 mmHg in ambient air, or arterial carbon dioxide pressure ($PaCO_2$) higher than 50 mmHg; discharge from hospital before conclusion of the protocol; neuromuscular disease or myopathies, paralysis or diaphragmatic paresis; patients who had received respiratory therapy with load (inspiratory or expiratory), in parallel with the protocol; those who do not consent to signing the Term of Free and Informed Consent (TFIC).

Randomization and Blinding

After initial evaluation, the individuals will randomly be allocated to one of the groups, with a ratio of 1:1 per one researcher, who will not have any contact with the participants. After performing simple randomization by means of the RandList® Software, each participant will be allocated to the respective group, defined by numbered opaque envelopes, opened after initial evaluation, for those participants who fulfilled the eligibility criteria.

All the participants will be evaluated by one single investigator, trained and blind to the allocation of the groups, research participants, and the researcher responsible for the data analysis will also be blind to the allocation of the groups.

Intervention

IMT Group

The participants will undergo 4 weeks of inspiratory muscle training, using a linear resistor of the Powerbreathe® brand, model Plus, with a light load level (Fig. 1), with resistance imposed of approximately 50% MIP. With posology of 1 series of 30 incursions, 2 times per day, for 7 days per week (totaling 56 sessions). As a safety measure, before each attendance, Cardiac Frequency (CF) and peripheral oxygen saturation (SpO_2) will be measured, and the Borg scale graded. For interruption of the intervention, the following criteria will be adopted: occurrence of dyspnea; headache; pain; tachycardia (higher than 20% of the initial CF); hypertension (higher than 20% of the initial arterial pressure); bronchospasm; dizziness, syncope, and epistaxis.

The sessions will be performed with the head of the bed elevated or in sedestation; IMT will be performed by introducing the nozzle of the equipment into the mouth, with the silicone anatomic part supported between the teeth and lips, associated with a nasal clip, to prevent air from escaping, which would diminish the effectiveness of imposing load. The participant will be encouraged to perform tranquil, maximum and successive inspirations, favoring maximum recruitment of the respiratory muscles.

SHAM Group

IMT will be performed with the same training device, however, without load, the frequency of sessions, their posology and method of application will be identical to those of the IMT Group.

Both group will receive standard physical therapy assistance daily. In this, kinesiotherapy without load, muscle stretching, technical coughing, sedestation and deambulation will be contemplated, if the participant is apt to do so.

Variables of Interest

The frequency of intubation and death during the period of the intervention until discharge from hospital will be counted. Inspiratory muscle strength will be evaluated by the MIP measurement taken by means of the analogical Vacuum manometer of the Wika® brand, model CL.1.6 with an amplitude from 0 to -160mmHg, which will be coupled to a face mask and a uni directional valve. For measurement, the patient will be positioned with the thorax elevated, or in sedestation, and tranquil maximum expiration will be requested, followed by sustained forced maximum inspiration (for longer than two seconds). Three conse-

cutive measurements will be made, and the highest in the module will be considered MIP[17]. MIP will be re-evaluated after 4 weeks of intervention, using the same method. To evaluate the respiratory endurance, maximum voluntary ventilation (MVV) will be measured in the pre- and post-intervention time intervals. For this purpose, the participant will be instructed to perform rapid and deep respiration for the period of fifteen seconds, with the corresponding volume graded by means of the Ferrari® brand ventilometer.

Peripheral muscle strength will be measured by using the Medical Research Council (MRC) scale for skeletal muscle assessment. Initially muscle strength will be evaluated by the Oxford[12] scale, grading strength from 0 (no contraction) to 5 (normal strength), for elbow and hip flexion, shoulder abduction, knee and wrist extension, and bilateral dorsiflexion. The MRC scale will be graded by the sum of the scores obtained for each muscle, and will have a final score of 0 (plegia) up to 60 points (normal strength)[18,19] For characterization of the sample, the gender, age, reason for admission to hospital, severity by means of the Acute Physiology And Chronic Health Evaluation (APACHE II), Barthel index (BI), functional independence measurement (FIM). Before conducting the study, all the evaluation instruments were calibrated in accordance with the existent technical standards.

Follow up

All the participants included will be submitted to an intervention protocol for 4 weeks, as from their inclusion in the study, and the occurrence of all outcomes up to discharge from hospital will be followed-up. Loss during follow-up

will be considered patients discharged from hospital during the period of the intervention, or those who desist from participating in the protocol.

Ethics and dissemination:

The study was approved by the research ethics committee of the hospital where the study will be conducted, with Report No.03/2014 in compliance with Declaration of Helsinki. The Term of Free and Informed Consent (TFIC) will be obtained from each participant or legal guardian, before any intervention. All the individuals will be informed of the right to withdraw their consent to participating in the study at any time. The research protocol was registered with Clinical Trials (ClinicalTrials.gov Identifier: NCT02459444).

Adverse Events

During the IMT sessions the physical therapists will notify the occurrence of any adverse event. To homogenize the adverse effects validated in the literature, the MedDRA dictionary of terms was used (available at, www.ich.org/products/meddra.html). The following are considered adverse events: dyspnea, headache, pain, tachycardia, hypertension, brochospasm, dizziness, syncope, epistaxis, and respiratory failure. The events will be monitored per session, and one and the same participant may present more than one adverse event. The report on frequency of adverse events will be sent to the ethics committee, which will decide about the need for adjustments in the protocol, or interruption of the research

Statistical Analysis

To express the demographic and clinical data, descriptive statistics will be performed. The continuous variables will be express by the mean and standard deviation. The data of dichotomic and categoric variables will be expressed by absolute and relative frequency.

To test normality of the distribution of variables, the central tendency measurements and dispersion measurements will be analyzed, in addition to performing the Shapiro-Wilk test. For normal distribution the paired t-test will be used for comparison of functional variables pre- and post intervention, intragroups, while for comparison the the means between groups, the Student's-t test will be used. For statistical analysis of dichotomic and categoric variables, the Chi-square test will be used. To measure the chance of risk for intubation and mortality, the Odds Ratio (OR) will be used, as well as the number necessary for treatment (NNT), inferring the safety of the intervention.

The level of significance established will be 5%. Statistical analysis will be performed with the use of the software SPSS (Statistical Package for the Social Sciences) for Windows (version 21.0).

DISCUSSION

Longer hospitalization time is associated with systemic complications and dysfunctions, such as muscle weakness. Jonghe et al[20] observed the hospitalizations longer than ≥ 7 days, lead to important muscle loss, favoring functional decline and dependence on MV. The adoption of early therapeutic measures that prevent muscle loss or revert conditions already established must be encouraged. IMT is effective for gaining respiratory muscle strength, with good

results for healthy[21], and elderly individuals[22] and chronic patients[8,12,14]. Hospitalized patients may benefit from these gains, preventing complications that increase morbimortality.

Adoption of preventive measures appears to be feasible for the maintenance of functional status and reduction in complications related to prolonged hospitalization.[1-3] Factors such as intubation, mechanical ventilation and prolonged hospitalization are known to be independent factors for worse prognosis of the hospitalized patient[3]. Therapies that prevent the development of these factor may converge in reducing mortality and their scientific investigation must be encouraged.

The IMT protocol will be based on studies with the same linear load resistor in diverse populations, using a training load of approximately 50% of MIP, with 30 incursions in a single series of training, in two daily rounds[6-8,15,23]. This type of protocol prioritizes gain in endurance, since it uses a high frequency of repetitions[22]. However, Griffiths and McConnell[7] in a study with rowers, and Azizimasouleh et al[24] with swimmers, conducted the protocol and obtained an improvement in MIP. A positive result was also obtained in the study of McConnell et al.[13] with asthmatic patients, cared for in an outpatient rehabilitation clinic. Our hypothesis is that similar gains will be found in hospitalized patients.

The process of gaining muscle strength respects periods of biologic adaptation: in the first days of IMT the gains in performance result from the “learning effect” made possible by repetition of the technique; with the sequence of training over a period of weeks, gain is based on the trophic arousal of the muscle, and improved nerve conduction provided by afferent stimulus of load; between 4 and 6 weeks the benefits are attributed to the increase in mitochon-

dria and oxidative enzymes, in addition to hypertrophy of the myocytes and consequent increase in respiratory performance. It is also known that the longer the period of exposure to IMT, the more sustained will be the adaptations achieved[3,4,14,15].

This is a pioneering study in the use of this specific linear resistor for IMT in hospitalized patients. The feasibility of using it lies in the fact of it being a low cost appliance, with graded inspiratory resistance, which facilitates the reproducibility of this training protocol. Various studies have demonstrated the benefit of IMT on MIP [6-9,11-14], as well as the gains in physical and functional capacity[21-24]. Nevertheless, the extent of these benefits in the hospital environment have not yet been consolidated. Preliminary evidence suggests that it is a low risk therapy with potential therapeutic effect[6,12,13, 22-24].

The limitation of the study is the adoption of IMT for only 4 weeks. It is worth pointing out this period was defined in a pilot study, when the mean time of hospitalization of long-staying patients in this hospital was observed. The fact of the study having been conducted in a single hospital unit is also a limitation, in spite of the strict methods of randomization and blinding. The absence of follow-up after patients were discharged from hospital is another limitation of the study, and thus the maintenance of the gains and mortality over the course of longer periods could not be evaluated.

In spite of the encouraging perspectives generated by the preliminary data of this research, future multicentric studies are necessary. Only then could this conduct be routinely incorporated into the care of the hospitalized patient.

Status of the Study

This clinical trial is at the stage of recruiting participants.

Competing interests

The authors declare that they have no competing interests with respect to the current trial.

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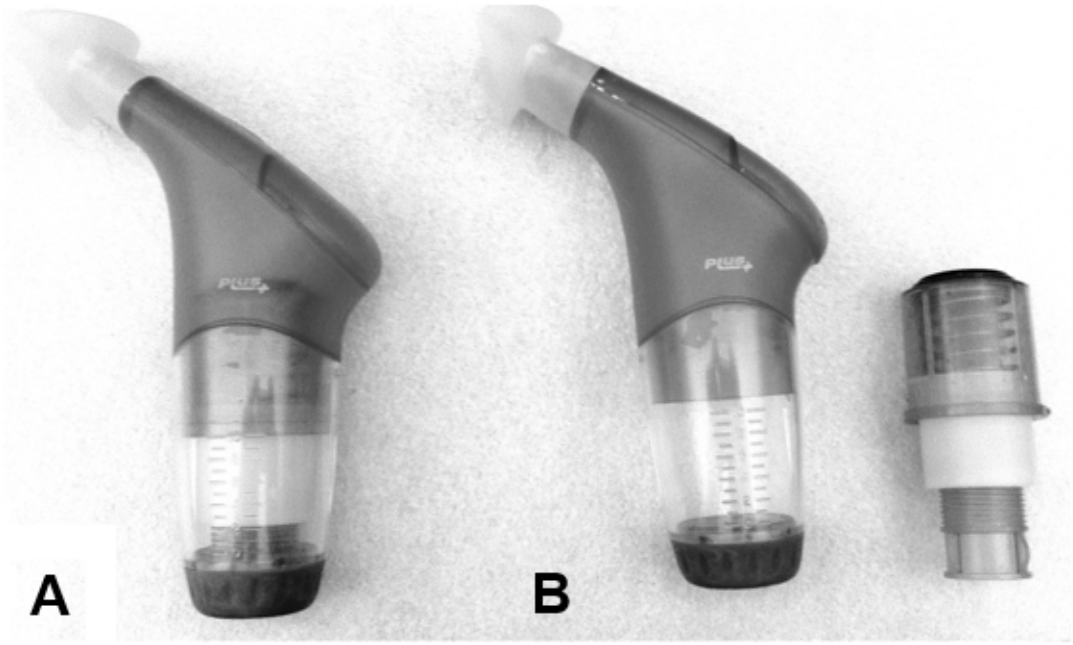

Fig 1: A. Powerbreathe® Light serie Plus IMT group; B SHAM group.

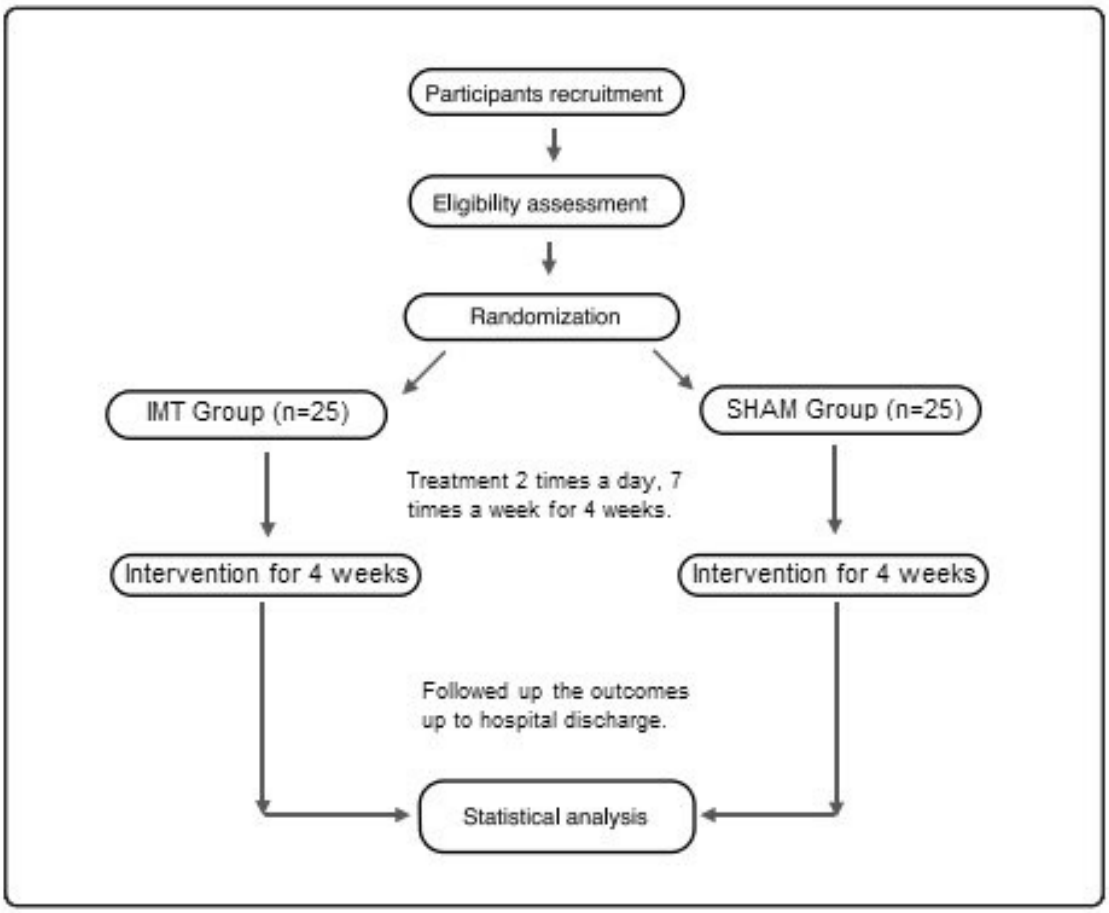

Fig. 2 Flowchart of the study design

5.2. ARTIGO 3

Número de submissão: CCMED- S-15-02854

EFFECT OF INSPIRATORY MUSCLE TRAINING ON THE PREVENTION AND TREATMENT OF COMPLICATIONS IN PATIENTS ADMITTED TO HOSPITALS: A RANDOMIZED TRIAL

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Keywords: Respiratory Muscles, Breathing Exercises, Muscle Weakness, Hospitalization, Length of Stay, Mortality.

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INTRODUCTION

The hypomobility associated with prolonged hospitalization (more than 8 days) decreases the physical demands on the body systems and correlates with increased rates of morbidity and functional decline (1–3). Body tissues are sensitive to changes in overload and physical demand (4). Previous studies have shown that prolonged periods (greater than or equal to 12 hours) of bed rest, hypomobility, and controlled mechanical ventilation induce muscle atrophy and reduce functional capacity (5,6).

This hypomobility makes patients vulnerable to complications such as muscle weakness, deconditioning, a decline in cardiorespiratory function, and increased in-hospital mortality (7,8). Research into the complications associated with prolonged patient hospitalization and the use of therapeutic and preventive strategies has aroused the interest of the scientific community, due to the negative effects of hospitalization on health and quality of life (6,8,9). Exercise-based rehabilitation has been investigated in hospitalized patients (9–11). Inspiratory muscle training (IMT) is a therapeutic modality that strengthens the inspiratory muscles by imposing an overload on them (11–13).

The proper use of IMT requires an understanding of exercise prescription-related factors such as intensity, resistance, frequency, and duration. In a recent study of 265 hospital-based physiotherapists, 82% of workers used IMT in association with rehabilitation programs, whereas only 5% reported using IMT for patients with respiratory muscle weakness (14). However, evidence suggests that prescribing IMT is beneficial for patients with respiratory muscle weakness (14,15).

There is a paucity of investigations into the benefits of using IMT early in hospital patients who do not have muscle weakness (16) but have the potential to develop it due to prolonged hospitalization. Studies of different populations have demonstrated that the positive effects of IMT are not limited to the respiratory system (17–19); the muscular adaptations generated are associated with improvements in physical and functional capacity (20–22) and daily living activities (23), and may thus benefit hospitalized patients.

Very few studies have reported on the effectiveness and safety of combining IMT with physiotherapy early to prevent hospital stay-related complications (24). Therefore, the objective of this study was to investigate the efficacy and safety of inspiratory muscle training (IMT) in the prevention and treatment of complications in patients experiencing prolonged ward hospitalization.

METHODS

Design and Setting

We performed a randomized controlled trial in accordance with Consolidated Standards of Reporting Trials (CONSORT) guidelines (25). The randomized controlled trial was conducted in the medical ward of the Hospital Geral Roberto Santos (HGRS). The HGRS is a 600-bed tertiary teaching hospital serving a catchment population of approximately 68,000 annually. This study was approved by the Human Research Review Committee of the HGRS. All study subjects provided written informed consent prior to participation.

Patients

Adult patients who were expected to have a prolonged stay in the hospital ward were enrolled in the study. We excluded patients who had any of the following features from respiratory testing: cognitive disability; uncontrolled cardiac arrhythmias; circulatory shock; acute ischemic heart disease; acute respiratory failure [characterized by a partial pressure of arterial oxygen (PaO2) < 60 mmHg or a partial pressure of arterial carbon dioxide (PaCO2) > 50 mmHg]; and neuromuscular disease, diaphragmatic paresis, or paralysis myopathies. We also excluded patients receiving respiratory therapy with load (expiratory or inspiration), parallel to the protocol.

Experimental Protocol

Prior to the start of data collection, we conducted a pilot study to assess the feasibility of the protocol and calculate the sample size needed.

All participants were assessed by one investigator, and were trained and blinded to the allocation of the groups. After the initial assessment to establish which participants met the eligibility criteria, subjects were randomly allocated in a 1:1 ratio to one of two groups: physical therapy/inspirational muscle training (PT/IMT) or physical therapy/no IMT (PT/SHAM). The simple randomization was performed using RandList® software (DatInf GmbH, Tübingen, Germany) after which participants were allotted a group by concealed allocation using numbered, opaque, sealed envelopes.

All study participants and data analysts were also blinded to group allocation.

Interventions

Patients in the PT/IMT group performed 4 weeks of IMT using a POWERbreathe® Plus resistance training device (POWERbreathe International Ltd, Southam, UK) with a level of individual load, as previously described (Figure 1): one set of 30 breaths twice a day for 28 consecutive days (total 56 sessions) with an intensity of 50–60% of the maximal inspiratory pressure (12,13,26–29). Heart rate (HR) and peripheral oxygen saturation (SpO2) were measured before and during each session, along with an assessment of the effort required using the Borg Scale of Perceived Exertion (19). Criteria adopted for discontinuation of action included the occurrence of dyspnea, headache, pain, tachycardia (greater than 20% of the HR), hypertension (greater than 20% of the initial blood pressure), bronchospasm, and dizziness (15,22,24).

Patients in the PT/SHAM group performed the IMT with the same training device and following the same protocol, but without the use of resistance. Both groups performed physiotherapy (exercises and muscle stretching in a sitting position and with ambulation) twice a day.

Measurements: baseline, demographic, and clinical characteristics

Outcomes. The outcome measures were peripheral and respiratory muscle strength, functionality (using the Barthel Index of Activities of Daily Living), and hospital-stay mortality. The secondary outcome measure was safety (assessed via the incidence of adverse events).

Inspiratory muscle strength was evaluated through measurement of the maximal inspiratory pressure (MIP) using a Wika® CL 1.6 analog manometer (WIKA Instrument, LP, Lawrenceville, Georgia, USA) attached to a face mask and a one-way valve (30). The maximum voluntary ventilation (VVM) (31) was

measured by a Wright Mark 8 Respirometer (NSPIRE HEALTH INC, Longmont, USA).

Peripheral muscle strength was measured using the Medical Research Council Manual Muscle Testing Scale (MRC Scale), ranging from a strength of 0 (no contraction) to 5 (normal force) for elbow and hip flexion, abduction of the shoulder, and knee and wrist extension and bilateral dorsiflexion. The MRC Scale scores were calculated from the sum of the values obtained for each muscle to give a final score from 0 (palsy) up to 60 points (normal force) (32,33).

Patient functionality was evaluated through the Barthel Index (BI) and Functional Independence Measurement (FIM) (34,35). Frequency of occurrence of intubation, muscle weakness [defined by MRC Scale score of less than 48 points (5)], and death during the intervention period until hospital discharge was recorded.

Adverse events

Physiotherapists noted the occurrence of adverse events during the IMT sessions, including dyspnea, headache, pain, tachycardia, hypertension, bronchospasm, dizziness, syncope, epistaxis, and respiratory failure. All such events were monitored for each patient on a per-session basis (36).

Statistical analysis

A sample size of 25 patients in each group was required to demonstrate a difference of 15% in outcome with a statistical power of 80% and an α level of 0.05.

All continuous variables were expressed as mean ± standard deviation of the mean (m ± SD). Normality was tested using the Shapiro–Wilk test. Baseline characteristics were compared using t test. Risk of intubation, muscle weakness, adverse events, and death was assessed by the relative risk (RR), and safety of the intervention was inferred from the number needed to treat (NNT). The alpha level was set at $p < 0.05$ and data are reported as mean (SD). Statistical analyses were performed using SPSS software (version 20, SPSS Inc., Chicago, Illinois, U.S.A.).

RESULTS

The flow of subjects from evaluation to participation is shown in the CONSORT diagram (Figure 2). A total of 221 patients were screened for eligibility. Of the patients who were eligible for the study, 54 completed the protocol and were randomly allocated to the PT/IMT (n = 26) and PT/SHAM groups (n = 28).

Baseline characteristics of all patients completing assessments are summarized in Table 1. Characteristics of both groups were similar at baseline. There was no significant difference between the number of sessions between the groups ($p = 0.39$).

Table 2 describes the data regarding functional and respiratory variables. Within-group analysis showed a significant improvement in MIP, MRC Scale score, and BI in the PT/IMT group only. Between-group analysis showed significant differences in MIP and BI after the intervention. In particular, participants in the PT/IMT group appeared to benefit greatly when compared to

those in the PT/SHAM group. A significant group-by-time interaction was observed for MIP ($p = 0.001$) and BI ($p = 0.02$) (Figure 3).

The PT/IMT group also experienced shorter hospital stays than the PT/SHAM group (35.3 ± 2.7 versus 41.8 ± 3.5 days, respectively; $p < 0.01$). In addition, the PT/IMT combination protected against muscle weakness and mortality ($p < 0.05$). The prevalence of adverse events was not significantly different between the two groups (Table 3).

DISCUSSION

To our knowledge, this randomized clinical trial is the first to assess the effect of early addition of IMT to physiotherapy in patients who have been hospitalized for a long duration. The addition of IMT to physiotherapy was safe and beneficial to the patients in terms of inspiratory muscle strength, functionality, and length of hospital stay. The combination of IMT with physical therapy was also found to protect against tracheal intubation, muscle weakness, and mortality.

Measurements of inspiratory muscle strength showed an increase of 30 cmH_2O (52.4%) in the MIP for the PT/IMT group, whereas the PT/SHAM group showed a decline of 7.3 cmH_2O. This is a clinically significant difference as the MIP increase in the PT/IMT group brings it close to the normal value (37). Kulkarni et al (21) investigated the use of IMT for 2 weeks with different resistance training devices prior to abdominal surgery. It is of note that the same linear resistor used in this study was the only one that generated a significant increase in MIP of -51.5 to -68.5 ($p < 0.01$), with no MIP reduction after surgery.

A reduction in respiratory muscle strength is associated with a reduction in peripheral muscle strength. Jonghe et al (38) identified a strong correlation between MIP and the MRC Scale score ($p = 0.001$). Based on the principle of muscle reversibility, muscle training benefits the target muscles and their synergists. Chiang et al (35) tested a rehabilitation program that incorporated early mobilization and IMT for 5 days per week over a 6-week period. They identified an increase of 30.4% in MIP and improvement of peripheral muscle strength as measured by the MRC Scale (50.0 ± 10.8 to 55.1 ± 8.0; $p < 0.001$).

Here, the addition of IMT to physiotherapy also increased functionality measured through the BI (from 76.5 ± 24.0 to 87.5 ± 16.5; $p < 0.001$). In a previous clinical trial, Chiang et al (35) implemented a program of physiotherapy that included resistance and weight-bearing exercise together with IMT. They found increased functionality in the intervention group (BI = 35.0; 95% CI = 10.0–19.0) when compared with a control group that did not perform exercise (BI = 0.0; 95% CI = 0.0–8.8).

The evaluation of outcomes such as complications of hospitalization, intubation, and hospital mortality risk is important because of their important effect on health care, management of the public health, and welfare costs. In addition to the physical and functional benefits, the addition of IMT to physiotherapy was found to protect against complications of prolonged hospitalization, such as muscle weakness. The NNT analysis for this protective factor identified that 8 patients need to be treated with IMT in order to prevent one case of muscle weakness. We could not find any other studies that reported the effectiveness of IMT using NNT.

Here, the use of IMT also reduced the risk of tracheal intubation in 64%, with the necessity of treating only 4 individuals with IMT to prevent one intubation. Mortality rate was 3.8% for the PT/IMT group as opposed to 25.0% for the PT/SHAM group (RR = 0.15, 95% CI = -0.79–0.02), with 5 patients needing to be treated with IMT to prevent one death. In a recent trial, Wiskemann et al (39) reported an NNT of 6 to prevent death in one patient after performing an in-hospital exercise program for cancer patients for 6–8 weeks after discharge. In a case-control study exploring the effect of physiotherapy on stroke patients in a specialized or general intensive care unit, Saposnik et al (40) noted that physiotherapy in the specialized unit generated an NNT of 8 to prevent one death. The results reinforce the early addition of IMT to physiotherapy as a potential tool that can be used routinely to help combat the complications of prolonged hospitalization. Moreover, early rehabilitation in hospital patients has been associated with an improvement in muscle strength, functionality, and quality of life (41,42). Studies have also reported the association of early rehabilitation with a reduction in mechanical ventilation and hospitalization times, hospital readmission, and a consequent reduction in cost (42-44). Although the question of cost was not investigated here, the addition of IMT to physiotherapy was identified to be protective against death, tracheal intubation, and in-hospital muscle weakness, and may thus reduce hospital costs.

In this trial, we used a protocol of IMT with high load—between 50% and 60% of the MIP. The MIP increase in the IMT group was 52.4%. In a study of pre-operative abdominal surgery patients, Kulkarni et al (21) used the same resistance training device and frequency of training but a training load equal to

20-30% of the MIP. This intervention generated a 33.0% increase in the MIP. In a systematic review, Moodie et al (11) found that training with high loads led to greater muscle strengthening.

Our study pioneers the early use of IMT in patients who had been hospitalized for a long duration. The low cost of the apparatus used for IMT will facilitate the reproducibility of this training protocol, and the promising results presented here encourage future investigations including longer periods of training and follow-up after hospital discharge.

Nevertheless, our findings should be considered in the light of some potential limitations. The study was conducted at a single hospital, limiting the extrapolation of data for hospital units with different or specialized profiles. However, the use of a representative sample suggests that the benefits may extend to patients who experience prolonged ward hospitalization in other facilities. The absence of electrocardiographic monitoring during the IMT sessions is a second limitation, because arrhythmia is an adverse event reported in the literature for IMT—albeit with low frequency. We did, however, measure cardiorespiratory parameters for safety purposes. These parameters are associated with low cost and good reproducibility, and are applicable to patients of diverse complexity in the hospital environment.

CONCLUSIONS

The early addition of inspiratory muscle training to physical therapy using a linear load resistor is safe and may be an effective means of preventing complications due to prolonged hospitalization and reducing associated hospital mortality.

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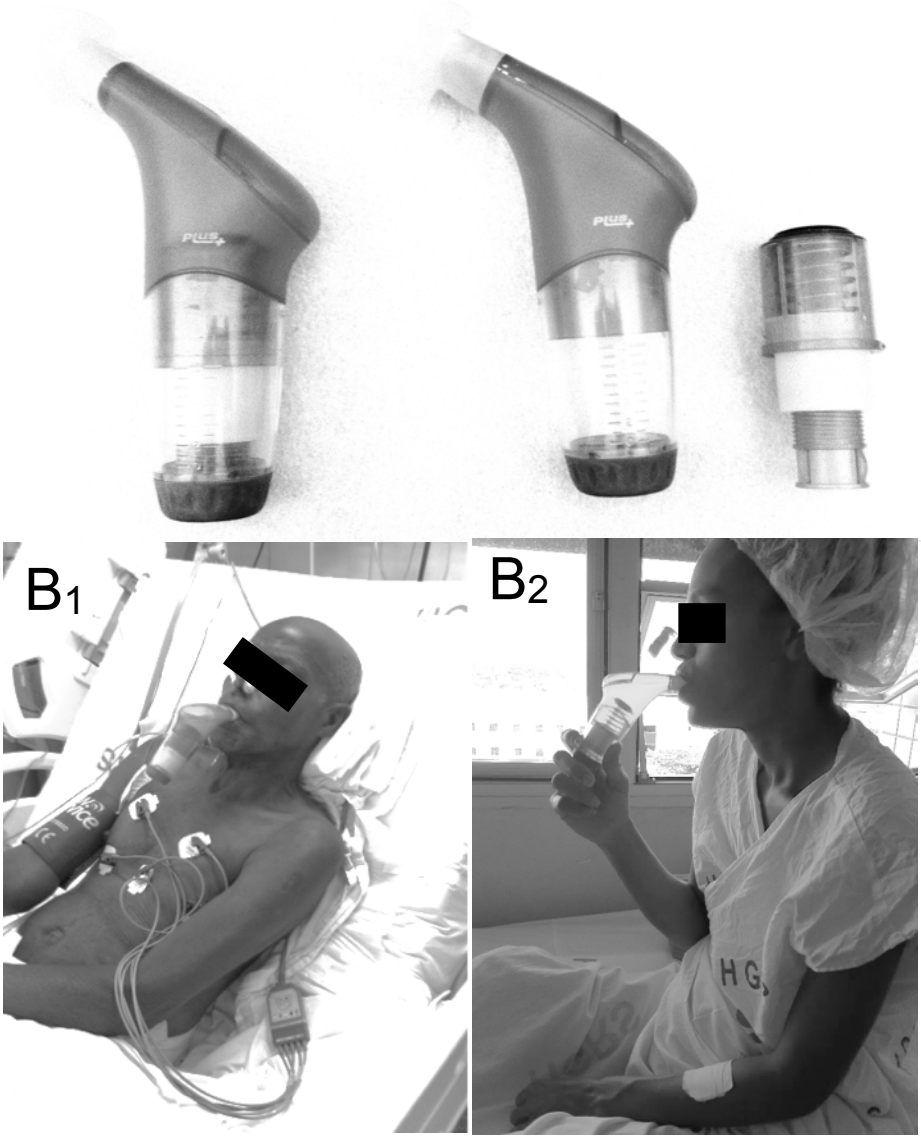

Figure 1: A. Powerbreathe® Plus with Light load to the IMT group and SHAM group; **B_1-B_2.** Patients in coaching.

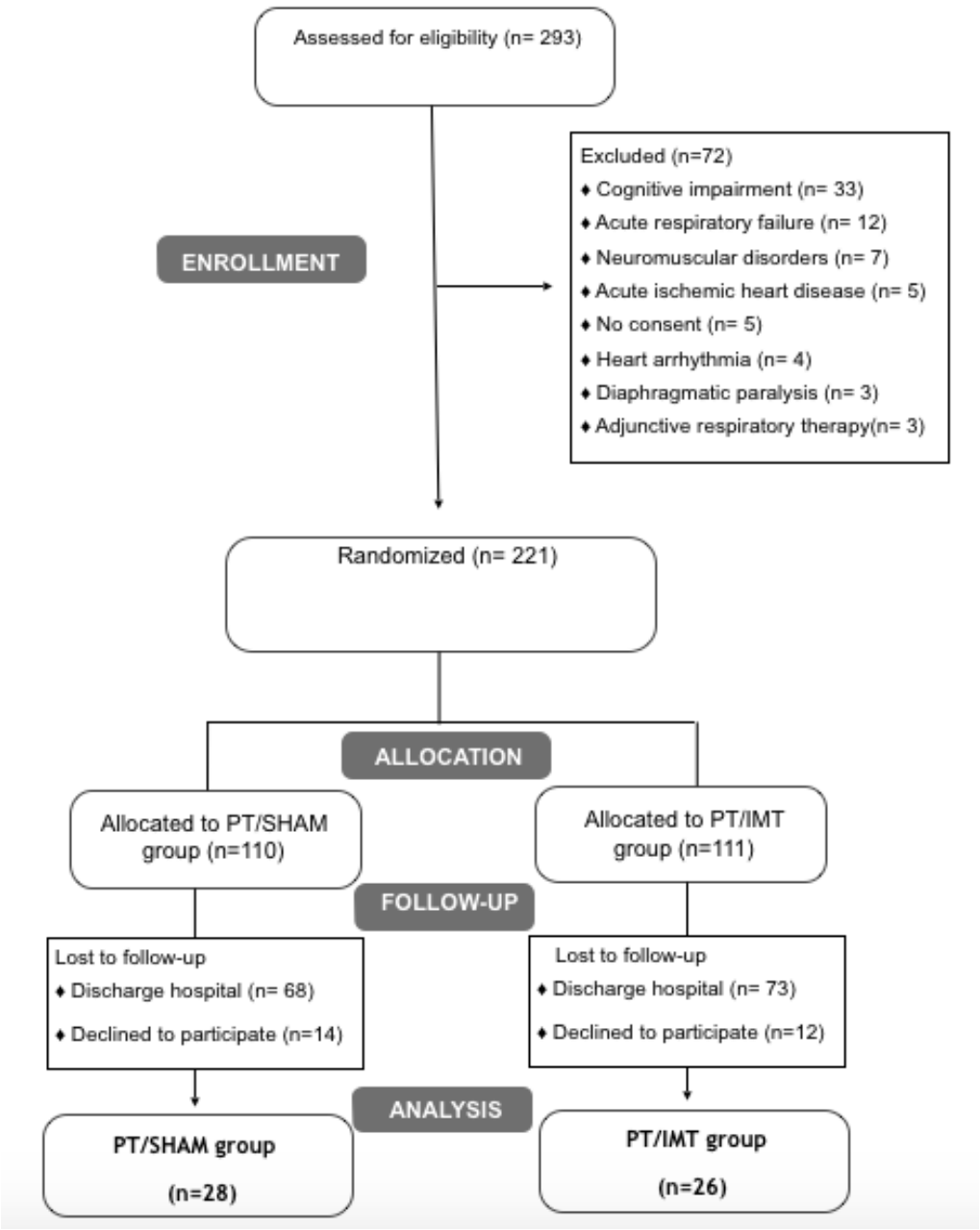

Figure 2: CONSORT flow diagram.

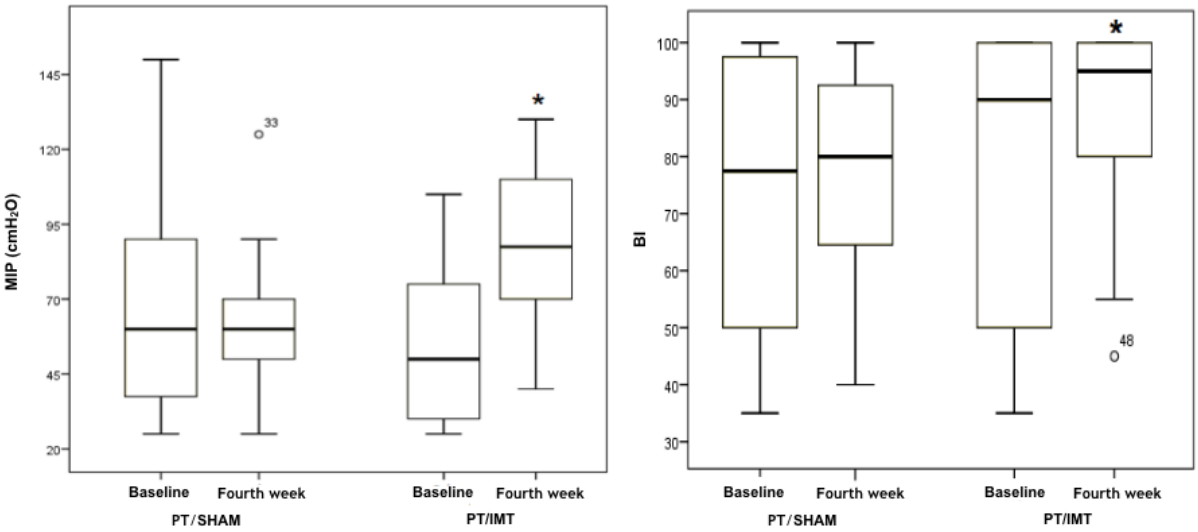

Figure 3: Box plot of progression MIP and BI variable between the groups.

Table 1: Demographic and medical data.

	PT/IMT (n=26)	PT/**SHAM (n=28)**	**p-value**
Gender:			
Female	15 (53.5)	17 (65.3)	0.29
Male	11 (46.5)	5 (34.7)	0.21
Age (years)	45.1 ± 1.5	44.0 ± 1.5	0.59
Diagnosis:			
Stroke	5 (19.3)	6 (21.4)	
Brain Tumor	4 (15.4)	4 (14.3)	
Sepsis	4 (15.4)	5 (17.9)	
Pneumonia	3 (11.5)	2 (7.1)	
Abdominal surgery	3 (11.5)	4 (14.3)	
Spinal cord tumor	2 (7.7)	3 (10.7)	
Endovascular revascularization	2 (7.7)	2 (7.1)	
Others	3 (11.5)	2 (7.1)	
Apache II	21.6 ± 0.4	20.8 ± 0.6	0.25
Assiduity to the protocol	49.4 ± 2.2	48.9 ± 2.0	0.39
FIM	4.7 ± 0.4	4.6 ± 0.3	0.57
BI	76.5 ± 4.7	74.8 ± 4.1	0.78

Diagnostics with less frequency than 5% were grouped in others. Apache II - Acute Physiology And Chronic Health Evaluation; FIM - Functional independence measure; BI - Barthel Index.

Table 2: Functional and respiratory variables data.

	PT/IMT (n=26)		PT/SHAM (n=28)		p-value†
	Baseline	**Fourth week**	**Baseline**	**Fourth** week	
MIP (cmH_2O)	-57.3 ± 27.1	-87.3 ± 28.2*	-67.6 ± 34.7	-60.3 ± 25.4	<0.01
MVV (liters)	11.9 ± 5.2	27.1 ± 15.5*	12.3 ± 6.3	12.9 ± 7.6	0.15
MRC	50.0 ± 10.8	55.1 ± 8.0*	51.1 ± 9.9	51.3 ± 8.9	0.11
BI	76.5 ± 24.0	87.5 ± 16.5*	74.8 ± 22.2	76.2 ± 19.2	0.02
FIM	4.7 ± 2.0	6.0 ± 1.7*	4.6 ± 2.0	5.0 ± 1.9	0.06

MIP - maximal inspiratory pressure; MVV - maximum voluntary ventilation; MRC - Medical Research Council (MRC); BI - Barthel Index; FIM - Functional independence measure. * Comparing Baseline with Fourth week intra-groups (p-value <0,05). † Comparing Baseline with Fourth week inter-groups.

Table 3: Outcome and adverse events of IMT in hospitalized patients.

	PT/ IMT (n=26)	PT/ SHAM (n=28)	p-value	RR (CI 95%)	NNT
Hospital LOS (days)	35.3 ± 2.7	41.8 ± 3.5	<0.01		
Patients intubated	4 (15.3)	12 (42.8)	0.03	0.36 (0.27-0.97)	3.64
Hospital mortality	1 (3.8)	7 (25.0)	0.03	0.15 (0.02-0.79)	4.72
Muscle weakness	2 (7.7)	6 (21.4)	0.02	0.36 (0.19-0.98)	7.28
Adverse Events*:	21 (1.6)	22 (1.6)	0.84	1.11 (0.39-3.22)	
Cephalalgia	6 (0.5)	7 (0.5)			
Dyspnea	6 (0.5)	6 (0.4)			
Pain	5 (0.3)	4 (0.3)			
Hypertensi-on	4 (0.2)	3 (0.2)			
Dizziness	1 (0.1)	2 (0.2)			

* Interventions 2655: 1370 for the SHAM group and 1285 for the IMT group.

6. CONCLUSÕES

- O TMI com resistor de carga linear é eficaz na redução do tempo de internamento hospitalar. Além disso, tal conduta se comportou como fator de proteção para complicações do internamento hospitalar prolongado como: fraqueza muscular, intubação traqueal e mortalidade intra-hospitalar. Sua aplicação precoce demonstrou-se segura, não aumentando os eventos adversos e apresentando taxa de assiduidade bastante elevada neste perfil de pacientes;

- Essa conduta é útil na preparação do atleta de modalidades esportivas como ciclismo, remo e natação. Os protocolos de aplicação do TMI são bastante semelhantes, adotando carga moderada e freqüência elevada. Sua aplicação melhora a capacidade muscular respiratória, além de incrementar a tolerância do atleta ao exercício. Nesta população o TMI demonstrou melhorar o rendimento esportivo contra o relógio em comparação com grupos controles que realizavam apenas o treinamento voltado a modalidade esportiva.

7. CONSIDERAÇÕES FINAIS

A fraqueza muscular respiratória dos pacientes hospitalizados é um grande problema de saúde pública, sendo a mesma um fator independente para aumento da morbidade e mortalidade para pacientes com internamento muscular prolongado. Na atualidade, o recondicionamento dos músculos respiratórios, neste ambiente, tem sido abordado com finalidade de reabilitação, frente a uma deficiência muscular já instalada.

A presente dissertação é pioneira na aplicação do TMI precoce em pacientes com risco de internamento hospitalar prolongado. Seus resultados são encorajadores, visto que a terapêutica tem baixo custo, fácil reprodutibilidade e demonstrou-se segura para aplicação nesta população. Os benefícios da TMI neste perfil de paciente, são semelhantes aos expostos na literatura para atletas. Aqui vale ressaltar, que o resistor de carga linear, permite a adequação do treino a individualidade biológica e às alterações patológicas, por vezes presentes.

O TMI pode ser utilizado em ambiente hospitalar em pacientes com fatores de risco para internamento prolongado. Seu emprego precoce deve ser encorajado, antecedendo o desenvolvimento de deficiências físicas e funcionais. Tal indicação melhora a capacidade muscular respiratória e funcional. Os resultados expostos nessa dissertação, demonstram que a associação entre o TMI e a fisioterapia convencional se comporta como fator de proteção para complicações do internamento hospitalar prolongado, reduzindo assim o tempo de internamento.

8. PERSPECTIVAS DE ESTUDOS

A presente dissertação desperta a comunidade científica para o emprego do TMI precoce anteriormente a instalação de deficiências físicas e funcionais. Tais dados, expõe a necessidade de novas pesquisas que consolidem de fato a TMI como conduta de rotina no ambiente hospitalar, para isso faz-se necessário a realização de estudo multicêntricos, aplicados á amostras com patologias específicas e com seguimento dos desfechos por períodos que extrapolem o internamento hospitalar.

Mesmo que o presente trabalho demonstre que o TMI precoce é bem tolerado pelos pacientes hospitalizados e não aumenta a taxa de eventos adversos em comparação com o grupo controle, são necessários novos estudos inferindo o impacto desta conduta em marcadores inflamatórios e metabólicos, excluindo a possibilidade desta terapêutica gerar danos a nível celular e na micro-hemodinâmica a longo prazo.

A revisão da literatura da aplicação do TMI em atletas, expõe a necessidade de futuros estudos com populações representativas e em uma diversidade maior de modalidades esportivas. Tal levantamento, também demonstra a baixa qualidade dos estudos realizados na área, com baixo rigor na seleção e randomização das amostra e cegamento dos participantes e avaliadores durante o estudo.

9. ANEXO

ANEXO A – PARECER DO COMITÊ DE ÉTICA

HGRS HOSPITAL GERAL ROBERTO SANTOS

GOVERNO DA Bahia | Secretaria da Saúde

HOSPITAL GERAL ROBERTO SANTOS
COMITÊ DE ÉTICA EM PESQUISA

Salvador, 09 de maio de 2014.

PARECER
Protocolo de Pesquisa CEP/HGRS **Nº 03/2014**

1. Identificação

Titulo do Projeto: Impacto do treinamento muscular inspiratório (TMI) utilizando o POWERbreathe na Pimax de pacientes hospitalizados
Pesquisador (es) Responsável(is): Balbino Vidal Ventura Nepomuceno Júnior
Instituição: União Metropolitana de Educação e Cultura

2. Sumário do Projeto

Pesquisa de abordagem quantitativa e prospectiva. O presente estudo será realizado em uma organização hospitalar pública de grande porte e alta complexidade situada na cidade de Salvador-Bahia. A justificativa da escolha se deu por conta da necessidade de otimizar a responsividade de pacientes com o uso de modernos recursos terapêuticos na hospitalização, preenchendo lacunas na área estudada. O objeto de estudo contempla a avaliação do impacto do treinamento muscular inspiratório (TMI) em pacientes internados, tendo como critério de inclusão:

- pacientes com mais de quarenta e oito (48) horas de internamento
- pacientes que aceitarem participar do estudo.

E como critério de exclusão:

- pacientes com incapacidade cognitiva para realizar o treinamento, com instabilidade clínica ou hemodinâmica que contraindique a realização da técnica.
- portadores de diabetes mellitus, hipotireoidismo, colagenoses e acalasia.
- pacientes que obtiverem alta durante o período do estudo.
- pacientes com fraqueza muscular e pneumopatia crônica.

Os caminhos teóricos e metodológicos se apresentam adequados, de forma clara e organizados com referenciais pertinentes à temática e objetivos propostos.

3. Objetivos

Geral

Avaliar o impacto do treinamento muscular inspiratório (TMI) com o POWERbreathe, força muscular medida através da Pimax e MRC em pacientes hospitalizados.

4. Considerações quanto ao atendimento aos requisitos das resoluções do CNS

A estrutura do projeto de pesquisa está adequada e segue os conteúdos da Resolução CNS 466/2012, evidenciando o retorno dos benefícios do estudo para a organização e para a comunidade. Apresenta informações quanto ao orçamento e cronograma de execução coerente.
Os dados serão coletados durante o período de trinta dias, mediante aplicação direta da técnica em pacientes selecionados.
Com as respostas apresentadas pelos pacientes mediante a aplicação da técnica eleita para o estudo, poderão ser observados os benefícios apresentados com a realização do TMI, assim como poderá proporcionar ao profissional fisioterapeuta um repensar sobre sua atuação com esses pacientes, com novas reflexões para melhoria da qualidade da assistência à comunidade.
O termo de Consentimento Livre e Esclarecido (TCLE) apresenta coerência com os princípios éticos da Resolução CNS nº 466/2012, com clareza e possibilitando anuência aos participantes do estudo, contemplando os riscos e garantindo o sigilo das informações.

5. Conclusão

Aprovado.

Atenciosamente,

Maria do Espírito Santo da Silva
Coren - 10623
Coordenadora do CEP/HGRS

ANEXO B – TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Temos a satisfação de convidar você para participar do projeto de pesquisa intitulado: Efeito do treino muscular inspiratório utilizando o Powerbreathe na complicações hospitalares em pacientes internados por períodos prolongados sob responsabilidade do pesquisador: Prof. Balbino Nepomuceno Júnior e Prof. Dr. Mansueto Gomes Neto. Informamos que o objetivo principal dessa pesquisa é identificar os benefícios de um programa de exercício respiratório na melhora fisico e respiratória, reduzindo também perda de força e piora respiratória durante o internamento no hospital. Esse programa de exercício será realizado na unidade de internação do Hospital Roberto Santos que fica no bairro do Cabula. Sua participação será iniciada com a avaliação de capacidade de respirar e de se movimentar de maneira independente. Em seguida, irá iniciar o programa de exercícios durante 4 semanas, realizado duas vezes ao dia, por equipe treinada para esta atividade.

DESCONFORTO E POSSÍVEIS RISCOS ASSOCIADOS À PESQUISA:

O possível desconforto está associado ao procedimento de exercício que pode trazer cansaço respiratório e dores musculares, contudo o nosso programa de exercício foi pensado com uma intensidade mediana, visando a boa tolerância do paciente. Para minimiza desconfortos outros durante as terapias, durante todos as sessões, você será acompanhado por profissionais treinados para identificar precocemente qualquer indicio de cansaço na realização do programa. Caso desconfortos significativos acontece, a equipe médica da unidade, estará em sobreaviso para prestar cuidados de média e grande complexidade.

BENEFÍCIOS DA PESQUISA:

Além do benefício direto da realização de um programa de exercício de bons resultados em pessoas saudáveis, atletas e alguns grupos de pacientes. Você

estará contribuindo para que seja levantado o real efeito desse exercícios em pacientes internados em hospital, possibilitando a melhora na qualidade da assistência prestada. Além disso, através deste estudo, você irá realizar avaliações da sua capacidade e física semanais. Você também receberá ao fim da pesquisa um relatório informando sobre sua avaliação e os resultados do seu programa. A pesquisa não trás beneficio financeiro adicional para seus participantes.

FORMA DE ACOMPANHAMENTO E ASSISTÊNCIA:

Se necessário, o voluntário receberá assistência médica e/ou social aos agravos decorrentes das atividades da pesquisa. Em caso de duvidas sobre como acessar essa assistência ou possíveis indenizações referente a dados inerente a pesquisa, comprovada por junta médica. Basta procurar a pesquisador Prof. **Balbino Nepomuceno**, pelo telefone pessoal 71-8809-3939 e/ou pelo correio eletrônico: brvn@ig.com.br.

ESCLARECIMENTOS E DIREITOS

Em qualquer momento você poderá receber orientações sobre o programa de exercício realizado e a possibilidade de desconforto. Será respeitado sua liberdade em retirar o consentimento para a participação em qualquer fase da pesquisa, sem prejuízo do atendimento usual fornecido pelos pesquisadores. Caso você tenha duvidas quanto a sua participação na pesquisa você deve entrar em contato com o comitê de ética localizado na Rua Estrada do Saboeiro s/ n° – Cabula Hospital Geral Roberto Santos, andar Intermediário. Cep.: 41.180-780 Salvador, BA, com Tel.: (71) 3117-7519 e e-mail: cep.hgrs.ba@gmail.com , com horário de funcionamento de segunda à sexta das 08:00 ás 16:30.

CONFIDENCIALIDADE E AVALIAÇÃO DOS REGISTROS

Todos os participantes da pesquisa terem seu nome e imagem mantidos em total sigilo por tempo indeterminado, tanto pelo executor como pela instituição onde será realizado. Os resultados deste trabalho serão analisados e organizados em tabelas, figuras ou gráficos e divulgados em eventos e revistas científicas do meio médico nacionais e internacionais.

CONSENTIMENTO PÓS-INFORMAÇÃO

Eu,_____,
portador da Carteira de identidade nº _____ expedida pelo Órgão _____, por me considerar devidamente informado(a) e esclarecido(a) sobre o conteúdo deste termo e da pesquisa a ser desenvolvida, livremente expresso meu consentimento para inclusão, como sujeito da pesquisa. Todas as informações por mim fornecidas e os resultados obtidos serão mantidos em sigilo e, estes últimos serão utilizados para divulgação em reuniões e revistas científicas sem a minha identificação. Serei informado de todos os resultados obtidos, independentemente do fato de mudar meu consentimento em participar da pesquisa. Não terei quaisquer benefícios ou direitos financeiros sobre os eventuais resultados decorrentes da pesquisa. Fui informado que meu número de registro na pesquisa é HGRS 03/2014 e recebi cópia desse documento por mim assinado.

_____ _____

Assinatura do Participante Voluntário Data

Impressão Dactiloscópica (p/ analfabeto)

_____ _____/_____/_____

Assinatura do Responsável pelo Estudo Data

ANEXO C – RESUMOS PUBLICADOS EM ANAIS DE CONGRESSOS

III Congresso Nordestino de Fisioterapia Cardiorrespiratória e Fisioterapia em Terapia Intensiva.


III CONEFIR
III CONGRESSO NORDESTINO DE FISIOTERAPIA CARDIORRESPIRATÓRIA E FISIOTERAPIA EM TERAPIA INTENSIVA
Hotel Ritz Lagoa da Anta
Maceió/Alagoas
15 a 17 de Outubro/2015
Promoção e Realização
ASSOBRAFIR
Certificado

Certificamos que o trabalho intitulado "TREINAMENTO MUSCULAR INSPIRATÓRIO E RISCO DE INTUBAÇÃO E ÓBITO NO AMBIENTE HOSPITALAR: ENSAIO CLÍNICO RANDOMIZADO", foi apresentado na forma de pôster durante o **III CONGRESSO NORDESTINO DE FISIOTERAPIA CARDIORRESPIRATÓRIA E FISIOTERAPIA EM TERAPIA INTENSIVA**, realizado no período de 15 a 17 de outubro, no Hotel Ritz Lagoa da Anta em Maceió/AL.

Autor (es): Balbino Rivail Ventura Nepomuceno Júnior, Mayana de Sá Barreto, Naniane Cidreira Almeida, Caroline Ferreira Guerreiro, Mansueto Gomes Neto.

Maceió, 17 de outubro de 2015.

Jocimar Avelar Martins
Presidente da ASSOBRAFIR

George Márcio da Costa e Souza
Presidente do III CONEFIR

Patrocinadores
PHILIPS RESPIRONICS
AIR LIQUIDE
Apoio
Estácio FAL