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RESEARCH ARTICLE

EFFECTS OF INSPIRATORY MUSCLE TRAINING ON RESPIRATORY FUNCTIONS AMONG UNCONTROLLED ASTHMATICS

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ABSTRACT

Background: Specific breathing exercises are reported to improve quality of life and reduce symptoms; although no significant benefit on lung function or reduction of exacerbation risk is indicated. Additionally, inspiratory muscle training (IMT) aims to increase diaphragm and inspiratory muscle endurance. In this study, IMT has been performed in uncontrolled asthma patients to investigate its effect on respiratory symptoms and pulmonary functions.

Methods: Twenty-two uncontrolled and partially controlled asthmatic patients were included in the study. Asthma control test (ACT), asthma quality of life questionnaire (AQLQ), and spirometric evaluations were performed. The study population was randomized into two groups. The standard care group (n=10) received standard medical treatment while the intervention (n=12) group practiced a portable threshold IMT device following standard medical treatment.

Results: The study was completed by 14 patients due to 7 lost during the follow up (one intervention group and 6 standard care) and one asthma exacerbation. We have found that the intervention group tended to have increased pulmonary function test parameters and AQLQ scores, moreover; MIP values and ACT scores have statistically significant increases after IMT(p=0.01, p=0.02 respectively).

Conclusion: Add-on IMT to standard medical treatment could improve asthma control by strengthening inspiratory muscles of uncontrolled asthmatic patients. IMT could be considered in the non-pharmacological treatments of uncontrolled asthmatic patients. Despite the limited number of patients, this study revealed that IMT might have positive outcomes for uncontrolled asthma patients.

Keywords: Uncontrolled asthma, inspiratory muscle training, pulmonary function, inspiratory muscle endurance, quality of life.

INTRODUCTION

Asthma is one of the most common chronic diseases among children and young adults (1). It is related to increased mortality and morbidity as well as school or work absence, and high healthcare payments(1,2). Therefore, adequate treatment of asthmatic subjects has become crucial. One of the main targets of the treatment is the involvement of the patients in daily life activities, along with disease control, and symptom relief (1).

Asthma control could be achieved by medical treatment in general; however, complete control is unattainable in some patients, especially in severe asthmatics (1). Despite adequate medical treatment,

some asthmatic patients complain of dyspnea and low physical activity level arising from increased respiratory effort (3). Decreased physical activity is also associated with asthma exacerbation risk, in addition to psychological stress and poor quality of life (3). Physical activity is one of the non-pharmacological treatments recommended for asthma after evaluation for exercise-related bronchoconstriction (1).

Pulmonary rehabilitation (PR) should be considered for all patients with respiratory diseases who have a low functional capacity and poor quality of life (3–6). The majority of the patients who are referred to PR clinics are still chronic obstructive pulmonary disease (COPD) patients(7). However, exercise and PR have been recommended for asthmatic patients too(3–5). The main feature of COPD is hyperinflation, which results in diaphragm shortening and flattening and weakened inspiratory muscle strength(3,4). Similarly, in some asthmatic patients, expiratory airflow limitation, early small airway collapse, and decreased compliance might cause hyperinflated lungs (8). Airflow resistance occurs especially during exercise resulting in dynamic hyperinflation and dyspnea (9,10). It has been previously shown that, in patients with decreased inspiratory muscle strength, respiratory muscle training in conjunction with the exercise programs induces higher improvements in exercise capacity compared to standard exercise (3,4). Depending on these facts, inspiratory muscle training (IMT) in resistive or threshold levels in asthmatic patients could decrease dyspnea and hyperinflation, normalize respiratory function, and increase exercise tolerance (11–13).

IMT technique aims to increase diaphragm and inspiratory muscle endurance. The main mechanism is to increase the resistance against inspiratory muscle load created by dynamic hyperinflation (14). For that purpose, to create definite structural and biochemical changes like peripheral muscle groups, patients have to exercise at the threshold level (15).

In the current literature, there is limited information about IMT practice in asthma treatment. IMT might be a future promising non-pharmacological treatment option for uncontrolled asthma, although there is no routine application for them. Further studies focused on the role of IMT for asthmatic patients are needed (15,16). Since that, besides supporting data for this novel intervention, this study aimed to evaluate the effect of pressure threshold IMT practice for partly controlled or uncontrolled asthmatics.

MATERIALS AND METHODS

Study Design

The study was designed as a randomized clinical trial. After obtaining local Dokuz Eylul University, Non-invasive Clinical Research Ethics Committee approval (Date and number: 24th November 2014/ 1509-GOA; 2014/ 35-27) the investigation was carried out in the pulmonary diseases department from February 1, 2015, to July 31, 2017. Asthma patients aged between 18 to 65 years who were admitted to pulmonary diseases outpatient clinic and were partly controlled or uncontrolled were included.

Partly-controlled asthma; was described as, day symptoms more than twice a week in the previous month, activity limitation, nocturnal symptoms and awakenings, reliever medication need for more than twice a week, and pulmonary functions (peak expiratory flow or FEV1) under 80% of expected value or the best personal value if it is known (1). Uncontrolled asthma was pronounced if three or more partly controlled asthma criteria were present (1).

The subjects with neuromuscular diseases that obstacle to participating in the study, impaired cognitive functions to understand and perform the inspiratory muscle training, asthma exacerbations during the study, and accompanying pulmonary diseases (Chronic obstructive pulmonary disease, bronchiectasis, lung cancer) were excluded.

Subjects who met the inclusion criteria were invited for the first visit. At the first visit, demographic characteristics of the study, the population was recorded and asthma control was determined by the asthma control test (ACT) (17). Health-related quality of life was evaluated with the Asthma Quality of Life Questionnaire (AQLQ) (2).

After the baseline evaluation, the subjects were randomized according to a simple random numbers table. Both groups were treated according to standard medical treatment recommended by Global Initiative for Asthma (GINA) guidelines (1). In addition to standard medical treatment, the intervention group receives IMT program.

Evaluation Parameters

Pulmonary Function Tests

An experienced single technician has performed respiratory function tests with the Jaeger Master Screen Pneumo device. FEV1, FVC, FEV1/FVC, MIP, MEP, RV, TLC were measured according to ERS/ATS criteria(18). MIP was measured at RV level

by maximum inspiratory (Mueller) maneuver and MEP was measured at TLC level by maximum expiratory (Valsalva) maneuver. MIP and MEP values were recorded for a minimum of 1 second(11). PFT was performed in the baseline and the second visit.

Asthma Control Test (ACT)

ACT is a self-administered test developed to determine the asthma control level. The test includes five questions, evaluating asthma control in the last four weeks. Every question is scored from one to five and the maximum total score is 25. An ACT score of 25 indicates that asthma is "controlled," whereas a score between 20 and 24 is partially controlled and <20 indicates "uncontrolled" asthma. Turkish validity and reliability of the ACT have been done (9).

Asthma Quality of Life Questionnaire (AQLQ)

The Juniper AQLQ is a questionnaire, which contains 32 items from four disease-specific domains. Activity limitation (11 questions), symptoms (12 questions), emotional function (5 questions), environment stimuli (4 questions) are evaluated. This instrument measures the quality of life over the two weeks before the interview. Every question has the same significance and is analyzed with a 7 point-Likert type system, in which "1" means "no impairment" while "7" means "maximum impairment". Each domain score is computed as the means of domain-specific items and the global AQLQ score is computed as the mean of the domain scores. For minimum clinical significance, a 0.52 unit increase is needed. Turkish validity and reliability analysis of the ACT has been done (20).

Inspiratory Muscle Training (IMT)

'Threshold IMT, Philips Respironics' device was used to perform inspiratory muscle trainıng(21). A flow velocity independent unidirectional valve generates constant and specific resistance for inspiratory muscle strength and endurance The physician can arrange pressure settings according to individual needs. When the patients inhale into ''Threshold IMT'', the valve loads with air and the resistance in the valve evokes inspiratory muscle exercise and conditioning.

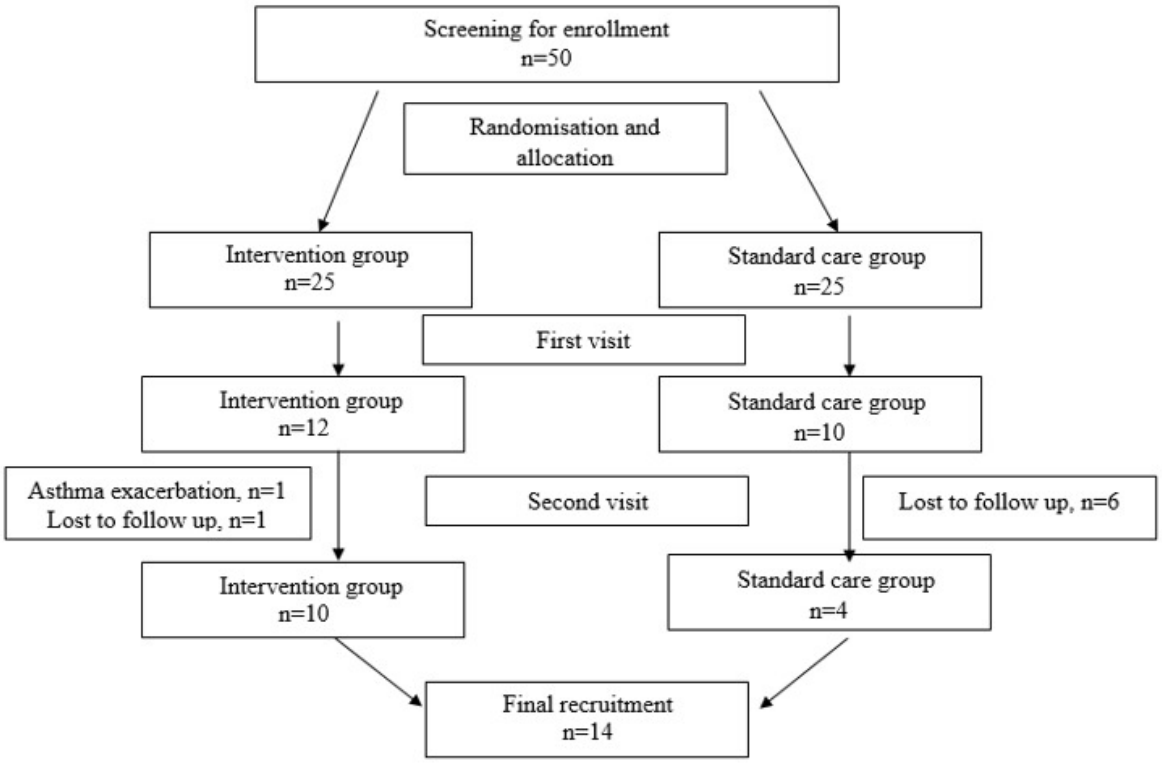

Figure 1. Study protocol

At the first step: The patient inhales within the IMT device.
A second step: The patient repeats the process leading to increased inspiratory muscle strength.
The intervention group received inspiratory muscle training (IMT) in addition to standard medical treatment. IMT exercise program was adjusted as five days/week, three-session/day, 15 repeats in a session with a 40-60 % force of MIP. All subjects were re-evaluated after 3 months with ACT, AQLQ, and pulmonary function tests applied in the first visit.

Statistical Method

Data were analyzed with SPSS software (Statistical Package for the Social Sciences, version 22, 0 SSPS Inc., Chicago, IL). Median values were calculated for the pulmonary functions and clinical features of study participants. Baseline and 'after the IMT' values were analyzed by using the Mann-Whitney U test and the Wilcoxon test. For categorical evaluations, Chi-square or Fisher exact tests were used. A *p value<0.05* was determined as significant.
Based on a study similar to this research (10), The differences in MIP (Pimax) values between the before and after IMT were used to determine the sample size; after the analysis of the G Power 3.1.9.2 program, the number of subjects required to be included for 85% statistical power and a 0.05 α value was determined as 22 subjects (with 9 subjects in each group + 3 subjects per group, considering drop outs).

Table 1: Demographical and clinical features of the groups

	Intervention group n= 10 median (range)	**Standard care group n= 4 median (range)**	***p* value**
Age, years	47 (22-56)	36.5 (20-65)	0.47
Gender, F/M, n	9/1	3/1	0.46
FEV1, L/sn	2.14 (1.18-3.16)	3.30(1.63-4.22)	0.12
FVC, L/sn	2.81 (1.61-4.07)	4.05(2.41-4.61)	0.15
FEV1/FVC, %	75.00 (53.00-85.00)	81.40 (64.61-91.47)	0.39
PEF, L/sn	4.23 (2.52-6.53)	5.45 (4.22-7.24)	0.12
MIP, kPa	4.38 (2.35-6.73)	6.16 (3.64-8.21)	0.14
MIP, %	95.00 (58.00-104.00)	83.50 (69.00 – 96.00)	0.56
MEP, kPa	4.25 (2.36-7.26)	7.15 (4.10-7.92)	0.07
MEP, %	68.50 (38.00-112.00)	73.00 (55.00-87.00)	1.00
ACT	20.00 (8.00-24.00)	18.50 (14.00-23.00)	0.88
AQLQ	4.17 (2.06-6.09)	4.87 (4.41-5.59)	0.22
RV, L/sn	2.21 (1.52-2.94)	1.63 (1.39-2.70)	0.31
RV, %	152.00 (136.00-159.00)	132.00 (80.00-143.00)	0.08
TLC, L/sn	5.08 (4.04-5.87)	5.01 (4.85-5.29)	1.00
TLC, %	104.75 (96.00-120.00)	115.70 (72.30-117.20)	1.00

ACT: Asthma control test, AQLQ: Asthma Quality of Life Questionnaire, F: Female, $FEV_{1:}$ *Forced expiratory volume* in one *second*, FVC: Forced vital capacity, M: Male, MEP: Maximum expiratory pressure, MIP: Maximum inspiratory pressure, PEF: Peak expiratory flow RV: Residual volume, TLC: Total lung capacity

Table 2: Pulmonary functions and clinical features at the baseline and after the IMT of the intervention group.

Case, n=10	Before IMT	After IMT	*p-value*
FEV1, L/sn	2.14 (1.18-3.16)	2.22 (1.27-3.15)	0.09
FVC, L/sn	2.81 (1.61-4.07)	2.90 (1.78-4.07)	0.09
FEV1/FVC, %	75.00 (53.00-85.00)	74.00 (54.00-86.00)	0.55
PEF, L/sn	4.23 (2.52-6.53)	3.85 (2.65-6.57)	0.79
RV, L/sn	2.21 (1.52-2.94)	1.91 (1.02-3.08)	0.58
RV, %	152.00 (136.00-159.00)	151.20 (117.00-172.00)	1.00
TLC, L/sn	5.08 (4.04-5.87)	5.08 (4.02-5.85)	0.95
TLC, %	104.75 (96.00-120.00)	103.60 (99.20-104.30)	1.00
MIP, kPa	4.38 (2.35-6.73)	4.66 (2.56-6.75)	0.02
MIP, %	95.00 (58.00-104.00)	105.00 (101.00-118.00)	0.29
MEP, kPa	4.25 (2.36-7.26)	5.22 (3.20-9.219	0.05
MEP, %	95.00 (58.00-104.00)	96.50 (51.00-117.00)	0.46
ACT	20.50 (13.00-24.00)	22.50 (15.00-25.00)	0.01
AQLQ	4.17 (2.06-6.09)	5.12 (3.03-6.50)	0.11

*Data was given as median value (minimum-maximum) unless otherwise specified.

ACT: Asthma control test, AQLQ: Asthma Quality of Life Questionnaire, FEV_1: *Forced expiratory volume* in one *second*, FVC: Forced vital capacity, MEP: Maximum expiratory pressure, MIP: Maximum inspiratory pressure, PEF: Peak expiratory flow, RV: Residual volume, TLC: Total lung capacity

RESULTS

In the baseline, the study was planned to include 50 patients (25 patients for each group) however, 12 patients in the intervention and 10 patients in the standard care groups could be included in the study between the specified dates. 14 of these 22 subjects could complete the study protocol (Figure 1).

There was no statistically significant difference for age, gender, pulmonary function test, ACT, health-related quality of life between the two groups at the baseline evaluation (Table 1). Median values for FEV1, FVC, PEF, and MIP of the intervention group tended to be lower than the standard care group. The intervention group was also more likely to have better-perceived asthma control, worse quality of life, and higher residual volumes, yet they did not reveal any statistical significance (Table 1).

After the IMT, there was no difference in terms of FEV1 and FVC values (p=0.09 and p=0.09, respectively). There was a significant increase in MIP values by reaching the median of 4.66 (2.56-6.75) (p=0.02). ACT values also showed a noteworthy improvement in the intervention group (20.50 vs 22.50, p=0.01), yet quality of life did not differ after the IMT (p=0.11).

In the standard care group, MIP values tended to decrease between two visits (6.16 vs 5.70, p=0.27). ACT scores were also found higher in the second visit, but they did not show any statistical significance (18.50 vs. 23.00, p=0.19) (Table 3).

DISCUSSION

We aimed to show the effect of IMT on asthma control for patients in whom asthma control was not achieved. In this randomized controlled study, we observed an increase in inspiratory muscle strength in the IMT practice that may also introduce a better level of asthma control.

Table 3: Spirometric evaluation and asthma control parameters of standard care group at the first and second visit.

Control, n=4	First visit	Second visit	*p-value*
FEV1, L/sn	3.30(1.63-4.22)	3.35 (1.51-4.20)	0.47
FVC, L/sn	4.05(2.41-4.61)	4.08 (2.46-4.44)	1.00
FEV1/FVC, %	81.40 (64.61-91.47)	81.84 (61.29-95.17)	0.72
PEF, L/sn	5.45 (4.22-7.24)	6.46 (3.49-7.10)	0.72
RV, L/sn	1.63 (1.39-2.70)	1.68 (1.43-3.06)	0.11
RV, %	132.00 (80.00-143.00)	138.00 (84.00-162.00)	0.11
TLC, L/sn	5.01 (4.85-5.29)	5.54 (5.12-5.91)	0.11
TLC, %	115.70 (72.30-117.20)	118.00 (79.20-121.10)	0.11
MIP, kPa	6.16 (3.64-8.21)	5.70 (1.24-8.72)	0.27
MIP, %	83.50 (69.00-96.00)	83.00 (24.00-87.00)	0.19
MEP, kPa	7.15 (4.10-7.92)	5.76 (2.97-7.89)	0.27
MEP, %	73.00 (55.00-87.00)	50.00 (45.00-93.00)	0.27
ACT	18.50 (14.00-23.00)	23.00 (15.00-25.00)	0.19
AQLQ	4.87 (4.41-5.59)	5.82 (3.38-7.34)	0.72

Data were given as median value (minimum-maximum) unless otherwise specified.

ACT: Asthma control test, AQLQ: Asthma Quality of Life Questionnaire, FEV_1: *Forced expiratory volume* in one *second*, FVC: Forced vital capacity, MEP: Maximum expiratory pressure, MIP: Maximum inspiratory pressure, PEF: Peak expiratory flow, RV: Residual volume, TLC: Total lung capacity

Although anti-inflammatory drugs are the key stone of asthma treatment, currently non-pharmacological approaches are recommended more frequently to achieve asthma control(1). Asthmatic patients experience chronic and exercise-induced bronchoconstriction related to increased inspiratory muscle load(14). From a different perspective, the frequent need for corticosteroid use might cause peripheral muscle weakness, especially in uncontrolled asthmatic patients(22). Considering these facts, improvement of inspiratory muscle strength in asthmatic patients was claimed to decrease dyspnea and increase exercise tolerance(23).

There are limited data about the effect of inspiratory muscle training in asthmatic patients with different severity. Some of these studies could not enlighten IMT effectiveness, on the other hand, it is difficult to make an exact decision since there is no standardization since the studies used different protocols(12,24).

In our study, we have found an improvement in lung volumes. In parallel with our findings, an increase in the inspiratory muscle power after IMT was also reported in previous studies(12). Furthermore, some studies reported that IMT in asthmatic patients decreased symptoms and the need for medication(13,25). However, some studies that measured static and dynamic lung volumes of asthmatic patients after IMT have revealed contradictory results(13,25). It might be due to the IMT device type and application as well as the study population's traits.

In our study, we detected an improvement in asthma control measured by ACT, reflecting both symptoms and disease control. To our knowledge, our study is the first study that evaluates IMT efficiency with ACT in the literature. Reflection of the benefits of IMT on the ACT, as a novel finding, points out that; PR

performance can be evaluated fast and easily by ACT in asthmatic patients.

Since the limited number of subjects completed the study, the sample size is the major limitation of the study. The study population was predicted according to the number of our potentially uncontrolled asthmatic subjects. We had many losses during the follow-up, especially in the standard care group. It may be explained that IMT practiced subjects were keener on the follow-up due to the additional procedure and they were followed up more closely. Despite the non-significant p-values, all parameters had improved in the patients who receive IMT addition to standard care. On contrary, no improvement could be observed in the standard care group. Low statistical significance might be a result of the limited number of participants.

As a result, our study points out that inspiratory muscle training could be used to improve asthma control. IMT should be considered in the non-pharmacological treatments of uncontrolled asthmatic patients. Our study contributes to raising awareness for non-pharmacological treatments. IMT could be beneficial for asthmatic patients in addition to standard care and should be considered as an add-on therapy especially in uncontrolled asthma.

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Conflict of interest: None to be reported.

Ethical statement: The study designed as a randomized clinical trial, was approved by Dokuz Eylul University Non-invasive Clinical Research Ethics Committee (Date and number: 24th November 2014/ 1509-GOA; 2014/ 35-27).

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