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# Improvement in Respiratory Muscle Strength and Exercise Tolerance after Pulmonary Rehabilitation Program in Diabetics with Inspiratory Muscle Weakness

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## ABSTRACT

Previous investigations have demonstrated that inspiratory muscle training resulted in positive changes in patients with chronic lung disease, although the effect of it on diabetics with inspiratory muscle weakness is yet to be determined. This study aimed at evaluating the effect of inspiratory muscle training on ventilatory function, inspiratory muscle strength and exercise tolerance in diabetics with inspiratory muscle weakness. Thirty four diabetics were enrolled. They were divided into inspiratory muscle training group and control group. Subjects in the training group received a 30 minutes inspiratory muscle training three times per week for 2 months and simple disease information sessions. The control group received simple disease information sessions only. Inspiratory muscle training increased significantly the ventilatory function, inspiratory muscle strength and peak oxygen consumption with no significant changes in the control group. This study concluded that inspiratory muscle training is recommended to decrease the restrictive lung impairment in diabetics.

**Key Words:** Diabetes mellitus, Exercise tolerance, Inspiratory muscle training.

## INTRODUCTION

According to World Health Organization (WHO), the term diabetes mellitus (DM) describes a metabolic disorder of multiple etiologies, characterized by chronic hyperglycemia with disturbances of carbohydrate, protein and fat metabolism, resulting from defects in insulin secretion or insulin action or both<sup>1</sup>. Diabetes mellitus is a leading public health problem with increasing incidence and long term complications. According to WHO, the prevalence of diabetes has reached epidemic proportions. The total number of diabetics worldwide is projected to rise from 150 million in 2000 to 435 million in 2030<sup>41</sup>. There is one person in the world dying of diabetes every ten seconds and new diabetic cases being identified every ten seconds. The worst affected are people in the age group of 40 to 59 years<sup>41</sup>.

Practically every system is affected by complications of diabetes. Attention is usually paid to angiopathy (micro, macro), retinopathy and nephropathy, but respiratory system is often neglected<sup>29</sup>.

The presence of an extensive micro vascular circulation and abundant connective tissue in the lungs raises the possibility that lung tissue may be affected by microangiopathy process and non-enzymatic glycosylation of tissue proteins, induced by chronic hyperglycemia, thereby rendering the lung a "target organ" in diabetic patients. Since normal lung mechanics and gas exchange are influenced by the integrity of pulmonary connective tissue and microvasculature, abnormalities in either of these two structural components of the lung may lead to the development of measurable abnormalities of pulmonary function<sup>35</sup>.

These abnormalities may include reduction in lung volumes<sup>8</sup> and carbon monoxide diffusion<sup>15</sup>, as well as decreased pulmonary compliance, lung elastic recoil<sup>38</sup>, and inspiratory muscle strength<sup>24</sup>. The performance of inspiratory muscles is of particular interest because it may influence exercise capacity in diseases in which inspiratory muscle weakness (IMW) is present. Diabetics may present increased ventilatory response to exercise, affecting exercise tolerance<sup>19,31</sup>.

The inspiratory muscles are morphologically and functionally skeletal muscles and, therefore, should respond to training in the same way as would any locomotor muscle if an appropriate physiological load is applied<sup>27</sup>. Inspiratory muscle

training (IMT) was defined as any intervention with the goal of training the inspiratory muscles<sup>12</sup>. The loads applied to the inspiratory muscles for the purpose of training are flow, threshold or resistive in nature<sup>20</sup>. However, controversy exists in the literature regarding the mode and intensity of training required to result in improvements of pulmonary functions and work capacity.

Inspiratory muscle training has been shown to improve inspiratory muscle function, lung volumes and physical capacity in patients with chronic heart failure<sup>32</sup>, lung disease<sup>19</sup>, cerebrovascular disease<sup>37</sup>, or neuromuscular disorders<sup>5</sup> and in healthy people<sup>4,11,26</sup>; however, there is some conflicting results.

Threshold inspiratory muscle training devices impose a threshold or critical opening pressure that must be overcome prior to inspiratory flow commencing. During the task, inspiratory muscles initially perform an isometric contraction until the threshold valve opens to allow inspiratory flow, after which the contraction becomes isotonic in nature. In contrast to resistive loading, threshold loading has the advantage of inspiratory pressure being largely independent of flow rate such that manipulations in breathing pattern to change inspiratory flow rates will not alter the inspiratory load imposed by the device. For this reason threshold loading devices have become a popular choice<sup>17</sup>.

Diabetics with autonomic neuropathy had reduced inspiratory muscle strength, suggesting that IMW might be associated with autonomic dysfunction<sup>25</sup>. However, the effect of IMT on diabetics with inspiratory muscle weakness is yet to be determined. Therefore, the current study evaluated its effect on those patients.

## SUBJECTS AND METHODS

### Participants

A controlled clinical trial was conducted in sedentary women with diabetes mellitus, recruited from the Endocrinology Outpatient Clinic of Faculty of Medicine and Outpatient Clinic of Faculty of Physical Therapy, Cairo University. The subjects in the age group between 50-60 years were included with duration of diabetes mellitus  $\geq 10$  years. Their maximal inspiratory pressure was ( $PI_{max}$ )  $< 70\%$  of predicted<sup>30</sup>. This cutoff value has been arbitrarily chosen to define patients with inspiratory muscle weakness<sup>32</sup>. Exclusion criteria were body mass index  $> 30$  kg/m<sup>2</sup>, history of exercise-induced asthma, infectious disease, cardiac diseases, respiratory diseases, and smokers or ex-smokers. All subjects signed a written informed consent form. The study was conducted at Faculty of Physical Therapy, Cairo University.

Patients were evaluated at baseline by medical history, physical examination, and determination of ( $PI_{max}$ ). Of the screened 45 patients with DM evaluated for inspiratory muscle strength, 34 of them had ( $PI_{max}$ )  $< 70\%$  of predicted. Eligible patients were randomly assigned into two groups (training and control groups). The training group consisted of 17 patients who received inspiratory muscle training program for 3 days/week for 2 month, in addition to simple disease information sessions aimed to reinforce patient education about diabetes mellitus signs and symptoms, ensure compliance with medications, advice on how to live with diabetes mellitus and emphasis was given to dietary counseling. The control group consisted of 17 patients who received only the same disease

information sessions received by the training group through frequent visits. Of the 34 patients randomized to the training and control groups. Two patients from the training group and one from the control group didn't continue in the protocol. Therefore, after 2 month, 16 patients in the control group and 15 patients in the training group were analyzed. Before and after the study period, ventilatory function tests, inspiratory muscle function test and determination of  $VO_2$  peak, were obtained. Analysis of glycosylated hemoglobin (Hb A1c %), fasting and 2-hour postprandial blood glucose level were obtained at baseline. Plain chest X-ray was performed to all participants to exclude any chest diseases prior to the study.

## Evaluation

### A- Anthropometric and body composition.

Body height (cm) was measured with patient standing barefoot. Body weight (kg) was measured with subjects in light clothing and was established to the nearest 0.1 kg. Body surface area (BSA) was measured with Mosteller formula<sup>13</sup>:  $BSA = (\text{Weight}^{0.5} \times \text{Height}^{0.5}) / 60$ .

### B- Pulmonary function test:

Each patient underwent PFT (Pulmonary function test) including:

1. Spirometry. It was performed in accordance with the recommended techniques using a computerized spirometer (1085 D Medical Graphics Corporation, USA). The participants completed three acceptable maximal forced expiratory maneuvers to obtain forced vital capacity (FVC), forced expiratory volume in 1 second ( $FEV_1$ ), and forced mid-expiratory flow ( $FEF_{25-75\%}$ ). Technical procedure criteria were those recommended by the American Thoracic Society (2). During all measurements, participants were seated. All lung function measurements were expressed in liters and as percentage of the predicted value for age, height, and sex.

2. Maximal voluntary ventilation (MVV). It was directly determined with the subjects using nose clips and breathing deeply (with a volume greater than the tidal volume preceding the maneuver but less than the vital capacity) and rapidly for a 12-s interval (1085 D Medical Graphics corporation, USA). The subjects were actively encouraged to maintain the same volume and frequency by following an online display of the maneuver on a computer screen, that is, the end expiratory level remained relatively constant. At least two acceptable maneuvers were obtained after flow integration, the highest value recorded by extrapolating the 12-s accumulated volume to 1 min.

3. Inspiratory muscle function. Maximal inspiratory pressure is the maximum pressure generated by the inspiratory muscles against an occluded airway<sup>20</sup>. Maximal inspiratory pressure ( $PI_{max}$ ) actual value and % predicted was determined in deep inspiration from residual volume against an occluded airway with a minor air leak (1085 D Medical Graphics Corporation, USA). Predicted values were corrected for age and gender (30). The ( $PI_{max}$ ) was the maximum pressure (cm H<sub>2</sub>O) developed in the first second of inspiration and represented a measure of inspiratory muscle strength. The value obtained from the best of at least three efforts was used.

### C- Exercise capacity

Peak oxygen consumption ( $VO_2$  peak) was predicted by the following equation:

$VO_2$  peak = (maximum voluntary ventilation  $\times$  0.024) + (forced mid expiratory flow  $\times$  0.47) + (body surface area  $\times$  0.988) - 0.913<sup>9</sup>.

### Inspiratory muscle training (IMT):

Patients in the training group had received inspiratory muscle training for 30 min three times per week for 2 month using the threshold inspiratory muscle trainer device (Threshold IMT – Philips). For the training group, inspiratory load was set at 30% of  $PI_{max}$ , and monthly measures of  $PI_{max}$  were obtained to maintain training loads at 30% of the  $PI_{max}$ . They started breathing at a resistance that required generation of 15% of their  $PI_{max}$  for 1 week. The load was then increased incrementally 5% each session to reach generation of 30% of their  $PI_{max}$ . Loaded breathing was intermittent for 3-minute periods, with a 2-minute rest period in between.

### Data Analysis

**Table (1): Baseline characteristics of patients.**

Characteristic	Training group	Control group	P-value
Age (years)	52.4 + 2.12	52.81+ 2.27	0.668
BMI (kg/m <sup>2</sup> )	26.92+ 3.2	26.5 + 1.32	0.737
Diabetes time (years)	11.7 + 1.2	11.18+ 1.40	0.370
Fasting blood glucose (mg/dL)	221.2+ 38.65	205.73+ 72.5	0.130
Post prandial blood glucose (mg/dL)	281.3+ 39.25	255+ 80	0.098
Hb A1c (%)	9.1+0.85	8.82+ 2.41	0.120

BMI: body mass index; Hb A1c: glycosylated hemoglobin.

### Pulmonary function test results

At pre treatment measurements, no significant difference was found between the 2 groups regarding forced vital capacity (FVC), forced expiratory volume in 1 second (FEV<sub>1</sub>), maximal voluntary ventilation (MVV), maximal inspiratory pressure ( $PI_{max}$ ) actual value and % predicted. Upon comparing between pre and post measurements of training group, significant increase was noticed in FVC, MVV, ( $PI_{max}$ ) actual value and % predicted (P = 0.006, 0.039, 0.002 and 0.000 respectively), but

Data were analyzed on the Statistical Package for Social Sciences (version 18.0 for Windows; SPSS, Inc., Chicago, IL). All variables were tested for normality. Descriptive data are presented as mean + SD. Non-parametric tests (the Mann-Whitney test) were used to analyze values of fasting, post prandial blood glucose level and glycosylated hemoglobin (HbA1c%) between the groups. The paired and unpaired t-test was used to compare the pre- and post-treatment values of other variables within and between the groups. A difference was considered significant if the P-value was < 0.05.

### RESULTS

The baseline characteristics of patients are summarized in Table 1. There were no significant differences between the groups regarding age, body mass index, Diabetes time, fasting and post prandial blood glucose and Hb A1c (%).

non significant increase in (FEV<sub>1</sub>). There was no significant change in the control group regarding FVC, FEV<sub>1</sub>, MVV, ( $PI_{max}$ ) actual value and % predicted (P = 0.341, 0.506, 0.307, 0.07 and 0.068, respectively), see Table 2. Comparing the post-treatment results of the two groups, no significant difference was found for FVC, FEV<sub>1</sub>, MVV (p = 0.325, 0.157 and 0.156, respectively), but there was a significant difference for ( $PI_{max}$ ) actual value and % predicted in favor of the training group (P = 0.028 and 0.017, respectively), see Fig. 1 and 2.

**Table (2): Statistical analysis of pulmonary function test within each group and between groups.**

Variable	Groups	Pre	Post	% of Change	P <sup>1</sup> -value
FVC % predicted	Training	67.8 ± 7.58	68.37± 7.77	↑ 0.84	0.006*
	Control	72.18±8.17	71.91±8.22	↓ -0.37	0.341
	P <sup>2</sup> -value	0.22	0.325		
FEV <sub>1</sub> % predicted	Training	63.7± 10.07	64.32± 10.47	↑ 0.97	0.073
	Control	72.55± 14.01	72.36± 14.09	↓ -0.26	0.506
	P <sup>2</sup> -value	0.116	0.157		
MVV % predicted	Training	58.8± 10.47	60.1± 10.57	↑ 2.2	0.039*
	Control	68.72± 14.35	68.36± 14.51	↓ -0.52	0.307
	P <sup>2</sup> -value	0.89	0.156		
$PI_{max}$ actual value	Training	48.7+ 9.10	64.4+ 9.66	↑ 32.24	0.002*
	Control	54.09+ 11.64	53.27+11.53	↓ -1.52	0.07
	P <sup>2</sup> -value	0.255	0.028*		
$PI_{max}$ % predicted	Training	54+ 9.57	69.1+ 5.38	↑ 28	0.000*
	Control	59.63+11.51	58.81+11.28	↓ -1.38	0.068
	P <sup>2</sup> -value	0.240	0.017*		

FVC: Forced vital capacity; FEV<sub>1</sub>: forced expiratory volume in 1 second; MVV: maximal voluntary ventilation; PI<sub>max</sub>: maximal inspiratory pressure; P<sup>1</sup>-value: difference within each group; P<sup>2</sup>-value: difference between groups; \* significant.

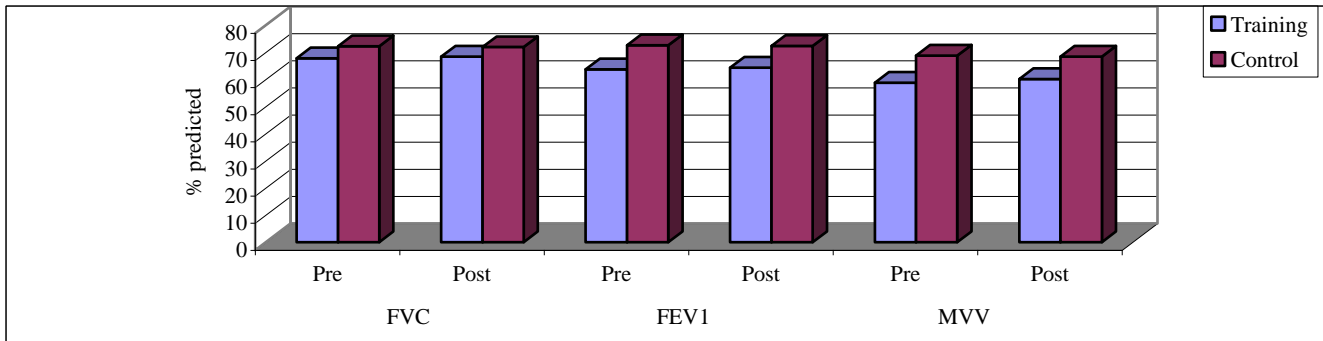


Fig (1): Comparison of pre and post treatment mean values of FVC, FEV1 and MVV between groups.

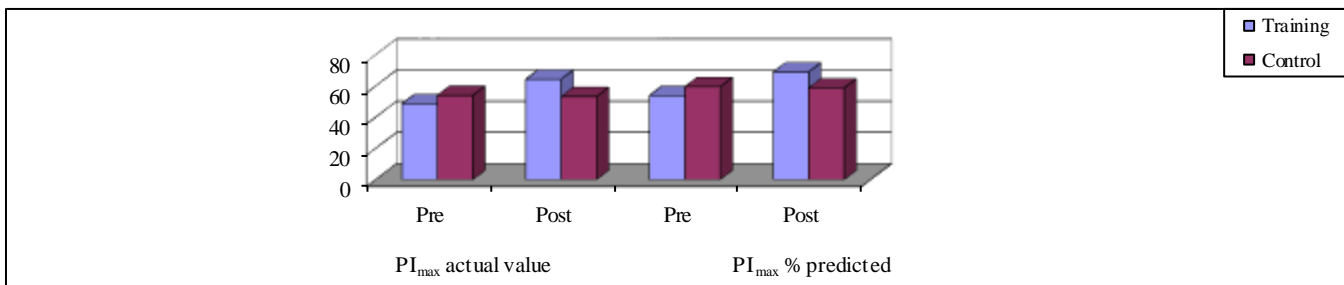


Fig (2): Comparison of the pre- and post-treatment mean values of PI<sub>max</sub> actual value and % predicted between the groups.

### Exercise tolerance results

Regarding VO<sub>2</sub> peak, no significant difference was found between groups at pretreatment (P = 0.079). In the training group, the VO<sub>2</sub> peak was increased significantly (P = 0.026)

with no significant change in the control group (P = 0.204), (see table 3); post-treatment comparison between groups found non significant difference (P = 0.225), (Fig. 3).

Table (3): Statistical analysis of VO<sub>2</sub> peak within and between groups.

Variable	Groups	Pre	Post	% of change	P <sup>1</sup> -value
VO <sub>2</sub> peak (L/min)	Training	2.55 ± 0.23	2.59 ± 0.25	↑ 1.57	0.026*
	Control	2.91 ± 0.57	2.86 ± 0.64	↓ -1.72	0.204
	P <sup>2</sup> -value	0.079	0.225		

VO<sub>2</sub> peak: peak oxygen consumption; P<sup>1</sup>-value: difference within each group; P<sup>2</sup>-value: difference between groups; \* significant.

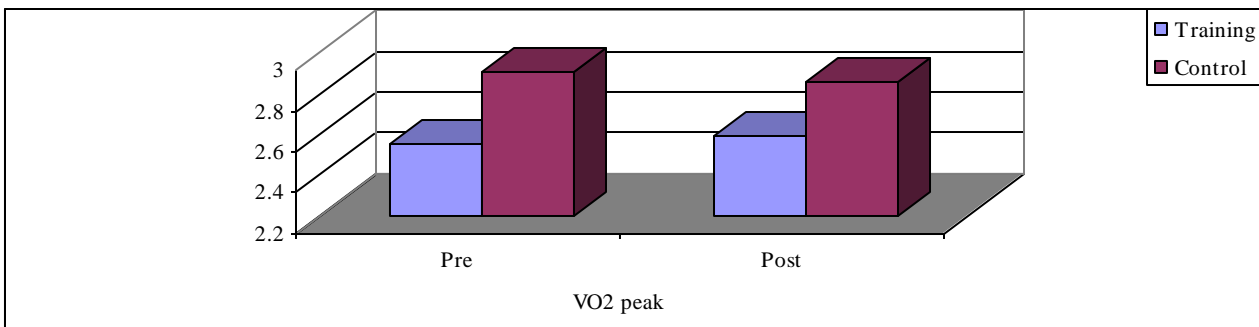


Fig (3): Pre and post treatment mean values of VO<sub>2</sub> peak between the groups.

## DISCUSSION

Even though Type 2 diabetic patients did not have any respiratory symptoms they did have underlying sub clinical restrictive pattern of lung functions<sup>3</sup>. As the duration of diabetes increases the restrictive profile is more prominent.

Spirometry is a cost effective, a simple non-invasive diagnostic tool and its judicious use can give warning signal for patients to take early preventive measures. Despite the theoretical benefits, the role of inspiratory muscle training (IMT) in diabetic patients with inspiratory muscle weakness (IMW) remains unclear and it is currently not included as a standard component of a pulmonary rehabilitation in these patients. The present study was done to assess the effects of IMT on pulmonary

function test (FVC, FEV1, MVV,  $PI_{max}$ ) using spirometry and on exercise capacity ( $VO_2$  peak). The major findings of the current study were that IMT is able to improve measured pulmonary functions' parameters (FVC and FEV1) and reverse the loss of inspiratory muscle strength in diabetic patients with IMW. The improvement in inspiratory muscle strength after training was accompanied by changes in exercise capacity. The mechanisms responsible for the development of IMW in DM are still poorly understood. Experiments have identified respiratory muscle weakness in rats with streptozotocin – induced diabetes, with evidence of phrenic nerve neuropathy, characterized by axonal atrophy and significant reduction in myelin<sup>33</sup>. Respiratory muscle strength in diabetics and healthy controls was assessed by measuring transdiaphragmatic pressures and  $PI_{max}$  during bilateral stimulation of the phrenic nerve and from voluntary muscle contraction. Although only patients with more accentuated polyneuropathy presented reduced respiratory muscle strength, phrenic nerve latencies were normal, suggesting that impaired diaphragm function was not caused by phrenic neuropathy<sup>39</sup>. In contrast, Kabitz et al.,<sup>24</sup> demonstrated an association between diabetic polyneuropathy and impaired respiratory muscle function assessed by phrenic nerve stimulation in DM. In the current study, diabetic autonomic neuropathy was not evaluated; therefore, this is an area of research to elucidate the underlying mechanism of IMW in DM.

There is contradiction in the literature regarding the effect of IMT on inspiratory muscle strength. Some studies agreed with our results, like Chiappa et al.,<sup>6</sup> Dall'Ago et al.,<sup>7</sup> and Winkelmann et al.,<sup>40</sup>. They concluded that IMT improves inspiratory muscle strength, induces diaphragm hypertrophy, and increases functional capacity in patients with chronic heart failure and IMW. Therefore, contrary to what has been proposed by others like<sup>32</sup>, the training stimulus of this protocol results in clear functional adaptations. The differences in previous studies regarding the effects of IMT could be related to the differences either in the magnitude or in the duration of inspiratory muscle loading. Taking this into consideration, specific IMT has been found to be capable of improving inspiratory muscle function when intensity is monitored and at least 30% of the  $PI_{max}$  are required before improvements in strength are achieved<sup>17</sup>. In addition, some studies have simultaneously included multidimensional intervention as a part of the rehabilitation of patients. From a methodological view, such an assessment could make it difficult to independently analyze the specific effect of IMT.

Our patients had preserved peak exercise capacity at baseline, and IMT resulted in significant change in  $VO_2$  peak. Some authors including the present one have demonstrated that IMT may have a more general impact when tolerance is evaluated in terms of exercise capacity, endurance time on a treadmill, or dyspnea<sup>18</sup>. Similar to the present findings, even in chronic obstructive pulmonary disease patients, IMT may be associated with a significant improvement in  $VO_2$  peak. In a Meta-analysis included 32 randomized controlled trials on the effects of IMT in chronic obstructive pulmonary disease patients, they concluded that IMT improves inspiratory muscle strength and endurance, functional exercise capacity, dyspnea

and quality of life<sup>14</sup>. Also, studies in cystic fibrosis<sup>10</sup> and chronic heart failure<sup>28</sup>.

Perhaps the noted improvements in the measure of exercise capacity are likely to be related to the magnitude of the gains in inspiratory muscle strength. It appears that a minimum of 30% improvement in inspiratory muscle strength from baseline measures is necessary before improvements in exercise capacity are conferred<sup>21</sup>.

Training-induced gains in inspiratory muscle strength result from both structural remodeling due to increase in the proportion of type I fibers (as assessed by the increase in fibers expressing MyHC-I) and in the size of type II fibers<sup>34</sup> and adaptation of neural pathways<sup>22</sup>. In healthy adults, strength gains following IMT correlate with a reduction in inspiratory motor command, possibly reflecting a decrease in the percentage of motor units required for a ventilatory task<sup>22</sup>.

Inspiratory muscle training using threshold devices has been demonstrated to reduce inspiratory time during loaded breathing tasks. Providing the total respiratory cycle time remains unchanged, adopting a reduced inspiratory time during exercise would increase expiratory time for any given level of ventilation. Such an increase in expiratory time could increase relaxation time and oxygen delivery to the diaphragm, thereby reducing inspiratory muscle fatigue<sup>17</sup>.

As is the case with peripheral muscles following whole body exercise training, it is possible that IMT induces changes in muscle metabolism. Improved efficiency of the respiratory pump muscles with a decrease in inspiratory muscle oxygen requirement has been postulated to account for the lower levels of ventilation and coexistent reduction in oxygen consumption during exercise following IMT. Changes reflecting improved oxidative capacity of the respiratory muscles reported following IMT<sup>34</sup> may serve to lower lactate production or facilitate increased lactate metabolism thereby contributing to the reduction in exercise ventilation<sup>17</sup>.

Respiratory muscle function was evaluated with volitional noninvasive tests and, therefore, part of the improvement in these measures could have been influenced by learning effect due to the type of training. In a study by Hart et al.,<sup>16</sup> evaluated the effects of IMT using the Power breathe device in healthy individuals, showing that improvement in  $PI_{max}$  after intervention could be due to a learning effect because it had no influence on diaphragm strength assessed by magnetic stimulation of the phrenic nerve. However, we took care to control the breathing strategy in the inspiratory muscle tests, probably reducing this confounding factor. Moreover, both groups had their  $PI_{max}$  measured monthly, and despite these repeated measures, the control group showed no significant learning effect. Also, it can be expected that if a learning effect plays a role it would be the same in the various groups.

The reasons for trying to predict peak  $VO_2$  from measures of resting pulmonary functions are multiple. Patients could possibly save time, expense, and invasive procedures if an accurate prediction of their maximum exercise tolerance could be made based upon resting pulmonary function parameters. Also, this knowledge may help the patient to get advice about how to do exercises or to be physically active. This might indicate a need for further evaluation of the patient, with

"unexplained" exercise limitation in an individual whose exercise tolerance is reduced out of proportion to that predicted.

The current findings may have clinical implications during situations where pulmonary functional reserve may be of clinical relevance. One such a situation is in the preoperative evaluation for major surgery. For instance,  $PI_{max}$  is associated with functional capacity after coronary artery bypass<sup>36</sup> and preoperative IMT has been shown to reduce pulmonary complications post surgery<sup>23</sup>. Therefore, the measurement of  $PI_{max}$  may be particularly important in the preoperative evaluation of diabetics and this should be addressed in future studies. Also, studies comparing differing intensities of IMT seem to be warranted.

## Conclusion

As pulmonary dysfunction may be one of the earliest and easily measurable non-metabolic alterations in diabetes, the patients with diabetes are suggested to undergo pulmonary function testing along with other investigations. Inspiratory muscle training reverses inspiratory muscle weakness, improves pulmonary function and functional capacity in diabetic patients with inspiratory muscle weakness.

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## تحسن قوة عضلات التنفس والقدرة على تحمل التمرين بعد برنامج أهيل رئوي في مرضى البوال السكري المصحوب بضعف في عضلات الشهيق

لقد أثبتت الدراسات السابقة أن تدريب عضلات الشهيق يؤدي إلى نتائج ايجابية في أمراض الرئة المزمنة و على الرغم من ذلك فان تأثير تدريب عضلات الشهيق على مرضى البوال السكري المصحوب بضعف في عضلات التنفس لم يتضح بعد . لذا كان هدف هذه الدراسة هو تقييم تأثير تدريب عضلات الشهيق على التهوية الرئوية، قوة عضلات الشهيق وكذلك القدرة على تحمل التمرين في مرضى البوال السكري المصحوب بضعف في عضلات التنفس . أجريت هذه الدراسة على أربعة وثلاثون مريضا تراوحت أعمارهم ما بين الخمسين والستين عاما ، تم تقسيمهم عشوائيا إلى مجموعتين متساويتين في العدد (مجموعة تدريب عضلات الشهيق و مجموعة ضابطة) . تلقت مجموعة التدريب (عدد = 17) برنامج تدريبي لعضلات الشهيق لمدة 30 دقيقة ثلاث مرات أسبوعيا وكذلك جلسات توعية عن مرض السكر في حين تلقت المجموعة الضابطة (عدد = 17) جلسات توعية عن مرض السكر فقط. تم عمل تقييم لكلا المجموعتين قبل و بعد شهرين و هي مدة الدراسة. اظهر التحليل الإحصائي للنتائج زيادة ذات دلالة إحصائية في التهوية الرئوية، قوة عضلات الشهيق و كذلك القدرة على تحمل التمرين وعدم حدوث تغييرات ذات دلالة إحصائية في هذه القياسات في المجموعة الضابطة. استخلصت الدراسة أن تدريب عضلات الشهيق يقلل التغييرات التقيدية للرئوي مرضى البوال السكري .

الكلمات الدالة : البوال السكري - القدرة على تحمل التمرين - تدريب عضلات الشهيق .