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A New Frontier in Hypertension Control: The Functional Benefits of Inspiratory Muscle Training

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Abstract: ***Background**: Hypertension is a leading risk factor for cardiovascular diseases, and improving functional capacity is crucial for overall health. Inspiratory Muscle Training (IMT) has emerged as a potential non-pharmacological intervention to enhance respiratory function and cardiovascular health. However, its effects on blood pressure and functional capacity remain under explored. **Objective**: This study aimed to evaluate the impact of IMT on blood pressure and functional capacity in adults through a randomized controlled trial. **Methods**: A randomized controlled trial was conducted involving 120 participants with elevated blood pressure. Participants were assigned to either an IMT group and a control group. The IMT group performed a structured inspiratory muscle training regimen for 6 weeks, while the control group followed only diaphragmatic breathing exercises. Blood pressure (systolic and diastolic) and functional capacity (six-minute walk test]) were measured at baseline and post-intervention. **Results**: The IMT group demonstrated significant reductions in systolic and diastolic blood pressure compared to the control group ($p < 0.05$). Additionally, functional capacity improved in the IMT group, as evidenced by increased test performance scores ($p < 0.05$). No adverse effects were reported. **Conclusion**: IMT is an effective, non-invasive intervention for reducing blood pressure and enhancing functional capacity. These findings suggest that IMT could serve as a valuable adjunct therapy in hypertension management and physical rehabilitation programs. Further studies are warranted to explore long-term effects and optimal training protocols.*

Keywords: Essential hypertension, IMT- Inspiratory Muscle Training, 6minute walk test, adjuvant therapy

1. Introduction

Essential hypertension, also known as primary or idiopathic hypertension, is defined as elevated blood pressure without an identifiable secondary cause. It is the most prevalent form of hypertension, accounting for approximately 85% of cases, while the remaining 15% result from secondary causes. Essential hypertension frequently runs in families and arises from a complex interaction between genetic predisposition and environmental influences [1].

Contemporary classifications categorize blood pressure into specific ranges: normal, prehypertension, and stages I and II hypertension. Isolated systolic hypertension, particularly common among older adults, is defined as a systolic pressure of ≥140 mmHg with a diastolic pressure of <90 mmHg. In individuals over 50 years, hypertension is diagnosed when systolic blood pressure is ≥140 mmHg or diastolic is ≥90 mmHg on repeated measurements 2.

Early detection and effective management are crucial in reducing hypertension-related disabilities and mortality. Among non-pharmacological treatments, inspiratory muscle training (IMT) has emerged as a promising approach. IMT, which involves applying resistance to inspiratory muscles, has shown beneficial effects in cardiovascular patients, including those with chronic heart failure. Evidence indicates that IMT may enhance blood pressure control, restore autonomic balance, and lower systemic vascular resistance in both healthy individuals and those with hypertension [3]. A reduction in systolic blood pressure by as little as 5 mmHg significantly lowers the risks of type 2 diabetes, heart failure, and stroke, supporting IMT as a viable intervention[4].
Diaphragmatic breathing (DB), which emphasizes slow, deep breaths using the diaphragm with minimal chest movement, also demonstrates therapeutic benefits. It modulates autonomic activity through the phrenic nerve's influence on the vagus nerve, thereby affecting motor responses and brain function [5].

When combined, IMT and diaphragmatic breathing have demonstrated superior outcomes, including improved blood pressure regulation, enhanced functional capacity, and rebalanced autonomic function. These physical therapy techniques serve as valuable adjunctive therapies for essential hypertension, reducing the need for pharmacological agents and enhancing overall patient outcomes [6].

Objectives

Primary Objective:
1) To evaluate the effect of Inspiratory Muscle Training (IMT) on blood pressure control in individuals with primary hypertension.

Secondary Objectives:
1) To assess changes in inspiratory muscle strength following IMT.
2) To determine the impact of IMT on cardiovascular functional capacity (e.g., 6-minute walk test).

Hypothesis

Null Hypothesis (H_0):
Inspiratory muscle training (IMT) and breathing exercises have no significant effect on reducing blood pressure and functional capacity in individuals with essential hypertension.

Alternate Hypothesis (H_1):
Inspiratory muscle training (IMT) and breathing exercises

significantly reduce blood pressure and functional capacity in individuals with essential hypertension.

2. Methodology

This **randomized controlled trial (RCT)** was conducted at **Prudence College of Physiotherapy, Bengaluru**, with additional data gathered from clinics and health camps. The study was ethically approved by the **Institutional Ethics Committee of Garden City University, Bengaluru** (CTRI registration: **CTRI/2024/04/066216**). Written informed consent was obtained from all participants.

A total of **120 participants** aged **40–55 years** with **Class 2 hypertension** were recruited through physician referrals, advertisements, and health camps. Participants were randomly assigned into two groups (n=60 each) using a computer-generated randomization method:

Group A (Intervention): Received Inspiratory Muscle Training (IMT) using a RESPIRONICS Threshold IMT device along with diaphragmatic breathing exercises.Group A performed IMT for 30 minutes/day, 6 days/week, at 30% of their maximal inspiratory pressure (Pimax), completing 30 breaths in 5 sets with 1-minute rest between sets. Diaphragmatic breathing at 15–20 breaths per minute was also practiced.

Group B (Control): Performed only diaphragmatic breathing exercises. The intervention spanned 12 weeks, including a 6-week supervised phase in an OPD setting and a 6-week unsupervised phase with weekly follow-ups. Group B performed diaphragmatic breathing alone for 30 minutes/day, 6 days/week for the entire duration.

Parameters and Outcome Assessments

1) **Blood pressure (BP)**: was measured using a sphygmomanometer and stethoscope, following AHA guidelines. Participants were instructed to avoid tea or coffee for at least 10 minutes before the measurement and to remain seated for at least 5 minutes. For individuals with a BP reading of ≥140/90 mmhg, BP was remeasured after 3 minutes, and the average of the two readings was recorded. The average BP was rounded to the nearest whole number. Systolic and diastolic blood pressure measurements were taken on day 1, at the 6th week, and at the 12th week following the intervention
2) **Functional Exercise Capacity**-The 6-min walk test (6MWT) was performed in a 30-m unobstructed corridor to assess submaximal functional capacity and the result was expressed in meters. Measurement was done according to ATS guidelines. Heart rate, oxygen saturation measured using pulse oximetry, during the test. A modified Borg dyspnea scale was used before and after test. This was repeated at day 1, 6th week and 12th week following intervention session

Statistical Analysis

The statistical analysis was conducted using SPSS software (version 23). The normality of pre-test and post-test scores for different parameters in Group A and Group B was assessed using the Shapiro-Wilk test. The comparison of pre-test and post-test scores for systolic blood pressure (SBP), diastolic blood pressure (DBP), the 6-minute walk test between Group A and Group B was performed using the Mann-Whitney U test. Additionally, the comparison of pre-test and post-test scores within each group (Group A and Group B) for SBP, DBP, the 6-minute walk test was conducted using the Wilcoxon matched pairs test. Statistical significance was determined at a 5% level, with a p-value <0.05 considered significant.

Table 1: Normality of pretest and post test scores of different parameters in Group A and Group B by Shapiro-Wilk test

Parameters	Times	Groups	Shapiro-Wilk	Df	P-value
SBP	Pretest	Group A	0.6900	58	0.0001*
		Group B	0.7100	57	0.0001*
	6 week	Group A	0.7640	58	0.0001*
		Group B	0.8350	57	0.0001*
	12 week	Group A	0.7230	58	0.0001*
		Group B	0.8220	57	0.0001*
DBP	Pretest	Group A	0.5340	58	0.0001*
		Group B	0.8010	57	0.0001*
	6 week	Group A	0.9190	58	0.0010*
		Group B	0.9330	57	0.0040*
	12 week	Group A	0.8590	58	0.0001*
		Group B	0.9220	57	0.0010*
6MWD	Pretest	Group A	0.9070	58	0.0001*
		Group B	0.9810	57	0.4910
	6 week	Group A	0.9590	58	0.0490*
		Group B	0.9790	57	0.4320
	12 week	Group A	0.9540	58	0.0290*
		Group B	0.9740	57	0.2440

Table 2: Comparison of Group A and Group B with different treatment time points with SBP scores by Mann-Whitney U test

Time points	Group A			Group B			U-value	Z-value	P-value
	Mean	SD	Mean rank	Mean	SD	Mean rank			
Pretest	147.58	10.21	61.56	146.45	8.32	59.44	1736.50	0.3307	0.7409
6 week	139.28	8.59	52.51	142.02	7.99	68.49	1320.50	-2.5141	0.0119*
12 week	136.03	8.16	47.72	139.40	7.77	68.46	1057.00	-3.3311	0.0009*
Pretest to 6 week	8.30	5.47	75.11	4.43	3.21	45.89	923.50	4.5978	0.0001*
Pretest to 12 week	11.60	6.48	74.78	6.95	3.18	40.92	679.50	5.4428	0.0001*
6 week to 12 week	3.26	2.75	60.60	2.54	1.85	55.35	1502.00	0.8419	0.3999

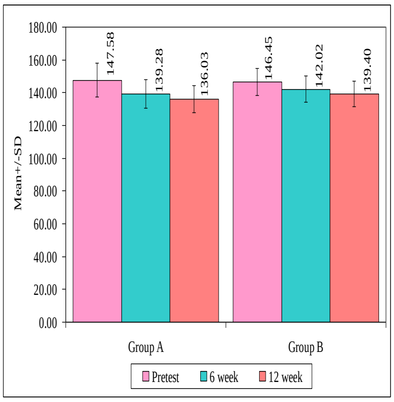
Table 3: Comparison of Group A and Group B with different treatment time points with DBP scores by Mann-Whitney U test

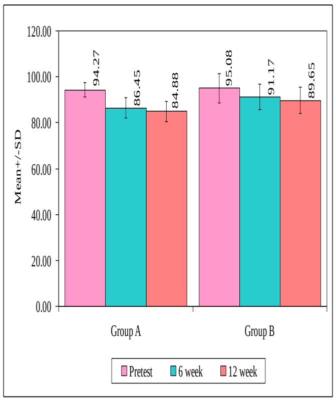
Time points	Group A			Group B			U-value	Z-value	P-value
	Mean	SD	Mean rank	Mean	SD	Mean rank			
Pretest	94.27	3.18	64.32	95.08	6.37	56.68	1571.00	1.1993	0.2304
6 week	86.45	4.43	46.42	91.17	5.64	74.58	955.00	-4.4325	0.0001*
12 week	84.88	4.49	42.80	89.65	5.67	73.46	771.50	-4.9282	0.0001*
Pretest to 6 week	7.82	4.81	75.97	3.92	3.64	45.03	872.00	4.8681	0.0001*
Pretest to 12 week	9.38	4.18	74.00	5.33	3.66	41.72	725.00	5.1883	0.0001*
6 week to 12 week	1.52	3.91	59.14	1.72	2.86	56.84	1587.00	0.3664	0.7141

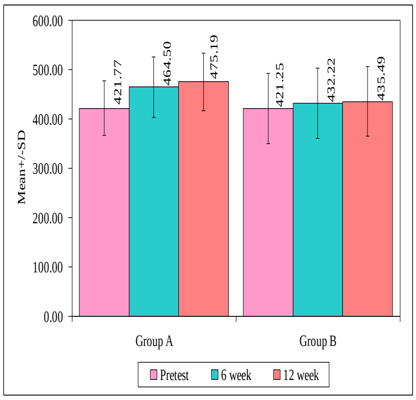
Table 4: Comparison of Group A and Group B with different treatment time points with 6MWD scores by Mann-Whitney U test

Time points	Group A			Group B			U-value	Z-value	P-value
	Mean	SD	Mean rank	Mean	SD	Mean rank			
Pretest	421.77	54.84	60.67	421.25	71.56	60.33	1790.00	0.0499	0.9602
6 week	464.50	61.47	68.55	432.22	70.88	52.45	1317.00	2.5325	0.0113*
12 week	475.19	57.82	67.79	435.49	69.96	48.04	1085.00	3.1745	0.0015*
Pretest to 6 week	42.73	55.27	75.93	10.97	7.51	45.08	874.50	4.8550	0.0001*
Pretest to 12 week	54.12	51.55	77.28	16.81	11.78	38.39	535.00	6.2511	0.0001*
6 week to 12 week	12.19	9.33	69.34	5.96	8.32	46.46	995.00	3.6780	0.0002*

Figure 1,2 and 3: Comparison of Group A and Group B with different treatment time points with SBP DBP ,6mimute walk test scores







3. Discussion

Diaphragmatic Breathing (DB) has various physiological effects in humans. The diaphragm is the major respiratory muscle. DB that controlled RR at six breaths/min reduces the chemoreflex response to hypoxia and hypercapnia compared with normal breathing. Therefore, Diaphragmatic Breathing has a potential to improve the blood oxygen levels [7]

Breathing has a close relationship with autonomic nervous system function. The phrenic nerve that controls the movement of the diaphragm is connected to the vagus (parasympathetic) nerve. Decreasing the RR by DB activates the parasympathetic nervous activity while suppressing the sympathetic nervous activity [6]. Chang et al. Reported that slow breathing with eight breaths/min makes the balance of the parasympathetic nervous activity dominant. Autonomic dysfunction, for example, a reduction in heart rate variability, is associated with an increased risk of cardiovascular mortality and morbidity. Hyperactive sympathetic nervous activity and hypoactive parasympathetic nervous activity can be regulated by DB, which will improve the cardiovascular health [7].

The Shapiro-Wilk test- indicated that the data for most parameters did not follow a normal distribution ($p < 0.05$ for most cases). This lack of normality supports the use of non-parametric tests, such as the Mann-Whitney U test and the Wilcoxon matched-pairs test, which were appropriately applied in subsequent analyses.

Comparative Analysis Between Groups **(Mann-Whitney U Test)**- Pretest Comparisons For each parameter (SBP, DBP, 6MWD), no significant differences were found between Group A and Group B at the pretest stage (p-values > 0.05). This suggests that the baseline values were comparable across both groups, ensuring that any post-treatment differences observed are less likely to be attributed to initial disparities. Post-Treatment Comparisons: At both the 6-week and 12-week evaluations, Group A demonstrated significantly greater improvements in several parameters, including SBP, DBP, 6MWD compared to Group B ($p < 0.05$).

Within-Group Changes Over Time (**Wilcoxon Matched-Pairs Test**)-Changes from Pretest to Post-Test: Each parameter, such as SBP, DBP, 6MWD showed significant improvement within both groups over time, with positive changes from pretest to 6 weeks, pretest to 12 weeks, and 6 weeks to 12 weeks ($p < 0.05$ for both groups). This trend of continuous improvement across the 12-week period indicates treatment effectiveness in both groups, reflecting consistent progress in each measured outcome.

4. Conclusions

Overall, both groups demonstrated significant improvements in various clinical parameters, including blood pressure, exercise capacity, and lung function. However, Group A consistently showed a larger magnitude of improvement across multiple measures. These findings suggest that the intervention applied to Group A was more effective in eliciting positive physiological changes compared to the intervention in Group B. The results underscore the importance of selecting appropriate interventions tailored to achieve optimal clinical outcomes and highlight the potential for further investigation into the mechanisms underlying the differences in response between the groups.

Clinical Significance and Practical Implications

1) Systolic and Diastolic Blood Pressure (SBP and DBP): Even modest reductions in SBP and DBP (around 5-10%) can meaningfully decrease cardiovascular risk. Thus, the observed differences in blood pressure reduction between the groups might reflect notable health benefits.
2) 6-Minute Walk Distance (6MWD): An increase in 6MWD indicates improved functional capacity, which is clinically relevant as a measure of physical enhancement.

The findings from this study suggest that the intervention used in Group A provides significant clinical benefits over the course of 12 weeks, particularly in improving cardiovascular, functional, and respiratory outcomes. Key parameters such as systolic and diastolic blood pressure, 6-minute walk distance showed notable improvement in Group A compared to Group B, indicating enhanced cardiovascular and respiratory health and physical endurance in the intervention group.

Both groups demonstrated positive changes over time, yet the significant between-group differences suggest that Group A's intervention may offer superior benefits for patients needing improved exercise tolerance and respiratory function. These results imply that this treatment approach could be an effective medium-term strategy for enhancing physical resilience and quality of life in populations with similar health profiles. Future studies could build on these findings to further explore the long-term effects and applicability of this intervention in diverse patient populations.

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