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Effect of Neutral Pulmonary Douche on Pulmonary Functions among Bronchial Asthma Patients

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ABSTRACT

Introduction: Bronchial Asthma is the second-most significant contributing factor to mortality rates for chronic respiratory diseases. It is characterized by hyperreactivity of the airways and reversible episodes of bronchoconstriction. Douche is a general application in hydrotherapy, which is a stream of water directed against the body generally or locally. The neutral pulmonary douche (NPD) is employed to improve pulmonary functions, but there is no scientific report validating its effect. **Materials and Method:** A randomized control trial study of a total of 60 subjects belonging to the age group of 18–44 years participated in the study. The study participants were randomized into intervention and control groups (1:1). The intervention group (30) underwent NPD for 30 minutes. No intervention was given to the control group (30) and was followed up. The assessments were taken at baseline and after 10 days of the study. **Result:** The collected data was subjected to statistical analysis, employing interferential statistical tests. These analyses showed a significant difference in all parameters (FEV1, FVC, the FEV1FVC ratio, and PEFR) within (t-tests, the Wilcoxon rank test) and between (ANCOVA) groups. **Conclusion:** The implementation of hydrotherapy-facilitated NPD has demonstrated notable enhancement of pulmonary functionality in Bronchial asthma (BA) sufferers, in conjunction with conventional medical interventions. This discovery contributes to the progressively accumulating substantiation endorsing the efficacy of hydrotherapy within the domain of naturopathy.

Key words: *Hydrotherapy, Douche, Pulmonary Function, Spirometry, Bronchial Asthma.*

INTRODUCTION

Asthma is a common chronic disorder that affects both adults and children. It is characterized by airway inflammation and bronchial hyper-responsiveness.[1] Asthma is the second most significant contributor to mortality rates worldwide, affecting about 8% of individuals.[2] The prevalence of asthma in India is estimated to be around 2% for women and 1% for men aged 15-49.[3] The prevalence of asthma is increasing, and there have been significant developments in its management.[4] In the past century, ideas about the pathogenesis of asthma have evolved, with changes in our understanding of airway smooth muscle, mast cell accumulation, specific mediators, eosinophils, cytokines, and T-lymphocytes.[5] Therapeutic approaches have also changed, with a shift from considering asthma as a smooth muscle disorder to the use of inhaled drugs and other treatments.[6] Despite these advancements, asthma still poses a significant burden on patients, with considerable morbidity and the need for emergency care or hospitalization.[7] Clinical guidelines for pharmacotherapy of asthma include various medications that can help relieve symptoms and reduce the progression of the disease.[8] current therapies for asthma include inhaled

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corticosteroids, phosphodiesterase inhibitors, leukotriene modifiers, and β2-adrenoceptor agonists.[9] Patients with severe asthma are at risk of adverse health outcomes, including exacerbations and deterioration of lung function. Long-term use of oral corticosteroids may not prevent asthma progression and can lead to medication-related morbidity.[10] Chronic use of systemic glucocorticoids in patients with severe asthma is associated with complications and increased healthcare resource utilization.[11] The National Asthma Education and Prevention Program (NAEPP) guidelines emphasize the importance of assessment, education, control of environmental factors, and evidence-based decision-making for pharmacologic therapy.[12] The prevalence of asthma is increasing globally, leading to a significant economic burden due to healthcare costs and decreased productivity.[13] There is a need for continued efforts to improve the care and management of asthma, including reducing risk factors, controlling environmental factors, and providing patient education.

Complementary and alternative therapies have been studied for their effects on asthma. These therapies aim to improve lung function, reduce symptoms, and enhance the quality of life for children and adolescents with asthma. Some studies have shown that certain therapies, such as massage therapy and acupuncture, can improve lung function and quality of life.[14] Pulmonary rehabilitation, which includes physical training, respiratory physiotherapy, and comprehensive patient education, has also been found to be beneficial in improving muscle strength, exercise capacity, and symptomatology.[15] However, it is important to note that the evidence for the effectiveness of these therapies is limited, as many studies are small and of poor quality.[16] Hydrotherapy is a modality of naturopathic medicine that has been practiced for centuries for treatment by using water in various forms (Stream, Hot, Cold, or Dry). Douches involve the use of water directed towards specific areas of the body to produce therapeutic effects. They can be used for various purposes such as cleansing, local medication, and hydrotherapeutic treatment.[17,18] Different types of douches exist, each with its therapeutic benefits and uses.[19] The effectiveness of douching depends on factors such as water temperature, pressure, and mass.[20] Apparatus and systems have been developed to facilitate the application of douches, ensuring safe and hygienic treatment.[21] Overall, douches play a significant role in modern hydrotherapy and offer potential benefits for various health conditions.

A review of previous research on douches reveals that they have a notable impact on autonomic and respiratory variables, enhancing parasympathetic activity.[22] While studies on neutral pulmonary douches have been somewhat limited, none have been conducted to assess their impact on pulmonary functions in patients with BA. Thus, the present study aims to evaluate the effects of neutral pulmonary douches on pulmonary functions in this particular patient population.

Materials and Methods

Study setting and ethical considerations

The study was conducted between July 2021 and August 2023 in an Outpatient hospital setup and an Inpatient setup at Alva's Anandamaya Arogyadhama Hospital. This project was approved by the Institutional Ethical Committee of Alva's College of Naturopathy and Yogic Sciences, Mijar, DK (D) (ACNYS/IECHS/2021/59) and registered in the Clinical Trial Registry of India (CTRI/2022/07/044022). All the participants signed a written informed consent form before the commencement of the study.

Study design

This was an open-label, randomized controlled trial: one that underwent a 10-day intervention of medically supervised NPD (study group) and one that followed with regular medication (control group).

Participants

The individuals who sought consultation at Alva's Anandamaya Arogyadhama hospital were determined to have BA after a comprehensive analysis of their medical records. All of the individuals underwent a

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screening process using Spirometry to distinguish between various respiratory ailments. The criteria for including and excluding participants in the study were as follows.

Inclusion Criteria

The study included both genders between the age group of 18 to 44 years who have been diagnosed with BA with Pulmonary function tests and using inhalers. Participants who are willing to participate in the study. In spirometry the forced expiratory volume in one second (FEV_1) is reduced, confirming that the ratio of the two volumes (FEV_1/FVC) is reduced it is usually <0.80 (less than 80%). [23]

Exclusion Criteria

We excluded participants if they (a) had a contributing diagnosis of systemic infection, respiratory infection, pulmonary tuberculosis, or any secondary causes for BA and (b) if hospitalized due to acute exacerbation of asthma in the past month. (c) if any other co-morbidities.

Randomization

Randomization was achieved by utilizing the random numbers generated from the computer randomization software. The participants were then divided into either the experimental group or the control group, with a ratio of 1:1. Following the completion of the informed consent form by the patients. A comprehensive overview of the trial can be found in Figure 1.

Intervention

Study group: The study group both genders aged between 18 and 35 underwent ten days of medically supervised Intervention NPD(n=30)

(a) Pre-operative procedure: Participants were asked to drink a glass of warm water or warm up by doing simple exercises.

(b) Operative Procedure: Participants were asked to stand 15 feet apart and face opposite to the aperture with minimal cloth and the neutral douche of temperature 92° to 97° F, Pressure of 20 to 40 pounds is applied to the back of the chest, the procedure is carried out about 15 minutes.

(c) Post-operative procedure: After the douche, they were asked to rub the area by using a towel to avoid induce of cold, later rest for 15 minutes is advised.[24]

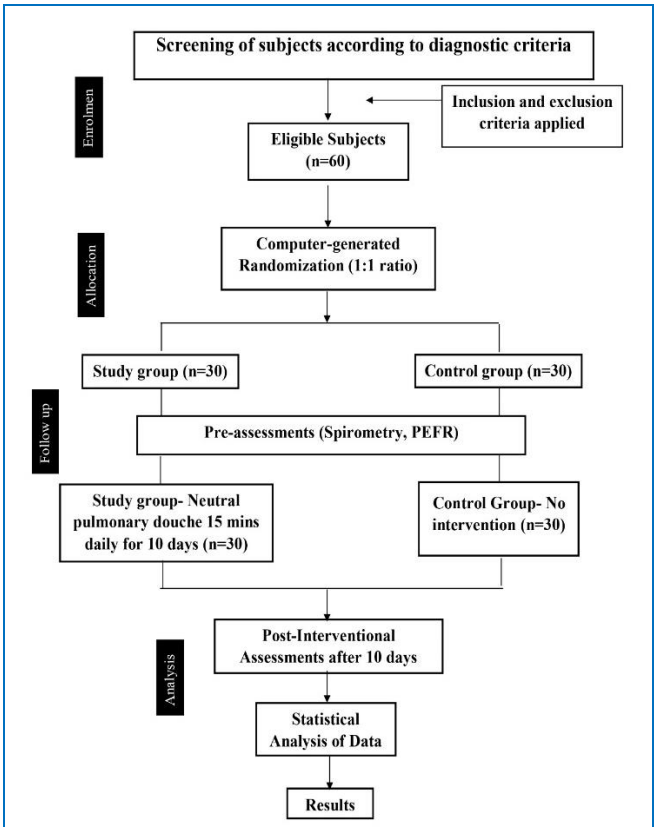

Figure 1: Consort flow chart

Control group: Participants assigned to the control group were subjected to the maintenance of their customary daily regimen for a period spanning ten consecutive days, thereby refraining from any form of experimental intervention, while concurrently being requested to adhere to their established allopathic medicinal protocols, primarily in the form of inhalers.

Assessments

The assessments were carried out at baseline (Before the intervention) and post-intervention. The following tools were used to assess the primary and secondary outcome measures:

Primary Outcome Measure

Spirometry: Spirometry is the most frequently used measure of lung function and is a measure of volume against time. The patient should take a full, deep

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breath while sitting straight. The mouthpiece is then placed in the patient's mouth followed by a forceful expiration as much as possible. MIR Spiro lab Portable Spirometer will be used in this study. Spirometry and the calculation of FEV1/FVC allow the identification of obstructive or restrictive ventilatory defects.[25]

Secondary Outcome Measures

Peak expiratory flow rate

Peak expiratory flow rate will be measured by using a JSB N02 Peak Flow Meter for Adults (Black-White) (Health & Personal Care) it is a simple and quick procedure to perform. First, the patient should reset the meter by sliding the marker to zero on the scale. While sitting straight, the patient should take in a full, deep breath. The mouthpiece is then placed in the patient's mouth followed by a single, fast, forceful expiration. The marker will slide outward on the numbered scale, indicating the peak expiratory flow rate for that attempt. Using the best reading from several repeated attempts is recommended.

Statistical analysis

The normality of the variables at baseline and post-data of both groups was assessed using the Shapiro-Wilk test. The t-test is done for the normally distributed variables and the Wilcoxon rank test(W) is done for variables that are not normally distributed. Between-group changes were performed using analysis of covariance for variables. The data were analyzed using IBM SPSS statistics version 26.0. For all the analyses, we present 95% confidence intervals and considered *P*< 0.05 as significant.

RESULTS

Current study that determines the effectiveness of NPD among the intervention (NPD) and Control group. The results and outcomes from the interventional studies were monitored by assessing the Spirometry (FEV1, FVC, and Ratio of FEV1/FVC) and pulmonary function test using the PEFR test, which were further subjected to statistical analysis.

Baseline data

The below table represents the descriptive statistics of variables of interventional and control groups, The following demographic data of age, Height, predicted (Pred) FEV_1, Pred FVC, and Pred FEV1/FVC ratio of participants n (60) were expressed in Mean± SEM (Table 1). The baseline data of Lung function was within normal limits.

Table 1: Demographic variables

Characteristics	I	C
Total Participants (n)	30	30
Age (y)	30.4±5.3	29.3±6.12
Height (cm)	162±9.15	160±9.20
Pred-FEV1(L)	3.17±0.594	3.05±0.488
Pred-FVC (L)	3.78±0.796	3.64±0.627
Pred-Ratio	84.2±3.31	83.97±2.83

I: Intervention, C: Control (30), Pred: Predicted, Y: years, cm: Centimeter, L: Liters

Intervention Group (IG)

Paired t-test is done for IG where all the parameters (FEV1, FVC, FEV1/FVC, and PEFR) show a significant difference in p-value (*P*<0.001) with 95%CI shown in Table 2.

Table 2: Paired T-Test

	Pre (Mean ± SE)	Post (Mean ± SE)	Mean difference	95% CI		p
				Lower	Upper	
FEV1	2.26±0.435	2.20±0.714	-0.449	-0.487	-0.411	< .001
FVC	3.33±0.700	3.63±0.780	-0.298	-0.331	-0.266	< .001
FEV1/FVC Ratio	68.1±4.37	74.5±5.54	-6.905	-7.507	-6.303	< .001

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PEFR	187±35.8	257±31.7	-69.5	-80.87	-58.13	< .001

Pre-post comparison of the Intervention group

Control Group (CG)

Wilcoxon rank test(W) is used for CG where all the parameters (FEV1, FVC, FEV1/FVC, and PEFR) show a significant difference in p-value (P<0.001) with 95% CI shown in Table 3.

Table 3: Paired Samples T-Test

	Pre (Mean ± SE)	Post (Mean ± SE)	Mean difference	95% CI		p
				Lower	Upper	
FEV1	2.14±0.343	1.83±0.531	-0.1561	-0.192	-0.132	< .001
FVC	3.20±0.552	3.28±0.562	-0.0732	-0.08	-0.066	< .001
FEV1/FVC Ratio	67.0±2.33	70.1±2.68	-3.2552	-4.4171	-2.364	< .001
PEFR	187±35.8	218±26.5	-30	-35	-27.5	< .001

Pre-post comparison of the Control group

Comparison between the groups

Between-group changes performed using analysis of covariance for variables of interest adjusted for their respective baseline values indicated a significant difference in all the parameters with the p-value of P≤0.000 shown in Table 4.

Table 4: ANCOVA

	F (1, 57)	Sig. (P)	Partial Eta Squared (pη2)
FEV1			
FVC	334.18	0.000	0.854
FEV1/FVC Ratio	45.54	0.000	0.444
PEFR	19.046	0.000	0.25

Between-group changes, adjusted for respective baseline using Analysis of covariance, P≤0.001

Discussion

The current investigation of NPD for 10 days has manifested significant improvement in contrast to the baseline and between the intervention and control groups. According to the guidelines of the Global Initiative for Asthma (GINA), confirmation of asthma in patients is established through expiratory airflow limitation, particularly the FEV1/FVC ratio, which should be less than 75–80%.[26] The severity of asthma is also assessed using the FEV1/FVC ratio, classifying and grading it as mild, moderate, or severe asthma.[27] The baseline FEV1/FVC ratio in the current patient was 68.1%, thereby reflecting moderate asthma. Following the application of NPD for 10 days, the FEV1/FVC ratio improved from 70% to 74.5%, leading to a shift from the category of moderate to mild. The outcomes of the PFT parameters support the impact of NPD intervention in asthma patients on lung volumes. In addition to the above results, the patient has reported that breathing has improved and coughing has subsided in the subsequent days and early mornings. It appears that NPD intervention stabilizes or reduces mucus accumulation or alleviates bronchospasm.[28]

The literature review of the research was very limited, the physiological mechanisms were explained in Kellogg's hydrotherapy book. The interaction of air and water causes a single water column to break into smaller columns on the skin's surface. These columns receive increased pressure from the air behind them, similar to water being released from a nozzle. By adjusting the pressures of both air and water, different forms of water columns can be achieved, from a dispersed shower to a concentrated stream that feels like a barrage of water bullets. The physiological effects of the neutral douche are similar to those of a neutral immersion bath in terms of reducing muscular tone and capacity. But it differs in the mechanical effect

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which increases its efficiency by increasing blood volume and movement in the skin, relieving the brain and viscera. The mechanical effect of the NPD widens the cutaneous vessels, similar to other hydric applications. It does not have thermic effects or a significant reflex influence, therefore it minimally affects the central nervous system. The congested brain is drained of blood without being disturbed by sensory impressions. The neutral douche acts rapidly and can achieve the same results as a longer application. The rapid effect is due to its ability to decongest the central nervous system. A 5-minute neutral douche has the same effect as a 30-minute full bath. The neutral douche is advantageous because it can produce physiological congestion without preliminary brain and internal viscera congestion, and thermic reaction.[19] A rapid percussion douche, or horizontal jet with strong pressure, at 60°, to the arms and shoulders produce a derivative effect in that it is capable of producing physiological congestion of the skin without provoking preliminary congestion and relieving congestion over the bronchial area; then the broken jet to the front and sides of the chest, ending with the percussion douche to the back and vertebra prominins which produce effective means of quieting reflex excitability of the spinal centers; the duration being from 10 to 15 seconds to each part. The neutral douche to the back of the chest is of value in cases of asthma which influences the pulmonary circulation.[29]

The impact of psychological stress on individuals with asthma is manifested through the modification of the airway inflammatory response to irritants, allergens, and infections. This phenomenon is attributed to various biological pathways, such as the hypothalamic-pituitary-adrenal (HPA) axis, the sympathetic-adrenal-medullary (SAM) axis, and the sympathetic (SNS) and parasympathetic (PNS) arms of the autonomic nervous system.[30] Furthermore, neutral douche has a calming effect on the nervous system, which reduces the spinal center's excitability and contributes to stress management. Our investigation was carried out during periods of sunshine and avoided in cold environments as a precautionary measure against cold-induced asthma.[31] The pulmonary lavage procedure has a relatively limited application but may be utilized in situations that require either suppression or stimulation of respiratory movements. This inquiry was executed in conjunction with the utilization of inhalers, which may serve as a confounding variable in the study, and the control cohort also exhibited an enhancement in the FEV1/FVC ratio (PRE-67.0, POST-70.1) due to the daily administration of medications.

The advantageous impact of hydrotherapy's therapeutic applications on asthma is most pronounced in the hot pulmonary douche administered to the back. This method may be employed advantageously in asthma cases. Conversely, the cold douche is equally valuable for sedentary neurasthenics, necessitating boosted pulmonary activity to increase the supply of oxygen and foster portal circulation. Additionally, the neutral douche administered to the back of the chest is of particular worth in asthma cases, particularly when accompanied by the Scotch douche administered to the feet and legs. Consequently, the use of NPD as an add-on therapy in naturopathic BA treatment is feasible. Nevertheless, additional research is required to fully comprehend the physiological mechanisms underlying the respiratory effects of neutral pulmonary douche.

The study concluded that the use of neutral pulmonary douche, along with conventional medicine, significantly improved the pulmonary function of BA patients. The practice of hydrotherapy-mediated NPD has been shown to significantly improve FEV1 and PEFR, thereby strengthening pulmonary function. This finding adds to the growing body of evidence supporting the effectiveness of hydrotherapy in improving respiratory function. The study also confirmed the diagnosis of BA based on spirometry results, which showed decreased PEF, scooping of the curve indicating airflow limitation, and decreased FEV1 and FEV1/FVC ratio. The use of bronchodilators to assess reversibility further supported the diagnosis of an obstructive disorder, most likely BA.

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