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Changes in pulmonary function tests after needle versus laser acupoint stimulation

Inas E. M. Ahmed Kamel[1]*, Hala H. Shaaban[2], Emad N. Zikri[1]

1 Complementary Medicine,National Research Centre, NRC affiliation:60014618, P.O. 12622,Dokki, Egypt
2 Pediatric Department, Faculty of Medicine, Cairo University

Abstract

Introduction

 Bronchial asthma

 is a disease affecting the pulmonary functions and the gaseous exchange and pulmonary. Various untraditional management protocols such as acupuncture could be implemented to improve outcomes and clinical course of the disease.

Methodology

The present study is a randomized clinical trial done on 75 asthmatic children under conventional medical treatment divided randomly in to 3 groups. Group A: Twenty children were subjected to laser Acupuncture session three times per week for four weeks, group B 25 patients using needle acupuncture sessions for 1 month (3times / week) and group C (control group) under conventional medical treatment only. Cases have been followed up and assessed for one month.

Results:

LASER and needle acupuncture research groups revealed statistical significant elevation of pulmonary functions ((**VC %,FVC %,FEV1%,FEF25-75% ,PEF%,FEV1/FVC%)(p values <0.001**). After intervention the pulmonary functions were statistically significantly highest among LASER and needle acupuncture research groups, with no statistical significant difference between them.

Conclusions: Application of laser or needle acupuncture sessions beside conventional medical treatment results in more improvement of the pulmonary functions and reduces the medications used

1. Introduction

Bronchial asthma   is a chronic inflammatory illness conjoined with respiratory airway obstruction and bronchial hyperreactivity. It clinically presents   as episodes of wheezes, cough, strangulation sensation and chest compression. It is a multifactorial illness, which pathologically develops under the impact of environmental factors in the existence of individual's genetic predilection .**1,2**

Broncho-obstructive syndrome, the cornerstone of bronchial asthma clinical presentation is polymorphic in nature by the its formation course, and regulates the heterogeneity of bronchial asthma pathophysiological development pathway due to the anatomical and functional linkage   with the cardiovascular system, these pathophysiological pathways should   be considered systematically, in addition to changes in the combined cardiopulmonary system composition .Recent updates in the understanding of pathogenical pathways and its cornerstone role are in the clinical description of asthma as an allergic inflammatory process   of the respiratory tract,   including bronchial hyper responsiveness to various triggers   . On this origin, it could be hypothesized that the effectiveness of the cardiopulmonary system functional performance and the opportunity of asthmatic pathological development is chiefly ffected by the influences of its autonomic process of regulation. **3,4,5**

Laser acupuncture therapy is a pain free, aseptic management   protocol widely used as a complementary therapy for various childhood diseases including bronchial asthma. **6,7,8**

Acupuncture, in the form of needles, as electro acupuncture, laser acupuncture, and transcutaneous

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electrical nerve stimulation, has been implemented for the management of asthma. Randomized Controlled research trials have revealed efficacy of acupuncture for the treatment of allergic rhinitis, and some research studies have revealed positive impact of acupuncture for the management of asthma, atopic dermatitis, and itch.**9,10**

2. Methodology

The current research is a randomized controlled trial conducted at the laser and acupuncture clinic in excellence center National Research Center 75 cases were recruited from chest and allergy clinic in pediatric hospital Cairo university, the study categorized into 3 research groups inclusive research criteria were as follows in which all cases had an age range of 5 to 11 years, bronchial asthmatic cases, exclusive research criteria involved any coexisting medical disorder e.g type 1 DM, congenital disease or any organ system failure, cases refusing participation, informed written consent was obtained from study subjects parents. Sixty asthmatic children under regular medical treatment divided in a random manner in to 3 research groups. Research Group A: Twenty-five children were subjected to laser Acupuncture session three times per week for four weeks, Research group B twenty five cases under gone needle acupuncture sessions for 1 month (3times / week) and research group C (control group) twenty five under conventional medical treatment only. Assessment and evaluation of Pulmonary functions indices and medication usage of the cases before and after interventional management protocol in the study was performed. The study was conducted from September till November 2023, ethical approval took by number 17152 from the ethical committee in national research center.

Laser device used was diode (semiconductor laser) , low power (cold laser).The machine used Acculaser point with 100 WATT (or milliwatts) power and 3000 HZ frequency . It has two probes, one shower that was not used in this study, the other one have tunable wave length ranging from 650 to 860 nm. In this study,we used the wavelenghth of 860 nm , the power of 100(milliwatts) for 20 seconds over each acupoint giving power density of 3 Joules /Cm2. (the laser wave was continuous) to stimulate acupuncture points: DU20 (BaiHui), BL23 (ShenShu), BL28 (PangGuangShu), SiShenCong (3cm from the point BaiHui), RN6 (QiHai), GB20 (FengChi) and Du16 (FengFu).

Needle acupuncture: we used fine ,sterile disposable acupuncture needles 0.25x25mm) to stimulate acupuncture points: DU20 (BaiHui), BL23 (ShenShu), BL28 (PangGuangShu), SiShenCong (3cm from the

point BaiHui), RN6 (QiHai), GB20 (FengChi) and Du16 (FengFu).

Sites of needle on skin of children had been sterilized on by alcohol swab before its application. Needles were entered till its ¼ th of their length.

We should mention here (also in the abstract) the number of sessions (how many times per week for how many weeks).
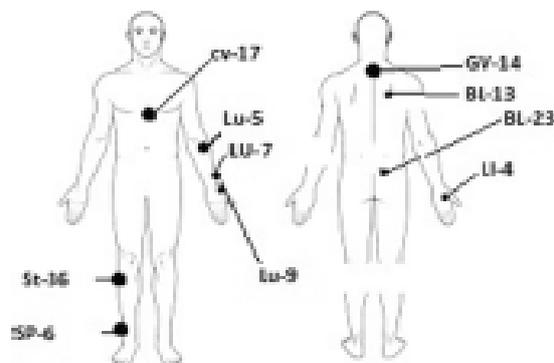
Sample size justification

Based on PASS 11th release (Hintze, 2011) the minimal sample size to detect significant difference between mean difference (Month 1 - baseline) of FEV1 % after using LASER acupuncture 16.7±18.3 (Elseify et al., 2013) and null change was 10 cases. We included 25 cases in LASER group, and similar 25 cases in each of Needle and Control groups for possible attrition and further analyses.

3. Statistical references:

Faul, F., Erdfelder, E., Buchner, A., & Lang, A. G. (2009). Statistical power analyses using G* Power 3.1: Tests for correlation and regression analyses. Behavior research methods,41(4), 1149-1160.

Mohamed, N. H., Meguid, I. E. A., Shaaban, H. H., & Kamel, I. M. A. (2013). Evaluation of needle acupuncture actions on clinical improvement, pulmonary functions, and cytokines of asthmatic children. Medical Research Journal, 12(1), 43-48.

4. Statistical methods

The collected data were coded, tabulated, and statistically analyzed using IBM SPSS statistics (Statistical Package for Social Sciences) software version 28.0, IBM Corp., Chicago, USA, 2021. Quantitative data tested for normality using Shapiro-Wilk test, then described as mean±SD (standard deviation), and then compared using independent t-test (two independent groups) and ANOVA test (three independent groups) as well as paired t-test (paired data). Qualitative data described as number and percentage and compared using Chi square test as well as Fisher's Exact test according to expected numbers

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in cells (independent groups) as well as marginal homogeneity test (paired ordinal data). Bonferoni test used for post hoc comparisons. The level of significance was taken at p-value <0.050 was significant, otherwise was non-significant.

5. Results
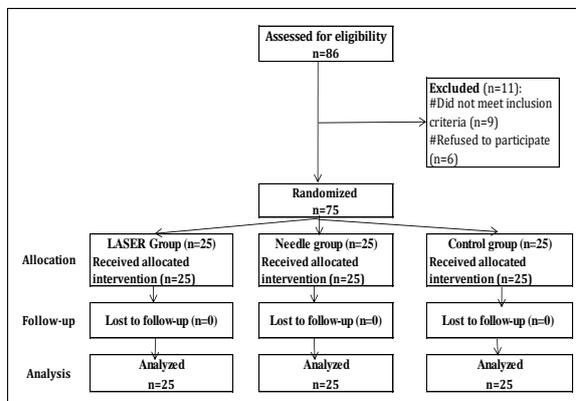
Figure (1): CONSORT flow chart of the studied cases

Fi8gure 1 shows that 86 cases were assessed for elgibility ,11 cases were excluded 9 cases didn't meet inclusion research criteria ,2 cases refused to participate.75 study subjects were randomly allocated into three research categorical groups equally 25 study subjects each (laser,needle,and control research groups).

Table (1): Demographic and clinical history between the study groups

Variables		LASER Group (Total=25)	Needle Group (Total=25)	Control Group (Total=25)	p-value
Age (years)		9.6±1.8	9.5±1.8	8.8±1.8	^0.214
Gender	**Male**	15 (60.0%)	13 (52.0%)	15 (60.0%)	#0.804
	Female	10 (40.0%)	12 (48.0%)	10 (40.0%)	
Weight percentile		75.5±8.9	74.2±7.6	72.8±9.4	^0.562
Asthma severity	**Intermittent**	1 (4.0%)	3 (12.0%)	3 (12.0%)	¤0.693
	Mild persistent	7 (28.0%)	10 (40.0%)	7 (28.0%)	
	Moderate persistent	13 (52.0%)	7 (28.0%)	11 (44.0%)	
	Severe persistent	4 (16.0%)	5 (20.0%)	4 (16.0%)	
Treatment	**SABD**	25 (100.0%)	25 (100.0%)	25 (100.0%)	NA
	LABD	11 (44.0%)	12 (48.0%)	9 (36.0%)	#0.683
	Montelukast	25 (100.0%)	25 (100.0%)	25 (100.0%)	NA

SABD: Short acting bronchodilators. LABD: Long acting bronchodilators. NA: Not Applicable. #Chi square test. ¤Fisher's Exact test. ^ANOVA test.

Table (1) reveals that there is no significant statistical difference between the study groups regarding age, gender, weight, asthma severity and antiasthma treatment (p values=0.214,0.804,0.562,0.693 and 0.683 consecutively).

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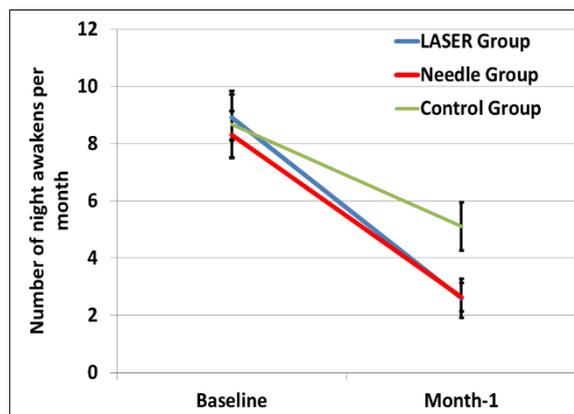**Table (2): Changes in the clinical condition between the study groups**

Variables	LASER Group (Total=25)	Needle Group (Total=25)	Control Group (Total=25)	^p-value
Number of attacks per week				
Baseline	6.7±2.3	6.2±3.3	5.9±3.3	0.613
Month-1	1.8±1.9a	2.0±1.9a	4.1±3.7b	**0.005***
Change	-4.9±2.3a	-4.2±2.3a	-1.8±1.8b	**<0.001***
§p-value	**<0.001***	**<0.001***	**<0.001***	
Number of night awakens per month				
Baseline	8.9±4.0	8.3±4.1	8.7±5.9	0.903
Month-1	2.6±3.4a	2.6±2.5a	5.1±4.2b	**0.016***
Change	-6.3±3.6a	-5.7±2.9a	-3.6±2.6b	**0.005***
§p-value	**<0.001***	**<0.001***	**<0.001***	

Change= Month-1 – Baseline, negative values indicate reduction. §Paired t-test. ^ANOVA test. Homogenous groups had the same symbol "a,b" based on post hoc Bonferroni test. *Significant**.**

Table (2) reveals and displays that there is no significant statistical difference between the study groups regarding baseline number of attacks per week and number of night awakens per month(pvalues=0.613,0.903). Number of attacks per week and number of night awakens per month one month after treatment were statistically significantly highest in control group with no significant difference between LASER and Needle groups. Reductions in number of attacks per week and number of night awakens per month were significantly lowest in control group with no significant difference between LASER and Needle groups. Number of attacks per week and number of night awakens per month significantly decreased in all the study groups.
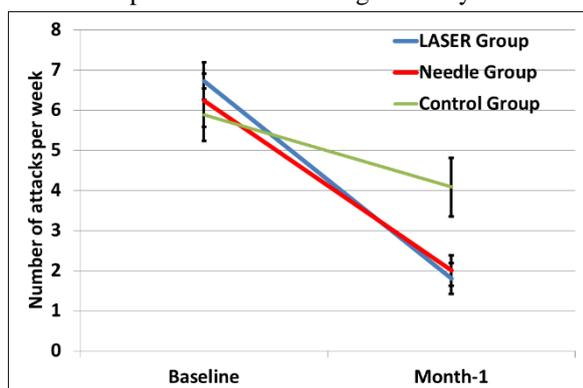
Figure (2): Number of attacks per week between the study groups

Figure (3): Number of night awakens per month between the study groups

Table (4): Changes in the pulmonary function between the study groups

Variables	LASER Group (Total=25)	Needle Group (Total=25)	Control Group (Total=25)	^p-value
VC (%)				
Baseline	85.2±5.3	86.0±5.8	86.2±3.6	0.769
Month-1	94.8±2.9a	94.6±3.8a	90.7±1.7b	**<0.001***
Change	9.6±5.2a	8.6±4.8a	4.4±3.5b	**0.004***
§p-value	**<0.001***	**<0.001***	**<0.001***	
FVC (%)				
Baseline	82.7±3.8	83.5±4.3	83.3±4.7	0.809
Month-1	96.6±2.3a	95.6±3.0a	90.5±2.5b	**<0.001***
Change	13.9±4.9a	12.2±5.5a	7.2±4.0b	**<0.001***
§p-value	**<0.001***	**<0.001***	**<0.001***	
FEV1 (%)				
Baseline	72.3±10.9	70.8±10.0	71.7±5.0	0.835
Month-1	95.7±3.4a	94.9±3.0a	87.1±2.6b	**<0.001***
Change	23.4±10.2a	24.2±9.3a	15.4±4.1b	**0.005***
§p-value	**<0.001***	**<0.001***	**<0.001***	
FEF 25-75 (%)				
Baseline	73.7±9.8	73.3±11.7	75.8±7.3	0.614
Month-1	95.4±3.0a	95.5±3.4a	86.2±2.6b	**<0.001***
Change	21.6±9.4a	22.2±9.5a	10.3±7.6b	**<0.001***
§p-value	**<0.001***	**<0.001***	**<0.001***	
PEF (%)				
Baseline	67.5±6.7	67.3±6.4	70.0±9.6	0.394
Month-1	95.2±2.7a	95.2±3.6a	81.4±2.1b	**<0.001***
Change	27.7±5.6a	28.0±7.2a	11.5±9.2b	**<0.001***
§p-value	**<0.001***	**<0.001***	**<0.001***	

Change= Month-1 – Baseline, negative values indicate reduction. §Paired t-test. ^ANOVA test. Homogenous groups had the same symbol "a,b" based on post hoc Bonferroni test. *Significant

Table (4) showed that: No significant statistical difference between the study groups regarding baseline pulmonary functions (VC, FVC, FEV1, FEF 25-75 and PEF). Pulmonary functions one month after treatment were significantly lowest in control group with no significant difference between LASER and Needle groups. Elevations in pulmonary functions were significantly lowest in control group with no significant difference between LASER and eedle groups. Pulmonary functions significantly increased in all the study groups.
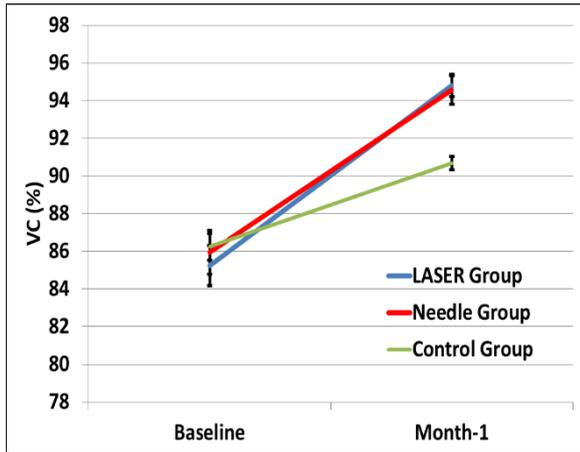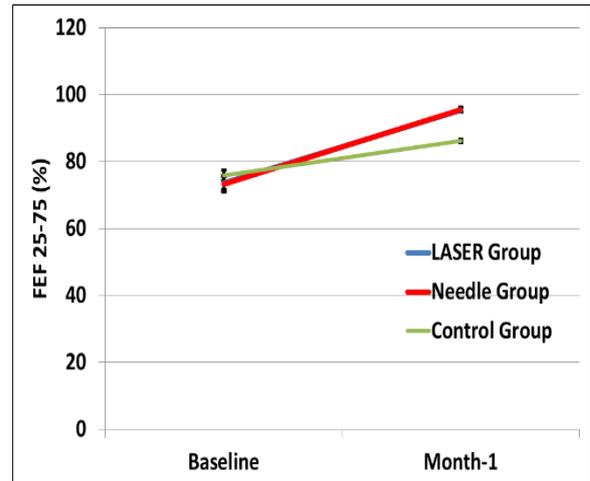
Figure (8): VC between the study groups
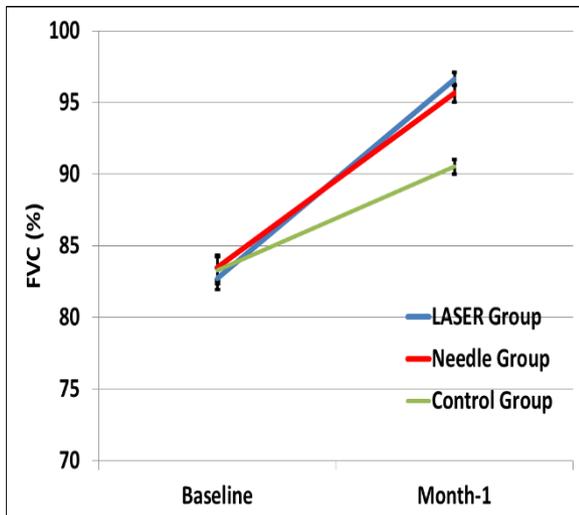

Figure (9): FVC between the study groups

Figure (10): FEV1 between the study groups

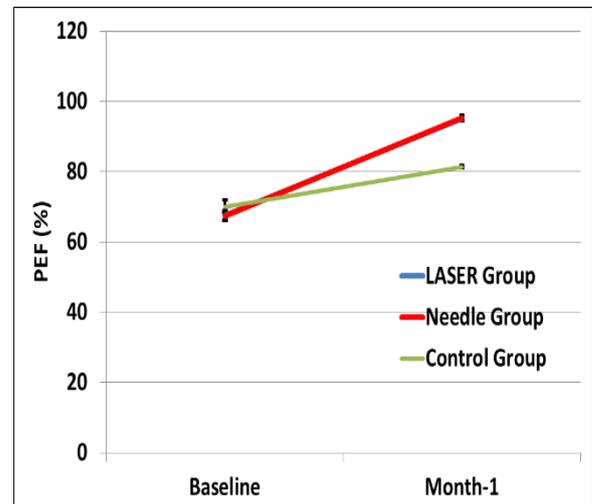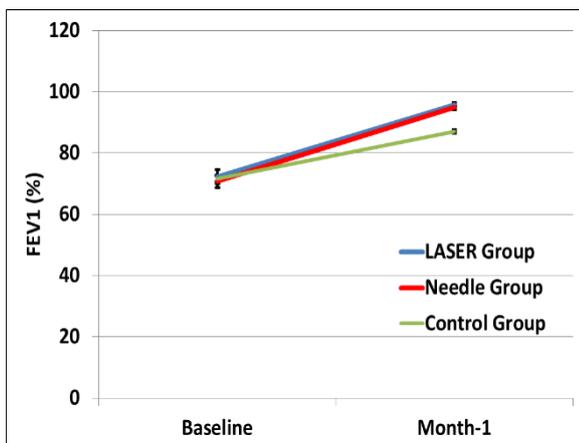**Figure (11): FEF 25-75 between the study groups**

Figure (12): PEF between the study groups

Table (5): Improvement of pulmonary function one month after medical treatment discontinuation between the study cases

Improvement	LASER Group (Total=25)	Needle Group (Total=25)	Control Group (Total=25)	p-value
Continued	18 (72.0%)a	17 (68.0%)a	8 (32.0%)b	**#0.007***
Discontinued	7 (28.0%)	8 (32.0%)	17 (68.0%)	

#Chi square test. Homogenous groups had the same symbol "a,b" based on post hoc Bonferroni test. *Significant.

Table (5) showed that: Continued improvement one month after medical treatment discontinuation significantly was significantly least frequent in control group with no significant difference between LASER and Needle groups
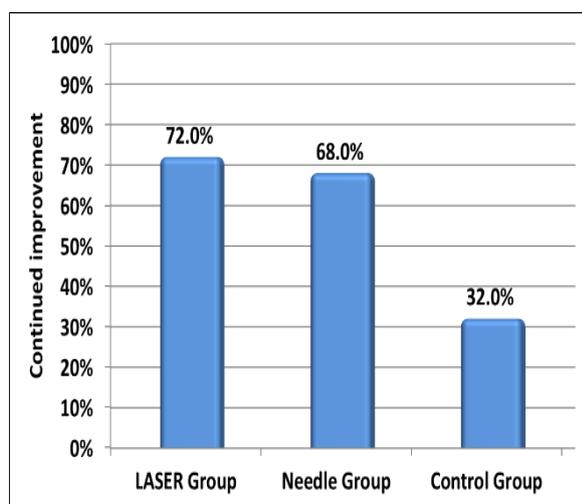

Figure (13): Improvement one month after medical treatment discontinuation between the study cases

5. Discussion

 A research systematic review have revealed that the results indicate that acupuncture used in the form of traditional needle acupuncture or laser acupuncture as a complementary management beside medical treatment, could   provide medical improvement as regards PEF and possibly FEV1, and these findings are in harmony with the current research study results . However, these findings are based on the results of three studies and should be interpreted with caution. In addition, the results of   prior research studies similar in methodology to the current research denote similarly a significant impact of acupuncture on medication usage and symptoms in younger children. 11,12. However, the acupuncture points implemented in previous research studies varied among studies. The research outcome measures evaluated in prior research studies were different making it complex to directly compare results. In which six of the seven research studies evaluated in the research review evaluated

objective lung functional indices (FEV1, FVC, PEF), the presentation as PEF variability, FEV1/FVC, % fall, % predicted value, and presentation in graphic vs. numeric form preventing direct comparative analysis. In the current research study, the research team implemented multiple sessions in which prior studies revealed that single sessions may not have been adequate to provoke a clinical effect**. 13,14**
Contradicting to our research study finding. Fung et al. research team implied the possibility of a placebo effect,but there is great concern that the placebo points implemented in their research study may not be firmly placebo (ie, they   could be relevant to bronchial asthma) , as well as concern regarding the relevance of the acupuncture points   implemented   to   manage bronchial   asthma. It should also be considered that acupuncture could in an indirect manner impact allergic diseases by influencing the production levels of inflammatory cytokines .**11,15**
Contradicting to the current research study findings however as regards   Bronchial asthma in children, a previous research systematic review evaluated the effectiveness of laser acupuncture in the management of asthma, and revealed   no convincing evidence regarding the efficacy of laser acupuncture in children with asthma.**9,10**

6. Conclusions
Methodologic variability in asthma management remains a research issue particularly when analyzing research clinical outcomes. However, the current research results denote that acupuncture could have a beneficial impact on pulmonary function indices and reduces medication requirements particularly when performed on multiple sessions in children with bronchial asthma. Future research studies are recommended as regards bronchial asthma in pediatric population to consider larger sample sizes, racial, ethnic differences that could influence the response to

various forms of acupuncture and pulmonary function indices before and after management to aid in future implementation of clinical guidelines of management

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