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PULMONARY FUNCTION TEST CHANGES BY AYURVEDIC TREATMENT IN TAMAKA SHVASA (BRONCHIAL ASTHMA): A RANDOMIZED CONTROLLED CLINICAL TRIAL

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Abstract

Background- Asthma is a chronic lung disease affecting people of all ages. It is caused by inflammation and muscles tightening around the airways in lungs which can be any combination of coughing, wheezing, shortness of breath and chest tightness. Asthma affects an estimated 262 million people in 2019 and caused 455000 deaths.

Objective: The study design to evaluate the effect of "*Simhyadi Kwath"* in comparison with Tablet Doxofylline on Bronchial Asthma by Pulmonary Function Test.

Methods- In the open label randomized controlled clinical trial 30 patients in trial group was treated with *Simhyadi Kwath* for 45 days and 30 patients in control group was managed by tablet Doxofylline for 45 days. Assessment was done on the basis of Pulmonary Function Test by spirometer, PEFR and SMI.

Result- *Simhyadi Kwath* is better to increase FEV1, FVC, FEV 25-75, PEFR and SMI than the tablet Doxofylline by considering mean difference*. Simhyadi Kwath* is significant in treatment of Tamaka Shvasa with increases FEV1 by 20.733±6.628 (t-17.134 & P<0.0001), FVC by 15.633±6.825 (t-12.546& P<0.0001), FEV 25-75 by 35.033±18.891 (t- 10.158 & P<0.0001), PEFR by 109.53±31.065

(t- 19.277 & P<0.0001), SMI by -2.033±0.9279 (t-12.003 & P<0.0001) and reduces lung age by 19.90±8.531 (t-12.77 & P<0.0001). Tablet Doxofylline improves PFT parameter with increasing FEV1 by 17.667±8.185 (t-18.823 & P<0.0001), FVC by 15.167±7.264 (t-11.436 & P<0.0001), FEV 25-75 by -26.767±21.66 (t-6.767 & P<0.0001), PEFR by -85.33±31.154 (t- 15.003 & P<0.0001), SMI by-1.533±0.7303 (t- 19.277 & P<0.0001) and lung age by 16.467±10.817 (t- 8.338 & P<0.0001).

Discussion and Conclusion- The comparative study showed that Ayurvedic *Simhyadi Kwath* was more effective in treatment of *Tamaka Shvasa* with improvement in PFT parameters without side effects.

Keywords: Bronchial Asthma, Tamaka Shvasa, Ayurvedic Treatment, Pulmonary Function test [PFT], Simhyadi Kwath, Tablet Doxofylline

Introduction-

Asthma is a prevalent chronic inflammatory respiratory condition affecting millions of people worldwide and presents substantial challenges in both diagnosis and management. It is caused by inflammation and muscles tightening around the airways in lungs which can be any combination of coughing, wheezing, shortness of breath and chest tightness. Asthma affects an estimated 262 million people in 2019 and caused 455000 deaths.[1] Bronchial asthma is a serious global health problem. 5% to 10% of person of all ages suffers from this chronic airway disorder. Bronchial Asthma is a chronic inflammatory disease of airways characterized by bronchial hyperactivity and a variable degree of airway obstruction. It is diagnosed on the basis of clinical history, physical examination, and pulmonary function test including reversibility testing and measurement of bronchial reactivity. [2] Recurrent episodes of acute shortness of breath, typically occurring at night or in early morning hours are cardinal manifestation of bronchial asthma. Further symptoms include cough, wheezing and feeling of tightness in chest. [3] Asthma manifests with diverse phenotypes, likely influenced by intricate interactions between genetic and environmental factors. Genome wide association studies have linked childhood onset of asthma. [4] Asthma needs long term treatment includes inhaled corticosteroids and bronchodilators which has many side effects.[5] COPD and Asthma made the second largest contribution to total mortality burden of India at 10.9%. the crude prevalence rate of asthma 8.6% (6.1-11.4) in 1990-2016 period. Asthma affects an estimated 280 million people in 2022 and caused half of million deaths globally. India contributes to 12.9% of global asthma cases and 42.4% of global asthma death. [7]

Primary Objectives-

Evaluate the effect *Simhyadi Kwath* in management of Tamaka Shvasa.

Secondary Objectives-

Comparing *Simhyadi Kwath* and Tablet Doxofylline on PFT parameters.

Withdrawal Criteria - The participants was withdrawal from the trial if he / she developed any serious adverse effect or any serious condition which required ICU management Patient was refers to higher center.

Sample Size- Control group- 30

Trial group- 30

Study Population- 958 participants were screened to assess out of which 574 had exclusion criteria, 218 with severe bronchial asthma, 38 had acute attack of exacerbation were excluded. Eligible 128 participants 90 were selected for randomization with consent for participation in study.

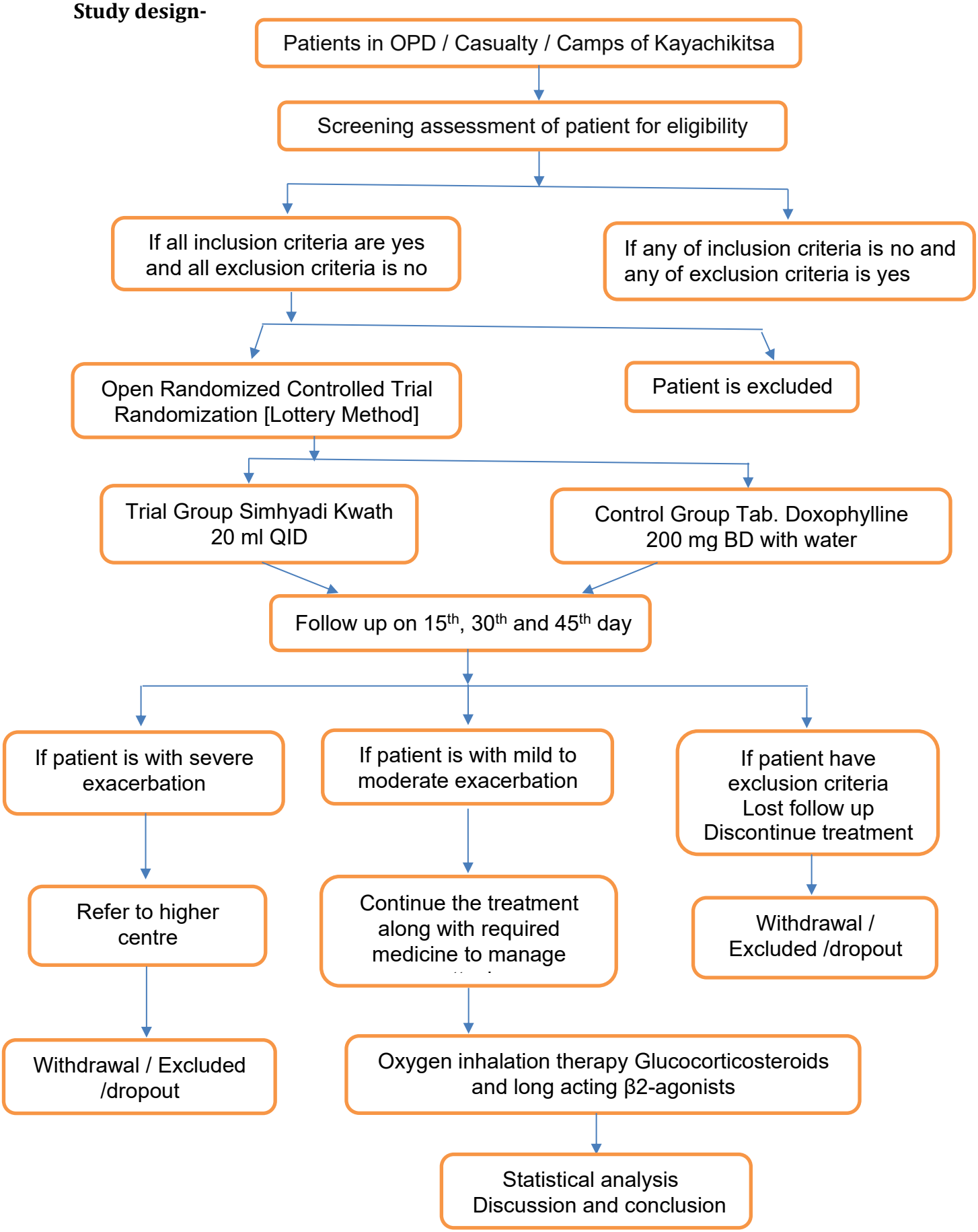
Randomization – Randomization done by lottery method.

***Simhyadi Kwath* –** *Simhi [Bruhati]* (*Solanum indicum*)*, Nisha [Haridra]* (*Curcuma Longa*)*, Simhamukhi [Vasa]* (*Adhatoda vasica*)*, Guduchi* (*Tinospora Cordifolia*)*, Vishva [Shunthi]* (*Zingibar officinale*)*, Upakulya [pimpali]* (*Piper longum*)*, Bhrunguja [Bharangi]* (*Clerodendeun serratum*)*, Ghana [Nagarmotha]* (*Cyperus rotundus*) *were Kwath Dravya and Upakulya [pimpali]* (*Piper longum*), *Marich* (*Piper nigrum*) were *Prakashep* Drug Purchased and send it for standardization. After standardization, *Simhyadi churna* was prepared by Unijules pharma, Nagpur.

Preparation of *Kwath* – Method of preparation of *Simhyadi Kwath* mention by the *Acharya Yogaratnakara* in *Shvasa Chikitsa* was one part quantity of *Churna* was mixed with 16 times of water. Heated it up to ½ of the water remains in container. Took *Saviryataavadhi* of *Kwath* in mind, for preparation of 80 ml *Kwath*, 10 gm *Churna* was add in 160 ml water and boiled it up to 80 ml remaining in container.

Methodology - 80 ml *Kwath* divided into 4 doses i.e. 20ml QID *Muhurmuhur* gave to 30 patients in trial group for 45 days with lukewarm water. Tablet Doxofylline 200 mg Bd with water for control group was prescribed for 30 patients for 45 days.

Study design-



Study centre- Patients were recruited in this study from OPD, Casualty, and camps of Kayachikitsa Department in Government Ayurvedic College, Nagpur after taking informed consent from the patients for clinical trial.

Inclusion Criteria – Patients aged between 18 to 70 years, respiratory rate was between 22 to 42 per minute, 1 to 10 years chronic patients included, went through mild to moderate exacerbation, showed positive test of reversibility by PFT, increased in FEV1 Of ≥12% and ≥200 ml after of a bronchodilator, participated for 6 weeks, showed symptoms, sign and medical history of Tamaka Shvasa, Haemoglobin ≥ 10 gm %, ECG was normal.

Exclusion criteria- patient had severe asthma exacerbation by GINA Criteria, pregnant or lactating mother, poorly controlled Hypertension [>160/100 mmhg], uncontrolled Diabetes Mellitus [Blood sugar fasting > 130 mg / dl and post meal 250 mg / dl], active lung disease other than Bronchial asthma, had major surgery within 2 weeks prior to screening visit and Patients with evidence of malignancy, major diseases immunosuppressant diseases like AIDS and cardio vascular diseases were excluded from this study.

Statistical Analysis - In study for data analysis paired t test and for comparison in between to drugs unpaired t test were used which is showed in the table no 1, 2, 3.

Table No.1

Table Showing Effect of Therapy on Pulmonary Function Test of 60 Patients of *Tamaka Shvasa*

SN	PFT Parameters	Group	PFT Parameters Score			% of Relief (Diff/BT)
			BT	AT	Diff	
1	FEV1	Trial Group Control Group	2030 2011	2652 2541	622 530	30.6403% 26.3550%
2	FVC	Trial Group Control Group	1682 1650	2151 2105	469 455	27.8834% 27.57%
3	FEV1/FVC	Trial Group Control Group	3664 3689	3712 3674	48 15	1.31004% 0.4066%
4	Lung age	Trial Group Control Group	3950 3950	3353 3456	597 494	15.1139% 12.5063%

5	FEV25-75	Trial Group Control Group	1729 1954	2780 2757	1051 803	60.7865% 41.095%
6	SMI IN SEC	Trial Group Control Group	54 45	115 91	61 46	112.962% 102.22%
7	PEFR L/MIN	Trial Group Control Group	4570 4480	7850 7040	3280 2560	71.7724% 57.143%

Table No. 2

Table Showing Effect of Therapy on PFT Parameters of 60 Patients of *Tamaka Shvasa*

SN	PFT	Gr	Mean ± SD		Mean of diff. ± SD	Sed	't'	P
			BT	AT				
1	FEV1	TG	67.667±4.046	88.40±6.916	20.733±6.628	1.210	17.134	<0.0001
		CG	67.033±4.846	84.70±8.710	17.667±8.185	1.494	11.823	<0.0001
2	FVC	TG	56.067±7.520	71.70±7.316	15.633±6.825	1.246	12.546	<0.0001
		CG	55±6.297	70.167±7.311	15.167±7.264	1.326	11.436	<0.0001
3	FEV1 / FVC	TG	122.13±11.855	123.73±9.359	1.60±6.719	1.227	1.304	0.2024
		CG	122.97±11.834	122.47±9.691	0.50±7.243	1.322	0.3781	0.7081
4	Lung Age	TG	131.67±5.378	111.77±6.947	19.90±8.531	1.558	12.77	<0.0001
		CG	131.67±5.707	115.20±9.736	16.467±10.817	1.975	8.338	<0.0001
5	FEV25-75	TG	57.633±14.25	92.667±23.170	35.033±18.891	3.449	10.158	<0.0001
		CG	65.133±12.676	91.90±23.31	26.767±21.66	3.956	6.767	<0.0001
6	SMI	TG	1.80±0.9613	3.833±1.416	2.033±0.9279	0.169	12.003	<0.0001
		CG	1.50±0.861	3.033±1.129	1.533±0.7303	0.133	11.50	<0.0001
7	PEFR	TG	152.33±27.503	261.67±46.615	109.53±31.065	5.672	19.277	<0.0001
		CG	149.33±22.73	234.67±36.458	85.33±31.154	5.688	15.003	<0.0001

Table No. 3

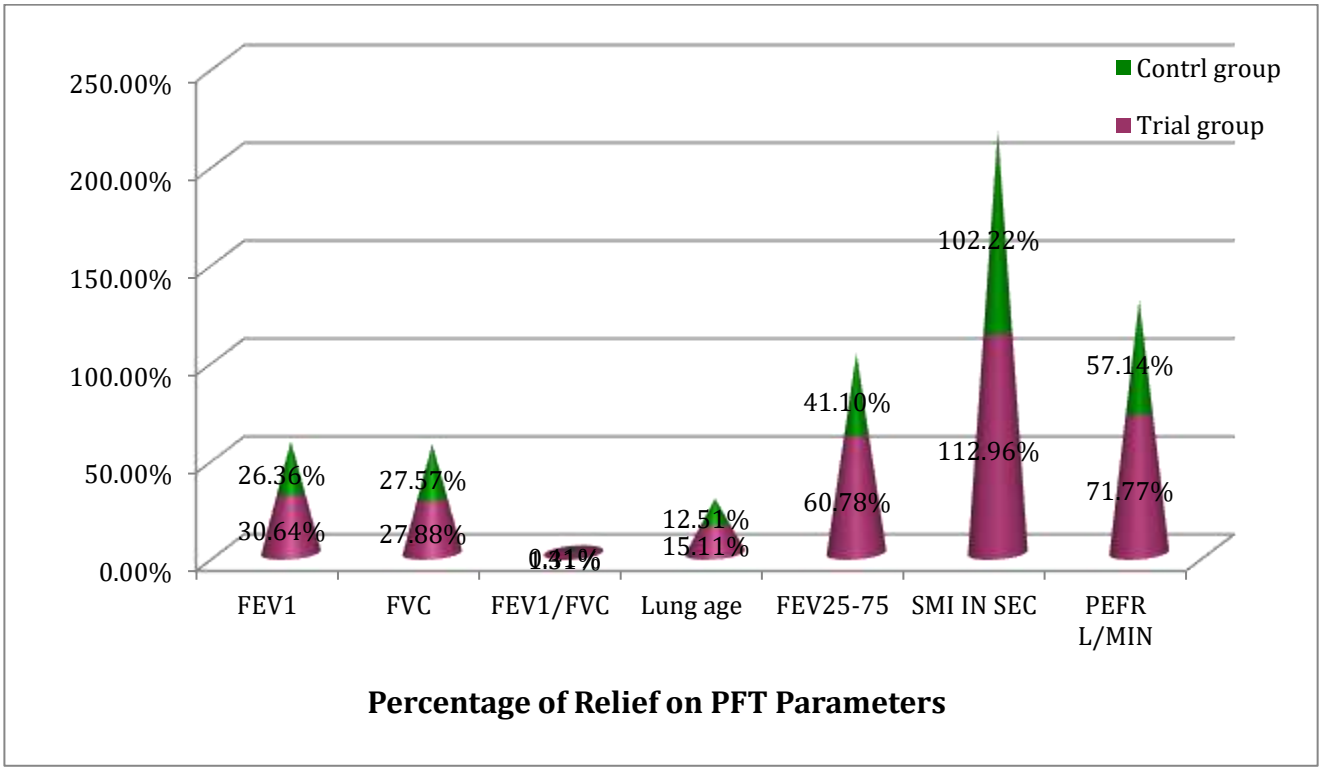
Table Showing Comparison between Two Groups on The Basis of Unpaired-t-test for PFT Parameters

SN	PFT Parameters	Mean of diff±SD(T.G.)	Mean of diff±SD(C.G.)	Diff of mean	Pooled SD (S_P)	SEd	T	P
1	FEV1	20.733±6.628	17.667±8.185	3.066	7.4469	1.81704	1.68703	>0.05
2	FVC	15.633±6.825	15.167±7.264	0.466	7.0480	1.71971	0.2709	>0.05
3	FEV25-75	35.033±18.891	26.767±21.66	8.266	20.325	4.9593	1.6667	>0.05
4	SMI	2.033±0.9279	1.533±0.7303	0.5	0.8348	0.20369	2.4630	<0.001
5	PEFR	109.53±31.065	85.33±31.154	24.2	31.1097	7.59076	3.18808	<0.001

Graphical Presentation –

Figure -1

Figure Showing Effect of Therapy on Pulmonary Function Test of 60 Patients of *Tamaka Shvasa*



Percentage of Relief on PFT Parameters

(Note: Trial group – *Simhyadi Kwath* & Control group – Tab Doxofylline)

Result-

Simhyadi Kwath increased FEV1 from 67.667 ± 4.046 to 20.733 ±6.628 which is increased by 20.733±6.628 (t-17.134 with P<0.0001), FVC from 56.067 ± 7.520 to 71.70±7.316 (t-12.546 with P<0.0001) which increased by 15.633 ±6.825, FEV1 / FVC from 122.13 ± 11.855 to 123.73± 9.359 which increased by 1.60 ±6.719(t-1.304 with P- 0.2024), FEV 25-75 from 57.633 ± 14.25 to 92.667±23.170 which increased by 35.033 ± 18.891 at t was 10.158 with P<0.0001, SMI from 1.80 ± 0.9613 to 3.833±0.1.416 which increased by 2.033 ± 0.9279 at t was 12.003 with P<0.0001, PEFR from 152.33 ± 27.503 to 261.67±46.615 which increased by 85.33 ± 31.154 at t was 19.277 with P<0.0001, and decreased lung age from 131.67 ± 5.378 to 111.77±6.947 which reduced by 19.90 ±8.531 (t was 12.776 with P<0.0001).

While Tablet Doxofylline increased FEV1 from 67.033±4.846 to 17.667± 8.185 which is increased by 17.667±8.185 (t- 11.823 with P<0.0001), FVC from 55±6.297 to 70.167 ± 7.311 which increased by 15.167±7.264 (t- 11.436 with P<0.0001), FEV1 / FVC increased from 122.97±11.834 to 122.47 ± 9.691 which decreased by 0.50 ±7.243 (t-0.3781, P- 0.7081), FEV 25-75 was 65.133 ± 12.676 to 91.90 ± 23.31 which increased by 26.767± 66 at t was 6.767 with P<0.0001, SMI was 1.50±0.861 to 3.033 ± 1.129 which increased by 1.533 ± 0.7303 at t was 11.50 with P<0.0001, PEFR was 149.33 ± 22.73 to 234.67 ± 36.458 which increased by 85.33 ± 31.154 at t was 15.003 with P<0.0001 with Lung Age was 131.67±5.707 to 115.20 ± 9.736 which reduced by 16.467 ±10.817 (t was 8.338 with P<0.0001).

Discussion-

Doxofylline inhibits phosphodiesterase enzyme activity thus increase in level of cAMP and promoting smooth muscles relaxation resulting bronchodilation. Doxofylline may exert anti-inflammatory effects through adenosine receptor antagonism and by increasing IL-10 release. Elevated cAMP level can suppress innate immune function like inflammation and phagocytosis with increase heart rate, cortisol secretion, breakdown of glycogen. Increased level of IL-10 generally leads to reduced inflammation and suppression of the immune system with severe HDL deficiency. Due to its immunomodulatory properties there is also a potential for increase the risk of infections, autoimmune disorders or b-cell lymphoproliferative disorders.

Simhyadi Kwath break Tamaka Shvasa Samprapti by Vata-Kaphahara, Dipana, Pachana, and *Vatanulomana* properties. *Dipana and Pachana* were carried out because of *Ushna Virya, Tikta* and *Katu Rasa* dominance with *Katu Vipaka* of drug which used to digest the *Ama* and removed

Strotasavarodha. By digesting the *Aama* it helped to improve *Jatharagni, Dhatavagni (Rasa* and *Rakta)* with *Bhautikagni.* During treatment of *Tamaka Shvasa* considered two types of *Samprapti*. One of them was due to vitiated *Vata* which caused *Bronchospasm*. *Vataghna Bruhana Chikitsa* was beneficial but if *Tamaka Shvasa* caused due to vitiated *Kapha then Kaphaghna* and *Vatanulomaka* treatment was beneficial.

Rasa Dhatudushti and Rakta Dhatudushti was mostly observed in *Tamaka Shvasa* due to *Dhatavagnimandya. Rasayanchikitsa* was beneficial which used to improve *Dhatavagnimandya. Rasadhatudushti* caused *Margavarodha* and *Raktadhatu Phena* helped to construct *Phuphphusa* hence required a drug acted on *Dhatavagnimandya.* Genetics was one of the causes of bronchial asthma and 40% people had positive family history of bronchial asthma. It can be co-related with *Sukradhatavagnimandya.*

The pharmacological studies already reported on individual drug of Simhyadi Kwath shows Anti-inflammatory –*Haridra, Guduchi, Maricha, Pippali, Shunthi*. Anti-allergy- *Haridra, Bharangi, Guduchi*. Anti-tissue – *Vasa, Shunthi*. Bronchodilator- *Vasa, Pimpali*. Anti-catarrhal – *Shunthi, Maricha*. Anti-spasmodic – *Vasa*. Expectorant – *Vasa*. Immunomodulator – *Guduchi and Pippali*.

Conclusion – *Simhyadi Kwath* is one of the best drugs for treatment of *Tamaka Shvasa* (Bronchial Asthma) to improve pulmonary function test with better mode of action without side effects.

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