International Journal of Medical Science and Clinical Research Studies

ISSN(print): 2767-8326, ISSN(online): 2767-8342

Volume 03 Issue 06 June 2023

Page No: 1056-1061

DOI: https://doi.org/10.47191/ijmscrs/v3-i6-04, Impact Factor: 6.597

Clinical Study of Polyherbal Formulation in the Management of Bronchial Asthma (Tamaka Swasa)

Mukamchem Yim[1], Rigom Pegu[2], B.P. Sarma[3]

[1,2]PhD Scholar, Department of Medical Science, Guwahati University under the faculty of Medicine, Jalukbari, Guwahati-14, Assam, India

[2]Nagaland Ayurvedic Clinic & Research Centre, Dimapur-798612, Nagaland, India

[3]Govt, Ayurvedic College & Hospital, Jalukbari, Guwahati-781014, Assam, India

ABSTRACT

Tamaka Swasa is described as one of the five varieties of swasa mentioned in various Ayurvedic classics like Charaka Samhita, Susruta Samhita, Astanga Hrdaya, Madhava Nidana etc. In classics various single/multiple herbs and minerals has been well establish in the practice of Ayurveda. In the present study an open clinical trial has been made in 100 (one hundred) patients of bronchial asthma with an attempt to explore the efficacy of polyherbal formulation in the management of bronchial asthma. The polyherbal formulation is prepared in coarse powder and made it into kwath (decoction) form by boiling 10 gms in 200ml of water for 5-10 minutes or more till concentrated by evaporation to 50 ml. The decoctions is then keep for cooling for some time and is advice to take twice daily preferably after food continuously for three months. The result after completion of the treatment in all sign and symptoms following inclusion and exclusion criteria is seen to be so satisfactory and encouraging and further no adverse or side effect was observed in any of the patient in the entire study.

KEYWORDS: Tamaka Swasa, Bronchial Asthma, Polyherhal Formulation

ARTICLE DETAILS

Published On:
05 June 2023

Available on:
https://ijmscr.org/

INTRODUCTION

Asthma in a single word is very difficult to define because of its multifactorial disease and numbers of parameter can be adopted to make the diagnosis the disease. Each and every specialty in their own field like the clinician, physiologist, pathologist, pharmacologist, and immunologist have their own perspective view of bronchial asthma which is difficult to be compiled into a comprehensive definition which is sufficiently specific to exclude other diseases. However, during the past one decade there have been major changes in the concept of patho-physiology of asthma. It is now recognized that it is primarily an inflammatory disease of the respiratory system, the inflammation underlying extrinsic and intrinsic stimuli resulting in widespread spasmodic narrowing of the air passage[1].

According to the Global Initiative for Asthma (15 May 2012)[2], asthma can be defined as – A chronic inflammatory disorder of the airways in which many cells and cellular elements play a role.

Bronchial Asthma is a worldwide distributed disease and is quite common in all economic strata of all the age group and sex predominately in early life affection 10-20% of general population. WHO has estimation that there are 300 million people of different ages either background suffering from asthma[3] and 15 million daily adjusted lives yearly are lost annually due to asthma representing 15 of the global disease burden in the world[4]. The burden of the disease on the Government, Health care system, families and patients is increasing nowadays. Data on prevalence of asthma is now available from several countries varies from region to region depending upon the definition used for diagnosis [5-14]. Current asthma is reported in 1.2 to 6.3% adult in most country [5-9]. Whereas, diagnosed asthma in adult is generally reported as 2.7 to 4.0% in most European country, 12.0% in England and 7.1% in the US [5-10-12]. In Australia, the prevalence is rather higher (9.5 to 17.9%) [4,6]. Tristan da Cunha is a unique example where more than half the population i.e., 55.6% is reported to suffer from asthma, supporting a strong genetic link[13]. In US, asthma is the leading cause of hospitalization among children under 15 years of age[15]. Annual expenditures for health and lost productivity due to asthma are estimated at over $20 billion, according to National Heart, Lungs and Blood Institute. In India the overall burden of asthma is

estimated to be more than 15 million patients[14] and is recognized to be a major cause of morbidity and mortality in people of all age groups (Claverly 1990).

Because of the increased in prevalence among related individuals, asthma was understood quite long back that it is a genetic disorder[16], whose presence dates back to at least the time of Hippocrates who noted a condition of deep and heavy breathing and this disease was labeled "asthma/painting" by the Greeks[17]. In terms of its genetic influence asthma was found that Chromosomal region 5q31 harbors a number of genes associated with atopic phenotypes[18], eg coding for interlukin and beta adrenoreceptor. A new within the region was identified very recently. The encoded protein- uteroglobin related protein 1 (UGRP1) is thought to act as an anti-inflammatory agent and is mainly expressed in the lung and trachea. The functional promoter polymorphism A-112G in UGRP1 was found to be associated with bronchial asthma in a Japanese population [19]. In asthma, there are quantitative and qualitative changes in proteins of erythrocyte membranes. The absence of band 4.2 protein may cause impairment of the erythrocyte membrane integrity, and presence of galectin-3 may lead to the activation of various inflammatory cells. The altered protein profile may possibly lead to altered response of the inflammatory cells to the asthmogenic stimuli, which may be responsible for path physiology and manifestation of the symptoms of bronchial asthma [20]. Apart from above mentioned genes, hundreds of genome-wide linkage analyses and association studies have identified several chromosomal regions harboring asthma susceptibility genes like chromosome 2q, 5q, 6q, 11q, 12q and 13q. Also, about 100 candidate genes for asthma have been described. However, not all of them have been confirmed in independent studies [21].

Although the synthetic drugs currently used in the treatment of bronchial asthma are successful in overcoming the symptoms, but they cause lots of undesirable effects and their efficacy decreases on their continuous use, so an alternative search is always needed. There is need of holistic medicine of traditional indigenous origin which is very effective, non-toxic, affordable and acceptable. Keeping this in view a polyherbal formulation has been formulated from herbs as mentioned in the ancient Ayurvedic literature and referring to previous clinical study and review in various medical colleges and research institute in the country and abort, the present study has been taken up in the Department of Kayachikitsa. Government Ayurvedic College and Hospital, Jalukbari, Guwahati-14 hoping for long term relief to the patient suffering from bronchial asthma.

MATERIALS AND METHODS

Subject

Total number of 100 patients of either sex suffering from bronchial asthma between the age group of 10-70 years was carried out for clinical study at Government Ayurvedic College & Hospital, Jalukbari, Guwahati-14, Assam, India based on exclusion and inclusion criteria mentioned as follows.

Inclusion Criteria

Patients suffering from breathlessness, cough, wheezing, tightness of chest, difficulty in expectoration, rhinitis, sneezing, insomnia and fever between the age group of 10-70 of either sex with chronicity less than 10 years and uncomplicated case were considered.

Exclusion Criteria

Besides having bronchial asthma, patients less than 10 years of age and more than 70 years of ages, dyspnoeic problem of cardiac and other systemic origin like: pulmonary tuberculosis, massive pulmonary embolism, psychogenic dyspnoea, acute exacerbation of COPD, renal pathology, metabolic acidosis, status asthmaticus, pneumonia, malignancy, left ventricular failure and surgical intervention etc alone with that of those who were not willing for the particular herbal treatment are excluded. The institutional ethical committee approving for clinical studies, certificate of test or analysis from state drug testing laboratory and the written consent was made for each patient.

Allocation

100 patients were treated by polyherbal formulation. All the subjects were advised to take the formulation during the scheduled period of time and to undergo methodical investigation before treatment and after completion of treatment. All the patients were advice to take the medicine for 3 (three) months at the interval of 30 days follow up for clinical examination and investigation.

THERAPEUTIC STUDY

Selection of trial Drug

The drug was selected on classical references considering the action on respiratory tract.

Preparation of Trial Drug

The coarse powder was obtained from Banaras, India. The coarse powder of Shirish 2gm, Kantakari 2gm, Yastimadhu 2gm, Vasaka 2gm and Tulsi 2gm is prepared in kwath (decoction) form by boiling 2 tsf (10 gms) of prepared powder in 200 ml of water and concentrated by boiling to till 50ml. The decoction was given twice daily after food for three months.

Assessment of Treatment

To assess the sign and symptoms and severity of the disease the patients were evaluated once a month for their different follow-ups and depending upon the severity the grade rating was done for absent = 0, mild = 1, moderate = 2 and severity = 3. The assessment of the result of the patient based on inclusion and exclusion criteria and subjective and objective criteria at 100 patients of bronchial asthma at Government Ayurvedic College & Hospital in both OPD and IPD treated with the polyherbal formulation in due course of the study.

Statistical analysis

The data obtained from the above treatment were then organized and summarized using the online and offline software known as t-test calculator (GraphPad) [22] following Chose data entry format (Enter or paste up to 2000 rows), Chose t test (Paired t test), Enter Data (Before treatment and After treatment), View the result (Calculate Now and Clear Form). The data were then analyzed using appropriate statistical tools such as arithmetic mean, percentage, standard deviation and t-test of significance.

Results

The result of the study is done mainly under two different headings.The first part consist of demographic study and the second part consist of therapeutic response the trial drug in the patient of bronchial asthma meeting both the subjective and objective parameters of assessment.

Clinical study was done on 100 patients for the period of 3 months with 1 month interval of each patient for follow-up in IPD and OPD at Government Ayurvedic College and Hospital, Jalukbari, Guwahati-14. An open trial was conducted on the patients between 10 to 80 years of age irrespective of sex and religion based on inclusion criteria and exclusion criteria. Patient having classical sign and symptoms of Tamaka swasa were selected for the clinical study. Special designed Performa was made for observation and assessment of the therapeutic effect. Assessment of result on the basis of subjective and objective parameters was done.

Observation

The observation (Table- 1.1) seen on 100 patients of bronchial asthma shows maximum number of patients i.e. 51.00% is in the age group of 21 – 40 years. Female is dominated having 58.00% of cases while Hindu were dominant among the sufferer having 71.00%. Maximum number of patients was student at 36.00% followed by service at 21.00%. Middle class having 47.00% and the history of addiction to beetle nut, tobacco and cigarette smoking at 40.00% were found to be affected more in the study. Majority of patients i.e. 68.00% were belonging to urban habitat and almost all are non-vegetarian at 94.00% comparing to vegetarian with the family history of bronchial asthma found positive in 38.00% of cases and positive in personal history of allergy at 62.00% were found in the study. Majority of the patient i.e 26.00% found to be suffering with the duration of 1-2 years.

The effect of therapy (Table 1.2) was found to be very satisfactory and encouraging. In sing and symptoms remarkable relief was observed in the symptoms like paroxysmal dyspnoea 85.00%, cough 89.00%, prolonged expiration 84.00%, rhonchi/wheezing 84.00%. Whereas the other associated symptoms such as tightness of chest were relieved in 77.53% of cases, frequent coryza was relieved in 73.97% of cases, crepitations in 74.19% of cases, headache in 93.55% of cases, insomnia in 75.00% of cases and fever in 100% of cases.

Effect of the drug (Table-1.3) on Peak Expiratory Flow Rate, Breath Holding Time, therapy on ESR, Absolute Eosinophil Count, Treatment on Dysponea, therapy on Cough, Ronchi/wheezing, Prolonged Expiration, Tightness of Chest, Crepitations, Frequent Coryza, Insomnia, Headach and Fever were found to be highly significant with the p-value < 0.01. Thus the overall outcome of the study was significant indicating that the polyherbal compound has an effective role in the treatment of Bronchial Asthma

Table 1.1. Demographic Profile of 100 patients of Bronchial Asthma

S.No	Demographic profile	Observation	Percentage
1	Age in years	21-40	51.00%
2	Sex	Female	58.00%
3	Religion	Hindu	71.00%
4	Occupation	Student	36.00%
5	Socio Economical Status	Middle Class	47.00%
6	Addiction	Bettle nut, tobacco & cigarette smoking	40.00%
7	Habitat	Urban	68.00%
8	Dietary Habit	Non-veg	94.00%
9	Family History of Bronchial Asthma	Positive	38.00%
10	Personal history of allergy	Positive	62.00%
11	Duration of Illness	1-2 years	26.00%

Table1.2. Effect of Therapy on Sign and Symptoms after 90 days in 100 cases of Bronchial Asthma

Sl. No.	Sign & Symptoms	Number of Patients		Percentage of Relief
		BT	A T	
1	Paroxysmal dyspnoea	100	18	85.00%
2	Cough	100	11	89.00%
3	Prolonged Expiration	100	16	84.00%
4	Rhonchi/Wheezing	100	16	84.00%
5	Tightness of Chest	89	20	77.53%
6	Frequent Coryza	73	19	73.97%
7	Crepitations	31	08	74.19%
8	Headache	31	02	93.55%
11	Insomnia	24	06	75.00%
12	Fever	11	00	100%

Table 1.3. Effects of Trial Drug in 100 Patients of Bronchial Asthma after Treatment

S. No	Effect of Drug	Mean Value			SD			SED	t-value	p-value
		BT	AT	BT-AT	BT	AT	BT-AT			
1	PEFR	153.23	248.58	95.35	±56.22	±50.17	±6.05	3.01	31.72	<0.01
2	BHT	12.78	20.28	7.5	±2.50	±2.39	±7.5	0.26	29.16	<0.01
3	ESR	30.51	19.66	10.85	±19.24	±7.61	±11.63	1.32	8.19	<0.01
4	Ab EC	417.22	254.51	162.71	±169.62	±100.60	±69.02	11.04	14.74	<0.01
5	Dysponea	2.55	0.23	2.32	±0.50	±0.53	±0.03	0.06	37.57	<0.01
6	Cough	2.44	0.15	2.29	±0.53	±0.40	±0.13	0.89	25.88	<0.01
7	Ronchi/wheezing	2.26	0.22	2.04	±0.58	±0.52	±0.06	0.08	25.90	<0.01
8	Prolonged Expiration	2.09	0.24	1.85	±0.59	±0.61	±0.02	0.06	32.17	<0.01
9	Tightness of Chest	1.59	0.21	1.38	±0.78	±0.43	±0.35	0.08	18.42	<0.01
10	Crepitations	0.49	0.08	0.41	±0.79	±0.28	±0.51	0.08	4.91	<0.01
11	Frequent Coryza	1.13	0.20	0.93	±0.87	±0.43	±0.44	0.08	12.30	<0.01
12	Insomnia	0.33	0.07	0.26	±0.67	±0.29	±0.38	0.05	5.15	<0.01
13	Headach	0.35	0.06	0.29	±0.56	±0.24	±0.32	0.05	5.82	<0.01
14	Fever	0.11	0.31	0.02	±0.00	±0.00	±0.00	0.03	3.50	<0.01

Further no adverse or side effect was observed in any of the patient in the entire clinical study and overall therapeutic response was highly encouraging.

DISCUSSION AND CONCLUTION

Ayurveda is the World most ancient and complete science of natural medicine which is rich with natural remedies and time-tested therapies for various diseases. Although Ayurveda is rich with time tested remedies but it is often being criticized by scientific fraternity for its ambiguity and paucity of evidences required to bring a strong scientific footing to its belief. On the contrary, hard-core Ayurvedic physicians are often found emphasizing the inadequacy of scientific tools in evaluating the intricate subjective details of human biology as are perceived in Ayurveda.

So, a paradigm shift from traditional knowledge-based paradigm to modern scientific paradigm is needed in Ayurveda. There is a need of revolution of our traditional system of Ayurveda which needs substantial renovation in terms of molecular level studies and clinical studies with implementation of Information Technology for better study and practice of the subject. There is an urgent need of amalgamation of various modern sciences with the Ayurveda for getting outstanding discoveries and remedies.

So, this study are the first step towards this urgent need, bridging the gap between both Ayurveda and Modern science and strengthening both the sciences with the goodness of each other. In Ayurveda, Drug Discovery is based on ancient knowledge or evidence-based methods, but the experiments at protein ligand interaction studies, in-vitro synthesis/extraction of that compounds and test of such

compounds on animal model followed by human clinical trial is yet to be done at fullest[1, 23-24]. So many studies in-collaboration with the other system of science and approaches will pave the foundation of modern Ayurveda research. Many new plants can be identified for the cure of a particular disease and aliments in general. This ancient science is an asset of Indian subcontinent and we need to assist this valuable rich Medical science which needs strong attention and support of experts from modern molecular and information technologies domain, for betterment of mankind.

Clinical Trial Registration of India (CTRI),Ethical Clearance and Drug Testing Laboratory statement

The clinical trials conducted is registered with CTRI, REF/2023/02/063963, trial drug permission has been taken from the Institutional Ethical Committee,Government, Ayurvedic College & Hospital Jaliukbari, Guwahati-14,Reference No. IEC/18/20-173,Dated: 11/06/2018 along with the Certificate of Test/Analysis from the Office of the State Drug Testing Laboratory (AYUSH), Jalukbari, Guwahati-14,Report No: DTL (AY)/PGR/032/19-20. Dated: 18/12/2019.

Acknowledgement

I express my feeling of gratitude and indebtedness to my teacher, guide and renowned academician of Ayurveda Dr. Bishnu Prasad Sarma, Ex-Professor & Head, Department of Kayachikitsa, GAC&H, Jalukbari, Guwahati-14.

I am equally indebted and solicit my deep gratitude to Dr. Rigom Pegu, PhD Scholar, Department of Medicine, GU under the faculty of Medicine & Allied Sciences who is also serving as an independent Ayurvedic Medicine Specialist Consultant at Arogyasala, Jonai, Dhemaji-787060, Assam, India.

I also thank specially to all the staffs of Nagaland Ayurvedic Clinic and Research Center, Dimapur-797112, Nagaland.

REFERENCES

I. Yim M. "Healing Human Lungs Through Ayurveda". LAP LAMBERT Academic Publishing. ISBN: 978-3-659-55313-4. Copyright © 2014. P:37-84.

II. 2.Global Initiative of Asthma. Pocket Guide for Asthma Management. ©2012. P:5. Available at www.ginastham.org.

III. World Health organization. Global surveillance, prevention and control of chronic respiratory disease: a comprehensive approach, 2007

IV. Masoli M, Fabian D, Hoplt S, Beasly R. The global Burden of asthma: executive summary of the GINA Dissemination Committee report. Allergy 2004;59(4):469-78.

V. Burney P, Malmberg E, Chinn S, Jarvis D, Luczynska C, Lal E. The distribution of total and specific serum IgE in the European Community Respiratory Health Survey. J Allergy Clin Immunol 1997; 99:314-22.

VI. Peat JK, Haby M, Spijker J, Berry G, Woolcock AJ, Prevalence of asthma in adults in Busselton, Western Australia. BMJ 1992;305: 1326-9.

VII. Dubosi P, Degrave E, Vandenplas O. Asthma and airway hyper-responsiveness among Belgian conscripts, 1978-91. Thorax 1998; 53: 101-5.

VIII. Peat JK, GrayEJ, Mellis CM, Leeder SR, Woolcock AJ. Differences in airway responsiveness between children and adult living in the same environment: an epidemiological study in two regions of New South Wales. Eur Respir J 1994; 7: 1805-13

IX. Veale AJ, Peat JK, Tovey ER, Salome CM, Thompson JE, Woolcock AJ. Asthma and atopy in four rural Asustralian aboriginal communities, Med J Aust 1996; 165: 192-6.

X. Chinn S, Burney P, Jarvis D, Luczynska C, Variation in bronchial responsiveness in the European Community Respiratory Health Survey (ECRHS). Eur Respir J 1997; 10:2495-2501.

XI. European Community Respiratory Health Survey. Variations in the prevalence of respiratory symptoms, self reported asthma attack, and use of asthma medication in the European Community Respiratory Health Survey (ECRHS). Eur Respir J 1996; 9:687-95.

XII. Devereux G, Ayatollahi T, Ward R, Bromly C, Bourke SJ, Stenton SC, et al. Asthma, airways responsiveness and air pollution in two contrasting districts of north England. Thorax 1996; 51: 169-74.

XIII. Zamel N, McClean PA, Sandell PR, Siminovitch KA, Slutsky AS. Asthma on Tristan da Cunha: Looking for the genetic link. The University of Toronto Genetics of Asthma Research Group. Am J Respir Crit Care Med 1996; 153:1902-6.

XIV. Viswanathan R, Prasad M, Thakur AK, Sinha SP, Prakash N, Mody RK, et al. Epidemiology of asthma in an urban population: a random morbidity survey. J Indian Med Assoc 1966; 46:480-3.

XV. World Health Organization. Global surveillance, prevention and control of chronic respiratory diseases: a comprehensive study approach, 2007.

XVI. Amrendra K, Balaram Ghosh, "Genetics of asthma: a molecular biologist perspective", Clinical and Molecular Allergy 2009, p 1-9.

XVII. D. Behera. Bronchial Asthma ©2000, First Edition: 2000, Published by Jitendar P. Vij, ISBN 81-7179-722-9.

XVIII. Kawakami Y. Genetic background of bronchial asthma. [Internet]. Available at http://www.ncbi.nlm.nih.gov/pubmed/130621.

XIX. Heinzmann A, Dietrich H, Deichmann KA. "Association of uteroglobulin-related protein 1 with bronchial asthma" [Internet]. Available at http://ww.ncbi.nlm.nih.gov/pubmed/ 12915772.

XX. Gupta P, Vijayan VK, Bansal SK. "Changes in protein profile of erythrocyte membrane in bronchial asthma". J Asthma. 2012 Mar;49(2).p129-133.

XXI. Bierbaum S, Heinzmann A. "The genetic of bronchial asthma in children". Respir Med. 2007 Jul;101(7),p1369-1375.

XXII. GraphPad by Dotmatics "t-test calculator". [Internet]. Cited on February 1-28, 2023. Available at. https://www.graphpad.com/quickcalcs/ttest1.cfm.

XXIII. Sarma, Pegu. " Herbs in the management of bronchial asthma and Adhatoda Vasica in Silico". LAP LAMBERT Academic Publishing. Copyright © 2019. ISBN: 978-613-9-99412-0.

XXIV. Yim M et al: Exploring the Possible Mechanism of Albizzia lebbeck Compound Binding with Drug Targets of Bronchial Asthma – an insilico and clinical analysis. Int J Pharma Sci Res 2014, 5(11). 5042-51.doi:10.13040/IJPSR.0975-8232.5(11).5042-51.

XXV. Rigom Pegu et al.2017, Clincal Anlysis of Poly Herbal Compounds In The Management of Tamaka Śwāsa (Bronchial Asthma) – An In Silico Approach of Vasaka (Adhatoda vasica Nees)". Int J Recent Sci Res. 8(12), pp. 22146-22152. DOI: http://dx.doi.org/10.24327/ijrsr.2017.0812.1209