Evaluation and Comparison of *Madanaphala*, *Jeemutaka* and *Ikshwaku Vamana* in *Tamakshwasa* - A Study Protocol

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ABSTRACT

Background: *Tamakshwasa* (bronchial asthma) is a disease of *Pranavaha Srotasa* (Respiratory system) in which *Kapha* and *Vata Doshas* are having supremacy. It is a chronic inflammatory airway disease characterized by dyspnoea, cough, expectoration, wheezing, coryza, dyspnoea, hoarseness of voice. It affects the quality of life and takes economical implication over the patient as well as society. *Vamana* (therapeutic emesis) is an internal purificatory practice which is the best among all the *Panchakarmas* for the elimination of morbid *Kapha Dosha*. It is mainly indicated in *Tamakshwasa* having *Bahudoshavastha*.

Objectives: To study the effect and safety of *Jeemutaka* and *Ikshwaku Vamana* and to compare with *Madanaphala Vamana* in *Tamakshwasa*.

Methods: In the present comparative clinical trial, 90 patients of *Tamakshwasa* will be divided into 3 groups (30 patients in each group). Group A: *Madanaphala Vamana*, will compare with Group B: *Jeemutaka Vamana* and Group C: *Ikshwaku Vamana* in *Tamakshwasa*. Patients with symptoms of *Tamakshwasa* will be assigned randomly into three groups and *Vamana* will be given after 1 day *Snehapana* and on the second day, *Vamana* will be performed after *Bahyasnehana* and *Swedana* at 7 a.m. *Samsarjana Krama* will be given for 3 days and assessment will be recorded on 0th, 5th day.

Expected Results: The Result will be evaluated based on subjective and objective parameters. Conclusion: *Madanaphala*, *Jeemutaka* and *Ikshwaku Vamana* will be effective and safe in *Tamakshwasa* to the improvement of Peak expiratory flow rate (PEFR).

Key Words: *Tamakshwasa*, *Sadyovamana*, Bronchial Asthma, *Vamana* therapeutic emesis

INTRODUCTION

Tamakshwasa (Bronchial Asthma) is a disease in which the process of respiration is disturbed due to the derangement of *Pranavayu*. In *Tamakshwasa* vitiated *Vata* gets *Pratiloma* (reverse) in its course, which reaches to the respiratory tract, induces airway obstruction. Due to excess bronchial secretion interfaces with the flow of air giving rise to *Gurghuraka* (wheezing sound) and breathlessness. *Tamakshwasa* encompasses of two words i.e. *Tamaka* and *Shwasa*. The word '*Tamaka*' means Sadness and the word *Shwasa* means breathing.¹ In Ayurvedic literature symptoms of *Tamaksh-*

wasa are *Gurghurkam* (audible wheezing), *Pinasa* (coryza), *Shirogaurava* (heaviness in the head region), *Kricchat bhashitum* (difficultly in speaking) etc.² All symptoms of *Tamakshwasa* showing *Kapha* predominance. In Ayurveda texts, *Tamakshwasa* is described as *Yappya* (palliable) disease. While describing the management of *Tamakshwasa*, *Shodhana* and *Shamana* treatment is mentioned.³ Bronchial asthma is having all over world prevalence and it influences all age groups. It is troublesome and it influences the quality of life and inflicts financial burden on diseased person and even society also. It is a recurrent demagogic, incidental and it is caustic even sometimes it is fatal too. As per the WHO

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report is a concern, Bronchial asthma can be high mortality rate disease. *Tamakshwasa* is mimic as Bronchial Asthma according to its clinical symptoms like Breathlessness Expectoration cough, wheezing and etiological factors like inhaling dust, fumes etc.⁴ Ayurveda can give promising results in the management of *Tamakshwasa* through various treatment modalities. *Vamana* is such modality by which *Kapha* gets dissolved in the body *Strotas*, and the body *Strotas* becomes softened due to the movement of *Vata* is restored to normal condition. *Vamana Karma* (therapeutic emesis) is the act of elimination of vitiated *Kapha* through the mouth⁵. *Vamana* is considered as the best line of treatment for *Kapha* dominant disorders.⁶ *Vamana* is indicated in many diseases viz. *Kasa*, *Putinasa*, *Shwasa*, *Kushtha*, *Amlapitta*, *Sleepada*, *Apasmara*, *Agnimandya*, *Unmada*, *Visha*, *Granthi*, *Garavisha*, *Arbuda*, *Stanya dosha*, *Medo-roga*, *Atisara*, *Prameha*, *Pandu* etc.⁷ *Bahudosh* and *Adhika-dosha* are the terms commonly used to eliminate the *Kapha* accumulated.⁸ *Madanaphala* (*Randia dumetorum*) is commonly used for *Vamana* procedures as an emetic drug along with it is having many health benefits. As per Ayurvedic classics, it does *Urdhva* and eliminates both *Apakva Kapha* and *Apakva Pitta*. Thus it clears the *Margavarodha* which is produced by vitiated *Kapha Dosha* which can carry out *Urdhvagati* to *Vata* in *Tamakshwasa*.⁹ *Jeemutaka* *Luffa echinata* is an Ayurvedic herb used in the treatment of *Tamakshwasa* along with it has antihelmentic, emetic and purgative, also used in bronchitis, cholera, colic and urinary trouble.¹⁰ *Jimutaka* can be the better option as an emetic drug in *Tamakshwasa* like *Madanaphala*.¹¹ *Ikshwaku* is having anti-allergic property therefore it is used in bronchial asthma. *Ikshwaku* has been recognized as an emetic drug as well as it is used in asthma, diabetes, jaundice, piles colitis and skin disorder from the period of *Charaka samhita*.¹² *Ikshwaku* carries *Samshodaka*, *Bhedaka* and *Kaphanissaraka* property therefore *Ikshwaku Ksheera Yoga* can be used safe emetic drug in *Tamakshwasa*. *Samshodhana*, *Bhedaka*, *Kaphanissaraka*. It reduces the chance of bronchoconstriction and episodes of *Tamakshwasa*.¹³ Hence, this study plans to validate the efficacy of *Jeemutaka* and *Ikshwaku Vamana* and compare with *Madanaphala Vamana*.

The *Vamana*, putative management of *Kapha* and curative aspect of *Tamakshwasa* are commonly practiced in *Vasanta Ritu* is attempted for research but not specified how *Kapha* is intended to develop *Tamakshwasa* and treated with *Vamana* as cost-effective management. Till date, no research studies in comparison identified the effect of *Madanaphala*, *Jeemutaka* and *Ikshvaku* on *Tamakshwas* in comparison.

OBJECTIVE

- 1) To evaluate the effect of *Madanaphala Vamana* in *Samyak Vamana Lakshane* and PEFR

- 2) To evaluate the effect of *Jeemutaka Vamana* in *Samyak vamana lakshane* and PEFR
- 3) To evaluate the effect of *Ikshvaku Vamana* in *Samyak vamana lakshane* and PEFR
- 4) To compare the effect of *Madanaphala*, *Jeemutaka*, and *Ikshvaku Vamana* in *Samyak Vamana lakshane* and PEFR.

Case definition: Diagnosed cases of *Tamakshwasa*

Research Question: Which *Vamana dravya* among *Madanaphala*, *Jeemutaka* and *Ikshvaku* is effective in *Tamakshwasa* for giving quick relief and improvement in PEFR?

Hypothesis: *Vamana* with either of *Madanaphala*, *Jeemutaka*, and *Ikshvaku* is affecting *Tamakshwasa*.

Null Hypothesis: *Vamana* with either of *Madanaphala*, *Jeemutaka*, and *Ikshvaku* do not have any effect on *Tamakshwasa*.

MATERIALS AND METHODS

Trial design: Randomized comparative clinical open-label study on three parallel groups having ratio 1:1:1

Study setting: The study will be conducted at Mahatma Gandhi Ayurved College, Hospital and Research Center, Salod (H), Wardha Maharashtra, India.

Registration Number: CTRI/2020/06/025967. [Registered on 18/06/2020]

Eligibility criteria

Inclusion criteria: Patients of Age between 20 to 50 years of either sex want to take treatment and willing to give written informed consent will be enrolled for the study. Patients are having symptoms and signs of *Tamakshwasa* will be included. Inclusion of patient in this study is optional and the recruitment of the patient will be based on inclusion and exclusion criteria. Eligible patients will be randomly registered for the *Madanaphala Vamana*, *Jeemutak Vamana* and *Ikshwaku Vamana* groups. The inclusion criteria include 1) Patients presenting with *Tamakshwasa* (Bronchial asthma) [ICD10 – J45.9]. 2) Asthmatic bronchitis NOS. 3) Late-onset asthma. Patients with symptoms of *Tamakshwasa* and low PEFR will randomly be allocated into three groups of the research study.

Exclusion criteria:

1) Patient Ages below 20 and above 50 years. 2) Patients suffering from any complications or chronic illness. 3) Pregnant and lactating women.

Interventions

Madanaphala Vamana:

Purvakarma: Patient will be given 48ml of *Murchit Ghruta* in the morning between 6.00 am to 7.00 am on the first day.

After digestion of *Sneha*, the patient is subjected to *Sarvang Snehana Swedana*. The patient is asked to have *Kaphotkleshaka Aahar* (Dahi,udidwada, Basundi, fish, etc) as a dinner.

Pradhana karma: On the second day, *Sarvang Snehana Swedana* will be performed and after *Samyak Snehana Swedana* patient will be asked to drink milk for full stomach (*Aakanthapana*). Then *Vamak Yoga* will be given to drink after 10 minutes in the combination i.e. *Madanphala Churna* 3.5 gms + *Saindhava* 1.75 gms + *Madhu* 15 ml. As the patient starts developing nausea, he is asked to slightly bend forward and vomit into *Vamana Patra*. *Vegiki*, *Maniki*, *Antiki* and *Laingiki* criteria will be assessed as *Pravara* (highest), *Madhyama* (moderate) and *Hina* (lowest) *Shuddhi* (cleansing) and the patient is asked rest for while.

Paschat Karma: Patient is asked for *Gandusha* with hot water and *Dhoompana* by *Dhoomvarti*. *Samsarjana Krama* will be advised for 3 days. Based on *Samyak Vamana* and clinical improvements in the signs and symptoms of *Tamakshwasa* patient will be taken for trial PEFR (Peak expiratory flow rate) to know the efficacy of *Vamana*.

Jeemutaka Vamana:

Purvakarm: Patient will be given 48ml of *Murchit Ghruta* in the morning between 6.00 am to 7.00 am on the first day. After digestion of *Sneha*, the patient is subjected to *Sarvang Snehana Swedana*. The patient is asked to have *Kaphotkleshaka Aahar* (Dahi,udidwada, Basundi, fish, etc) as a dinner.

Pradhana karma: On the second day, *Sarvang Snehana Swedana* will be performed and after *Samyak Snehana Swedana* patient will be asked to drink milk for full stomach (*Aakanthapana*). Then *Vamak Yoga* will be given to drink after 10 minutes in the combination i.e. *Jeemutaka Churna* 3.5 gms + *Saindhava* 1.75 gms + *Madhu* 15 ml. As the patient starts developing nausea, he is asked to slightly bend forward and vomit into *Vamana Patra*. *Vegiki*, *Maniki*, *Antiki* and *Laingiki* criteria will be assessed as *Pravara* (highest), *Madhyama* (moderate) and *Hina* (lowest) *Shuddhi* (cleansing) and the patient is asked rest for while.

Paschat Karma: Patient is asked for *Gandusha* with hot water and *Dhoompana* by *Dhoomvarti*. *Samsarjana Krama* will be advised for 3 days. Based on *Samyak Vamana* and clinical improvements in the signs and symptoms of *Tamakshwasa* patient will be taken for trial PEFR (Peak expiratory flow rate) to know the efficacy of *Vamana*.

Ikshwaku Vamana:

Purvakarm: Patient will be given 48ml of *Murchit Ghruta* in the morning between 6.00 am to 7.00 am on the first day. After digestion of *Sneha*, the patient is subjected to *Sarvang Snehana Swedana*. The patient is asked to have *Kaphotkleshaka Aahar* (Dahi,udidwada, Basundi, fish, etc) as a dinner.

Pradhana karma: On the second day, *Sarvang Snehana Swedana* will be performed and after *Samyak Snehana Swedana* patient will be asked to drink milk for full stomach (*Aakanthapana*). Then *Vamak Yoga* will be given to drink after 10 minutes in the combination i.e. *Ikshwaku Churna* 3.5 gms + *Saindhava* 1.75 gms + *Madhu* 15 ml. As the patient starts developing nausea, he is asked to slightly bend forward and vomit into *Vamana Patra*. *Vegiki*, *Maniki*, *Antiki* and *Laingiki* criteria will be assessed as *Pravara* (highest), *Madhyama* (moderate) and *Hina* (lowest) *Shuddhi* (cleansing) and the patient is asked rest for while.

Paschal Karma: Patient is asked for *Gandusha* with hot water and *Dhoompana* by *Dhoomvarti*. *Samsarjana Krama* will be advised for 3 days. Based on *Samyak Vamana* and clinical improvements in the signs and symptoms of *Tamakshwasa* patient will be taken for trial PEFR (Peak expiratory flow rate) to know the efficacy of *Vamana*.

Interventions – In three group sample size will be the same, follow up will be same. (Table 1)

Table 1: Intervention table

	Group A	Group B	Group C
Sample size	30	30	30
Intervention	<i>Madanaphala Vamana</i>	<i>Jeemutaka Vamana</i>	<i>Ikshvaku Vamana</i>
Preparation (Purvakarma) <i>Sadyasnehapana</i> (48ml <i>Murchit-aghrita</i>)	1 day	1 day	1 day
Main treatment (Pradhanakarma) <i>Bahya Abhyanga & Swedana</i> (Local) <i>Vamana Karma</i>	1 day	1 day	1 day
Follow up (Paschal karma) period <i>Samsarjana Krama</i>	3 days	3 days	3 days
Total duration	5 days	5 days	5 days

Criteria for discontinuation or modification of allocated intervention: Patient can be withdrawn from the study with their request at any time; if any unwanted evidence like features by treatment or any other serious problem arises.

EXPECTED OUTCOME

Primary outcome: To observe the *Samyak Vamana Lakshne* and to assess the relative effectiveness of *Madanaphala*, *Jeemutaka* and *Ikshwaku Vamana*.

Secondary outcomes: Improvement in Peak expiratory flow rate will be the secondary outcome.

Safety assessment: In Screening parameter, Hb%, TLC, DLC, E.C.G. and X-ray chest PA view will be done. PEFR, ESR, and Absolute Eosinophil count will be done before and after treatment, for the safety of patient those who are participating in the study. The patient is instructed if there is any adverse reaction it should be informed to the investigators by visit or phone or immediately come to the hospital. If the patient occurs any unwanted and serious adverse events it will be assessed thoroughly and will be reported to the nearest speciality hospital for further management. If there is such an adverse reaction participant will be vomited from the research trial.

Sample size: Considering 10% dropout a minimum number of 30 participants in each group total of 100 patients will be enrolled.

Sample size Estimation: Sample size is calculated in the study is Total 90 patients with a minimum of 30 patients in each group i.e. Group A: 30 patients, Group B: 30 Patients and Group C: 30 patients with irrespective of age, gender, caste and economical status.

Allocation and Recruitment of the subjects: Each patient will be identified by the unique sequential allocation number which will be with ascending order, starting with the smallest number. Patients who will discontinue that number will not be re-assigned. Allocated patients will be randomized into three groups as per the computer-generated randomization list after fulfilment of inclusion and exclusion criteria. A single-subject cannot be assigned more than one randomization number.

Procedure:

Patients are having signs and symptoms of *Tamakshwasa* which are attending to OPD will be screened out and written informed consent will be taken, history of past illness and medications will be taken and physical and systemic examinations will be done. The patient will be enrolled in the study according to the inclusion & exclusion criteria will be randomized for the study. After recruitment in the study, *Vamana* will be given to the patient after 1 day *Snehapana* and on the second day *Bahyasnehana*, *Swedana*. *Vamana* will be performed at 7 a.m. then 3 days *Samsarjana Krama* will be given to the patient. Assessment will be recorded on 0 and 5th day.

Statistical analysis

A confidence interval of 95% will remain for evaluation for all study parameters get going from baseline to follow up visits. Unpaired T-test, paired T-test and ANOVA with posthoc T-tests will be used for obtaining the statistical significance. Categorical variables will be compared between groups using the unpaired T-test; paired T-test and ANOVA with posthoc T-tests will be used for obtaining the statistical significance.

Data Collection Methods

Assessment subjective Parameters: Dyspnoea, cough, expectoration, wheezing, coryza, dysphonia, hoarseness of voice, headache & stiffness, chest Pain, discomfort at supine.

Assessment Objective Parameters: 1. Peak expiratory flow rate. 2. Erythrocytes sedimentation rate. 3. Absolute Eosinophilic count.

Data management: The data management will be done by Principal investigator.

Time Schedule of Enrolment, intervention:

Ethics and Dissemination: research ethics approval: Institutional ethical approval has prevailed for the research trial. No- Ref. DMIMS (DU)/IEC JUNE 2019/8158, Dated 15/07/2019.

Written inform Consent process: After screening patient, a written informed consent form printed in the language which is best understood by the patient will be taken voluntarily from the patient. During the informed consent process, patients will be explained the objectives, study design and possible risk and benefits of the study. Patients will be given enough time to fully understand the study and other related documents will be provided. If the patient is illiterate, an impartial witness will read the ICF, printed in the language best understood by the patient. After hearing ICF, if the patient is agreeing to participate in the study, his/her thumb impression will be taken on the ICF and also the signature (with date) of impartial witness will be obtained on the same ICF. Confidentiality of each subject will be maintained during the research trial.

Dissemination policy: The final results of the scientific report will be disseminated in various conferences and will be published in peer-reviewed journals.

DISCUSSION

Tamakshwasa is a chronic inflammatory airway disease which can affect the quality of life and it takes economical implication over patient society. According to previous researches, *Vamana* is effective for treating *Tamakshwasa*. Due to the availability of choice of treatment and effectiveness of *Vamana* treatment some patients prefer *Vamana* treatment for *Tamakshwasa*. Till date, no research studies in comparison identified the effect of *Madanaphala*, *Jeemutaka* and *Ikshwaku* on *Tamakshwasa* in comparison. The *Vamana*, putative management of *Kapha* and curative aspect of *Tamakshwasa* is commonly practised in *Vasanta Ritu* is attempted for research but not specified how *Kapha* is intended to develop *Tamakshwasa* and treated with *Vamana* as cost-effective management. Hence in this study, an attempt is made to give *Vamana* by *Madanaphala Jeemutaka* and *Ikshwaku* for *Tamakshwasa*. This clinical trial is also

expected to develop the capacity scientifically and evaluate *Vamana* in patients with *Tamakshwasa*. It will be able to validate scientific data on the effect of *Madanaphala Jeemutaka* and *Ikshwaku Vamana* in *Tamakshwasa*. This trial is expected to develop and validate Ayurvedic Principles with Modern Proof and Scientific proof of *Vamana* as well as claimed to have efficacy in the treatment of *Tamakshwasa*.

Strengths: If the present research study found positive results then it will give the parallel modality of treatment for the management of *Tamakshwasa*.

Limitations: *Vamana* is specified for *Vasanta Ritu* only, which is mentioned for prevention. The data or researches are carried on this topic even though available not specific for the influence of *Kapha* on it. The qualitative and quantitative evaluation of *Vamana* effect in *Tamakshwasa* either in *Vasanta* or in any other *Ritu* is still unexplored.

CONCLUSION

Conclusion will be drawing after analyzing the complete data.

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