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

Sahebrao K. Kadam¹, Shweta Parwe², Manoj Patil³, Milind Nisargandha⁴, Amoli Belsare⁵

Background: Tamakashwasa (bronchial asthma) is a disease of Pranavaha Srotas (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 Tamakashwasa having Bahudoshavastha.

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

Methods: In the present comparative clinical trial, 90 patients of Tamakashwasa 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 Tamakashwasa. Patients with symptoms of Tamakashwasa 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 Bahynesnehana 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 Tamakashwasa to the improvement of Peak expiratory flow rate (PEFR).

Key Words: Tamakashwasa, Sadyovamana, Bronchial Asthma, Vamana therapeutic emesis

INTRODUCTION

Tamakashwasa (Bronchial Asthma) is a disease in which the process of respiration is disturbed due to the derangement of Pranavayu. In Tamakashwasa vitiates 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. Tamakashwasa 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 Tamakashwasa are Gurghurkam (audible wheezing), Pinasa (coryza), Shirogaurava (heaviness in the head region), Kricchat bhashitum (diffi-culty in speaking) etc.² All symptoms of Tamakashwasa showing Kapha predominance. In Ayurveda texts, Tamakashwasa is described as Yappya (palliable) disease. While describing the management of Tamakashwasa, 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

Corresponding Author:
Shweta Parwe, Professor and HOD, Department of Panchakarma, Mahatma Gandhi Ayurveda College, Hospital and Research Centre, Salod (H), Wardha. Datta Meghe Institute of Medical Sciences. Nagpur, India; Mob: 9403142270; Email: drshwetaparve@gmail.com

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report is a concern, Bronchial asthma can be high mortality rate disease. Tamakshwasa is mimetic as Bronchial Asthma according to its clinical symptoms like Breathlessness Expectoration cough, wheezing and etiological factors like inhaling dust, fumes etc. 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 mouth. Vamana is considered as the best line of treatment for Kapha dominant disorders. Vamana is indicated in many diseases viz. Kasa, Putinasa, Shwas, Kushtha, Amlapitta, Sleepada, Apasmara, Agminandya, Ummada, Visha, Granthi, Garavisha, Arbuda, Stanya dosha, Medo-roga, Atisara, Prameha, Pandu etc. Bahudosha and Adhika-dosha are the terms commonly used to eliminate the Kapha accumulated. 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 Urdhvaabhaga Shodhana and eliminates both Apakva Kapha and Apakva Pitta. Thus it clears the Margavarodha which is produced by vitiated Kapha Dosha which can carry out Urdhwagati to Vata in Tamakashwasa. Jeemutaka Luffa echinata is an Ayurvedic herb used in the treatment of Tamakashwasa along with it has antihelmentic, emetic and purgative, also used in bronchitis, cholera, colic and urinary trouble. Jimutaka can be the better option as an emetic drug in Tamakshwasa like Madanaphala. 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. 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. 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 Ikshwaku on Tamakshwasa 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 Ikshwaku Vamana in Samyak Vamana lakshane and PEFR
4) To compare the effect of Madanaphala, Jeemutaka, and Ikshwaku Vamana in Samyak Vamana lakshane and PEFR.

**Case definition:** Diagnosed cases of Tamakshwasa

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

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

**Null Hypothesis:** Vamana with either of Madanaphala, Jeemutaka, and Ikshwaku 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 Sarvanga Sneha Swedana. The patient is asked to have Kapohkle-shaka Aahar (Dahi, udidwada, Basundi, fish, etc) as a dinner.

**Pradhana karma:** On the second day, Sarvanga Sneha Swedana will be performed and after Samyak Sneha Swedana patient will be asked to drink milk for full stomach (Aakanthapana). Then Yamak Yoga will be given to drink after 10 minutes in the combination i.e. Madanaphala 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 Yamana 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.

### 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 Sarvanga Sneha Swedana. The patient is asked to have Kapohkleshaka Aahar (Dahi, udidwada, Basundi, fish, etc) as a dinner.

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### 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 Sarvanga Sneha Swedana. The patient is asked to have Kapohkleshaka Aahar (Dahi, udidwada, Basundi, fish, etc) as a dinner.

**Pradhana karma:** On the second day, Sarvanga Sneha Swedana will be performed and after Samyak Sneha Swedana patient will be asked to drink milk for full stomach (Aakanthapana). Then Yamak 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 Yamana 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

<table>
<thead>
<tr>
<th></th>
<th>Group A</th>
<th>Group B</th>
<th>Group C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample size</td>
<td>30</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>Intervention</td>
<td>Madanaphala Vamana</td>
<td>Jeemutaka Vamana</td>
<td>Ikshwaku Vamana</td>
</tr>
<tr>
<td>Preparation (Purvakaarma)</td>
<td>Sadyasnehapana (48ml Murchit-aghrita)</td>
<td>1 day</td>
<td>1 day</td>
</tr>
<tr>
<td>Main treatment (Pradhana karma)</td>
<td>Bahya Abhyanga &amp; Swedana (Local) Vamana Karma</td>
<td>1 day</td>
<td>1 day</td>
</tr>
<tr>
<td>Follow up (Paschal karma) period Samsarjana Krama</td>
<td>3 days</td>
<td>3 days</td>
<td>3 days</td>
</tr>
<tr>
<td>Total duration</td>
<td>5 days</td>
<td>5 days</td>
<td>5 days</td>
</tr>
</tbody>
</table>

### 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 fulfillment 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, corzya, dysphonomia, 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 Tamakshwas in comparison. The Vamana, putative management of Kapha and curative aspect of Tamakshwasa is commonly practised in Vasant Ritu is attempted for research but not specified how Kapha is intended to develop Tamakashwasa 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 Tamakashwasa either in Vasanta or in any other Ritu is still unexplored.

**CONCLUSION**

Conclusion will be drowning after analyzing the complete data.

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**Conflict of Interest:** Nil

**Source of Funding:** Nil

**REFERENCES**

4. The global strategy for diagnosis and management and prevention of COPD (update 2020), the pocket guide (updated 2020) and the complete list of references examined by the committee is available on the gold website: www.goldcopd.org.