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AMRITA SCHOOL OF AYURVEDA  
AMRITA VISWAVIDYAPEETHAM  
(University under sec.3 UGC Act 1956)

PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION  
FOR AYURVEDA VACHASPATI (M.D) KAYACHIKITSA

OPEN LABEL SINGLE ARM CLINICAL STUDY TO ASSESS THE EFFICACY OF RAJANNYADI CHOORNA & VYAGHRADI KASHAYA IN TAMAKA SWASA (BRONCHIAL ASTHMA)

BY

CHILKY RAGHAVAN  
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AMRITA SCHOOL OF AYURVEDA,  
VALLIKAVU, CLAPPANA P.O. KOLLAM

GUIDE

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PROFFESSOR & HEAD OF THE DEPARTMENT  
DEPARTMENT OF KAYACHIKITSA  
AMRITA SCHOOL OF AYURVEDA  
SESSION 2013-14
1. BRIEF RESUME OF THE INTENDED WORK:

1. NEED FOR THE STUDY:

Tamaka swasa is a disease which have been elaborately mentioned by Acharyas in Ayurveda classics. "swasa krichrata (difficulty in breathing) peenasa (coryza), kasa (cough), kapha nishteeva (expectoration), ghurghuratvam (wheezing), krichra bhashana (difficulty in speaking), assene labdhe sukham (feel comfort in sitting), lalata sweda (perspiration on forehead), sleshmakala vardhana (attacks in morning & evening) are the symptoms seen. Disease characterized by obstruction of prana vata by kapha leading to further vitiation of vata resulting in upward movement or vimarga gamana of vata resulting in difficulty in breathing and associated symptoms.

This disease have similarity in clinical presentation with Bronchial Asthma characterized by intermittent airflow obstruction, airway inflammation and bronchial hyper responsiveness and the disease manifests with difficulty in breathing, cough, wheezing tightness of chest. Irrespective of age & gender it affects all categories of people and is seem to cause serious impairment in the quality of life of the patients.

The World Health organization estimated in 1998 that Asthma affect 155 million people world wide, based on the data collected in epidemiological studies in more than 80 countries. Asthma rates has sharply increased significantly in recent decade which is increasing 50% every decade world wide. Deaths from this condition have reached over 180,000 annually. It is estimated that the disease affects 5 to 10% of population.

Human & economic burden associated with this condition is severe. Symptoms interfere with sleep, work activities & psychological disturbances like anxiety, mood disorders e.t.c. Studies show that early & prolonged use of corticosteroids reduce lung function & may increase the frequency of attacks, may lead to other complications. High cost of the medicines make its availability difficult to poor classes of people.

In the context of explaining treatment modalities in Tamaka swasa, Acharya after mentioning sodhana & samana therapies, finally emphasizes more
on the importance of samana & brimhana therapies in swasa. When sodhana (purgation & emesis) and samana therapies are taken, sodhana even if considered superior to samana can be done only when dosa vitiation is more, need hospitalization and can be done only in persons of good body strength. Samana can be done in all age groups and even in patients of moderate and less body strength, can be done in OPD basis also. Here arises the need of an effective Polyherbal combination which can alleviate kapha and vata doshas, having agni deepana, srotho sodhana, anulomana properties and which can actively interfere in the disease pathology, which can be accessible to all sections of people.

2/3,4 Vyaghradi kashaya have vata –kapha samana property, Rajanyadi choorna have vata anulomana and agni deepana property. Evaluation of pharmacological properties of ingredients of the combination reveals that Rajani, Daru, Sarala, Prisniparni, Satahva have anti-inflammatory property. Kantakari and Sarala have antiseptic property. Satahva have anti-spasmodic property. Prisniparni and Kantakari are expectorants. Haridra and Pippali have immuno-modulatory action. Because of all these properties the selected combination is supposed to be effective in disrupting the etio-pathogenesis of Tamaka Swasa.

Therefore we decided to make a humble attempt to evaluate the efficacy of the compound in Tamaka swasa, so that if found effective serve useful to the society.

II. REVIEW OF LITERATURE:

1. Charaka samhita chikitsa sthana 3/1,2 both pratamaka and santamaka swasa are mentioned. Even if acharya mentions sodhana, brmhana (nourishing) or samana (alleviating) is considered more relevant in swasa.
2. Susrutha samhitha uttaratantra 4 only pratamaka type has been mentioned. Sodhana for strong patients and samana therapies have been mentioned.
3. Astanga Hridaya Nidanasthana & Chikitsa sthana 2/1,2 Pratamaka & santhamaka swasa are mentioned with their treatment modalities.
4. Madhavanidana 11 mentions tamaka swasa as which persists through the patient’s life even after suitable treatments.
5. Bhavaprakasha\textsuperscript{13} mentioned only pratamaka type of tamaka swasa, abhyanga, sweda and samana treatments are mentioned.

6. Yogaratnakara\textsuperscript{12} mentions tamakaswasa as caused by kapha dosa only, various samana and sodhana therapies had been mentioned.

7. Sharangdhara Samhita Madhyama Khanda \textsuperscript{9,10} mentions about swasa, in madhyama khanda various preparations which can be used in swasa are mentioned, but specific mentioning tamaka swasa is not found.

8. Kumar & Clark’s Text book of Medicine\textsuperscript{7} explained Bronchial Asthma as a common inflammatory condition of the Lung airways represented with symptoms cough, wheeze, chest tightness and shortness of breath often at night.

9. Fishmann’s Text book of Chest Diseases\textsuperscript{15} explains Bronchial Asthma as intermittent airflow obstruction, airway inflammation and airway hyper – responsiveness.

The Review of previous works on Tamakaswasa

1. A Clinical evaluation of Kanakasava & Swasanandam guliaka in Tamaka Swasa w.s.r. to Bronchial Asthma, by Dr. Rashin Chandrasekharan – 2012-13, Munial Institute of Ayurvedic Medical Science, Manipal, Uduppi, Karnataka.\textsuperscript{5}

2. A study of tamaka swasa w.s.r. to kasamarda. Swapna. K.S. - 1999- Government Ayurvedic College Kerala University Thiruvananthapuram.\textsuperscript{4}

3. A clinical study of management of tamaka swasa w.s.r. to virechana & samana. Sujatha. Tenginakai. - 2001- A.L.N. Rao Ayurvedic Medical College-Koppa.\textsuperscript{5}

4. Randomized controlled trial to assess the efficacy of Aya-Patra Pralipta Pippali Rasayana in Bronchial Asthma, Dr. Seeba -2003, Government Ayurveda College Trivandrum, Kerala.\textsuperscript{4}

5. Management of Tamaka swasa with Vyaghri Choorna w.s.r to Bronchial Asthma, Mahanteshwarayya 2007, A.L.N. Rao Memorial Ayurvedic Medical College and PG Centre, Koppa, Karnataka.\textsuperscript{5}

6. Clinical efficacy of the herbal Padmapathradi yoga in Bronchial asthma (Tamaka swasa) by Panda A.K.-2011 P.G. Department of Kaya Chikitsa, D.G.M Ayurveda Medical College, Gadag, Karnataka\textsuperscript{11}
Review of previous works reveals the efforts done to find a better remedy in the management of Tamaka swasa. It is found that so many works had been conducted in Tamaka swasa. In the search of a better remedy the polyherbal combination of Rajannyadi Choorna and Vyaghradi Kashaya has been selected based on the pharmacological properties of the ingredients to evaluate the combined effect.

III. AIM AND OBJECTIVE OF THE STUDY:

To clinically evaluate the efficacy of Rajannyadi Choorna & Vyaghradi Kashaya in mild to moderate condition of Tamaka swasa.

2. MATERIALS AND METHODS
1. **SOURCE OF DATA:**

30 Patients will be selected from O.P.D. and I.P.D. of Amrita Ayurvedic Hospital having classical signs & symptoms of Tamaka Swasa from mild to moderate will be selected. Detailed history taking will be done using a pre-designed case proforma.

---

**MATERIALS REQUIRED FOR THE STUDY**

**i. METHOD OF COLLECTION OF DATA:**

1) **SAMPLE:**
Consisting of 30 patients diagnosed as Tamaka swasa from OPD & IPD of Amrita Ayurveda Hospital, Vallikkavu.

2) **INCLUSION CRITERIA:**
1. Patients having classical signs and symptoms of Tamakaswasa & Bronchial Asthma of mild to moderate nature.
2. Age group between 18 to 60 years.
3. Patients having 75% of the history of following signs & symptoms:
   1. Swasa krichrata (Breathing difficulty)
   2. Ghurghuratvam (Wheezing)
   3. Kasa (Cough)
   4. Urah peeda (Chest tightedness)
   5. Inspiration and prolonged expiration with added sounds
   6. Use of broncho dilators

3) **EXCLUSION CRITERIA:**
1. Tamakaswasa associated with other systemic diseases.
2. Age group below 16 years & above 60 years.
3. Severe bronchial asthma cases, Pulmonary Tuberculosis
4. Lung carcinoma & Pneumonia.
5. Pregnant Women & lactating mothers.
6. Patients with Other Lung pathologies.

ii. PROCEDURE AND DESIGN OF THE STUDY:

MATERIALS AND METHODS:

Ingredients:

<table>
<thead>
<tr>
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<th>Vyaghradi Kashaya</th>
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<tbody>
<tr>
<td>Rajani</td>
<td>Vyaghri</td>
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<tr>
<td>Daru</td>
<td>Sunti</td>
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<tr>
<td>Sarala</td>
<td>Amrita</td>
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<td>Sreyasi</td>
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<td>Brihathi</td>
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<td>Kantakari</td>
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<td>Prisniparni</td>
<td>Pippali</td>
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<tr>
<td>Satahva</td>
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</table>

Preparation of Medicine

Drugs will be identified and collected as per classical reference in the Pharmacy of Amrita School of Ayurveda.

Rajannyadi Curna:

Ingredients of Rajannyadi Churna mentioned in the above table will be taken in equal quantity and grounded in to fine powder.

Vyaghradi Kashaya:

Ingredients of Kashaya currua as mentioned in the table will be taken in equal quantity will be mixed with 8 times of water $\frac{2}{5}$ boiled and reduced to $\frac{1}{4}$th. Pippali will be added as prakhepa currua.

2. Design Of The Study:

It will be a single group clinical study with pre-test and post-test design.
30 patients will be selected based on inclusion & exclusion criteria from OPD & IPD of Amrita Ayurveda Hospital. Pre-test according to subjective & objective parameters are done.

Rajannyadi Choorna 4gm will be advised to take thrice daily just before food (morning & lunch) along with kashaya. Kashaya 32 ml are advised to take three times daily (6am, 11am & 6pm). Patients are advised to take consultation once in a week for 30 days and to take follow up thereafter.

3. Assessment Criteria:
   a) Subjective Parameters:
      Grading as mild, moderate & severe was done considering cardinal symptoms of tamaka swasa like
      1. Swasa krichrata (difficulty in breathing)
      2. Ghrurghura dwani (wheezing)
      3. Kasa (cough)
      4. Kapha nishteevana (expectoration of sputum)
      5. Urah Peeda (Chest Tightedness)
   b) Objective Parameters:
      1. Peak Expiratory Flow Rate (PEFR)
      2. Breath Holding Time (BHT)
      3. Absolute eosinophil count (AEC)

4. Investigations:
   1. Total Blood Count (TC)
   2. Erythrocyte Sedimentation Rate (ESR)
   3. Hb%

   Peak Expiratory Flow Rate (PEFR), Breath holding time (BTH), Absolute Eosinophil Count will be measured at the beginning and at the end of the treatment.

A standard multi dimensional scoring will be adopted for assessment.

5. Statistical Methods:
Patients selected will be assessed subjectively & objectively before & after treatment and follow up will be recorded and analysed by using appropriate statistical methods and final conclusion will be drawn.

**Intervention:**

1. The patients will be assessed before & after the treatment as per assessment criteria.
2. The nature of the study will be explained to the patients in detail and pre treatment consent will be taken.
3. The confidentiality of the data will be maintained.

2. **LIST OF REFERENCES:**

   1) Nidana Sthana Chapter 4 Sloka No:6
   2) Chikitsa Sthana Chapter 4 Sloka No:2-6
   3) Chikitsa Sthana Chapter 1 Sloka No:61
   4) Uttara Stana Chapter 2 Sloka No: 38-40
   5) Kalpa- Siddhi Stana Chapter 6 Sloka 13
   1) Chikitsa Sthana Chapter 17 Sloka No:15
   2) Chikitsa Sthana Chapter 17 Sloka No: (147-150)
   Uttara Sthana Chapter 51 Page No:762,Sloka No:9-10
6. [www.rguhs.ac.in/curriculum/](http://www.rguhs.ac.in/curriculum/).
8. www.wikipepedia.org
9. Sarangadhara Samhitha Madhyama Khanda 2nd Chapter
10. Sarangadhara Samhitha Madhyama Khanda 6th Chapter
11. Madhava Nidana with Madhukosa commentary 12th Chapter page no: 51
   sloka number (27-34), published by Chowkambha Sanskrit Series.
12. Yoga Ratnakara with Vidyothini Hindi Commentary by Vaidya Sri Lakshmipathi
    Sastri, Published by Chaukhambha Sanskrit Bhavan, 2005 Edition Sloka: 2-4
13. Bhavaprakasa of Bhavamisra with Vidyothini Hindi Commentary, Published
    Adhikara Chapter 14 Sloka No: 14-21, Page No: 162
15. Fishman’s Pulmonary Diseases & Disorders, 4th edition 45th Chapter Page 773
16. Pubmed.gov.in
17. http://www.global burden asthma.com
PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION FOR
AYURVEDA VACHASPATI [M.D] IN KAYACHIKITSA

“Title”

OPEN LABEL CLINICAL STUDY TO EVALUATE THE COMPARITIVE
EFFECTIVENESS OF VAJIGANDHADI TAILA PANA AND MATRAVASTI IN
GRIDHRASI(SCIATICA)

BY
GOPIKRISHNA.A.S
1ST YEAR P.G SCHOLAR
DEPARTMENT OF P.G STUDIES IN KAYACHIKITSA
AMRITA SCHOOL OF AYURVEDA, VALLIKAVU, CLAPPANA P.O. KOLLAM

GUIDE
Dr.JAMES CHACKO
ASSOCIATE PROFESSOR
DEPT OF KAYACHIKITSA

CO-GUIDE
Dr.KRISHNAKUMAR.K
ASSOCIATE PROFESSOR
DEPT OF KAYACHIKITSA

SESSION – 2013 – 14
From  
Dr.GOPIKRISHNA.A.S.  
I Year M.D. (Ay) Scholar  
Department of Post Graduate Studies in Kayachikitsa  
Amrita School of Ayurveda, Vallikkavu, Clappana P.O, Kollam, Kerala.

To  
The Registrar  
Amrita Viswa Vidyapeetham, Ettimadai, Coimbatore, Tamilnadu

Through - The Principal and Head of Department of P.G. studies in Kayachikitsa, Amrita School of Ayurveda, Vallikkavu, Clappana P.O, Kollam, Kerala

Subject: Submission of Completed Proforma for Registration of Synopsis of Dissertation.

Respected Sir,

I request you to kindly register the below mentioned subject against my name for submission of the dissertation to the Amrita Viswa Vidyapeetham, Coimbatore, Tamilnadu, as partial fulfillment of M.D (Ay) in Kayachikitsa.

THE TITLE OF DISSERTATION

“OPEN LABEL CLINICAL STUDY TO EVALUATE THE COMPARITIVE EFFECTIVENESS OF VAJIGANDHADI TAILA PANA AND MATRAVASTI IN GRIDHRASI(SCIATICA)”

I am enclosing completed proforma for registration of subject of dissertation.

Thanking You.

Yours faithfully,

(Dr.GOPIKRISHNA.A.S.)

Date: Place: Vallikkavu
1. BRIEF RESUME OF THE INTENDED WORK.

I. NEED FOR STUDY

*Gridrasi* is one among the 80 types of *Nanathamaja Vata Vyadis*\(^1\). This is a clinical condition characterised by severe pain starting from the low back region and radiating down towards the foot. This is a common entity encountered in a clinical practice. *Stambha, Ruk, Toda* and *Spandana* starting from spik (waist) and extend through kati (low back) prishta (buttocks) uru (thigh) janu (knee) jangha (calf) padam (foot) in an order\(^2\).

Sciatica is a condition where there is distribution of pain along the course of sciatic nerve, i.e., which the pain radiates from the low back to buttock and leg\(^3\). This is commonly accepted as being caused by lumbar disc prolapses. Sciatica of contemporary Medical science is closely equivalent to *Gridrasi* by its similarity in the course of pain from low back radiating down through the posterior part of leg.

The chance of *gridrasi* is expected to increase in the upcoming years due to sedentary life style, the increased use of computerization and also due to increasing body weight, mental stress, hectic work schedules and transportation methods. All these adds on to the improper posture which is one of the highlighted cause for spine and nerve compression disorders in the present scenario.

Low back pain is the 2\(^{nd}\) most common reason for all physician visits\(^4\) and it is a condition that affects as many as 80-90\% of people during their life time, among them true sciatica cases occurs in about 5\% of cases. On considering sciatica as an independent disease it is a relatively common condition with lifetime incidences varying from 1.6\%-43\%. Sciatica is more common among the age group between 30-50 years of age.

It is a fact that despite recent progress of modern neurology, it is unable to provide an effective cure for Sciatica, except for giving temporary relief through analgesics or surgical interventions. Continuous use of NSAIDs and steroids for relieving pain may in later course lead to secondary complications like Kidney failures, Liver disorders and Gastritis.

Keeping these facts in mind this study has been undertaken to bring out a treatment modality with no side effects and long lasting relief.

In this study the role of *Vajigandadi taila*\(^6\) which is a simple and potent yoga described in *Yogaratnakara, Vatavyadhi adikaranam* with specified indication only on
Gridrasi will be researched by administering to two groups of patients as internal administration(snehapana) and Matra Basthi.\(^7\)

**II. REVIEW OF LITERATURE**

Gridrasi mentioned under vatavyadhi is again subdivided into into Vatika and Vata-kaphaja gridrasi. In Vatika gridrasi Shoola(pain) Sthamba(stiffness) and Thodam(pricking pain) are prominent symptoms while in vata-kaphaja gridrasi there will be more of tanda(stuper) gauravam(heaviness) and arochakam(anorexia). Pain starts from spik(waist) and extend through kati(low back) prishta(buttocks) uru(thigh) janu(knee) jangha(calf) padam(foot) in an order\(^2\).

The yoga Vajigandadi tailam is told in Yogarathnakaram vatavyadi chikitsa adhikaranam which is specifically indication only to gridrasi and the method of administration told as snehapanam and vasthi\(^6\).

Eranda taila is the main ingredient in Vajigandadi taila. Ŗeranda taila is quoted as the best snehavirechaka and vatanulomanam. Apart from these eranda taila is also having qualities such as vātakapha hara, deepana, srotoviśodhana, vayasthāpana, ārōgyakara, balakara and Adho dosa hara\(^8\). It also has specific indication in ruk and śopha of kati, and prusta\(^9\). It is the best drug for kaitiśūla\(^10\) as per Gadanigraha. These said qualities will be best suited for the selected condition. Eranda taila has a broad spectrum action depending upon its dose, duration, route of administration,combinations, mode of preparations etc..

Classical preparations like sindhuvara erandam, gandarvahasthadi erandam, sukumaram erandam etc had shown its efficacy in treating similar Vata vyadis. The trial drug here is also processed with potent drugs like Aswagandha, bala moola, vilwa, and dasamoola which is known for its deepana, grahi, pachana, vata kapha hara properties. So it is understood that the said combination will be a unique drug for subsiding both types of gridrasi.

**III. PREVIOUS WORK DONE**

1. Comparitive clinical trial of castor oil and diclofenac sodium in patients with Osteoarthritis\(^11\).

(Department of Pharmacology and Physical Medicine and Rehabilitation, Postgraduate Institute of Medical Education Research, Chandigarh and All India Institute of Medical Sciences, New Delhi, India)

3. Management of gridrasi with special reference to basthi at GCIM Mysoure, Karnataka. 12


8. Shridhar B. S. - Management of Gridhrasi w.s.r. to Basti. Mysore, Mysore University. 1991 12

9. Dhananjaya. K. - To evaluate the effect of Vishamusti vati and Matra Basti in the management of Gridhrasi, Mysore, RGUHS. 2002 12


On a review of the previous work done it can be concluded that neither efficacy of Vajigandhadi taila as pana and matra vasthi has been evaluated nor a comparison of route of administration has been done. So the study has been undertaken.

**IV. AIMS AND OBJECTIVES OF THE STUDY**

1. To evaluate the efficacy of Vajigandadi taila Snehapana in the management of Gridrasi.
2. To evaluate the efficacy of Vajigandadi taila Matra basthi in the management of Gridrasi.
3. To compare the efficacy of Vajigandadi taila administration as Snehapana and Matra basthi in the management of Gridrasi.
4. To standardize the dose of *vajigandadi taila* in gridrasi.

**2. MATERIALS AND METHOD**

**I. SOURCE OF DATA**

OPD and IPD of Post graduate Dept. of Kayachikitsa Amrita School of Ayurveda and Hospital,

**II. METHOD OF COLLECTION OF DATA**

A) Sample

40 patients fulfilling the criteria will be selected and divided randomly into 2 equal groups.

B) INCLUSION CRITERIA

1. Positive SLR test
2. Patient having Sciatica with mild to moderate osteoporotic changes and where surgical interventions are not absolutely necessary and medical management are suggested.
3. Patient between the age group of 20-60 years of either sex.
4. Patient with madhyama or kroora koshta.

C) EXCLUSION CRITERIA

1. Mrudu koshta
2. Fracture of vertebrae
3. Dislocation of vertebrae.
4. Deformities and congenital defects..
5. Known case of Tuberculosis of spine.
6. Known case of Neoplasm of spine.
7. Chronic osteoporotic degeneration.
8. Pregnancy
3. PROCEDURE AND DESIGN OF THE STUDY.

I. MATERIALS AND METHOD.

Collection of drug

Ingredients of the yoga will be identified and collected from the local market and vicinity of Vallikavu

Composition of the trial drug.

**Vajigandadi tailam.**

<table>
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<tr>
<th>Sl.no</th>
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<tr>
<td>1</td>
<td>ASHWAGANDAM</td>
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<tr>
<td>2</td>
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<td>VILWA</td>
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<td>AGNIMANTHA</td>
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<td>GOKSHURAM</td>
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<tr>
<td>13</td>
<td>ERANDA TAILA</td>
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</table>

PREPARATION OF MEDICINE

*Aswagandha, bala, vilwa and dasamoola*(whole 10 drugs together) will be taken in equal quantity and made into coarse powder. To this 16 times water is added and boiled and reduced to $\frac{1}{4}$.

This kasaya is mixed with sufficient quantity of eranda taila and kalka as per the classical reference 1:4:16 for kalkam, sneham and kasayam respectively. For kalkam the above mentioned drugs will be taken in appropriate quantity mentioned in classics for sneha kalpana.\(^{13}\)
The ratio of the individual drug is fixed as per the classical reference. The taila will be prepared in the pharmacy of Amritha School Of Ayurveda. The tailas prepared according to the direction available in the classical texts.\textsuperscript{14}

First the kasaya is made with drugs and water taken in the ratio 1:16 respectively and is reduced to 1/4\textsuperscript{th}.

For preparation of the medicine the kalka, eranda taila and kasaya are taken in the ratio 1:4:16.

The taila will be prepared in madhyama paka for the trial.

\textbf{II. DESIGN OF STUDY}

40 patients who fulfills the inclusion criteria in the duration of study period will be randomly divided into 2 groups Group VJ.P and Group VJ.M each consisting 20 patients.

\textbf{i. GROUPING & TREATMENT PROCEDURE}

Patients will be divided in to two Groups, VJ.P and VJ.M by random sampling method with 20 patients in each group.

For both groups deepana-pachana is planned to be done with trikadu till deepana and pakwamala darshana is attained.

Patients in VJ.P. will be administered \textit{Vajigandadi taila} orally as samana snehapana with initial Dose of 5ml and increased dose per day with 5ml for 15 days. If purgation occurs distressfully then the same dose of previous day would be fixed for the next day.

Patients in VJ.M. will be administered \textit{Vajigandadi taila} through anus as matravasthi in a dose of 1 ½ Pala (=70ml) for 15 days.

The findings are then statistically analysed.
Groups

Poorvakarmam

Deepana-pachanam with trikadu choorna till agni deepanam and pakva mala is observed.

Deepana-pachanam with trikadu choorna till agni deepanam and pakva mala is observed.

Pradhana karma

Sneha panaana starting with 5ml and adding on 5ml for each consecutive days for 15 days.

Matra basthi with 1\(\frac{1}{2}\) pala(72 ml) is done for 15 days.

Time of administration

7.30am

After lunch

Method of administration

Fixed dose is measured and given in empty stomach.

70ml is administered via anal route with disposable glycerine syringe.

Anupanam

Mudga yoosham

-

Pathyam

Ushna yavagu, ushnopacharam

Hithaaharam, ushnopacharam

Apathyam

Sheetopacharam, viruddha/guru aaharam, divaswapnam

Sheetopacharam, viruddha/guru aaharam, divaswapnam

4. ASSESSMENT CRITERIA

OBJECTIVE

1. Visual analogue scale for pain.
2. SLR test.
3. Lasegue’s sign.
4. Schober’s test.
5. Gaenslen’s test.
6. Sitz test
7. Flip test
8. Barbers test
SUBJECTIVE

1. Ruk - pain
2. Sthambhana-stiffness
3. Toda - pricking sensation
4. Spandana –fasciculation
5. Arochaka – anorexia
6. Gourava – heaviness
7. Tandra -stupor

FOLLOW UP

Two follow ups with 15 days interval

STATISTICAL METHODS

Subjective and Objective parameters before and after treatment and follow up will be recorded meticulously and analysed by using appropriate statistical methods and final conclusion will be drawn.

LABORATORY INVESTIGATIONS

1. Routine blood test
2. Lipid profile
3. X-ray of lumbo sacral spine AP and Lateral view
4. LFT

DOES THE STUDY REQUIRED ANY INVESTIGATION OR INTERVENTIONS TO BE CONDUCTED ON PATIENTS OR OTHER HUMANS OR ANIMALS?

The study requires;

1. X-ray lumbo sacral region AP and lateral view.
2. Blood routine
3. Lipid profile
4. LFT

No animal experiments will be carried out.

HAS ETHICAL CLEARANCE BEEN OBTAINED FROM YOUR INSTITUTION IN CASE OF HUMAN TRIALS?

Yes.

LIST OF REFERENCES

9. Acharya Vagbhata. Astanga hridayam, elaborated by Vagbhata, with joint commentaries Ayurveda rasayana by Hemadri and Sarvangasundara by Arunadatta,
10. Gadanigraham Kayachitsa khandam- Vatarogadhikaranam 156th sloka
11. www.onlinelibrary.wiley.com
13. Prof. Murthy Srikantha R.K, translated Sharangadhara Samhita, pub. Choukhamba Vidhya Bhavan 2009 Madhyamakhanda, Chapter 9/1

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Name and
Designation of HOD: DR. RATNA PRAVA MISHRA, M.D(Ayu), PhD
PROFESSOR AND HOD, PG DEPT. OF KAYACHIKITSA, AMRITA SCHOOL OF AYURVEDA.

Name and Designation of Head of the institution: DR. M.R. VASUDEVAN NAMBOOTHIRI, M.D(Ayu), PRINCIPAL, AMRITA SCHOOL OF AYURVEDA.
COMPLETE PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION FOR AYURVEDA VACHASPATI [M.D] IN KAYACHIKITSA

‘OPEN LABEL CLINICAL STUDY TO EVALUATE THE COMPARATIVE EFFECTIVENESS OF KARPASASTHYADI NASYA AND UTTARABHAUKTIKA SNEHAPĀNA IN APABĀHUKAM’

Submitted by,

KRISHNA PRABHA.A

1ST YEAR P.G SCHOLAR

DEPARTMENT OF P.G STUDIES IN KAYACHIKITSA

AMRITA SCHOOL OF AYURVEDA, VALLIKAVU, CLAPPANA P.O. KOLLAM

GUIDE

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2013-2014
AMRITA SCHOOL OF AYURVEDA,
VALLIKAVU, KOLLAM
From,
Dr. KRISHNA PRABHA. A
I Year M.D (Ayu) scholar
Department of PostGraduate studies in Kayachikitsa
Amrita School of Ayurveda , vallikavu , clappana (p.o), kollam,Kerala,

To
The Registrar,
Amrita vishwa vidyapeetam,
Ettimadai, Coimbatore,Tamilnadu

Through - The Principal and Head of Department of P.G. studies in Kayachikitsa,
Amrita School of Ayurveda,Vallikkavu,Clappana P.O, Kollam, Kerala

Subject: Submission of Completed Proforma for Registration of Synopsis of Dissertation.

Respected Sir,
I request you to kindly register the below mentioned subject against my name for the submission of the dissertation to the AMRITA SCHOOL OF AYURVEDA, AMRITA VISWAVIDYAPEETHAM, Coimbatore, Tamilnadu for partial fulfillment of M.D. (Ayurveda).

THE TITLE OF DISSERTATION:

‘OPEN LABEL CLINICAL STUDY TO EVALUATE THE COMPARATIVE EFFECTIVENESS OF KARPASASTHYADI NASYA AND UTTARABHAUKTIKA SNEHAPĀNA IN APABĀHU KAM’

Herewith I am enclosing completed Proforma for Registration of Subject of dissertation.

Thanking You
Yours faithfully,
(KRISHNA PRABHA. A)

Date:
Place: vallikavu
1. BRIEF RESUME OF THE INTENDED WORK:

1. NEED FOR THE STUDY:

In the fast developing technological era, most of the diseases may not be life threatening but hamper day to day life and human productivity. *Apabahuka* is one among those diseases which is painful and affects the normal routine life style of an individual. It is one among the *Vatavyadhi* which affects the normal functioning of the upper limbs.

Self-reported prevalence of shoulder pain is between 16% and 26% of general population. It is the third most common cause of musculoskeletal consultation in Primary Care. 5% of consecutive new patients attend a shoulder clinic for the complaint of Gleno-humeral disorders. Shoulder pain is the third most common cause of musculoskeletal consultation in primary care. 1% of adults with new shoulder pain consult their General Practitioner each year. Most common in 5th and 6th decades of life, with the peak age in mid 50s. Onset before the age of 30 is rare. Women are more often affected than men. The non-dominant shoulder is slightly more likely to be affected. In 6-17% patients the other shoulder becomes afflicted within 5 years.

Man has become more prone to many health problems due to altered food habits & life styles. If these problems are not dealt immediately they may lead to permanent disabilities. Ayurveda has given more importance to *vata vyadhis* since the era of Vedas and later on in *samhitha kala* the study of *vata vyadhis* have been done more elaborately.

*Apabahuka* is a *vata vyadhi* localizing around the *amsa pradesa* and there by causing *soshana* of *amsa bandha* as well as *akuncana* of *sira* at this site leading to symptoms like *bahupraspandita hara*. *Amsa shosha* can be considered as the preliminary stage of the disease where loss or dryness of the *Shleshaka Kapha* from the shoulder joint occurs. In the next stage, due to the loss of *Shleshaka Kapha* symptoms like *shoola* (pain) during movement, *amsa stabdada* (restricted movement) etc are manifested.

There are some clinical conditions of modern science, which may be compared with that of *Apabahuka*. These may be categorized as Gleno humeral disorders which include Frozen shoulder or adhesive capsulitis, Sub-coracoid bursitis, Bicipital tendinitis. Sub-acromial or sub-deltoid bursitis, Osteoarthritis of shoulder joint, Gleno-humeral arthritis.
In *Astanga Hridaya Vatavyadhi Chikitsa*, *Nasya* and *uttarabhaktika snehapana* are the main treatment principles indicated for *Apabahuka*\(^7\). The present study is on the comparative effect of both the *nasya* and *uttara bhaktika snehapana* with *karpasasastyadi taila* in *apabahukam*

*Nasya* is one of the important procedure of classical *Panchakarma* therapy and *nasa* is told as *dvara* for *Shiras*\(^8\) which is an *uttamanga*. Also the drug administered through nose nourishes the *Shiras*, *Skandha*, *Greeva* and *Vaksha*\(^9\)

In Ayurveda, oushada kala (time for administration of medicine) is stating that the drugs which are taking after sayam kala bhojana will have great impact on diseases due to udana vata\(^10\) affecting vak,pravritti,prayatna,oorja\(^11\) etc. and it is indicated in *Apabahuka*. *Uttarabhaktika sneha* is considered as *Brihmana snehana*.Here in this study for one group the sneha is administered in this modality.Also in *Yoga Ratnakara vatavyadhi chikitsa Acharya* mentions “masha taila rasonabhyam bahvoscha parivartanath” in the management of *Apabahuka*.\(^12\) From this the need of vyaayama in the management of Apabahuka is clearly highlighted.

As *karpasasthyadi taila* contains *karpasaasthi,devadaru,masha,bala,pippali moola,kushta,aja ksheera* etc it is a Vata-kaphahara and *Brihmana yoga* mentioned in *sahasrayoga*\(^13\). In the present study, it will be administered in the form of *Nasya* and *Uttarabhaktika snehapana* as indicated in its phala sruthi. Hence an effort has been made to evaluate the efficacy of *Nasya* and *Snehapana* along with vyaayama in the management of *Apabahuka*.

Due to increased prevalence & incidence rates need arises to treat the same with less cost & least side effects. Generally the sufferers go for usage of analgesics, corticosteroids, anti-inflammatory drugs. This approach may give only a timely cure but not permanent relief of the pain\(^14\) and the long term usage NSAIDs and steroids for relieving pain may in later course lead to secondary complications like Kidney failures, Liver disorders and Gastritis.

Considering all the above points, looking into the plight of patients with *Apabahuka* and also the beneficial effect of Ayurvedic therapies like *Nasya* and snehapan with *Karpasasthyadi Thaila* and to bring out a treatment modality with no side effects and long lasting relief.
II. REVIEW OF LITERATURE:

Apabahuka and its treatment has been explained in detail in both Brihatrayees and Laghutrayees. In Astanga Hridaya, Vata vyadhi nidana, it is mentioned that Apabahuka is a disease which affects movements of shoulder. The main lakshana is bahupraspandita haram. Ayurvedic classics explain the chikitsa of Apabahuka as follows.

1. In Ashtanga Hridaya, Nasya and uttarabhaktika Snehapana are mentioned in the management of Apabahuka.


5. Brimhana nasya is indicated in Apabahuka (Urdhwajatrugata rogas) in Astanga Hridaya surtastana Nasya vidhi.

6. In Yoga ratnakara vatavyadhi chikitsa, bahu parivartanam(vyaayama) is mentioned.

7. In Caraka samhitha chikitsa stana, Vatavyadhi chikitsa Uttarabhaktika snehapana is also having equal effect with Nasya in the management of Apabahuka.

PREVIOUS RESEARCH WORKS 15,16

1 1981 George P.J- ‘Classical management of Apabahuka GAC Trivendrum Kerala University Thiruvananthapuram.

The review of previous works indicate that some studies has been done on effect of nasya and about the efficacy of samana snehapana in Apabahuka. Only one study has been carried out on comparison of effect of nasya and uttarabhakthika snehapana with mashataila in the management of Apabahuka. But according to my knowledge no trial study was conducted on comparative study between routes of administration of karpasasthyadi taila as nasya and

3 1990  Jayan T S- Assessment of the effect of conventional treatment & rehabilitation therapy in Abhighbajanya Apabahuka comparing with the conventional treatment alone Trivandrum Kerala University.

4 1997  Shukla Niranjan - ‘Effect of Nasya and abhyanga on Apabahuka w.s.r to masha taila Gopabandhu Ayurveda Mahavidyalaya utkal university Bhuvaneshwar.

5 2004  Naveen.C.J.- A study on Apabahuka & its management through Nasya & Vatagajankush Rasa Ayurveda Mahavidyalaya Hubli.RGUHS

6 2010  Gajendra singh- A clinical study with karpasasthyadi taila and tila taila in the management of Apabahuka, Hassan

7 2010  Dr. Febin p. Jose-To evaluate the efficacy of Nagara Taila Nasya in the management of Apabahuka

8 2011  Dr. Rohini M. Hosagoudar “A comparative clinical study of nasya karma and uttarabhaktika snehapan in apabahuka w.s.r to frozen shoulder”

9 2012  Dr. Kiran B Nair- To evaluate the effect of karpasasthyadi thail nasya in the management of apabahuka w.s.r to frozen shoulder”

10 2010  Dr. Gayathri M. S A clinical study to evaluate the efficay of nasyakarma with parinata keriksheeraditailam in the management of apabahuka”

The review of previous works indicate that some studies has been done on effect of nasya and about the efficacy of samana snehapana in Apabahuka. Only one study has been carried out on comparison of effect of nasya and uttarabhakthika snehapana with mashataila in the management of Apabahuka. But according to my knowledge no trial study was conducted on comparative study between routes of administration of karpasasthyadi taila as nasya and
uttarabhakthika snehapana in Apabahuka. Hence this study is to carry out the comparative effectiveness of karpasasthyadi taila through nasal and oral routes of administration.

III. AIMS AND OBJECTIVES OF THE STUDY:

1) To analyse the effect of Karpasasthyadi taila nasya in Apabahukam

2) To analyse the effect of uttara bhakthika snehapana with karpasasthyadi taila in Apabahukam

3) To compare the efficacy of mode of administration as nasal and oral route in Apabahuka.

2. MATERIALS AND METHODS

I. SOURCE OF DATA

The patients attending the OPD and IPD of PG Department of kayachikitsa, Amrita Ayurveda Hospital with classical signs and symptoms of Apabahuka are selected. Detailed history taking will be done using a predesigned case proforma.

II. MATERIALS REQUIRED FOR THE STUDY

i) METHOD OF COLLECTION OF DATA:

1. SAMPLE:

Minimum number of 30 patients are randomly selected from the OPD and IPD, PG Department of kayachikitsa, Amrita ayurveda Hospital, vallikavu.

2. INCLUSION CRITERIA:

- Either gender and age group of 20-60 years
- Patients having classical signs and symptoms of Apabahuka.
  - Bahupraspanditahara (Restricted movements)
  - Amsa Sthabdatha (stiffness),
  - Amsasandhi Shoola (pain),
- Bahushosha (wasting)
- Patients Fit for Brihmana Nasya Karma and snehapan.

3. EXCLUSION CRITERIA

- Age group: less than 20yrs & exceeding 60yrs are to be excluded.
- Patients with history of Fracture of Shoulder,
- Any other Physical injuries to the shoulder joint (trauma)
- Infective Conditions
- Patients undergoing steroid therapy
- Pregnancy & Lactating mothers
- Pain related to secondary systemic diseases.

ii) PROCEDURE AND DESIGN OF THE STUDY:

1. MATERIALS AND METHODS:

i) Composition of trial ingredients: i) Karpasasthyadi Thaila

The following drugs will be identified and procured from the local markets of vallikavu.

- Karpasa asthi
- Bala
- Masha Dravadravya
- Kulatha
- Devadaru
- Bala
- Rasna
- Kushta
- Sarsapa
- Nagara Kalka
- Satahwa
- Pippalimoola
- Chavya
- Sigru
- Punarnava
- Tila taila Sneha
- Ajaksheeram
ii) Preparation of medicine:

The drugs for preparing drava dravya will be taken in equal quantity and made into coarse powder. To this 16 times water is added and boiled and reduced to 1/4th. This kashaya is mixed with sufficient quantity of ajaksheera and Kalka. As per the classical reference 1:4:16 is the ratio for kalkam, sneham and kashayam respectively. For kalkam the above mentioned drugs will be used.17

The thaila will be prepared in the Pharmacy, Amrita Ayurveda Hospital, according to classical method and mridu paaka is taken for Nasya and madhyama paaka is taken for paana.

2) Design Of The Study

30 Patients who fulfill the inclusion criteria in the duration of study period will be randomly divided into 2 Groups – Group A and Group B each consisting of 15 patients.

3) Grouping and treatment / Procedure etc.

Patients are divided into 2 groups by random sampling method.

- Group A – In this group 15 patient will be given Nasya with karpasasthyadi taila for 7 days along with vyayama
- Group B - In this group 15 patients will be given karpasasthyadi taila as Uttarabhaktika Snehapana (in samana matra) along with vyayama.

a. Both the groups will be undergoing vyayama for 30min in these 15 consecutive days
4) ASSESSMENT CRITERIA

Assessment will be done on the subjective and objective parameters before and after treatment. A special scoring pattern will be prepared for the assessment of subjective parameters.

SUBJECTIVE PARAMETERS:

a. Pain (amsa sandhi soola) by Visual Analogue scale (0-10 scale)

b. Stiffness of the shoulder joint (amsa stabdada)

c. Bahusosha (wasting)
OBJECTIVE PARAMETERS:

a. Bahuprasandita haram(Range of shoulder movements,Goniometer examination & scales)
   * Flexion
   * Extension
   * Abduction
   * Adduction
   * External Rotation
   * Internal Rotation
   * Elevation

• FOLLOW UP:
  2 months (weekly once)

5. STATISTICAL METHODS

Subjective and Objective parameters before and after treatment and follow up will be recorded meticulously and analysed by using appropriate statistical methods and final conclusion will be drawn.

3. Does the study require any investigations or interventions to be conducted on Patients, Healthy volunteers, cadaver or animals? If so, please describe briefly:

Yes, Study requires investigations in Goitre patients using medicated drugs. No healthy volunteers, cadaver or animal experiments will be conducted.

a) Investigations:

To exclude other disorders following investigations will be done if necessary.
- Hb%, TC, DC, ESR, RBS, Routine urine, X-ray shoulder (AP & Lateral)

b) Intervention:

1) The patients will be assessed before and after the treatment and after follow up as per assessment criteria.
2) The nature of the study will be explained to the patients in detail and pre-treatment consent will be taken.
3) The confidentiality of the data will be maintained.

2. Has ethical clearance been obtained from your institution in case of (3)? (Human / animal)
STUDY PLAN

Step 1
Minimum number of 30 patients are randomly selected from the OPD and IPD, PG Department of kayachikitsa, Amrita ayurveda Hospital, vallikavu on the basis of inclusion and exclusion criteria.

Step 2
Lab investigations ie. Haematological, X-ray etc will be done for proper diagnosis of the disease.

Step 3
Grouping of the patients

<table>
<thead>
<tr>
<th>Group A (Nasya)</th>
<th>Group B (snehapana)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients will be given karpasasthyadi Nasya</td>
<td>30 ml karpasasthyadi taila given</td>
</tr>
<tr>
<td>8 drops in both nostrils in 2 consecutive 7 days</td>
<td>after sayamkala bhojana for 15 days</td>
</tr>
<tr>
<td>With 2 days interval with poorva, pradhana and Paschat karma</td>
<td></td>
</tr>
</tbody>
</table>

Step 4
Effect of therapy will be observed on the basis of clinical pictures, Range of movements, VAS and investigations after completion of therapy (16 days)

Step 5
To compare the effectiveness between Nasya and uttara bhakthika snehapana with karpasasthyadi taila in Apabahuka.
LIST OF REFERENCES: Write references in Vancouver style

7. Vaghbata AstangaHridaya with commentaries Sarvansundari of Arunadatta& Ayurveda Rasayana of Hemadri, annotated by Dr.AnnaMoreshwaraKunte and KrishnaRamachandraShastrinarve edited by Pt.Bhishagacharya Harisadashiva shastri paradigmara Published by KrishnadasAcademy,Varanasi;Reprint 2010.chikitsa stana21/44 PN 725
11. Vaghbata AstangaHridaya with commentaries Sarvangsundari of Arunadatta & Ayurveda Rasayana of Hemadri, annotated by Dr. AnnaMoreshwaraKunte and KrishnaRamachandraShastrinarve edited by Pt. Bhishagacharya Harisadashiva shastri paradakara Published by KrishnadasAcademy, Varanasi; Reprint 2010 sutrastana 12/5 PN.193


14. [link](www.wikipedia.org.in/orthoinfo.aaos.org/topic.cfm)


16. [link](www.rguhs.ac.in/curriculum/)

17. Prof. Murthy Srikantha R.K translated Sharangadhar Samhita, pub. Choukhamba Vidhya Bhavan 2009 Madhyamakhanda, Chapter 9/7

18. Vaghbata AstangaHridaya with commentaries Sarvangsundari of Arunadatta & Ayurveda Rasayana of Hemadri, annotated by Dr. AnnaMoreshwaraKunte and KrishnaRamachandraShastrinarve edited by Pt. Bhishagacharya Harisadashiva shastri paradakara Published by KrishnadasAcademy, Varanasi; Reprint 2010 sutrastana 20/9 PN.289

Name of the researcher/Scholar : KRISHNA PRABHA.A

Signatures :

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PG DEPARTMENT OF KAYACHIKITSA.

Remarks of the Guide :

Signatures with official seal :

Name and designation of

The Co-guide : DR. KRISHNA KUMAR.K,

M.D(AYU)

ASSISTANT PROFESSOR

PG DEPT.OF KAYACHIKITSA

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Head of Department : DR. RATNA PRAVA MISHRA,

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PROFESSOR & HOD

PG DEPARTMENT OF KAYACHIKITSA
Signatures with official seal: 

Name & designation of Head of Institution: Dr. M. R. VASUDEVAN NAMPOOTHIRI.

   MD(AYU), PRINCIPAL,
   AMRITA SCHOOL OF AYURVEDA

Signatures with official seal:
PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION FOR

AYURVEDA VACHASPATI [M.D] IN KAYACHIKITS

“OPEN LABEL SINGLE ARM CLINICAL STUDY TO EVALUATE THE
EFFICACY OF VAGBHATOKTHA BRAHMI GHRTA IN VISHADA W.S.R. TO
DEPRESSIVE ILLNESS”

BY

DR. SETHULEKSHMI.S

GUIDE: DR.C.NAGARAJAN
CO-GUIDE: DR.MAHESH.C.KUNDAGOL

DEPARTMENT OF POST GRADUATE STUDIES IN KAYACHIKITSA
AMRITA SCHOOL OF AYURVEDA, VALLIKKAVU
CLAPPANA P.O, KOLLAM, KERALA

SESSION - 2013-14
From,

DR. SETHULEKSHMI. S
Preliminary M.D. (Ayu) Scholar,
Dept of Post Graduate studies in Kaya Chikitsa
Amrita School of Ayurveda, Vallikkavu, Clappana P.O, Kollam, Kerala.

To

The Registrar
Amrita Viswa Vidyapeetham, Ettimadai, Coimbatore, Tamilnadu

Through - The Principal and Head of Department of P.G. studies in Kayachikitsa, Amrita School of Ayurveda, Vallikkavu, Clappana P.O, Kollam, Kerala

Subject: Submission of Completed Proforma for Registration of Synopsis of Dissertation.

Respected Sir,

I request you to kindly register the below mentioned subject against my name for submission of the dissertation to the Amrita Viswa Vidyapeetham, Coimbatore, Tamilnadu, as partial fulfillment of M.D (Ay) in Kayachikitsa.

THE TITLE OF DISSERTATION

“OPEN LABEL SINGLE ARM CLINICAL STUDY TO EVALUATE THE EFFICACY OF VAGBHATOKTHA BRAHMI GHIRITA IN VISHADA W.S.R. TO DEPRESSIVE ILLNESS”

I am enclosing completed proforma for registration of subject of dissertation.

Thanking You.

Yours faithfully,

DR. SETHULEKSHMI. S

Date:
Place: Vallikkavu
1. BRIEF RESUME OF THE INTENDED WORK

I NEED FOR THE STUDY

Vishada is one of the Vatananatmaja Vikaras and it is further said that Vishada is the main factor that increases the range of all the diseases “Vishado Rogavardhanaanaam Shreshthah”. Dalhana commented “Asiddhi Bhayat Vividhesu Karyasu Sado Apravruthi”, i.e. a condition originated from apprehension of failure, resulting in Incapability of mind and body to function properly with significant reduction in activity. Symptomatic representation of the state of Vishada is explained in Shrimad Bhagvad Geeta.

Depression is a state of low mood and aversion to activity that can affect a person’s thoughts, behaviour, feelings and physical well-being. It may include feeling of sadness, anxiety, emptiness, hopelessness, worthlessness, guilty, irritability or restlessness. The symptoms of Vishada which are found in various references in Indian science when compared to depression almost appear similar, so we can co-relate Vishada with depression.

According to contemporary science Depression is a serious mental health concern that will touch most people’s life directly or indirectly. Depression affects 121 million people worldwide. It can affect a person's ability to work, form of relationships, and destroy their quality of life. At its most, severe depression can lead to suicide and is responsible for 850,000 deaths every year. 15% of the population of most developed countries suffers with severe depression. 80% of depressed people are not currently having any treatment.

Vaghbhata explains Brahmi Ghrita in Unmada Chikitsa and is indicated as ‘Vakswara Smritimedhakrut. Acharya doesn’t explain its indication in any specific doshic unmada or Vishada. Samanya Unmada Chikitsa can be used in all kind of Manasika Rogas based on the understanding of the Doshas predominant in that particular condition. In Manorogas Chikitsa Ghrita Pana is directly indicated, and we find most of the formulations in Ghrita forms. Therefore it may be an appropriate medicament to manage this condition.

Hence this study is planned to explore the efficacy of Vaghbhatokta Brahmi Ghrita Pana in the management of Vishada (Depression).

II) REVIEW OF LITERATURE

In ancient Indian science too, the term “Vishada” has been used as a catastrophe, which may be correlated with depression. “Rigveda” – the first ever-authentic human literature denotes the use of a special invocation to God for getting rid of Vishada i.e. this denotes to the fact that awareness about Vishada prevention was prevalent. According to the first chapter of “Shrimad Bhagvad Geeta” – Arjuna Vishada Yoga, the condition of Arjuna in the
battle field is mentioned as Sidanti Gatrani (loosening of muscles), Mukhashosha (dry mouth), Vepathu (tremors), Aruchi (anorexia), Prasveda (sweating), and Twak Paridaha (burning sensation in the skin) etc\(^{12}\), which commensurate with the symptoms of depression. Charaka Samhita mentions “Vishada” as one of the Nanatmaja Vata Vikara and it is further said that, Vishada is the main factor that increases the range of all the diseases.\(^{13}\) Sushruta has mentioned it under the Mano Vikaras.\(^{14}\) Further he mentioned that Vishada is common among Tamasika Manasa Prakruti.\(^{15}\) Whereas Vagbhata has stated that person with predominant Tamasa Guna are more prone to suffer from Vishada.\(^{16}\) Commenting on Anumanagamya Bhavas in Charaka Samhita says “Bhayam Vishadena”\(^{17}\)” i.e. understanding the feeling of fear in a person by seeing his depressed state or behaviour.

**Depression**- is a state of low mood and aversion to activity that can affect a person’s thoughts, behaviour, feelings and physical well-being. It may include feeling of sadness, anxiety, emptiness, hopelessness, worthlessness, guilty, irritability or restlessness.\(^{18}\) Charaka has mentioned the benefits of Ghrita as Medhya, Smriti Vardhaka and Indriya Parsadaka.\(^{19}\) Brahmi Ghrita is explained in the context of Unmada Chikitsa Adhyaya of Ashtanga Hridaya.\(^{20}\)

**Drug review**

Drugs used in Brahmi Ghtrita are:

Brahmi, Vyosha, Syama, Trivrut, Danti, Sankhupushpi, Saptaparni, Aragwada, Vidanga

**III) Previous works done**

1. Nath Sushil Kumar (1988)- A clinical study on depressive illness and its Ayurvedic management-IMS,BHU

2. Tripathy A.K.(1994)-Studies on some plant drugs as anti depressive w.s.r. to kapikacchu(mucuna prurieus)


6. Chandra R (2004) - Therapeutic evaluation of nasya karma medicated ghrita and Ayurvedic drugs in cases of depressive illness. IMS, BHU.


8. C. B. Singh (2005) - A clinical study on etiopathogenesis of Vishada (depression) and role of jyotishmati taila and Satvavajaya chikitsa (counselling) in its management. R. G. U. H. S.

Conclusion - Jyotishmati Taila and Satvavajaya Chikitsa proved significant relief in sign and symptoms of the patients of Vishada (Depression), but the quantum of relief provided by Jyotishmati oil was better in compression to Satvavajaya Chikitsa.


Conclusion - On comparing the effect obtained in both groups, it was observed that oral administration of Jyotishmati Taila provided significant improvements in the signs and symptoms of Vishada, in comparison with the improvement obtained in Jyotishmati Taila Nasya group.


Conclusion - Hapushyadi yapana basti was found to have significant improvement in the symptoms of depression and was statistically significant too.

IV) OBJECTIVES OF STUDY

1. To evaluate the efficacy of Vaghbhatokta Brahmi Ghrita Pana in the management of Vishada w. s. r. to Depressive Illness

2. MATERIALS AND METHODS:

1) SOURCE OF DATA:

30 Patients attending the OPD and IPD of Amrita School of Ayurveda, Kollam, who will be diagnosed with depression and eligible and willing patients will be enrolled in the study.
II) METHODS OF COLLECTION OF DATA:

Patients will be selected on the following criteria

1. CRITERIA FOR DIAGNOSIS:

1. The diagnosis will be made on the basis of diagnostic criteria for mild and moderate depression in ICD 10

A. Depressed Mood
1) Loss of interest and pleasure in activities that are normally pleasurable.
2) Decreased energy or increased fatigability.

B. 3) Loss of confidence or self-esteem.
4) Unreasonable feelings of self-reproach or excessive and inappropriate guilt.
5) Recurrent thought of death or suicidal behaviour.
6) Diminished ability to think or concentrate.
7) Change in psychomotor activity, with agitation or retardation.
8) Sleep disturbance of any type.
9) Significant changes in appetite-increase or decrease.

Mild depressive episode: at least 2 of A and at least 2 of B.
Moderate depressive episode: at least 2 of A and at least 4 of B.
Severe depressive episode: all 2 of A and at least 5 of B.

2. The diagnosis will be made on the basis of signs and symptoms of Vishada as per Ayurveda:

A) Psychic Symptoms:

Dukhita (Distressed, unhappy, grieved in mind)
Avasada (hopelessness, lassitude)
Manah khledah (feeling of depression)
Vishanna (dejection, sorrow)
Chitta glani (fatigue of mind)
Asiddhi bhaya (fear and anxiety or apprehension of failure)
Dainya (miserable state / depression)
Chittodvega (Anxiety), Feeling of inadequacy, Thought of death/suicide.

B) Somatic Symptoms:
Sidanti gatrani (loosening of muscles)
Mukha Shosha (Dryness of mouth)
Prasveda (Exessive sweating)
Bramati Manas (Wandering mind)
Tvak paridaha (Burning sensation of skin)
Vepathu (Tremor)
Roma Harsha (Horripilation)
Sransanam (Inability to hold)

2. **INCLUSION CRITERIA:**
   1. Patients diagnosed as per the criteria for mild and moderate depression as per ICD 10.
   2. Age between 18 to 50 years.
   3. Patients of either gender, irrespective of socioeconomic status.
   4. Patients willing to sign the informed consent form.

3. **EXCLUSION CRITERIA:**
   1. Patients with other psychiatric disorders.
   2. Pregnant women and children.
   3. Patients with chronic illness like Cancer, Hypertension, Diabetes mellitus, Hyper and Hypo thyroidism.
   4. Patients with suicidal tendency/ thoughts.
4. **PLAN OF STUDY:**

1. **BRAHMI GHRITHA:**

<table>
<thead>
<tr>
<th>S.NO.</th>
<th>SANSKRIT NAME</th>
<th>BOTANICAL NAME</th>
<th>PART USED</th>
<th>PROPORTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Brahmi</td>
<td><em>Bacopa monnieri</em></td>
<td>whole plant</td>
<td>2prastha=1536gm</td>
</tr>
<tr>
<td>2.</td>
<td>Shunthi</td>
<td><em>Zingiber officinalis</em></td>
<td>Root</td>
<td>12gm</td>
</tr>
<tr>
<td>3.</td>
<td>Maricha</td>
<td><em>Piper nigrum Linn.</em></td>
<td>Phala</td>
<td>12gm</td>
</tr>
<tr>
<td>4.</td>
<td>Pippali</td>
<td><em>Piper longum linn.</em></td>
<td>Phala</td>
<td>12gm</td>
</tr>
<tr>
<td>5.</td>
<td>Syama trivrut</td>
<td><em>Ipomoea petaloides chois</em></td>
<td>Moolam</td>
<td>12gm</td>
</tr>
<tr>
<td>6.</td>
<td>Danti</td>
<td><em>Baliospermum montanum</em></td>
<td>Moolam</td>
<td>12gm</td>
</tr>
<tr>
<td>7.</td>
<td>Sankhu pushpin</td>
<td><em>Convolvulus pluricaulis</em></td>
<td>Whole plant</td>
<td>12gm</td>
</tr>
<tr>
<td>8.</td>
<td>Sapta parni</td>
<td><em>Alstonia scholaris</em></td>
<td>Twak</td>
<td>12gm</td>
</tr>
<tr>
<td>9</td>
<td>Aragwada</td>
<td><em>Cassia fistula</em></td>
<td>Twak</td>
<td>12gm</td>
</tr>
<tr>
<td>10</td>
<td>Vidanga</td>
<td><em>Embelia ribes Burm</em></td>
<td>Seed</td>
<td>12gm</td>
</tr>
</tbody>
</table>
2.

<table>
<thead>
<tr>
<th>POORVA KARMA</th>
<th>PRADHANA KARMA</th>
</tr>
</thead>
<tbody>
<tr>
<td>10gm Trikatu choorna is given twice daily for 3 days</td>
<td>Brahmi ghrita will be given to the patient in Arohana matra till attains 4pala and dose is maintained till 7 days.</td>
</tr>
</tbody>
</table>

3. **DOSE**

<table>
<thead>
<tr>
<th>Day-1</th>
<th>Day-2</th>
<th>Day-3</th>
<th>Day-4</th>
<th>Day-5</th>
<th>Day-6</th>
<th>Day-7</th>
</tr>
</thead>
<tbody>
<tr>
<td>1pala</td>
<td>2pala</td>
<td>3pala</td>
<td>4pala</td>
<td>4pala</td>
<td>4pala</td>
<td>4pala</td>
</tr>
<tr>
<td>(48ml)</td>
<td>(96ml)</td>
<td>(144ml)</td>
<td>(192ml)</td>
<td>(192ml)</td>
<td>(192ml)</td>
<td>(192ml)</td>
</tr>
</tbody>
</table>

4. The patient should follow the Pathya-Apathya indicated in Virechna.

**METHOD OF PREPARATION**

Ghrita will be prepared till Madhyama Paka as mentioned in classics Pharmacy Amrita School of Ayurveda, Kollam.

5. **ASSESSMENT CRITERIA:**

1. Hamilton's depression rating scale will be used to measure the difference between before and after the treatment.

2. Manasika Bhava Pareeksha scale will be used to measure the difference between before and after the treatment.
6. FOLLOW UP

<table>
<thead>
<tr>
<th>Before treatment</th>
<th>After completion of 7 days of snehapana</th>
<th>15th day</th>
<th>30th day</th>
<th>45th day</th>
</tr>
</thead>
</table>

7. STATISTICAL TEST TO BE USED:
Statistical evaluation of results will be done by using student ‘t’ test method.

3) DOES THIS STUDY REQUIRE ANY INVESTIGATIONS OR INTERVENTION TO BE CONDUCTED ON PATIENTS OR OTHER HUMANS OR ANIMALS?
The study will be a clinical study.

4) HAS THE ETHICAL CLEARANCE IS OBTAINED FROM YOUR INSTITUTION IN CASE OF 7.2?
Yes

5) LIST OF REFERENCE :


Subrahmanyam A. Rangnekar H, A clinical study on the effect of hapushadi yapana basti in the management of vishada w.s.r. to depressive disorder. PG thesis. HASSAN: RGUHS, 2013. (ongoing)


24. Sadock BJ, Sadock VA. Psychiatric rating scales. US. Comprehensive text book of


26. Tanna IR. Role of Omega 3 fatty acids in aetiopathogenesis of Depression(chittavasada) and evaluation of Atasi(Linum usitatissimum) as adjuent to Ashwagandharista in its management.PhD[dissertation]. Jamnagar: Gujarat Ayurvedic University

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Signatures with official seal