Comparative Evaluation of Manjishthadi Taila and Mahamasha Taila Nasya in the Management of Avabahuka (Frozen Shoulder) – A study Protocol

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Abstract: The *Avabahuka* symptoms can correlate with adhesive capsulitis, commonly called frozen shoulder. Frozen shoulder is a condition having painful restricted movements of passive and active shoulder joints. It maximally occurs between the age group of 40-60 years. Females are more prone to this condition than males. *Snehan Nasya* is indicated as the preferred treatment for *Avabahuk*. The Ayurveda text mentions that *Manjisthadi tail Nasya* shows effective results in *Avabahuka;* it can be compared with *Mahamasha tail*, which has 36 ingredients. So the simple formulation of drug therapy can be tried in *Avabahuka*. **Aim:** Comparative Evaluation of the Efficacy Of *Manjisthadi Taila Nasya* and *Mahamasha Taila Nasya* in the Management of *Avabahuka* (Frozen Shoulder).**Materials and Methods:** It is a Randomized, open clinical control trial. A total of 60 patients will be selected. Two groups are made group **A** (intervention) *manjishtadi tail nasya* for 14 days, and group **B** (control group) will be given *Mahamasha taila nasya* for 14 days. Follow-up will be taken on the 15th day. **Result:** The result will be declared based on the efficacy of *manjishtadi taila nasya* compared to *Mahamasha taila nasya* and whether *manjishtadi taila* is more effective than *mahamasha taila* for *Nasya karma* in the treatment of *Avabahuka*. **Conclusion:** This trial may provide evidence of the efficacy of *manjishtadi taila nasya karma* in the treatment of *avabahuka*

Keywords- *Avabahuka***,** Frozen Shoulder, *Nasya*, *Mahamasha Taila Nasya*, *Manjishtadi taila nasya*.

I. INTRODUCTION

Background and rationale:

An individual's daily routine work activities get disturbed due to the condition of the disease called *Avabahuka*. It is considered as one of the *vataja nanatmaja vyadhi* [1]. *Ansashosh* and *Avabahuka* are the two disease conditions mentioned in some *Ayurveda* texts [2]. It is made up of two words *Ava* + *Bahuka*; the prefix *Ava* means Away, down, *Vikrita*, off. All these terms mean dysfunction or physiological separation, not anatomical, resulting in restriction of moment hampering all activities of that particular part, as there is absolute separation. Therefore, *Avabahuka* means immobile shoulder joint. *Sushruta* explained the condition of *Avabahuka* for the first time where he explained the *samprapti* and *rupa* of

Avabahuka. Ashtang Hridaya and Ashtang Samgraha give the complete details of Avabahuka. *Bhavamishra* and *Sharangadhara* have described A*vabahuka* under eighty types of *vata nanatmaja vyadhis* . *Arunadutta* and *Dalhana*, have discussed *avabahuka samprapti*, *lakshana* and *chikitsa* in their description. The disease has been described in the conditions *Amsa shosha* and Avabahuka [3].

Avbahuka is a *Vatavyadhi* prevalent in the middle and old age population. The causative factors responsible for *kapha prakopa* are excessive intake of *atisnigdha*, *atigurudravya* causes *vikruta Kapha*, which further leads to *Kaphavrita vata* condition. In both courses of action, the *vikruta vata dosha* gets collected into the bio channels (*srotas*) and noticeable symptoms. It is a disease that routinely affects the *Ansasandhi* (shoulder Joint). The first stage is called *Ansashosh* occurs in *Ansasandhi* due to the dryness of *shleshak kapha*. The disease *avabahuka* occurs in the next step because of the dryness of *shleshak kapha*, and symptoms are shown clear [4]. This includes *Ansashoola* while doing movement and the movements will be restricted. Only *Vata* dosha involved condition is known as *Ansashosh*, and the involvement of both *vata* and *kapha dosha* causes *avabahuka* [5]. The general line of treatment includes *snehan*, *swedan*,*basti*, *agnikarma* and oral medications. *Acharya vagbhat* has mentioned *Nasyakarma* in the *urdhwa jatrugata rogas* [6]. All the *Brihatrayees* have mentioned in detail the role of *Nasyakarma* in managing *Avabahuka*.

The synonyms for Frozen shoulder are given and called Peri-arthritis or Adhesive capsulitis, which leads to notable movement dropping. It occurs explicitly in mainly three phases: painful, stiff, and thawing. In most cases, the first indication of the disease is pain; hence, the patients consult the physician for proper treatment. [7] .

The two words frozen + shoulder are collectively known as frozen shoulder. Frozen means motionless, and shoulder means the upper joint of a person's arms. Therefore, the symptoms indicating continuous pain, stiffness and decreased joint shoulder movement are known as frozen shoulder. It damages the actions of the shoulder joint both actively and passively, irrespective of it may be flexion, extension, abduction, adduction, external rotation, or internal rotation.

The human shoulder is the most mobile joint in the body, a ball and socket type joint. The shoulder joint enjoys excellent freedom of mobility at the cost of stability. The shoulder is the most moving and flexible joint of the body, and no other joint is more versatile than the shoulder joint. Due to the laxity of its fibrous capsule, more range of mobility is there—the large size of the humerus's head compared with the shallow glenoid cavity.

The main structures and bones included in the shoulder joint comprised of three bones, namely the humerus (upper arm bone), clavicle (collar bone) and scapula (shoulder blade) and main structures like the rotator cuff, bursa, labrum and capsule. Usually, the shoulder joint capsule is flexible and lets or does a considerable range of motion. Still, tenderness, thickening or scarring and contraction of the capsule may lead to restriction of movement immersed in a frozen shoulder. Frozen shoulder is sometimes also known as adhesive capsulitis or painful, stiff shoulder. Adhesive capsulitis is the other name for a frozen shoulder, having symptoms of pain and stiffness in the shoulder region. As time passes, the shoulder becomes hard to move. When the symptoms worsen, the condition improves by itself, but a maximum of 3 years is required for a full recovery. The primary treatment suggested for a frozen shoulder is physical therapy, with the main focus on shoulder flexibility. Diabetic patients can develop frozen shoulders at higher risk [8]. Frozen shoulder affects patients aged 35 to 70 years, with a frequency of 3% to 5% in everyday people and up to 20% in those with diabetes. It is the third most common cause of musculoskeletal cases in primary care. Males tend to be affected less frequently than females, and there is a preference for race.

Nasya is a treatment modality included in Panchakarma by Ayurveda Acharyas; even one can find it in *Rigveda*. It is the administration of different medicines through a nasal passage systematically. The word *nasya* is derived from '*nasa' dhatu,* which indicates nose or things beneficial to the nose [9]. *Siras* is considered the mahamarma or uttamanga, an essential part of the human body. And often, Acharyas compare human beings with an inverted tree whose roots are above, and branches are below; once the roots are irrigated, it stimulates the entire tree. *Nasya* is a

procedure used in different Ayurveda branches but mainly in *Panchakarma* and practices. It is used in treating *urdhwajatrugata roga* and many Physical Disease conditions. *Nasya* helps to purify these organs and removes aggravated *doshas* through the nasal openings. Many diverse conditions like *ardita, pakshaghata, shirasoola* and *dushta pratishyaya, Avabahuka* etc., are effectively treated with *nasya karma*. Different types of *nasya karma* are described in *Ayurveda*, and the *navan nasya (snehan nasya)* is one of them we prescribe in this study.

Taila is the best *vata shamak dravya* and being *sneha dravya*, and it is *kaphaghna* [10]. *Nasya Karma* is one of the crucial procedures of classical *Panchakarma*, particularly the *Urdhwajatrugata Vyadhi*. In *Ayurveda, Acharyas* have mentioned that *Manjishtha* and *guggulu* are the most valuable drugs. *Manjishhta* acts as *Kapha pitta shaman, and Guggulu* balances the *tridoshas.* It is also a well-known *rasayana* [11]. No such study has been conducted before, so this study is undertaken with the aim of comparing the efficacy of *Manjishtadi taila* and *Mahamasha taila Nasya karma* in the management of *Avabahuka.*

Many studies have been conducted on *Avabahuka,* but no study was conducted on *Manjishthadi taila nasya;* also, no study was conducted considering the properties and efficacy of *manjishtha* and *guggulu* . Both have anti-inflammatory and healing properties. *Guggulu's* unique properties relieve joint inflammation. *Mahamasha Taila* acts as *Bruhan* and *vedana shamak*, *Mahamasha taila nasya* is found effective in *Avabahuka.* Hence the study is planned to evaluate the efficacy of *Manjishtadi taila Nasya* Compared to the effectiveness of *Mahamasha Taila Nasya* in the Management of *Avabahuka.*

II. METHODOLOGY

Type Of Trail: It is a Randomized, open clinical control trial.

Ratio - 60 patients will be randomly divided into two groups(each group contains 30). In group **A** (Experimental) *manjishtadi taila nasya* for 14 days is given, and group **B** (control group) will be given *Mahamasha taila nasya* for 14 days. Follow-up will be taken on the 15th day.

Drug Collection/ authentication - The raw material will be procured from the department of *dravyaguna* and authenticated by the dept of *Rasa Shastra*, Mahatma Gandhi Ayurved College, Hospital And Research Centre, Salod [H], Wardha.

Formulations:

***Manjishtadi* taila –**

Sr. no	Name of Drug	Latin Name	Family	Part Used	Gana
1	*Manjishtha* [12]	Rubia Cordifolia	Rubiaceae	Root	*Priyangaw adi gana.*
2	*Guggulu* [13]	Commiphora wightii	Burseraceae	Gum	*Charak - Samjnastha pan Sushruta- Eladi.*

Study setting :

Patients will be selected from OPD and IPD of P*anchakarma* as well as specialized peripheral camps.

Registration number - The trial is registered under CTRI with the trial number -

REF/2021/10/047911

Inclusion criteria –

1. *Avabahuka* diagnosis will be made as the given signs and symptoms include restricted movement and pain in the affected shoulder, stiffness and muscle wasting.
2. Male and female patients between 18-60 years of age.
3. Patients fit for *Nasya-karma*.
4. Patients are ready to consent and abide by the study protocol.

Exclusion criteria -

1. Patients are complaining of Fracture and dislocation.
2. Patients with a history of Hemorrhagic Hemiplegia.
3. Patients having nasal disorders.
4. Patients having diabetes.

Interventions :

Group A (Experimental) - Treatment of *nasya* with *Manjishtadi Taila nasya* for 14 days [14] **Group B** (Control) - Treatment of *nasya* with *mahamasha taila nasya* for 14 days .

Discontinuation criteria -

1. Any adverse effect of the therapy is seen.
2. Any acute or severe illness.

3. Patients who are not willing to continue the treatment.

Follow-up: Patients will be followed up on the 15th day.

Primary outcome: The immediate work is to check the effect of an interventional drug on *Avabahuka* (Frozen shoulder).

Secondary outcome: The secondary effect is to compare the efficacy of *manjishtadi taila* with *mahamasha taila nasya Avabahuka* (Frozen shoulder).

Statistical Analysis: To evaluate the recovery of suggestive relief and examine it analytically, the examination will be monitored before and after the treatment. The mean, percentage, SD, SE, paired t-test [t -value] and unpaired t-test were studied from the review recorded.

Patients Recruitment: By computerized random chart sampling methods, 60 patients will be recruited (30 in each group).

Implementation: Principle Investigator will enrol and allocate the patient.

III. DATA COLLECTION METHOD

Subjective Parameter [11]

Scoring Pattern -

Main symptoms -

- ***Bahupraspanditahara Score -***

  Grade 0 - Can do work without being affecte

  Grade 1 - Can do strenuous work with difficu

  Grade 2 - Can do daily routine work with great difficulty.

  Grade 3 - Cannot do any work.

- ***Shula -***

  Grade 0 - No pain.

  Grade 1 - Mild pain & can do difficult work.

  Grade 2 - Moderate pain & can do the least work.

  Grade 3 - Severe pain & cannot do any work.

- ***Stambha -***

  Grade 0 -No stiffness.

  Grade 1 - Mild & can lift without support.

  Grade 2 - Moderate & can lift with help.

  Grade 3-Severe stiffness & cannot lift.

- ***Sparsha asahishnuta* (Tenderness) -**

  Grade 0 - No inflammation .

  Grade 1 - Tenderness to palpation without pulling back (Mild).

  Grade 2 - Tenderness with pulling back to palpation (Moderate).

  Grade 3 - Tenderness with withdrawal (Severe).

Associated Complaints -

- ***Atopa***

No *Atopa* 0

Palpable *Atopa* 1

Audible from a little distance 2

- ***Ansashosha (Wasting of muscles) -***

No wasting 0

Mild wasting, can do work 1

Moderate wasting, works with difficulty 2

Severe wasting, cannot move 3

- ***Sroto Dushti -***

No symptoms 0

Presence of only one symptom 1

Presence of two symptoms 2

Presence of more than two symptoms 3

Objective Parameter -

To assess the range of movement of the shoulder joint with the help of the angle of the goniometer (1) Normal Range of Motion of the shoulder.

MOVEMENT	NORMAL READING
Flexion	**80^0-90^0**
Extension	**70^0**
Right Lateral	**20^0-45^0**
Left Lateral	**20^0-45^0**
Right Rotation	**90^0**
Left Rotation	**90^0**

The improvement in both groups will be recorded through analytical importance. The subjective and objective variables will be evaluated by asking questions to patients, and we have to assess the signs and symptoms before and after treatment. The outcome of the therapy in trial and control groups will be regularly evaluated.

Plan to promote a participant's retention and complete follow-up. We will stay in touch with the patient by taking contact numbers and advising them on proper medication practices and follow-up. The follow-up data will be stored in the documentation with valid reasons—after taking a written consent form from the patient. Data will be entered in the main.

Data management: The assessor will collect the data from patients by doing a clinical sheet and analyse using appropriate statistical techniques. The principal investigator will do data coding.

Ethics and dissemination :

Research Ethics Approval: Approval has been issued and taken from the research ethics committee.

Ref. No. MGACH RC/IEC/July-2021/350.

Consent or assent: The patient's written permission will be taken before starting the study. The confidential information of each patient is maintained during the study.

Dissemination policy: The data will be circulated with the help of paper publication.

Result: We hypothesise that in the group of manjishtadi *taila nasya*, we may improve the patients of *Avabahuka* than the control group because *manjistha taila* contains two drugs *manjistha and guggulu*. Both act as a " rejuvenating herb " that confers potent detoxifying effects. *manjistha* is an incredible herb that shows the presence of bioactive constituents like anthraquinones and their glycosides, naphthoquinones and glycosides, terpenes, bicyclic hexapeptides, iridoids, carboxylic acids (malic, citric, quinic, rosmarinic acids) and saccharides (xylose, ribose, fructose, glucose, sucrose, primeverose) were isolated from various parts of R.Cordifolia11. Saponins and some naphthalene derivatives are also separated. It contains alizarin, pseudo parpurins, rubiadin along with glucoside, lucidine, purpurin and manjistha A, B, C [15] . It is the best *raktashodhak dravya*. *Guggulu* contains diterpenoids, triterpenoids, steroids etc. It acts as an anti-inflammatory and antioxidant. It is mentioned in the Ayurveda text that *manjistha* and *guggulu taila nasya* is effective in the treatment of *avabahuka*.

Mahamasha thailam has been mentioned in the context of Vatavyadhi chikitsa. It cures almost all Vata disorders, including hemiplegia, facial paralysis, sciatica, trembling of hand, foot, head and neck, slow movement, frozen shoulder, etc. It can be used in oral intake, enema, nasal instillation, dropping in eyes and ears, and externally for body massage [16].

IV. DISCUSSION

Study will observe that *manjishtadi taila Nasya* can show effective results, which helps reduce the signs and symptoms of *Avabahuka*. *Manjishtadi taila* is made up of two drugs that are manjistha and *guggulu. Manjishta* has qualities of *madhura, tikta, kashaya rasa* and *guru* as well as *ruksha guna*. *Madhura* and *tikta rasa* increases *kapha* and decreases *vata*. *Guggulu* having qualities of *tikta rasa, laghu , ruksha,v ishada* and *picchila guna* and both drugs having *katu vipak* and *ushna virya*. Hence it can cure the dryness of *shleshak kapha* and aggravation of *vata*. *Guggulu* is widely used in various types of *vata vyadhi* as it balances the *tridoshas* and acts as an antioxidant anti-inflammatory. Guggulu works as a binding

agent. *Manjistha* and *guggulu* both are well known *rasayana* . Therefore collectively, this drug helps treat *vatavyadhi* and a rejuvenating therapy in the treatment of *Avabahuka*.

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