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Research article

COMPARATIVE CLINICAL STUDY OF AMSABASTI AND SNEHAN – SWEDAN THERAPY BY LAGHUVISHGARBHA TAIL ALONG WITH TRAYODASHANGGUGGULU IN AVABAHUKA (FROZEN SHOULDER)

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ABSTRACT
Avabahuka is caused mainly by vitiated vata. Avabahuka is not mentioned in nanatmajvatavyadhi but acharya sushruta and other acharyas considered avabahuka as vatavyadhi. Avabahuka is a disease that affects amsa sandhi. Avabahuka is correlated with frozen shoulder of modern science. It is also known as adhesive capsulitis, or stiff shoulder where joint pain and stiffness of shoulder joint both occur. Therefore as avabahuka causes major limitations in activities of daily living casting a negative influence on the quality of life as well as long-term or even permanent disability in a few of the patients, proper treatment is needed for the problem. In ayurveda basic principle of avabahuka treatment is vata shaman chikitsa. The general line of treatment for vatavyadhi issnehana, swedana, mrudusamshodhan, basti, nasya, and so on. Snehana – swedana for the treatment of avabahuka which is generally given in vatavyadhichikitsa has gained popularity for its efficacy. Evaluation of the utility, safety, and efficacy of laghuvishagarbha tail amsabasti by amsabasti yantra along with trayodashangguggulu as compare to laghuvishagarbha tail snehana – swedana along with trayodashangguggulu in the management of avbahuka (frozen shoulder). In this study, 140 patients will be divided randomly into 2 groups (70 in each). In group a (experimental) –amsabasti of laghuvishgarbha tail and oral drug trayodashangguggulu (500 mg thrice a day) after meals with plain water will be given for 21 days and group b (control) –snehana of laghuvishgarbha tail, swedana of by plain water and oral drug trayodashangguggulu (500 mg thrice a day) after meals with plain water will be given for 21 days. Assessment of avabahuka will be recorded on day 0, on 7th day, on 14th day and on 21st day. Changes will be observed in objective outcomes. Amsa basti will be more efficacious thansnehana -swedana in the management of avabahuka.

KEYWORDS: Avabahuka, Frozen Shoulder, Amsa Basti, LaghuvishgarbhaTaila, TrayodashangGuggulu.

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INTRODUCTION
In this competitive world pain is an annoying experience for anyone. If any part of the body is having pain or stiffness then the person gets irritated, intolerant, and sometimes depressed. As pain makes an individual's life difficult, Avabahuka is one such condition due to which day to day life gets hampered.

Vata[(1)] plays a chief role in the physiological maintenance of the body. Vata if gets disturbed or aggravated by various factors then it leads to various types of diseases which may be life threatening. So according to Ayurveda diseases produced by vitiated Vata are more important than diseases produced by other two Doshas i.e. KaphaDosha and Pitta Dosha.

Avabahuka is caused mainly by vitiated Vata. Avabahuka is not mentioned in NanatmajVatavyadhi but Acharya Sushruta and other Acharyas considered Avabahuka as Vatavyadhi. Avabahuka is a disease that affects Amsa sandhi.

Cardinal features of Avabahuka are Bahupraspandidahara[(2)] [difficulty or loss of movement of the upper limb], Shoola[(3)] [pain] Amsabandhana Shosha[(4)] (stiffness of shoulder joint).

Avabahuka is correlated with Frozen Shoulder of Modern science. It is also known as adhesive capsulitis, or stiff shoulder where joint pain and stiffness of shoulder joint both occur. Frozen shoulder is classified into two types; Primary and Secondary. Primary Frozen Shoulder is idiopathic and Secondary Frozen Shoulder occurs due to systemic diseases like diabetes mellitus, hypothyroidism, and injury or surgery. The main symptoms of Frozen Shoulder are described in three stages [(5)]-1] Freezing 2] Frozen 3] Thawing stage.

2% of the general population is affected by frozen shoulder [(6)] with incidence of 2.4 per 1000 person/years. Before the age of 40, it is rare in human beings, more common in between the age of 40 to 60 years of age. Diabetes mellitus is the disease that is commonly associated with frozen shoulder[(7)]. Diabetes patients have 10% to 20% risk of developing frozen shoulder. Therefore as Avabahuka causes major limitations in activities

of daily living casting a negative influence on the quality of life as well as long term or even permanent disability in a few of the patients, proper treatment is needed for the problem.

The goal of treatment is to give relief in pain, movement restoration, and recover proper functions of the shoulder joint.

In Ayurveda basic principle of Avabahuka treatment is Vata Shaman chikitsa. The general line of treatment for Vatavyadhi[8] is Snehana, Swedana, Mrudusamshodhan, basti, Nasya, and so on. Snehana – Swedana[9] for the treatment of Avabahuka which is generally given in Vatavyadhichikitsa has gained popularity for its efficacy.

Our study aims to compare the results of LaghuVishagarbha tail[10] Snehana- Swedana and Trayodashang Guggulu[11] with those of LaghuVishagarbha tail Amsa basti[12-16] and TrayodashangGuggulu which seems to be the most commonly prescribed treatment for Avabahuka at present,

Janu basti[12,13], Kati basti[14,15], and Greeva basti[16] which are evolved from Shirobasti are bahyaSnehan procedures. These are given for different types of vatvyadhi. On the same parameters Amsabasti will be given to Avabahuka patients. Amsabasti is an innovative procedure. The attempt of this study is to evaluate the synergistic action of LaghuVishagarbha tail Amsabasti and TrayodashangGuggulu on Avabahuka.

Rationale of the study

As Avabahuka disease has its impact on daily life activities, there is a need to introduce a traditional unique and inexpensive treatment for such disabled patients. The disease is managed by NSAID, analgesic drugs, physiotherapy & corticosteroids, etc. These drugs are very costly and have side effects. Even surgical management does not give complete relief. While collecting the review article, no such work is done previously. As Amsabasti is an innovative procedure and like Janu basti, Kati basti, and Greevabasti it will be a more efficient treatment for Avabahuka.The LaghuVishgarbha tail used for Amsabasti will be having the Snehana effect and due to the agniSamyoga in this procedure, it will have a Swedan effect simultaneously. This procedure will be a unique; in the sense comprising both Snehan and Swedan or it may be termed as 'SnehayuktaSwedan'.TrayodashangGuggulu which acts as Shothhara (anti-inflammatory), Shoolhara (analgesic), Todhara, Stabhdatahara (muscle relaxant) together with Amsabasti will have synergistic effect in the management of Avabahuka so results will be more pronounced. Ayurvedic treatment is having minimal side effects and economically viable also. After introducing such formulation, there may be some relaxation to the people who are facing pain, stiffness and sometimes loss of function of hand as no other treatment is giving complete relief from the disease.

Aim and objectives

Evaluation of the utility, safety and efficacy of Amsabasti by Amsabasti yantra as compare to Snehana – Swedanain the management of Avbahuka (Frozen Shoulder)

- To assess the effect of LaghuVishgarbha tail Amsabasti and Trayodashang Guggul in the management of Avabahuka.
- To assess the effect of LaghuVishgarbha tail Snehan with Swedan and Trayodashang Guggul in the management of Avabahuka.
- Comparison between the two Treatments.

Case definition

Diagnosed and confirmed cases of either sex between the age group of 40 to 60 years having Patients with cardinal signs and symptoms of Amsasandhishoola(shoulder pain), Amsasandhistabdhata(shoulder stiffness), Sparshaas-ahishnuta(Local tenderness), Bahupraspandhitahara(Restricted movements of shoulder region), with or without Amsasosha(muscle wasting).

Research Question

Whether LaghuVishgarbha tail Amsabastiand Trayodashang guggul is more effective in the management of Avabahuka as compared toLaghuVishagarbha tail Snehan – Swedan and Trayodashangguggul ?

Hypothesis

Amsabasti may be more efficacious than Snehana - Swedana in the management of Avabahuka.

Null Hypothesis

Amsabasti may not be more efficacious than Snehana - Swedanain the management of Avabahuka.

Trial design

Open Randomized reference standard Controlled clinical trial.

METHODOLOGY

Study setting

The study will be conducted Patients of Avabahuka will be selected from OPD and IPD of Mahatma Gandhi Ayurved College, Hospital and Research centre (MGACH&RC), Salod (H), Wardha, and Jawaharlal Nehru Medical College (JNMC), Sawangi (Meghe).

Registration Number

REF/MGACHRC/IEC/August-2020/101
I have applied for CTRI

Eligibility criteria

Patients of both sexes in the age group of 40 – 60 years, Patients with Freezing and Frozen stages of Frozen Shoulder, Patients having cardinal signs of Amsasandhishoola (shoulder pain), Amsasandhistabdhata (shoulder stiffness), with or without Amsasosha (muscle wasting), Sparshaasahishnuta (Local tenderness), Bahupraspandhitahara (Restricted movements of the shoulder region, patients willing to take treatment after giving a detailed description about therapy are included for the study. Diagnosed cases of - Patients with Thawing stage of Frozen Shoulder, Dislocation of Shoulder joint, Radiating pain in Neck, Diabetes, Generalized arthritis, Fractures and dislocations of humerus, Cervical Spondylitis,

Cardiopulmonary disease, Parkinson's disease, Rotator cuff tear, tendinitis, Pregnant and Lactating women, Autoimmune disorders like SLE and Rheumatoid Arthritis, Patients who refuse to participate in the study will be excluded.

Table 1: Interventions of both groups

Groups	No. of patients	Age	Sex	Intervention	Dose/day	Duration
Group A Study Group	70	40 yr to 60 yr	Male and Female	Amsabasti-LaghuVishgarbha tail	200 ml to 300 ml	21 Days
				Oral Drug-Trayodashang Guggulu with plain water	500 mg Thrice a day	21 Days
Group B Control Group	70	40 yr to 60 yr	Male and Female	Snehana-LaghuVishgarbha tail	50 ml	21 Days
				Swedana- By plain Water	With Plain water	21 Days
				Oral Drug-Trayodashang Guggulu	500 mg Twice a Day	21 Days

Criteria for discontinuing or modifying allocated interventions: The subject will be withdrawn from the study if any untoward incidence, features of drug sensitivity or any other disease or problem arises, the subject will be offered free treatment till the problem subsides.

Follow up: on day '0', on 7th day, on 14th day, and 21st day.

Primary Outcomes: Outcome of Both the Treatment will be seen in –

Pain (at rest, on movement, at night), Range of movement (e.g. internal and external rotation, elevation), Function and disability, Quality of life, Time to recovery, Return to work, and recreation and Adverse effects of treatment if any.

DISCUSSION

Limitations of Modern medicine Treatment for Frozen Shoulder are-

NSAID'S[17], physiotherapy[18], oral and injectable corticosteroids[19] can't be given for long-term use. Long-term oral steroids have side effects like hyperglycemia, gastritis, gastric ulcer, hypertension, osteoporosis,[19] etc. Also injectable Steroids give short-term relief in pain.[20] Surgical management does not offer complete relief.[21]

Limitations of Snehan (application of oil) with Swedan[22] are-

These are two procedures that can't be given at a time. Only after Snehan procedure Swedan is given to the patients. Pre preparation, main treatment, and post-treatment requires approximately 1 hour 15 minutes. So it's a time consuming treatment. This treatment is dependent on personal skill, Man power requirement is high (1massure,1 attendant), At the time of procedures patient's feel some discomfort[23], Maintenance of Temperature, Volume, Pressure is not possible, Efficient absorption of the treatment oil is not possible, The frequent handling of hot pots is risky and accident- prone.

To overcome all these limitations of Snehan-Swedan an innovative procedure Amsabasti will be given.This procedure will be unique; in the sense provides the dual effect of Snehan and Swedan at the same time or it may be termed as 'Snehayukta Swedan. It's not a time consuming treatment as compared to Snehan-Swedan. The time required to complete will be 45 minutes. It's not dependant on personal skill. Manpower requirement is not high.(only 1 attendant). Amsa Basti will be highly beneficial oil pooling treatment for Avabahukin following ways –

- It will maintain the required pressure of oil by its volume.
- As a larger area will be covered by Amsabasti Yantra there will be more efficient absorption [26] of the treatment oil.
- Effective temperature of medicated oil will be intelligently achieved and maintained by insulated heating device
- Insulated heating device will be shockproof and safe.
- Insulated heating device will be capable of preventing accidental injuries through automatic restriction of very high oil temperatures.
- Highly accurate digital temperature sensor which communicates with the intelligent controller will inform the current temperature of treatment oil at frequent intervals.
- The previous clinical studies have been done on Snehan-Swedan which has got certain limitations, that's why to overcome these limitations this study is initiated to validate the concept of AmsaBasti. This 'SnehayuktaSwedan' Amsa Basti will be time-consuming treatment and will be more efficacious in relieving pain, stiffness, and range of movement of AmsaSandhi (Shoulder Joint)as compare to Snehan-Swedan.

Statistical analysis: The changes from baseline will be analyze by using Mann–Whitney U test.

Time duration till follow-up: The patient will be followed up during the treatment of 21 days.

Time schedule of enrolment, interventions: Drug will be given from 0 to 21 days.

Recruitment: 140 (70 in each group) patients will be recruited by simple random sampling Lottery method, and PI will allocate and enroll the patient.

METHODS

Data collection methods: Assessment criteria:

Bahupraspandhitahara (Restricted movements of shoulder region) -range of movement for shoulder will be measured using a Goniometer., Amsasandhishoola (shoulder pain) – will be assessed by the Visual Analogue Scale, Sparshaasahishnuta (Local tenderness) - by scoring method, Amsasandhistabdhata (Shoulder stiffness) - by scoring method and DASH questionnaire. [Disability of Arm, Shoulder, and Hand] will be assessed before and after treatment. We will stay in touch with patient by taking contact no. and timely advise them for

medication and follow up and data of follow up the patient will be stored in documentation with reason.

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

Statistical methods: Statistical assessment will be done through Mann – Whitney U test.

Ethics and dissemination: Research ethics approval; approval from research ethics committee has taken. Ref.No.-REF/MGACHRC/IEC/August-2020/101.

Consent or assent: The written consent will be taken from the patient before starting the study. During the study the confidentiality of each patient will be maintained.

Dissemination policy: The data will be disseminated by paper publication.

Authorship eligibility guidelines and any intended use of professional writers.

Informed consent materials: With all the information model consent form and other related documentation will be given to participants.

Strengths: If Laghuvishgarbha tail Amsabasti and TrayodashangGuggulu will work together [synergistic action of the treatment] in the improvement of Shoulder Joint functions it will be beneficial for the cure of Avbahuka. Amsabasti Yantra is anticipated to help in other Amsa sandhi [shoulder joints] ailments also. This study will contribute to safe and effective therapy of Avabahuka.

Limitations: This study will not be conducted on major systemic diseases, local injury, post traumatic conditions.

Figure 1: Gantt chart (On Quarterly basis 1 Quarter = 3 months)

Item	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9
Pilot Study									
Enrolment of Volunteer									
Data collection									
Writing the thesis parts up to methods									
Data analysis									
Writing the thesis parts up to results and Conclusions									
Submission									

CONCLUSION

Conclusion will be drawn by suitably analyzing data.

CONFLICT OF INTEREST

Nil

SOURCE OF FUNDING

Nil

ETHICAL CLEARANCE

Taken from institutional ethics committee

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