

Efficacy of *Gunja Beeja* Ointment versus Diclofenac Sodium Ointment in the Management of *Avabahuka* (Frozen Shoulder): A Research Protocol for a Randomised Controlled Trial

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ABSTRACT

Introduction: *Avabahuka*, primarily caused by vitiated *Vata* affecting the *Amsa Sandhi*, manifests as shoulder dysfunction. *Acharya Sushruta*, categorise *Avabahuka* as a *Vata Vyadhi*, recommending *Vatavyadhi Chikitsa*. Symptoms include loss of upper limb movement, pain, and shoulder joint stiffness. In modern medicine, *Avabahuka* is analogous to Frozen Shoulder or Adhesive Capsulitis, impacting 2-5% of people in general and 10-15% of diabetics. *Charaka Samhita* recommends *Lepa* (paste) for immediate relief.

Need of the study: The modern treatment includes analgesics and local intra-articular injections of corticosteroids, and physiotherapy. Nonsteroidal anti-inflammatory drugs have side effects such as nephrotoxicity, infectious arthritis and cartilage damage. There is a need for a safe and effective *Ayurvedic* herbal drugs which can be beneficial in such cases. *Gunja Beeja* contains *Abrin* and *Abralin* that has analgesic, anti-inflammatory and antimicrobial activities. No randomised controlled trial has been conducted on *Gunja Beeja* ointment in *Avabahuka*.

Aim: To evaluate the efficacy of *Gunja Beeja* ointment versus diclofenac sodium ointment in the management of *Avabahuka* (Frozen Shoulder).

Materials and Methods: This single-blind, parallel randomised controlled trial will take place over a period of one and a half years (February 2025-January 2026) at the Mahatma Gandhi Ayurved College Hospital and Research Centre (MGACH & RC), Salod (H) Wardha, Maharashtra, India. The study registered under CTRI/2024/07/070559 involves 60 patients meeting the inclusion criteria, randomly assigned into two groups of 30 each. Group 1 will receive Diclofenac sodium ointment while Group 2 will receive *Gunja Beeja* Ointment with shoulder exercises in both groups, once daily for seven days. Assessments will be conducted on days 0, 7, and 14, with follow-up on day 14. Outcomes will be measured using range of shoulder movement (Goniometer), pain (Visual Analogue Scale), stiffness (scoring method), muscle atrophy (measured in centimeters), and the Disability of Arm, Shoulder, and Hand (DASH) questionnaire.

Keywords: *Amsa sandhi*, Adhesive capsulitis, *Lepa*, *Vatavyadhi chikitsa*

INTRODUCTION

Avabahuka is caused mainly by vitiated *Vata* which affects *Amsa Sandhi* [1]. Therefore, *Avabahuka* means dysfunction of shoulder. *Acharya Sushruta* and other *Acharyas* considered *Avabahuka* as *Vata Vyadhi*. *Madhavidana* describes two stages of *Avabahuka*: *Amsashosha* (caused by vitiated *Vata*) and *Avabahuka* (caused by vitiated *Vata* and dryness of *Shleshak Kapha*) [2]. The three main characteristics of *Avabahuka* are *Bahupraspandidhara* (difficulty or loss of movement of the upper limb), *Shoola* (pain) and *Amsabandhana Shosha* (stiffness of shoulder joint) [3]. In modern science, *Avabahuka* is correlated with frozen shoulder or adhesive capsulitis as the pathology involves the capsule of the joint as mentioned by various researches in their study [4]. It affects around 2% to 5% of the general population and 10% to 15% of those with diabetes [5,6]. *Shamana Chikitsa* can be given in the form of *Bahya* and *Abhyantar chikitsa* [7]. In *Bahya chikitsa* for pain and stiffness *Lepa Chikitsa* with various *Vatashamaka* herbs is indicated for instant relief [8]. Most of the studies available are on *Nasya* and *Agnikarma* but studies on *Bahya Chikitsa* are not conducted for *Avabahuka*. In *Yogarajnakar Gunja Beeja Lepa* is mentioned for *Avabahuka Chikitsa* [9]. In this study *Gunja Beeja Lepa* is modified to ointment to increase the duration of retention and easy applicability. *Gunja* contains alkaloids like *Abrin*, *Abusine*, *N-Methyltryptophan*, glycosides like *Abrusion A*, *Precatorine*; Flavonoids like *Quercetin*, *Kaempferol*

and saponins like *Abrus sapogenin* which shows anti-inflammatory, antioxidant and analgesic effect. It Inhibit inflammatory mediators, interact with opioid receptors for analgesia, scavenge free radicals, reducing oxidative stress, modulate immune responses, reducing inflammation and relax muscles, improving mobility [10]. Diclofenac sodium ointment is a topical non-steroidal anti-inflammatory drug used to treat pain, inflammation and stiffness. But in some cases, it causes skin irritation, pruritus, burning sensation and contact dermatitis [11]. Hence, there is a need of safe and effective *Ayurvedic* herbal drug beneficial in such cases. No randomised controlled trial has been conducted on *Gunja Beeja* Ointment for the treatment of *Avabahuka*.

REVIEW OF LITERATURE

According to the *Sushruta* and *Vagbhata*, *Avabahuka* is a *Vatavyadhi*, or illness brought on the vitiation of *Vatadosha*. *Sushruta* promoted adhering to *Vatavyadhi Chikitsa*. The *Avabahuka* is described by *Madhavkar* in the *Madhav-Nidan Vatavyadhi* chapter. According to *Madhukosha*, there are two stages of *Avabahuka*. *Amsashosha* (caused by vitiated *Vata*) and *Avabahuka* (caused by vitiated *Vata* and dryness of *Sheshak Kapha*). The *Yogarajnakar* brought up the use of shoulder joint movements, or *Bahu-Parivartana*, as a cure for frozen shoulder [12]. Descriptions of *Avabahuka* can also be found in other *Ayurvedic* texts, such as *Bhaisajya*

Ratnawali, Sahasrayoga, Gadnigraha, Bangsen, Vangasena and Vrihatnighanturatnakar, etc., [13]. The study conducted by Wadnerwar NN et al., concluded that *Gunja Beeja Lepa* has been proved to be effective in comparison with standard anti-inflammatory Ayurvedic drug *Shunthi* in inflammatory conditions of either mono or bi Arthritis. But the local application should be restricted for limited time only to avoid adverse drug reaction. Similar study can be conducted with red variety of *Gunja* with *Shodhana* and white variety of *Gunja* with and without *Shodhana* to assess their efficacy without any adverse effects. As *Gunja* has been proved efficacious for external application in reducing pain and inflammation, the liniments or spray with the ingredients of *Gunja* may open new dimensions in sports medicine to relive the pain and swelling instantly [14]. The study conducted by Akki M et al., concluded that *Avabahuka* can be co-related to Frozen Shoulder based on the clinical features mentioned in classics. Overall, *Svalpa Masha Taila Nasya* (Group A) is more effective clinically and statistically than *Parinata Kerikskeeradi Taila Nasya* (Group B) in almost all the parameters. Highly significant results indicated that therapeutic effects like *Vedanasthapana*, *Sthambhara*, i.e., improvement in degree of shoulder joint movement is achieved to great extent by *Nasya Karma* [15]. The study conducted by Tankitjanon P et al., compared the Topical Diclofenac (TD) and Court-type Traditional Thai Massage (CTTM) in a randomised controlled experiment to treat frozen shoulder. In terms of enhancing Shoulder Range Of Motion (SROM) and reducing the severity of discomfort, the results indicated that CTTM was superior than TD. Over the course of six weeks, both treatments significantly improved SROM and discomfort, although CTTM made more progress than TD in these areas. After therapy, the CTTM group also had considerably superior quality of life scores. Additionally, CTTM has shown no adverse effects, indicating that it is a viable non pharmacological option for treating frozen shoulder [16].

The aim of the present study is to evaluate the comparative efficacy of *Gunja Beeja* ointment versus Diclofenac Sodium ointment in the management of *Avabahuka* (frozen shoulder).

Primary objective:

- To assess the efficacy of *Gunja Beeja* Ointment on objective and subjective parameters of *Avabahuka* (frozen shoulder).
- To assess the efficacy of Diclofenac Sodium Ointment on subjective and objective parameters of *Avabahuka* (frozen shoulder).
- To compare the effectiveness of *Gunja Beeja* Ointment and Diclofenac Sodium Ointment on subjective and objective parameters of *Avabahuka* (frozen shoulder)

Null Hypothesis (H0)- *Gunja Beeja* Ointment is not as efficacious as Diclofenac Sodium Ointment in management of *Avabahuka* (frozen shoulder).

Alternate Hypothesis (H1)- *Gunja Beeja* Ointment is as efficacious as Diclofenac Sodium Ointment in management of *Avabahuka* (frozen shoulder).

MATERIALS AND METHODS

This single-blind, parallel randomised controlled trial will take place over a period of one and a half years (February 2025-January 2026) at the Mahatma Gandhi Ayurved College Hospital and Research Centre, Salod (H) Wardha, Maharashtra, India with a sample size of 60 subjects, 30 in each group. The ethical approval is obtained from the Institutional Ethical Committee (IEC) (MGACHRC/IEC/Jun-2024/841). The CTRI/2024/07/070559. Registration number for the experiment is attached to it. Prior to the trial commencing, informed consent will be obtained. [Table/Fig-1] shows the study protocol's Gantt chart.

Sample size calculation: Sample size by Cohen's effect size by comparing two means for assessing pain using VAS between

Scholar/Investigator	Dr. Shreya Parkhi					
Title	Evaluation of comparative efficacy of Gunja Beeja ointment versus Diclofenac sodium ointment in the management of avabahuka (frozen shoulder): A randomised controlled trial					
Steps	Q1 (June 2024)	Q2 (October 2024)	Q3 (February 2025)	Q4 (May 2025)	Q5 (August 2025)	Q6 (January 2026)
IEC authorisation						
Overview of the literature						
Medicine preparation						
Patients enrolled						
Collection of data						
Analysis						
Writing of thesis						
Submission						

[Table/Fig-1]: Study protocol's Gantt chart.

two groups Group A- *Gunja Beeja* Ointment Group B- Diclofenac sodium ointment:

$$\text{Effect size} = d = \frac{\mu_2 - \mu_1}{\sigma^2} = 0.8 \text{ (Estimated)}$$

Considering large effect size difference=0.8 (Large effect size)

$$\text{Sample size } N = \left(\frac{1+r}{r} \right) \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2}{d^2} + \frac{Z_{1-\alpha/2}^2}{2(1+r)}$$

$$Z_{1-\alpha/2} \text{ at 5 \% level of significance} = 1.96$$

$$Z_{1-\beta} \text{ at 80 \% Power} = 0.84$$

$$\text{Ratio allocation (Group 2/Group 1)} = 1$$

$$\text{Sample size } n = \left(\frac{1+1}{1} \right) \frac{(1.96 + 0.84)^2}{0.8^2} + \frac{(1.96)^2}{2(1+1)} = 26 \text{ per group.}$$

Considering 15 % drop out total=4

Total 30 samples required per group.

Inclusion criteria:

- Patient willing to participate with written informed consent
- Age group between 31-60 years of either sex
- Painful/Freezing Stage (10 to 36 weeks) and Frozen Stage (4 to 12 months) of *Avabahuka*
- Patients having clinical sign and symptoms of *Avabahuka*

Exclusion criteria:

- Known cases of Dislocation and fracture of shoulder joint
- History of trauma to shoulder
- Other disorders like uncontrolled diabetic mellitus, cancer, TB etc.,
- Pregnant and lactating women

Withdrawal criteria: Subject will be withdrawn from the study if any adverse effect or aggravation of symptoms arise. Then the subjects will be offered treatment free of cost till the problems subside.

Preparation of drug: The local market will be the source of the raw medications.

Identification and authentication will be done by Dravayguna Department, MGACH & RC, Salod(H), Wardha, Maharashtra, India. Under the direction of subject matter specialists, Good Manufacturing Practices (GMP)-certified Rasa Shala (Dattatraya) of MGACH & RC will prepare *Gunja Beeja Churna*. Toxins will be removed from the *Gunja* seeds while maintaining their effectiveness using a 6-hour boiling process at 100°C in cow's milk (*Shodhana*) [17]. The *Gunja Beeja Taila* will be heated until the foam is removed.

Wax will become liquefied when heated. After adding *Gunja Beeja Taila* and stirring until a homogeneous mixture forms, a semisolid ointment formulation with a consistent consistency will be produced. It will be filled in suitable containers (tubes). The patients will be advised to apply it in quantity sufficient on affected area, once a day for seven days. Diclofenac sodium in the form of ointment will be purchased, under the brand name Dicloviv from Liveath BioPharma Pvt., Ltd.

Shoulder home exercise: Pendular exercise, wall climb stretching exercise (finger walk), scapular retraction and posterior capsule stretch will be advised all the participants, once a day for seven days, for twenty minutes in each group [18].

Primary outcomes: There will be reduction in objective *Bahupraspandhitahara* (range of movement) and *Amsashosh* (Muscle wasting) and subjective *Amsasandhi Shoola* (Pain in shoulder joint), *Amsasandhi Stabdhatta* (Stiffness of shoulder joint), and DASH questionnaire parameters.

Schedule of enrollment, interventions: Drugs administration will be once a day for seven days. Following the intervention, assessments will be made on days 0-7 and 14; follow-up will be conducted on day 14.

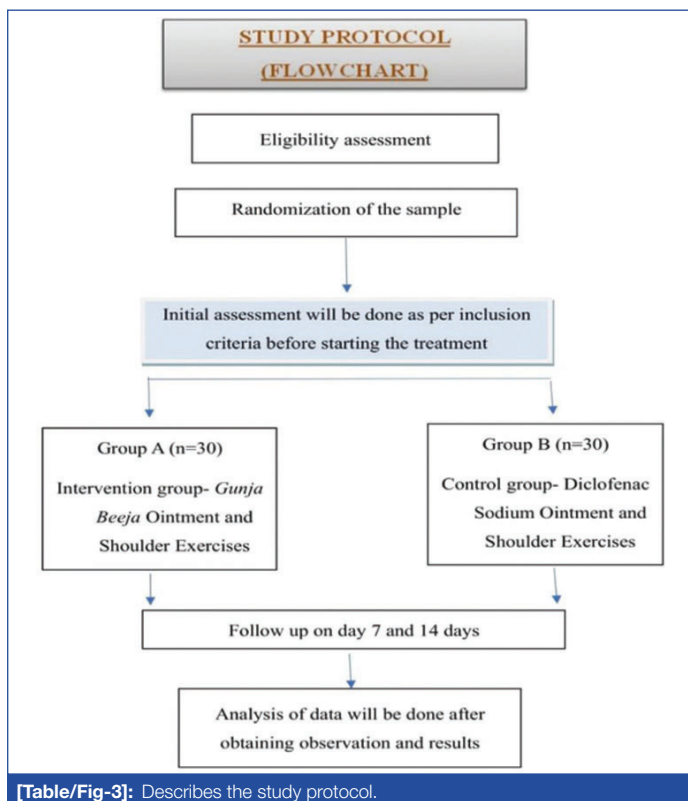
Implementation: The subjects will be registered by principal investigator, and assessment will be done by the second investigator, there will be two groups, each with 30 patients [Table/Fig-2].

Group	Sample size	Intervention	Dose and frequency	Duration	Follow-up
A	30	<i>Gunja Beeja</i> ointment	Q.S OD	7 days	On 7 th and 14 th day
B	30	Diclofenac Sodium ointment	Q.S OD	7 days	On 7 th and 14 th day

Should do home exercises for 20 mins, once daily in both groups.

[Table/Fig-2]: Posology and grouping.

The protocol for the study has been presented in [Table/Fig-3].



Assessment Criteria

Objective criteria

- Bahupraspandhitahara* (range of movement of shoulder)- using Goniometer [19].

- Amsashosh* (Muscle wasting)- measured in centimetres

Subjective criteria

- Amsasandhi shoola* (Pain in shoulder joint)- by Visual Analogue Scale [20].
- Amsasandhi stabdhata* (Stiffness of shoulder joint)- by scoring method [21]
- DASH questionnaire [22].

DASH questionnaire (Disability of arm, shoulder, and hand): It is an appropriate tool for the evaluation of upper limb pathology according to WHO guidelines. In 1996 Hudak published their move toward the assessment of disability-the DASH score, a self-administrated questionnaire which includes 30 points related to functional activities and symptoms in Activities of Daily Living (ADL). The patient is asked to point a score of 1 to 5 on all 30 points. Scores rise with increasing disability [Table/Fig-4].

	कोणतीच अडचण नाही	किंचित अडचण	मध्यम अडचण	तीव्र अडचण	अकार्यक्षम
1 घट्ट किंवा नवीन बरणी उघडा.	1	2	3	4	5
2 लिहिणे	1	2	3	4	5
3 चाबीला फिरविणे	1	2	3	4	5
4 जेवण बनविणे	1	2	3	4	5
5 जड दरवाजा उघडणे	1	2	3	4	5
6 वस्तूला वर ठेवणे	1	2	3	4	5
7 घरातील भारी कामे करावे (उदा. भिंती पुसणे, जमीन पुसणे)	1	2	3	4	5
8 बागीच्या मध्ये काम करा	1	2	3	4	5
9 अंधारूण घालणे	1	2	3	4	5
10 खरेदीची पिशवी किंवा ब्रीफकेस उचलणे	1	2	3	4	5
11 5 किलोपेक्षा जड वस्तू उचलणे	1	2	3	4	5
12 डोक्यावर लाइट बल्ब बदलणे					
13 केसना धुणे	1	2	3	4	5
14 अंधोल करताना पाठ धुणे	1	2	3	4	5
15 वरून स्टेयर घालणे	1	2	3	4	5
16 चाकूने भाजीला विरणे अथवा कापणे	1	2	3	4	5
17 मनोरंजक उपक्रमला करावे (उदा. पत्ते खेळणे, स्टेयर विणणे)	1	2	3	4	5
18 असे मनोरंजक उपक्रम ज्याने हाथ, हाथाचा संधिभाग, खांद्या भागावर ताण येईल करावे (उदा. गोल्फ खेळणे, टेनिस खेळणे)	1	2	3	4	5
19 असे मनोरंजक उपक्रम ज्यात हाथ मोकळेपणाने घुमवता येतो (उदा. बॅडमिंटन)	1	2	3	4	5
20 प्रवास करणे (एका जागेवरून दुसऱ्या जागी जाणे)	1	2	3	4	5
21 संभोग क्रिया	1	2	3	4	5
22 मागच्या आठवड्यात तुम्हाला तुमच्या रोजच्या उपक्रमांमध्ये किती त्रास झाला (कुटूंब, मित्र, शेजारी)	1	2	3	4	5
	काहीच त्रास नाही	किंचित मर्यादित त्रास	मध्यम मर्यादित त्रास	जास्त मर्यादित त्रास	तीव्र मर्यादित त्रास
23 मागच्या आठवड्यात तुम्हाला तुमचे नेहमीचे काम करताना हाथाच्या त्रासाने किती कष्ट गेले	1	2	3	4	5
कृपया मागील आठवड्यात अनुभवलेल्या लक्षणांना त्याच्या तीव्रतेनुसार खालील नंबरवर गोल करावे					
	काहीच नाही	किंचित	मध्यम	जास्त	तीव्र
24 हाताच्या वेदना (हाताचा वरील भाग) , खांद्याच्या वेदना, संपूर्ण हाताच्या वेदना	1	2	3	4	5
25 जेव्हा एखादा उपक्रम करता तेव्हा कोणत्या हाताच्या भागात वेदना जास्त होतात (हाताच्या वेदना (हाताचा वरील भाग) , खांद्याच्या वेदना, संपूर्ण हाताच्या वेदना)	1	2	3	4	5
26 येथे कोणत्या भागात सुई टोचल्या प्रमाणे वेदना होतात (हाताचा वरील भाग, खांद्या, संपूर्ण हात)	1	2	3	4	5
27 अथवाकापणा वाटणे (हाताचा वरील भाग, खांद्या, संपूर्ण हात)	1	2	3	4	5
28 कडकपणा जाणवणे (हाताचा वरील भाग, खांद्या, संपूर्ण हात)	1	2	3	4	5
	काहीच त्रास नाही	किंचित (सोम्य) त्रास	मध्यम त्रास	तीव्र त्रास	अतितीव्र त्रास कि झोपच आली नाही
29 मागच्या आठवड्यात, झोपताना हाताचा वरील भाग, खांद्या, संपूर्ण हातहा भागामध्ये दुखण्यामुळे किती त्रास झाला	1	2	3	4	5
	तीव्र निषेध	निषेध	निषेध पण नाही आणि सहमत नाही	सहमत	तीव्र सहमत
30 माझ्या हाताचा वरील भाग, खांद्या, संपूर्ण हातहा भागामध्ये दुखण्यामुळे मी स्वतःला कमी सक्रम, कमी विश्वास, किंवा कमी कार्यक्षम समजतो	1	2	3	4	5

Dash disability/Symptom Score= [(sum of n responses / n) - 1] x 25 Where 'n' is the number of completed responses

A DASH score May Not Be Calculated If there are greater than 3 missing items.

[Table/Fig-4]: DASH questionnaire

Data coding will be handled by the principal investigator. Prior to the study's commencement, the patient's written consent will be obtained. Every patient's confidentiality will be upheld throughout the investigation. Publication of papers will be used to spread the

data. The qualifying criteria for authors and the planned usage of expert writers. Informed written consent will be taken from each participant.

STATISTICAL ANALYSIS

All the result will be calculated using Statistical Package for Social Sciences (SPSS) software version 17. Descriptive statistics will be performed for describing all demographic variables, frequency and percentage will be calculated for qualitative measurement mean standard deviation will be calculated for quantitative measurement. Parametric and non-parametric tests will be used to calculate quantitative and qualitative data respectively. Comparison will be done by using Chi-square test for qualitative data. Paired and unpaired t-test will be used for analysing quantitative data. Outcome variables like *Amsasandhi shoola* (pain in shoulder joint) will be assessed by visual analogue scale. *Amsasandhi stabdhata* (Stiffness of shoulder joint) by scoring method and quality of life will be assessed by DASH questionnaire score. *Amsashosh* (Muscle wasting) will be measured in centimetre and *Bahupraspandhitahara* (range of movement of shoulder) will be measured in angles by goniometer. The level of significance is taken at 0.05 or 5%. The expected outcome of the study will be reduction in objective *Bahupraspandhitahara* (range of movement), *Amsashosh* (Muscle wasting) and subjective *Amsasandhi Shoola* (Pain in shoulder joint), *Amsasandhi Stabdhata* (Stiffness of shoulder joint), and DASH questionnaire parameters.

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