



## **A Protocol for Treatment of Avabahuk (Frozen Shoulder) with *Agnikarma* and Topical Diclofenac Sodium Gel**

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### **Authors' contributions**

*This work was carried out in collaboration among all authors. Author MK designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Authors RKS and RJ managed the analyses of the study. Author RJ managed the literature searches. All authors read and approved the final manuscript.*

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**Study Protocol**

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## **ABSTRACT**

**Background:** The Avabahuk is a disease described in ancient Ayurveda and is correlated with frozen shoulder of modern science. It is mainly due to vatadosha prakopa and the treatment adopted for this are for snayu-sandhi-asthi-gata-vata. Many treatment modalities mentioned in Ayurveda for treatment of *Avabahuka*. The treatment modality *Agnikarma*, the intentional therapeutic heat burn therapy is one among them.

**Aim and objectives:** The aim of the study is to compare efficacy of *Agnikarma* and topical Diclofenac sodium gel in Avabahuk (Frozen shoulder) treatment.

**Methodology:** The sample size will decide in pilot study and the patients will randomly divided equally into 2 groups. In Group A (Interventional) the *Agnikarma* will be done at weekly interval for 4 weeks along with physiotherapy. In Group B (comparator group) the topical diclofenac sodium gel application for 4 weeks with physiotherapy.

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**Results:** The changes will be observed and recorded in objective outcomes.

**Conclusion:** *Agnikarma* will be effective in lowering the pain and stiffness of frozen shoulder.

**Keywords:** *Agnikarma; avabahuka; diclofenac sodium gel; frozen shoulder.*

## 1. INTRODUCTION

*Acharya Sushruta*, the father of Surgery has included *Avabahuka* and *Anshashosha* in *vatavyaadhi* [1]. The description of *Avabahuka* is also available in *Charak Samhita* [2,3], *Ashtanga Hridaya* [4]. The general causes of *Avabahuka* are intake of excess *vatavardhak* ahara-vihara, trauma at neck region, dislocation of shoulder joint, fracture of clavicle, injury in brachial plexus. The *anshamarma* is a *vaikalyakar marma* that injury causes to *stabdhata (tatrastabdhahuta)* (*Sushrut. Shareer .6/27*). The similar features seen in *Avabahuka* diseases. The common features of *Avabahuka* are *sira-sankocha* at *Ansha-sandhi*, loss of functional activity of arm (*baahu- praspandithar*), atrophy of arm (*bahu- shosha*) (*anshamool sthitovaayu sira-sankochyatatragaah, baahupraspanditharamjanyatayavabaahukam- Astanga.Hridaya.Nidana.15/43*), *karmakshaya of bahu (arm)*. The treatment mentioned in *Ayurveda* for *Avabahuka* is *nasya karma, snehapaan*, food after intake of *sneha*, local *abhyana-swedana* (oleation - sudotion) [5]. The *Sushruta* mentioned that the main cause of *avabahuk* is *vataprapopa* and the treatment of *snayu-sandhi-asthigatavata* is by repeated *snehana* (oleation), *upnaha* (poultice application), *Agnikarma* (intentional therapeutic heat burn therapy), *bandhan* (bandaging), *mardan* (massage) (*Sushrut.Chikitsa.5/8*) [6]. *Sushruta* also mentioned to do *vatavyadhi-chikitsa* in cases of *Avabahuka* (*Sushrut Chikitsa.5/23*). The *Avabahuka* is correlated with frozen shoulder as described in modern medical science [7]. Somewhere the *Avabahuka* mentioned as paralysis of brachial plexus and *Ansha-shosha* as atrophy of shoulder joint [8].

The term frozen shoulder, adhesive capsulitis, painful stiff shoulder, peri-arthritis are used synonymously. The American Academy of orthopaedic surgeons define the Frozen shoulder as "A condition of varying severity characterized by the gradual development of global limitations of active and passive shoulder motion where radiographic findings other than osteopenia are absent" [9]. Most of the cases of frozen shoulder are idiopathic and some have secondary origin like trauma, after surgery etc. [10]. Mostly the

patient managed in the primary care setting by patient education, explaining natural history, increase compliance and removing fears [11]. Generally, the full range of movement not restored completely. The NSAIDs [12] (nonsteroidal anti-inflammatory drugs), glucocorticoids, intra-articular injections, physical therapy are common methods to cure frozen shoulder [13,14]. The NSAIDs reduces the pain and swellings.

The *Agnikarma* mentioned in *Ayurveda* as a simple intentional therapeutic heat burn therapy in heads of parasurgical procedure. *Agnikarma* are indicated in various medical and surgical diseases like musculoskeletal diseases, tennis elbow, *Avabahuka*, backache, osteoarthritis, corn, wart, mole, sinus, haemorrhage, etc. *Agnikarma* is performed with the help of *shalaka* at specific site in particular way [15].

## 2. RATIONALE OF THE STUDY

The common conservative treatment of frozen shoulder is anti-inflammatory analgesic drugs, but it is not helpful in curing the diseases. The different modalities like marma therapy, physiotherapy, surgery etc also available for treatment of frozen shoulder but have their limitations. The Physiotherapy requires costly instruments and is time taking procedure with their complications. The surgical treatment is available at higher centre, not an easy task and costly. The diclofenac gel have mainly pain relieving effect. The non-pharmacological treatment marma therapy are in practice but not have an established treatment.

It is worth mentioning that *Agnikarma* is day care procedure and non-pharmacological management of pain and stiffness of frozen shoulder. Various researches on effect of *Agnikarma* on frozen shoulder have been published in various journals. The detail will be provide in original article. The *Agnikarma* is *vata* and *kapha shamak* modality so selected for treatment of *Avabahuk (vatavyaadhi)*. The classics of *Ayurveda* such as *Sushruta Samhita* has categorized *Agnikarma* in parasurgical procedure for treatment of *vataja* and *kaphaja roga*, pain management etc. In other words, *Agnikarma* is indicated in *snayu-asthi-*

*sandhigatavata* (*Sushruta chikitsa sthana chapter 5/8*) in *vataavyaadhichikitsa*. It is non-pharmacological, cost effective, economically viable, easy to perform, even at remote areas and day care procedure for management of *Avabahuka*. This clinical study may be useful at all levels of community.

### 3. AIM AND OBJECTIVE

#### 3.1 Aim

To compare efficacy of Agnikarma and topical Diclofenac sodium gel in the management of Avabahuk (Frozen shoulder).

#### 3.2 Objectives

1. To assess efficacy of Agni karma in management of pain intensity and shoulder range of movement (ROM).
1. To assess efficacy of Diclofenac sodium gel in Management of Avabahuk (Frozen shoulder).
2. To compare efficacy of Agnikarma and topical diclofenac sodium gel in the management of Avabahuk (Frozen shoulder).

### 4. CASE DEFINITION

Diagnosed cases of Avabahuka (frozen shoulder). The patient should have normal X - Ray shoulder with sign symptoms of Avabahuka (frozen shoulder) i.e. Ansha-deshasthit vaayu (affected shoulder region), shool (pain), stambha (stiffness) and bahupraspandithar (significant restriction of movement).

#### 4.1 Research Question

Whether the Agni karma is more efficacious as compared to topical diclofenac sodium gel application in the management of Avabahuka (Frozen shoulder)?

#### 4.2 Hypothesis

- Alternative Hypothesis (H1): Agnikarma is more efficacious in the management of frozen shoulder as compared to topical diclofenac sodium gel application.
- Null Hypothesis (H0): There is no difference in efficacy between Agnikarma

and topical diclofenac sodium gel in the management of frozen shoulder.

### 4.3 Trial Design

A randomized control trial (RCT)-Reference standard control trial, open study. Interventional study on 2 parallel groups having 1:1 ratio.

### 5. METHODOLOGY

#### 5.1 Study Setting

The study will be conducted in academic hospital MGACH & RC, Salod (H), Wardha.

#### 5.2 Registration Number

REF/2021/02/040850, the CTRI registration for this trial is under process [Registered on: 10/02/2021].

#### 5.3 Inclusion Criteria

- a) Participant with clinical features of Avabahuka (frozen shoulder) having unilateral involvement will be included after screening.
- b) Participant with age group of 40 to 70 years.
- c) Participant irrespective of sex, occupation and economic status.
- d) Participants willing to give written informed consent

#### 5.4 Exclusion Criteria

- a) Participant suffering with hypertension, tuberculosis, HIV, hepatitis B, known cases of malignancy, gastritis
- b) Diabetes mellitus patient having fasting blood sugar more than 200 mg /dl and Less than 70 mg /dl
- c) Patient have past history of shoulder joint surgery d) Patient have history of fracture of shoulder joint, malunion, traumatic arthritis.
- d) Highly immunocompromised patient.
- e) Patient have major psychiatric illness.
- f) Pregnant lady, lactating mother.

#### 5.5 Interventions

There are two groups in this study. The participants will be divided into 2 groups as mentioned in Table 1.

**Table 1. Interventions of groups**

<b>Group A Agnikarma</b>	<p><b>A. Poorva-karma</b></p> <ul style="list-style-type: none"> <li>• Diagnose case of frozen shoulder</li> <li>• Informed written consent</li> <li>• Local part preparation with dashmool kwath</li> <li>• Collect the required material Aloe vera pulp, yastimadhu powder, sponge holder, gauze piece, cotton, bandage</li> <li>• Copper made Agnikarma Shalaka</li> </ul> <p><b>B. Pradhan karma</b></p> <ul style="list-style-type: none"> <li>• Site of Agnikarma at supero- posterior and lateral aspect (including deltoid insertion area) of shoulder joint, locally, tender side at shoulder region.</li> <li>• Bindu type agnikarma = bindu will be made</li> <li>• By copper made pointed shalaka (dahanopkarana) in red hot condition, exposure time 1 second, and creating specific sound "chit".</li> </ul> <p><b>C. Paschaat karma</b></p> <ul style="list-style-type: none"> <li>• After Agnikarma application of <i>Aloe vera</i> pulp (gel) and yastimadhu churna.</li> <li>• Application of bandage for 24-48 hours and advice to protect it from soaking or any contamination.</li> </ul> <p><b>D. Frequency of Agnikarma</b> – At every week on same days for 4 sitting.</p> <p><b>E. Duration of therapy</b> – 4 week</p> <p><b>F.</b> The fresh <i>Aloe vera</i> pulp applied at burn side with yastimadhu powder after each sitting..</p>
<b>Group B Diclofenac sodium gel – Topical application</b>	<ul style="list-style-type: none"> <li>• Topical application of Diclofenac sodium gel</li> <li>• Thin layer of gel, two times in a day morning evening, with gentle massage at affected shoulder region</li> <li>• Total days of application 4 weeks.</li> <li>• Avoid trauma, do not cover or bandage after its application.</li> </ul>

In each group the same physiotherapy (mobilization exercise) will offer.

**Pre-procedural method:**

- Obtained the consent regarding the procedure.
- Position the subject in a chair, or sitting or lying on a bed.

**Method:** Advice shoulder movement within the range of comfort and with maximum range. Instruct all not stretch suddenly, roughly, forcefully but do gently. Each of these gentle stretch needs to be held up to a count of 100, three rounds in a day. (Reference- <https://orthop.washington.edu/patient-care/articles/shoulder/home-exercises-for-the-stiff-or-frozen-shoulder.html>) [16]

1. Getting the arm up while lying down
2. Getting the arm up overhead while sitting down.
3. Getting the arm to externally rotate while lying down.
4. Getting the arm to externally rotate while standing.
5. Getting the arm up the back.
6. Getting the arm across the body.

### 5.6 Criteria for Discontinuing or Modifying Allocated Interventions

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.

#### 5.6.1 Follow up

14<sup>th</sup> day and 28<sup>th</sup> day after four week study.

### 5.6.2 Primary outcomes

The primary outcome of study is level of reduction of pain and stiffness of the frozen shoulder.

#### 5.6.3 Secondary outcomes

The secondary outcome of study is increase range of movement (ROM) in frozen shoulder patient.

## 5.7 Statistical Analysis

Discrete will be analysed using non-parametric tests. Data on continuous variables will analysed using parametric tests. The data on discrete variables will be presented as n (%). The continuous data will be presented as mean (SD) / Median (Min-Max). A p value of less than 0.05 will be considered significant.

### 5.11 Time Duration Till Follow Up

The patient will be followed up during treatment and on 14<sup>th</sup> day and 28<sup>th</sup> day after four week study.

#### 5.11.1 Follow up period

14<sup>th</sup> day and 28<sup>th</sup> day after four week study.

#### 5.11.2 Time schedule of enrolment, interventions

The intervention will be given for four week. Agnikarma at seven days interval for four week in group A.

#### 5.11.3 Recruitment

Patient will be recruited by randomization sampling method. The PI, supervisor & Co-I will allocate and enrol the patient. The sample size will be decided after pilot study. The study will be conducted in two phase.

- Phase 1 - Pilot study on 12 patient, to determine effect size which is required for calculation of sample size.
- Phase 2 Full research work

## 5.12 Methods

Data collection, management, and analysis.

### 5.13 Data Collection Methods

Case registration form with detailed history and examination i.e.

- Consent form in English, Hindi, Marathi
- Case Record Form (CRF)
- Assessment of objective criteria: The subjective parameters are pain, local tenderness and stiffness. The objective parameter is range of movement (ROM) of shoulder joint which will recorded

according to the actual values of goniometric readings.

- Data of all participants will be collected and reported in case sheet form
- We will stay in touch with patient by taking contact number and timely advise them for medication and follow up and data of follow up patient will be stored in documentation with reason.

## 5.14 Data Management

PI, supervisor & co-supervisor, will do the data entry coding.

## 5.15 Statistical Methods

Discrete will be analysed using non-parametric tests. Data on continuous variables will analysed using parametric tests. The data on discrete variables will be presented as n (%). The continuous data will be presented as mean (SD) / Median (Min-Max). A p value of less than 0.05 will be considered significant.

## 6. EXPECTED RESULT

After therapy, there may be reduction of pain and stiffness of frozen shoulder and increase range of movement of shoulder joint.

## 7. DISCUSSION

*The Avabahiuk* have features of *soshana* of *amsa bandha*, *akunchana* (constriction) of *Sira and .bahupraspandahara*. (*Sishir*) [17]. The many research studies conducted on *Agnikarma* proved its pain reduction property in frozen shoulder. The *Agnikarma* have good result in *Avabahuk* patients particularly that fail to respond with drugs therapy [18]. The reduction of pain, improvement in flexion, elevation and abduction movements noticed after *agnikarma* [19]. The *Agnikarma* have no adverse effect and scars are not permanent [20]. Few of the related studies were reviewed [21-24]. The final discussion of the study will be written on the basis of recorded observation analysis.

### 7.1 Dissemination Policy

The data will be disseminated by paper publication. Authorship eligibility guidelines and any intended use of professional writers.

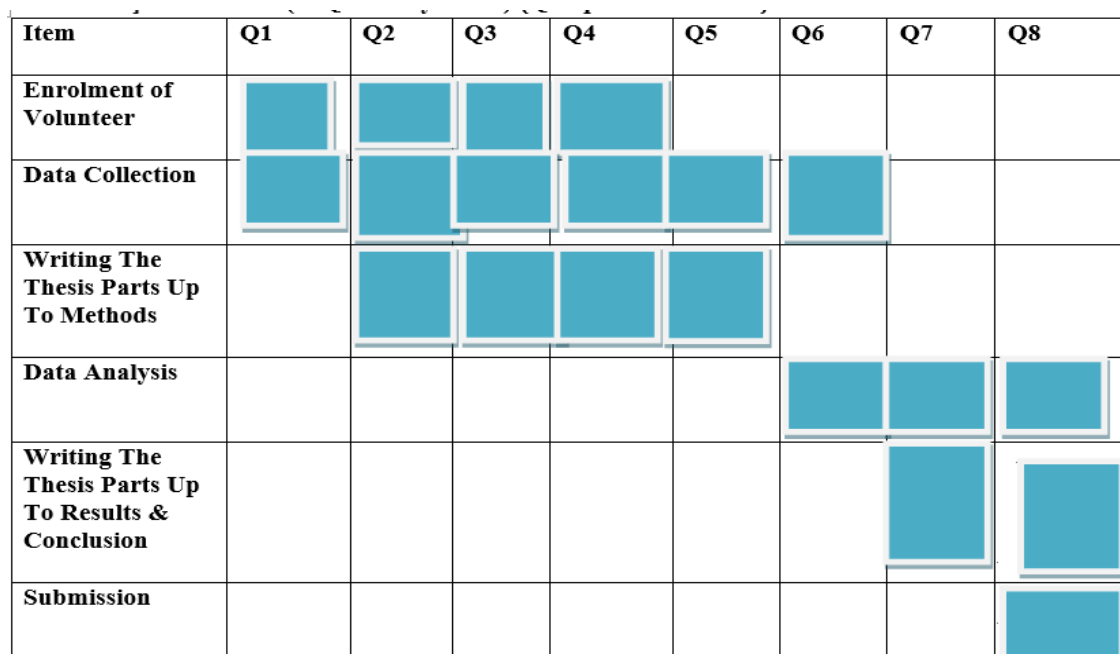


Fig. 1. Gantt chart (in quarterly based)

## 7.2 Informed Consent Materials

With all the information, model consent form and other related documentation will provide to participants.

## 7.3 Strengths

If *Agnikarma* and topical diclofenac gel application on frozen shoulder studied, it will provide the result status and their comparative result. If *Agnikarma* works and improves patient condition and functions, it directly corrects the frozen shoulder. If the proposed study results in the positive outcome then it will give the best parallel modality for the management of frozen shoulder. It may cure *Avabahuk*.

## 8. LIMITATIONS

It is a procedure and single drug therapy to evaluate the efficacy in the management of frozen shoulder. For better results other drugs can be added and combined formulation may be prepared. More patient may be registered to better result.

## 9. CONCLUSION

Conclusion will be drawn by suitably analysing data.

## CONSENT

The written consent will be taken from the patient before starting the study. During the study, the confidentiality of each patient will be maintained.

## ETHICAL APPROVAL

Approval from research ethics committee has taken and registered Number -Ref. No. MGACHRC/IEC/December-2020/166, dated- 11-12-2020.

## COMPETING INTERESTS

Authors have declared that no competing interests exist.

## REFERENCES

1. Sushruta: *Sushruta Samhita*, edited with *Ayurveda-tattva-sandeeepika* Hindi commentary by Shastri Kaviraj AmbikaDutta. Varanasi India: Chaukhambha Sanskrit Sansthan; part-1; Nidan Sthana. 2014; 1/82:304.
2. Shastri Pandit Kashinatha, Chaturvedi Gorakhanatha. *Charaka Samhita* of

- Agnivesh, edited with vidyotinihindi commentary, Chakhumbha Bharati Academy; part-1; Sutra Sthana 1992; 20/11:399.
3. Tripathi Bramhanand. Charaka Samhita of Agnivesh, edited with Charaka Chandrika hindi commentary, Chakhumbha Surbharati Prakashan; part-2; Chikitsa Sthana. 1998;28/98:956.
  4. Kanjiv Lochan. Vagbhata: Astanga Hridaya English commentary; Chaukhambha Publications; Nidhanasthana. 2017;2(15/43):140.
  5. Nirmal, et al. Management of *Avabahuka* (Frozen Shoulder) with Abhyanga Swedana, Pratimarsha Nasya and Ayurveda Medicines: A Case Study, World Journal of Pharmaceutical Research. 2017;6(8):2099-2103. ISSN 2277-7105.
  6. Shastri AD. Ayurveda Tattava sandeepika Hindi commentary on *Sushruta* Samhita, Chaukhambha Sanskrit Sansthan; part-1. Chikitsa Sthana. 2014;4/8.
  7. Negi Vineeta, *Avabahuka* vis-a-vis frozen shoulder: A review, World Journal of Pharmaceutical Research. 7(6):411-422.
  8. Sharma AK. Kayachikitsa part 3, chapter vatavyadhi, Chaukhambha publishers Varanasi, edition. 2011;66-67. ISBN :978-81-89469-06-1
  9. Jefferson R Roberts, Mary L Lan. American academy of orthopaedic surgeon Adhesive Capsulitis (Frozen Shoulder) Updated: Sep 18, 2018. Available:<https://emedicine.medscape.com/article/1261598-overview> last seen on 10-01-2020 7am
  10. Pogorzelski J, et al. Primary (idiopathic) shoulder stiffness: Definition, disease progression, epidemiology and etiology, Unfallchirurg. 2019;122(12):917-924.
  11. Harpal Singh Uppal, Jonathan Peter Evans, Christopher Smith, Frozen shoulder: A systematic review of therapeutic options, World J Orthop. 2015;6(2):263-268. ISSN 2218-5836 (online).
  12. McPherson ML, Cimino NM. Topical NSAID formulations. Pain Med. 2013;14Suppl 1:S35-9.
  13. Franz A, Klose M, Beitzel K, Conservative treatment of frozen shoulder, Unfallchirurg. 2019;122(12):934-940.
  14. Chan HBY, Pua PY, How CH. Physical therapy in the management of frozen shoulder. Singapore Med J. 2017;58(12):685-689.
  15. Tyagi Megha, A pilot study of *Agnikarma* on frozen shoulder (*Avabahuka*), M.S.(Ay) ShalyaTantra, RGUHS Karnataka; 2011
  16. Available:<https://orthop.washington.edu/patient-care/articles/shoulder/home-exercises-for-the-stiff-or-frozen-shoulder.html> last assess on 29-01-2021
  17. Dr Shishir Prasad, et al, Clinical Evaluation of Marma Therapy in Avabahuka W.S.R. to Frozen Shoulder JMSCR. 2017; 05(05):22411.
  18. Tyagi Megha. A pilot study of *Agnikarma* on frozen shoulder (*Avabahuka*), M.S.(Ay) Shalya Tantra, RGUHS Karnataka; 2011
  19. Kumar V, Tukaram SD, Gupta SK, Mahanta VD. From 5th World Ayurveda Congress 2012 Bhopal, Madhya Pradesh, India. 7-10 Dec 2012. OA01. 31. Role of agnikarma in degenerative disorder w.s.r. Avbahuka (Frozen shoulder) - case study. *Anc Sci Life*. 2012;32(Suppl 1):S31.
  20. Ganapathi Rao, Biradar Vijay, Naikar Ashok and Halli Chandranth. Agnikarma in the management of Avabahuka (frozen shoulder), International Journal of Current Research. 2017;9(03):48432-48434.
  21. Wadnerwar Nilima, Prasad KSR, Meena Deogade, Amol Kadu. Comparative study of efficacy of gunja beeja lepa and shunthi churna lepa in inflammatory conditions of arthritis - A Randomized Controlled Single Blinded Clinical Study. International Journal of Ayurvedic Medicine. 2020;11(2):200-204.
  22. Ghungrud Deepali. Effectiveness of mechanical hydrotherapy as a complementary therapy in the management of patients with arthritis pain. International Journal of Modern Agriculture. 2020;9(3):104-10.
  23. Morey Amruta Deepak, Bhushan Sevakram Madke, Adarsh Lata Singh, Sudhir Singh, Sandeep Kulkarni. Response to infliximab biosimilar in a case of reactive arthritis: Our experience.

Journal of Clinical and Diagnostic Research. 2019;13(12).

Available:<https://doi.org/10.7860/JCDR/2019/42695.13357>

24. Khanam Najnin, Vasant Wagh, Abhay Motiramji Gaidhane, Zahiruddin Quazi

Syed. Assessment of work-related musculoskeletal morbidity, Perceived causes and preventive activities practiced to reduce morbidity among brick field workers. Indian Journal of Community Health. 2019;31(2):213–19.

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