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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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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1. INTRODUCTION

Acharya Sushruta, the father of Surgery has included Avabahuka and Anshashosha in vatavyadhi [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 stabdha (tatrastabdhabahuta"(Sushrut. Shareer 5/27). 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- praspadithar), atrophy of arm (bahu-shosha) (anshamool sthitovayu sira-sankochyatratragaah, baahupraspaditharamjanyatayavabaahukam–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 vataprapoka and the treatment of snayu-sandhi-asthigatavata is by repeated snehana (oleation), upnaha (poultice application), Agnikarma (intentional therapeutic heat burn therapy), bandhan (bandaging), mordan (massage)(Sushrut.Chikitsa.5/8) [6]. Sushruta also mentioned to do vatavyadhichikitsa 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 (vatavyadhi). 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-

| Results: | The changes will observed and record 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.
sandhigatavata (Sushruta chikitsa sthana chapter 5/8) in vatavyaadhicikitsa. 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).
2. 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.

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

<table>
<thead>
<tr>
<th>Group A</th>
<th>A. Poorva-karma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agnikarma</td>
<td>• Diagnose case of frozen shoulder</td>
</tr>
<tr>
<td></td>
<td>• Informed written consent</td>
</tr>
<tr>
<td></td>
<td>• Local part preparation with dashmool kwath</td>
</tr>
<tr>
<td></td>
<td>• Collect the required material Aloe vera pulp, yastimadhu powder, sponge holder, gauze piece, cotton, bandage</td>
</tr>
<tr>
<td></td>
<td>• Copper made Agnikarma Shalaka</td>
</tr>
<tr>
<td>B. Pradhan karma</td>
<td>• Site of Agnikarma at supero- posterior and lateral aspect (including deltoid insertion area) of shoulder joint, locally, tender side at shoulder region.</td>
</tr>
<tr>
<td></td>
<td>• Bindu type agnikarma = bindu will be made</td>
</tr>
<tr>
<td></td>
<td>• By copper made pointed shalaka (dahanopkarana) in red hot condition, exposure time 1 second, and creating specific sound “chit”.</td>
</tr>
<tr>
<td>C. Paschaat karma</td>
<td>• After Agnikarma application of Aloe vera pulp (gel) and yastimadhu churna.</td>
</tr>
<tr>
<td></td>
<td>• Application of bandage for 24-48 hours and advice to protect it from soaking or any contamination.</td>
</tr>
</tbody>
</table>

| D. Frequency of Agnikarma | At every week on same days for 4 sitting.                                      |
| E. Duration of therapy   | 4 week                                                                            |
| F. The fresh Aloe vera pulp applied at burn side with yastimadhu powder after each sitting. |

<table>
<thead>
<tr>
<th>Group B</th>
<th>Diclofenac sodium gel – Topical application</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Topical application of Diclofenac sodium gel</td>
</tr>
<tr>
<td></td>
<td>• Thin layer of gel, two times in a day morning evening, with gentle massage at affected shoulder region</td>
</tr>
<tr>
<td></td>
<td>• Total days of application 4 weeks.</td>
</tr>
<tr>
<td></td>
<td>• Avoid trauma, do not cover or bandage after its application.</td>
</tr>
</tbody>
</table>

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

14th day and 28th 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 be 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 14th day and 28th day after four week study.

5.11.1 Follow up period

14th day and 28th 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 be 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 (Sishi) [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.
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.


15. Tyagi Megha. A pilot study of Agnikarma on frozen shoulder (Avabahuka), M.S.(Ay) Shalya Tantra, RGUHS Karnataka; 2011


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