A clinico analytical study on parinata Keriksheeradi Tailam as Nasya Yoga (Nasal Drug delivery) in the management of frozen shoulder

Gayathry MS, Muralidhar P Pujar, Ashutosh Chaturvedi, Ashvini Kumar M, KN Sunil Kumar, Lohith BA

Abstract

Background & Objectives: Nasya karma (Nasal Drug delivery) is the prime treatment modality for drug delivery. The properly administered Nasya Karma not only cures the disorders of head but also imparts strength to the cervical and thoracic region, and chest become thick and well developed. Frozen shoulder is a condition in which pain and stiffness in the shoulder joint will cause gross restriction in all the daily activities of an individual. Even with advanced allopathic treatment modalities, patients are not getting satisfactory relief. Nasya karma is one among the main treatments specially meant for frozen shoulder. Frozen shoulder is included among the indications of Bruhmana Nasya for its strengthen action. Parinata Keriksheeradi Tailam (Compound herbal Preparation) contains the herbs which may be useful in the management of frozen shoulder through nasal drug delivery. By considering these facts the study was conducted to assess the efficacy of Nasya with Parinata Keriksheeradi Tailam in the management for frozen shoulder.

Methods: 32 patients of frozen shoulder were taken in an open label single group clinical study with Nasya Karma with Parinata Keriksheeradi Tailam along with analysis of compound drug.

Results: Results of this study showed that Nasya with Parinata Keriksheeradi Tailam was effective in relieving the symptoms of frozen shoulder. The effect of the therapy proved to have statistically significant result in all the parameters (p<0.001).

Keywords: Nasyakarma, Brumhana Nasya, Vata Vyadhi, Frozen shoulder, Parinata Keriksheeradi Tailam

1. Introduction

Pain and stiffness in the shoulder joint will cause gross restriction in all the daily activities of an individual. Prevalence rate of shoulder joint pain is estimated to between 16% to 26% of the world human population. This condition mainly affects the upper limb and can be diagnosed as frozen shoulder. In ayurvedic classics frozen shoulder has specific line of management. Correct understanding of diagnosis and treatment of frozen shoulder need to be done for proper management of disease [1]. Panchakarma therapy primarily aims at cleansing the body of its accumulated impurities and nourishing the tissues. Once this is achieved, it becomes very easy to rejuvenate the tissues and prevent the process of ageing. This helps the individual to lead a disease free old age and he/she becomes capable of serving the society with his/her accumulated experience without any mental disability and physical decay. Frozen shoulder affecting the Amsa Moola exhibits the symptoms in Bahu [2]. In the management of frozen shoulder, Nasya Karma is one of the modality of treatment principle. Frozen shoulder is included among the indications of Bruhmana Nasya [3] there is a direct reference in the Phalashruti of Parinata Keriksheeradi Tailam that it will cure the frozen shoulder. Parinata Keriksheeradi Tailam contains Haridra, Devadhupa, Tila taila, Coconut milk and Jambeera swarasa [4]. The ingredients of this formulation are having Vatahara, pain reliving and Brumhana (strengthen) properties. By considering these facts it may be postulated that Nasya with Parinata Keriksheeradi Tailam may be the best effective management for frozen shoulder.

2. Materials and Methods

Analytical Study

Physico-chemical characterization, determination of total ash, acid insoluble ash and water soluble ash, loss on drying at 110 °C, water soluble extractive, and alcohol soluble extractive tests were done as per Ayurvedic Pharmacopoeia of India (API) and WHO standards [5].
High performance thin layer chromatography (HPTLC) studies of (WA) as were done at SDM Centre for Research in Ayurveda and Allied Sciences, Kuthpady, Udupi as per standard procedures [6] as per following methods

Clinical Study
Clinical trial was conducted to allow safety and efficacy data to be collected for health interventions (e.g., drugs, diagnostics, devices, therapy protocols). Prior to conduction of any clinical study, researcher has to design and fix the whole methodology of study after permission being obtained from IEC vide SDMCAH/IEC/92-13-14

Collection of Drug
Parinata keriksheeradi Tailam was purchased from The Arya Vaidya Sala, Kottakkal, Kerala.

3. Source of data
For the open label clinical trial 32 patients of frozen shoulder were selected from outpatient department and in patient department of S.D.M. College of Ayurveda and Hospital, Hassan.

Diagnostic criteria
Clinical symptoms of frozen shoulder, like,
- Amsa Sandhi Shoola –shoulder pain.
- Amsa Sthabdatha–shoulder stiffness.
- Bahupraspandahara- Restriction in the movement of shoulder joint.
- Bahushosha- Emaciation in Shoulder muscles.

Methods of Collection of data
Patients who were fulfilling the criteria for diagnosis and inclusion were included.

Inclusion Criteria:
- Either gender and age group of 20-70 year,
- Having signs and symptoms of Frozen shoulder,
- Fit for Nasya Karma.

Exclusion Criteria
- Rheumatoid Arthritis,
- Dislocation/Fracture of Shoulder,
- Infective Conditions or Systemic Disorders.

Method of Examination of the Patients
In this study the data was collected from the patients with the help of interview. The data related to general history, history of past illness, present illness, family history, food habits, history of treatment etc. and the systemic examination of the patients was also done and findings were recorded as per the Performa.

Intervention
Thirty patients of Frozen shoulder will be selected and Nasya Karma with Parinata Keriksheeradi Tailam in a dosage of 8 Bindu for each nostrils will be administered for 7 consecutive days between 7am to 9am in empty stomach.

Procedure
The whole procedure was under three steps, Purva, Pradhaana and Paschat Karma.

Purva karma
These are the materials required for Nasya karma.

Pradhaana karma
Desired amount of medicine is poured into two gokarnas.

Paschat karma
Kavala Graha with Saindhava Jala was given to the patient.

Assessment criteria:
The assessment will be based on the effect of the therapy on the signs and symptoms of the disease and Samyak Nasya Lakshanas, which will be given suitable scores and application of clinical tools.

Subjective parameter
Classical signs and symptoms of frozen shoulder, Amsa sandhi Shoola - shoulder pain, Amsa sandhi Stabdhatha - shoulder stiffness.

Objective parameters
Bahu prasandithahara - Range of motion (ROM) and Functional assessment for the shoulder by Goniometer. The assessment is based on the effect of the therapies will be given suitable scores and application of clinical tools. Samyak Lakshanas of Nasya, changes in signs and symptoms of frozen shoulder like restricted movements of hand, emaciation of muscles of shoulder, pain, tenderness, difficulty in lifting were taken for assessment.
### Grades of Assessment Parameters

<table>
<thead>
<tr>
<th>Variable</th>
<th>Score</th>
</tr>
</thead>
</table>
| 1. Pain in shoulder (Vedana)    | No pain - 0  
Occasional pain - 1  
Mild pain but no difficulty in Shoulder movements - 2  
Moderate pain & slight difficulty in Shoulder movements - 3  
Severe pain with severe difficulty in Shoulder movements - 4 |
| 2. Stiffness (Stambha)          | Absent - 0  
Present - 1 |
| 3. Restricted Movements of shoulder | **Flexion**  
160 – 180 degree - 0  
120 – 160 degree - 1  
80 – 120 degree - 2  
40 – 80 degree - 3  
0 – 40 degree - 4 |
|                                | **Extension**  
40 – 50 degree - 0  
30 – 40 degree - 1  
20 – 30 degree - 2  
10 – 20 degree - 3  
0 – 10 degree - 4 |
|                                | **Abduction**  
160 – 180 degree - 0  
120 – 160 degree - 1  
80 – 120 degree - 2  
40 – 80 degree - 3  
0 – 40 degree - 4 |
|                                | **Adduction**  
40-50 degree - 0  
30 – 40 degree - 1  
20 – 30 degree - 2  
10 – 20 degree - 3  
0 – 10 degree - 4 |
|                                | **External rotation**  
70 – 90 degree - 0  
50 – 70 degree - 1  
30 – 50 degree - 2  
0 – 30 degree - 3 |
|                                | **Internal rotation**  
70 – 90 degree - 0  
50 – 70 degree - 1  
30 – 50 degree - 2  
0 – 30 degree - 3 |
| 4. Tenderness                   | No tenderness - 0  
Subjective experience of tenderness - 1  
Wincing of face on pressure - 2  
Wincing of face and withdrawal of the affected part on pressure - 3  
Resist touch - 4 |
| 5. Swelling                     | Absent - 0  
Present - 1 |

**Statistical analysis**

Statistical Package for social science (SPSS) version 20 was used for data analysis. Friedman’s test was used to analyze the significance of change in Subjective parameters. Wilcoxon signed rank test is done as post Hoc with Bonferroni correction on parameters which show significance in Friedman’s test, to interpret the time of significant change. Wilcoxon signed rank test with Bonferroni Correction with $\alpha = 0.0125$
5. Results and Discussions
Analytical Study

Table 1: Organoleptic characters

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Parinata Keriksheeradi tailam</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>Yellowish brown</td>
</tr>
<tr>
<td>Odour</td>
<td>Not characteristic</td>
</tr>
<tr>
<td>Appearance</td>
<td>Oily viscous liquid</td>
</tr>
<tr>
<td>Touch</td>
<td>Greasy</td>
</tr>
</tbody>
</table>

Table 2: Results of standardization parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Parinata Keriksheeradi Taila</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refractive index</td>
<td>1.465</td>
</tr>
<tr>
<td>Specific gravity</td>
<td>0.920</td>
</tr>
<tr>
<td>Acid value</td>
<td>12.0</td>
</tr>
<tr>
<td>Iodine value</td>
<td>73.21</td>
</tr>
<tr>
<td>Saponification value</td>
<td>162.80</td>
</tr>
<tr>
<td>Unsaponifiable matter%</td>
<td>1.416</td>
</tr>
</tbody>
</table>

Fig 1: TLC Photo documentation of Unsaponifiable matter of Parinata Keriksheeradi Tailam

Track 1: Parinathakeri ksheeradi tailam - 8 µl
Track 2: Parinathakeri ksheeradi tailam - 12 µl
Solvent System - Toluene: Ethyl acetate (9:1)
Table 3: Rf values of Chloroform extract of unsaponifiable matter of Parinata keriksheeradi Tailam

<table>
<thead>
<tr>
<th>At 254 nm</th>
<th>At 366 nm</th>
<th>Post derivatisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>-</td>
<td>-</td>
<td>0.04 L Brown</td>
</tr>
<tr>
<td>0.09 L Green</td>
<td>0.31 F L Blue</td>
<td>-</td>
</tr>
<tr>
<td>0.39 L Green</td>
<td>0.39 F L Blue</td>
<td>0.39 D Pink</td>
</tr>
<tr>
<td>-</td>
<td>0.47 F L Blue</td>
<td>-</td>
</tr>
<tr>
<td>-</td>
<td>0.52 F G Blue</td>
<td>0.52 Violet</td>
</tr>
<tr>
<td>0.58 D Green</td>
<td>-</td>
<td>0.58 Violet</td>
</tr>
<tr>
<td>-</td>
<td>0.63 F Blue</td>
<td>-</td>
</tr>
<tr>
<td>0.69 L Green</td>
<td>-</td>
<td>0.69 L Pink</td>
</tr>
<tr>
<td>-</td>
<td>0.77 F G Blue</td>
<td>0.77 L Blue</td>
</tr>
<tr>
<td>0.85 Green</td>
<td>0.85 F L Blue</td>
<td>-</td>
</tr>
<tr>
<td>-</td>
<td>-</td>
<td>0.89 L Blue</td>
</tr>
<tr>
<td>0.98 Green</td>
<td>0.98 F Purple</td>
<td>0.98 Violet</td>
</tr>
</tbody>
</table>

L - Light, D- Dark, G - Greenish, F - Fluorescent

Fig 2.a. At 254 nm

Track 3, ID: Chloroform extract of unsaponifiable matter of Parinathakeri Ksheeradi Thailam
Out of 32 patients of frozen shoulder treated with 7 days of Nasya Karma, the patients marked improvement in 30%, moderate improvement in 43% and mild improvement in 27%. With signification over parameters Among the 32 patients of Apabahuka, majority were of age group of 51-60 years (25%), Females (59%), Hindus(100%), Married (88%), housewives (44%) and had attained Graduation (28%).31% of patients had duration of illness in between 1 month-1 year, all of which were of gradual onset. It was chronic in 53% of the patients. 47% of the subjects adopted during lifting heavy weights. 53% had Samagni, 31% had Madhyama Koshta, 69% had Alpa Nidra, 55% had Vata Kapha Prakruthi. All the 32 patients of this series had restricted range of movements of Shoulder. Half of the subjects had Pain, Stiffness and Temperature. Deformity was absent in all subjects, Wasting only on right (7%), tenderness (50%) RT and on the left shoulder LT (56%) subjects, Rigidity (16%) RT and (37%) on LT, crepitus (41%) on RT and (37%) on LT subjects.

**Probable mode of action of Nasya in Frozen shoulder**
The mode of administration of Aushada through Nasya Karma is having several advantages. The rich vascular plexus of the nasal cavity provides a direct route into the blood stream for medications that easily cross mucous membranes. This direct absorption into the blood stream avoids gastrointestinal destruction and hepatic first pass metabolism (destruction of drugs by liver enzymes) allowing more drug to be cost-effectively, rapidly, and predictably bioavailable than if it were administered orally. The probable mode of action of Nasya Karma can assed under many aspects, they are.

**Probable mode of action of Parinata Keriksheeradi Tailam in Frozen shoulder**
Ayurveda has mentioned medicated Sneha Dravya in a majority of the Nasya Karmas, because nose is a highly vascular structure and its mucous membrane provides a good absorbing surface. Hence, Siddha Sneha, on their
administration, spread along the nasal mucous membrane. An active principle along with Sneha gets absorbed inside the olfactory and respiratory mucosa. The networks of lymph vessels have communications with the subdural and subarachnoid spaces. This fact is one of the important factors contributing to the extension of the mentioned drugs from the nose into the cranial cavity. Therefore, these substances can pass easily through the blood-brain barrier and can exert their actions. Certain lipids are used for providing energy to the nervous tissue. Based on the results obtained from this study, Parinata Keriksheeradi Tailam Nasya can be adopted for the treatment of Frozen Shoulder.

7. References

6. Conclusion
Most of the Parameters showed gradual improvement during the course of Nasya with Parinatkai ksheeradi Tailam. It was observed that, Pain, Stiffness, Tendermess, Abduction, Adduction, Flexion, Extension, External Rotation, and Internal Rotation was not at all significant during the 3rd of treatment. Statistically it was analysed as significant on the 6th day, AT and AFU of Nasya treatment. Based on the results obtained from this study, Parinata