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

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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 it's 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 Keriksheeeradi Tailam along with analysis of compound drug.
Results: Results of this study showed that Nasya with Parinata Keriksheeradi Tailam was effective in reliving 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 perimission being obtained from IEC vide SDMCAH/IEC/92-13-14

Collection of Drug
Parinata keriksheeradi Tailam was purchased from The Arya Vaidya Sala, Kottakal, 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 Keriksheeeradi Tailam in a dosage of 8 Bindu for each nosrtils will be administered for 7 consecutive days between 7am to 9am in empty stomach.

Procedure
The whole procedure was under three steps, Purva, Pradhana and Pashchat Karma.

Purva karma
These are the materials required for Nasya karma.
The patient who has attended to his natural urges and in empty stomach or previously digested food is made to lie in room devoid of breeze.
Sthanika abhyanga to be done.
Nadi sweda is done by keeping the eyes covered with cotton gauze piece.
The positioning of the patient is important. He is made to lie straight with his legs and hands extended. “Kinchith unnatha paadasya kinchith moordhni naamyate” i.e. legs slightly raised and head slightly lowered which is achieved by pillows below the neck and calf region.
Ushnaambu taptam bhaishajyam i.e. the medicine is warmed by placing it in a hot water bath.

Pradhaana karma
Desired amount of medicine is poured into two gokarnas.
Then the medicine is instilled in each nosrtil alternatively keeping the other one closed. 3 fingers are used for this purpose. Pradeshini (Index), Madayama (middle finger) and the Kanishtika (ring finger).
It has been specifically told that the flow of the medicine should be uninterupted. I.e. Avichinnadhara.
After instilling the medicine, the ears, neck, palm and soles should be massaged mildly.
The patient is asked to lie down for 1min.
When the medicines reaches the mouth, the patient should turn to his both (right & left) sides and spit out into the sputum cough kept for the purpose till the medicine comes out.

Paschat karma
Kavala Graha with Saindhava Jala was given to the patient.
After the Nasya Karma, Patients were advice to-Stay in windless place; Drink lukewarm water; Avoid Dust; Avoid Smoke; Avoid Sun shine; Avoid Alcohol; Avoid Anger Avoid Divaswapna.

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 praspandithahara - 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

Variable	Score
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

4. Stastical 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 = 0.0125

5. Results and Discussions

Analytical Study

Table 1: Organoleptic characters

Parameters	Parinata Keriksheeradi tailam
Colour	 Yellowish brown
Odour	Not characteristic
Appearance	Oily viscous liquid
Touch	Greasy

Table 2: Results of standardization parameters

Parameter	Parinata Keriksheeradi Taila
Refractive index	1.465
Specific gravity	0.920
Acid value	12.0
Iodine value	73.21
Saponification value	162.80
Unsaponifiable matter%	1.416

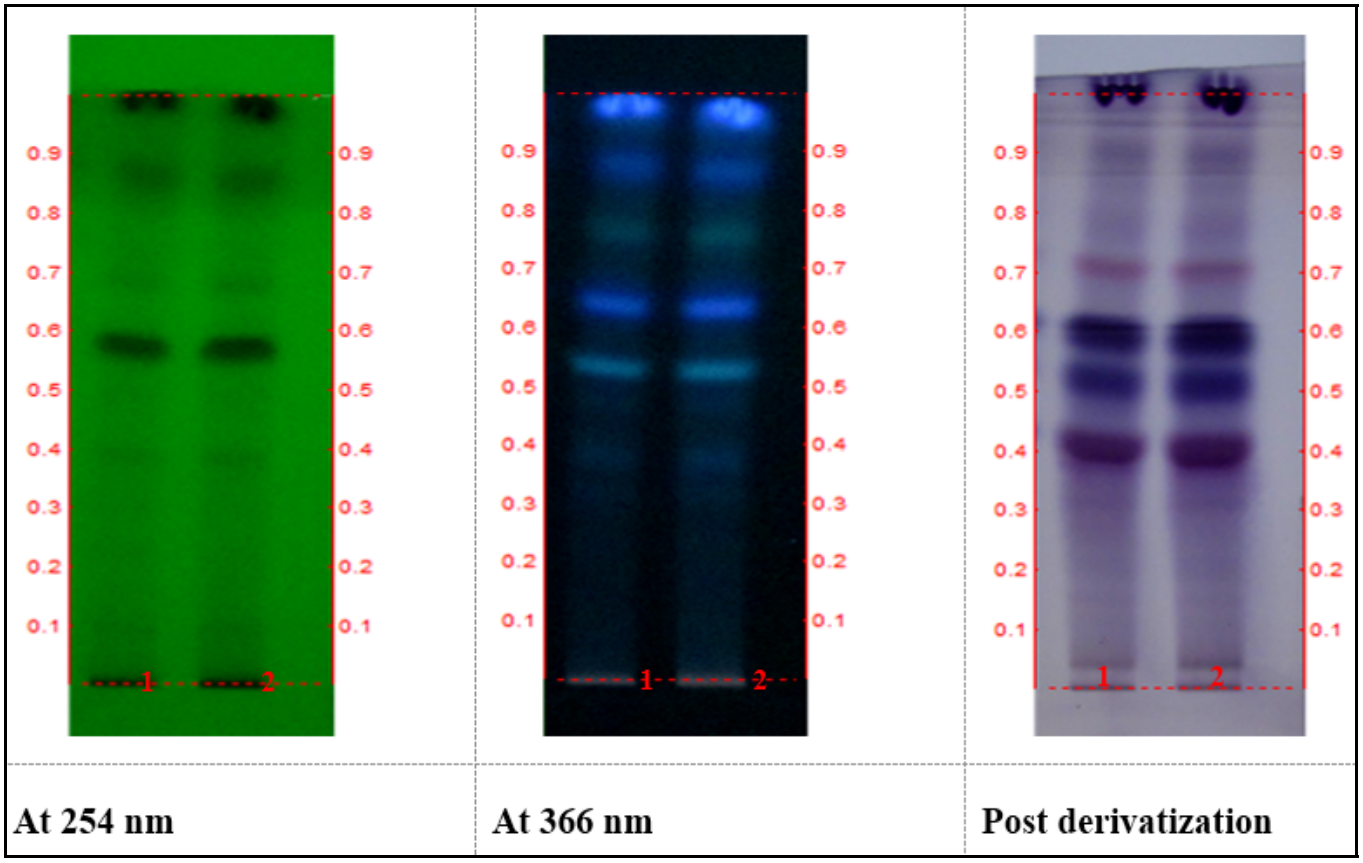


Fig 1: TLC Photo documentation of Unsaponifiable matter of Parinata Keriksheeradi Tailam

Track 1: Parinathakeri ksheeradi tailam - 8 µl
Track 2: Parinathakeri ksheeradi tailam - 12 µl
Solvent System - Toluene: Ethyl acetate (9:1)

Table 3: R_f values of Chloroform extract of unsaponifiable matter of Parinata keriksheeradi Tailam

At 254 nm	At 366 nm	Post derivatisation
-	-	0.04 L Brown
0.09 L Green	-	-
-	0.31 F L Blue	-
0.39 L Green	0.39 F L Blue	0.39 D Pink
-	0.47 F L Blue	-
-	0.52 F G Blue	0.52 Violet
0.58 D Green	-	0.58 Violet
-	0.63 F Blue	-
0.69 L Green	-	0.69 L Pink
-	0.77 F G Blue	0.77 L Blue
0.85 Green	0.85 F L Blue	-
-	-	0.89 L Blue
0.98 Green	0.98 F Purple	0.98 Violet

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

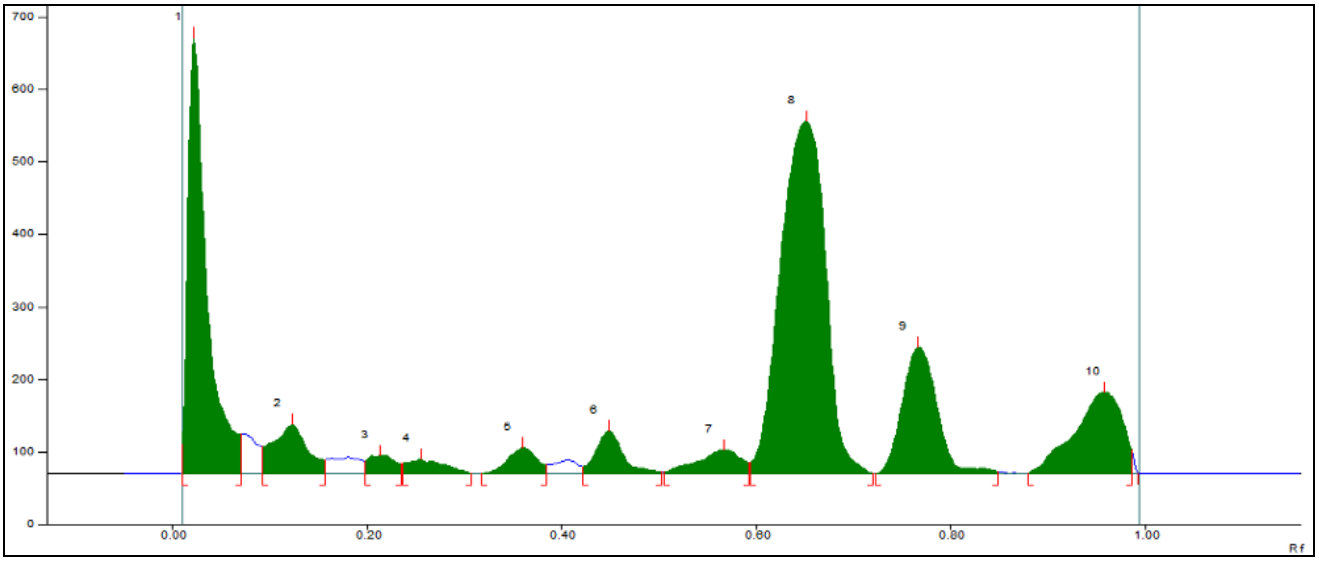
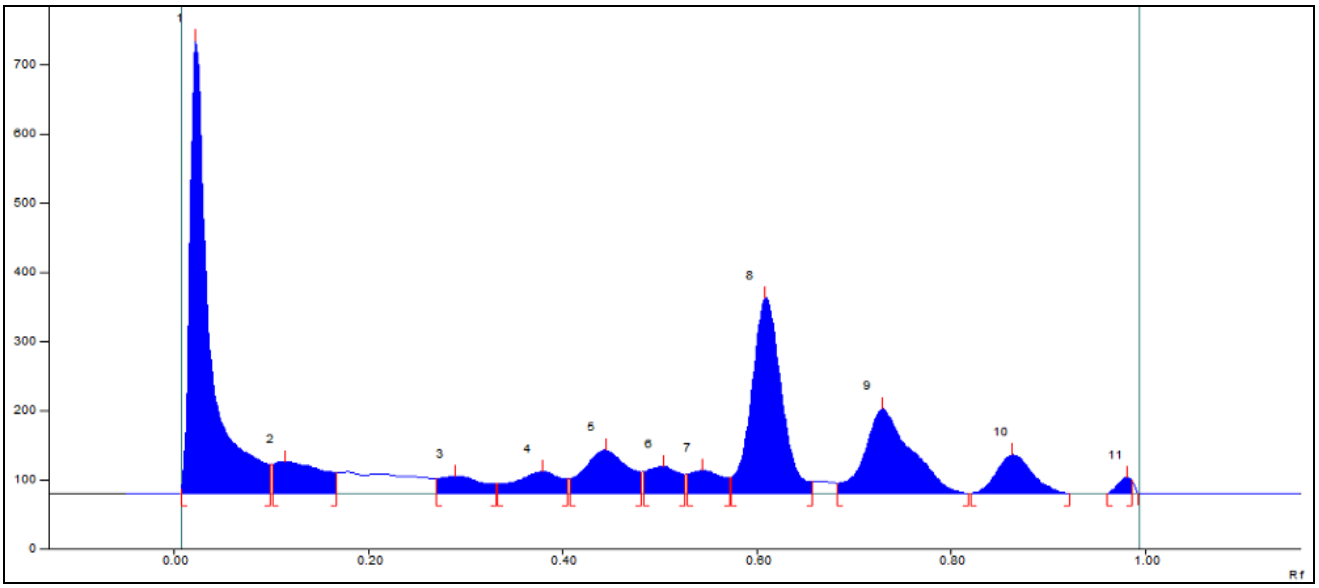


Fig 2.a. At 254 nm

Track 3, ID: Chloroform extract of unsaponifiable matter of Parinathakeri Ksheeradi Thailam

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	0.01 Rf	40.6 AU	0.02 Rf	600.3 AU	37.19 %	0.07 Rf	54.1 AU	8423.4 AU	21.77 %
2	0.09 Rf	37.7 AU	0.12 Rf	67.8 AU	4.20 %	0.16 Rf	19.2 AU	1742.2 AU	4.50 %
3	0.20 Rf	17.6 AU	0.21 Rf	25.3 AU	1.57 %	0.24 Rf	14.5 AU	509.6 AU	1.32 %
4	0.24 Rf	14.7 AU	0.26 Rf	20.3 AU	1.26 %	0.31 Rf	0.2 AU	552.2 AU	1.43 %
5	0.32 Rf	0.1 AU	0.36 Rf	36.2 AU	2.24 %	0.39 Rf	12.3 AU	769.1 AU	1.99 %
6	0.42 Rf	10.1 AU	0.45 Rf	59.0 AU	3.65 %	0.50 Rf	2.7 AU	1183.9 AU	3.06 %
7	0.51 Rf	3.4 AU	0.57 Rf	32.8 AU	2.03 %	0.59 Rf	15.3 AU	1052.3 AU	2.72 %
8	0.60 Rf	15.7 AU	0.65 Rf	485.1 AU	30.05 %	0.72 Rf	0.3 AU	16024.0 AU	41.41 %
9	0.72 Rf	0.1 AU	0.77 Rf	174.7 AU	10.82 %	0.85 Rf	3.5 AU	4468.2 AU	11.55 %
10	0.88 Rf	0.5 AU	0.96 Rf	112.7 AU	6.98 %	0.99 Rf	33.2 AU	3968.5 AU	10.26 %



Track 3, ID: Chloroform extract of unsaponifiable mater of Parinathakeri Ksheeradi Thailam

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	0.01 Rf	5.5 AU	0.02 Rf	652.3 AU	47.58 %	0.10 Rf	42.1 AU	9668.7 AU	33.51 %
2	0.10 Rf	42.2 AU	0.11 Rf	46.4 AU	3.38 %	0.17 Rf	30.3 AU	1648.8 AU	5.72 %
3	0.27 Rf	21.7 AU	0.29 Rf	25.2 AU	1.84 %	0.33 Rf	13.4 AU	780.4 AU	2.71 %
4	0.33 Rf	13.4 AU	0.38 Rf	31.8 AU	2.32 %	0.41 Rf	20.8 AU	1041.8 AU	3.61 %
5	0.41 Rf	21.1 AU	0.45 Rf	62.3 AU	4.54 %	0.48 Rf	30.6 AU	2015.2 AU	6.99 %
6	0.48 Rf	30.9 AU	0.50 Rf	38.6 AU	2.81 %	0.53 Rf	27.1 AU	944.5 AU	3.27 %
7	0.53 Rf	27.3 AU	0.55 Rf	33.1 AU	2.41 %	0.57 Rf	22.0 AU	797.5 AU	2.76 %
8	0.57 Rf	22.6 AU	0.61 Rf	281.7 AU	20.55 %	0.66 Rf	16.8 AU	6171.8 AU	21.39 %
9	0.68 Rf	14.7 AU	0.73 Rf	121.7 AU	8.88 %	0.82 Rf	0.6 AU	4114.3 AU	14.26 %
10	0.82 Rf	0.7 AU	0.86 Rf	55.2 AU	4.03 %	0.92 Rf	0.1 AU	1448.4 AU	5.02 %
11	0.96 Rf	0.2 AU	0.98 Rf	22.8 AU	1.67 %	0.99 Rf	19.6 AU	216.0 AU	0.76 %

Fig 2.b. At 366 nm

Fig 2: Densitometric scan of Parinathakeri ksheeradi tailam - 12 µl

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, Stiffnesss 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.

Chikitsa is Samprapti Vighatana. In the Samprapti of Frozen shoulder, there occurs Vata Prakopa as a result of particular Nidana. This Prakupita Vata moves out from its Ashaya to circulate in the entire body. During circulation, it gets localised in Sthana of Asthi, Majjavaha Srothas, ie. Amsa sandhi where Khavaigunya has occured because Vata & Asthi have Ashraya-Ashrayi Sambandha, [7] When aggravated Vata is localized in the Sandhi, it decreases the Kapha (Shleshaka) present there and further leads to karmahani & produce, Frozen shoulder. Nasya acts mainly due to the Veerya of the Oushadha; which in turn depends on the Gunas of the Oushadha as well. Haridra is having laghu rooksha Guna, ushna veerya & is Kapha vata shamaka. Tila Taila has considered best among oils, having snigda Ushna etc.' Tailam kapha sa vate cha', if the disease is caused by Vata along with Kapha. Taila has got both the action of Brumhana and Karshana property. By these properties Taila will help in Brumhana in Vataja condition of Frozen shoulder, and also Karshana if it is Vata Kaphaja. Parinatha keriksheera has Snigdha guna & Sheeta Veerya. It is Vata pithahara, Balya. Jambeera has Laghu, teekshna Guna, ushna veerya and kapha vata shamaka [8]. Hence, the ingredients of this Nasya mainly help to combat the Prakupita Vata. With respect to the Kalka Dravyas, haridra, devadhoopa have mainly Laghu, rooksha Gunas &

Ushna Veerya and kaphavata shamaka action of this Nasya. The Guru & Snigdha guna of Parinata keriksheera and sookshma, vyavayi, vikasi guna of tila taila balances the properties of other Kalka Dravyas. The lipid contents of the 'Parinata Keriksheeradi Tailam' may pass through the blood-brain barrier easily due to their transport. Some of the active principles may reach certain levels in the nervous system where they can exert their Vataghna property [9] Parinata Keriksheeradi Taila provides nourishment to the nervous system on its nasal administration; it reaches different Shirogata Indriya and causes Vatashamana and Brumhana [10]. On the basis of the foregoing observations we can state that the procedures, properties & conducts explained for Parinata Keriksheeradi Tailam in Nasya Karma are of vital importance in drug absorption & transportation. To conclude, Nasya Karma helps in frozen shoulder by its Vatashamana and Brumhana Karma.

6. Conclusion

Most of the Parameters showed gradual improvement during the course of Nasya with Parinatkai ksheeradi Tailam. It was observed that, Pain, Stiffness, Tenderness, 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 Keriksheeradi Tailam Nasya can be adopted for the treatment of Frozen Shoulder.

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