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Clinico-comparative Study of *Trayodasanga Guggulu* with and without *Nasya Karma* in the Management of *Avabahuka* (Frozen Shoulder Syndrome)

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ABSTRACT

INTRODUCTION

Frozen shoulder (adhesive capsulitis - capsule thickens and tightens around the shoulder joint, restricting its movement) is a condition characterized by stiffness and pain in the shoulder joint. non-steroidal anti-inflammatory drugs and local corticosteroid injection given as a therapy in frozen shoulder syndrome.

Frozen shoulder typically develops slowly, and in three stages. Each stage can last a number of months.

- Freezing stage: Any movement of shoulder causes pain, and shoulder's range of motion starts to become limited.
- Frozen stage: Pain may begin to diminish during this stage. However, shoulder becomes stiffer, and using it becomes more difficult.
- Thawing stage: The range of motion in shoulder begins to improve with proper treatment.

People having more than 40 years of age, particularly women, are more likely to have frozen shoulder. In a small percentage of cases, arthroscopic surgery may be indicated to loosen the joint capsule so that it can move more freely. People who have certain diseases i.e., diabetes, hyperthyroidism, hypothyroidism, cardiovascular disease, tuberculosis and Parkinson's disease appear more likely to develop frozen shoulder.

The prevalence of frozen shoulder is estimated to be 2 to 5 percent of the general population. It is more common in mid-50s. In 6 to 17 percent of patient, the other shoulder affected within 5 years. Frozen shoulder occurs predominantly and it is usually, lasting over 2 to 3 years sometime 40 percent of patient have persistence and have mild symptom beyond 3 years and 15 percent have long term debility. The condition affects diabetic(type 1) patients more often than healthy ones, with a prevalence of almost 11% in this population group.



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According to modern treatment non steroidal anti inflammatory drugs (NSAIDs) and steroidal injection at local site are given for relieving the symptoms of frozen shoulder syndrome, patient may keep continue these drugs. Long term use of these drugs causes side effects.

Most common side effects of NSAIDs are on cardio vascular system (hypertension), Gastro intestinal peptic ulcer, liver toxicity, kidney toxicity, ringing in ear. Also local application of corticosteroid injection causes side effects such as osteonecrosis, osteoporosis and nerve damage, tendon rupture, thinning of skin and soft tissues, joint infection.

According to *āyurveda*, here symptom of the *ceṣṭahani* is including in *vatavr̥ddhi*. *Nasya* karma is indicated in *bahugatavata*.

MATERIALS AND METHODS

Total 31 patients were enrolled for the treatment. 16 patients were enrolled in group A. One patient left the treatment due to non-medicinal cause. Hence, 15 patients completed the treatment course in group A with *trayodaśāṅga guggulu* and *nasya karma (māṣataiāla)*. In group B, total 15 patients were enrolled and all the patients completed the treatment with *nasya karma (māṣataiāla)*. Result was assessed by the relief in symptom index of *avabāhuka* (frozen shoulder syndrome), with the help of scoring pattern.

RESULTS

Group A: 66.67% patients belonged to group of marked improvement, 33.33 % patients had moderate improvement. There were no any patients found in group A in mild and unchanged improvement.

Group B: 53.33% patients belonged to group of moderate improvement, 40 % patients had mild improvement and 6.66% patient was found in unchanged group.

CONCLUSION

Both the treatment had significant effect when assessed individually with paired 't' test. However, more percentile results were obtained in group A. During the testing of hypothesis (comparing the effectiveness of both the therapy) p value is less than 0.001 in all the parameter. Means, null hypothesis was rejected and alternate hypothesis accepted. It suggests that *nasya karma* along with oral medicaments is more effective than only oral medicaments in the patients of *avabāhuka*.

KEYWORDS

Avabahuka, Frozen shoulder syndrome, *Masataila*



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INTRODUCTION

Vata is considered as a chief factor for the physiological maintenance of the body. Factors provoking *vata* result in the instantaneous manifestation of diseases, which can even prove to be fatal. Therefore, the *vataja nanatmaja vyadhi* are of utmost importance, rather than the *vyadhi* produced by the other two *dosa*. Contradictory approaches to pacify this vitiated state have to be restored to maintain the equilibrium.

In the modern point of view, the diseases involving the neurological, musculoskeletal, psychosomatic, and gastrointestinal system disorders have more similarity with the *vata vyadhi*. It indicates the wide ranging involvement of *vata* in various systems of the body. *Avabahuka* is one such disease that hampers the day-to-day activity of an individual. The fact that *vata vyadhi* is one among the *astaumahagada*, is itself explanatory, with regard to the consequences caused by *avabahuka*. Even though a definite factor responsible for the manifestation of this disease is not mentioned, a set of etiological factors can be interpreted.¹

AIMS AND OBJECTIVES

1. To study and observe the efficacy and effectiveness of *trayodasanga guggulu*

and *Nasya karma* in the management of *avabahuka* (frozen shoulder syndrome).

2. To study the clinical entity of frozen shoulder syndrome through *ayurveda*.

MATERIALS AND METHODS

SELECTION OF PATIENTS

Patients fulfilling the inclusion criteria of frozen shoulder syndrome were selected from Out-patient department (O.P.D.) of P. D. Patel Ayurveda Hospital, Nadiad for the present study irrespective of demographical division. Detailed history was taken according to the proforma prepared for the study incorporating all the relevant points from both *Āyurveda* and modern medical science. A written informed consent from each patient was taken before enrolling in the clinical trial. Diagnosis will be done on the basis of signs and symptoms of frozen shoulder. Physical examination will be done to evaluate restriction in the movements of shoulder joint.

INCLUSION CRITERIA:

1. Clinical features of Frozen shoulder syndrome.
2. Patient will be selected from 18 to 70 years of age.



3. The clinically diagnosed patients of Frozen Shoulder with confirmatory tests for shoulder joint pain are included in the study.

EXCLUSION CRITERIA:

1. The patients having fractures & dislocation in the shoulder region are excluded from the study.
2. Patients on corticosteroids, who received psycho pharmacological agents in last 6 months.
3. Pregnant and lactating women.
4. Patient having any other clinical condition i.e. diabetes, hyperthyroidism, hypothyroidism, cardiovascular disease,

tuberculosis and Parkinson's disease along with the frozen shoulder will be excluded.

TRIAL DRUGS

Masataila and *Trayodasanga guggulu* will be prepared from Sundar Ayurved Teaching Pharmacy of *Rasasastra* and *Bhaisajyakalpana* Department of J. S. Ayurved College. Raw drugs will be authenticated by Dravyaguna department of J. S. Ayurveda College.

Approval of the institutional Ethics Committee for research project:

JSAM/IECHR/43/18-2015

Table 1 Contains of *Trayodasanga guggulu*. (Bha.Pra-Madhyam khand)

NO.	DRUG NAME	LATIN NAME	PART USED	PROPORTION
1.	<i>Abha</i>	<i>Acacia Arabica</i>	Bark	1 part
2.	<i>Asvagandha</i>	<i>Withania somnifera</i>	Root	1 part
3.	<i>Hapusa</i>	<i>Juniperus communis</i>	<i>Panhcanga</i>	1 part
4.	<i>Guduchi</i>	<i>Tinospora cordifolia</i>	Stem	1 part
5.	<i>Satavari</i>	<i>Asparegus recemosus</i>	Root	1 part
6.	<i>Goksura</i>	<i>Tribulus terrestris</i>	Fruit	1 part
7.	<i>Rasna</i>	<i>Pluchea lanceolata</i>	<i>Panchanga</i>	1 part
8.	<i>Trivrta</i>	<i>Operculina turpenthum</i>	Root bark	1 part
9.	<i>Satahva</i>	<i>Anthem suwa</i>	Seed	1 part
10.	<i>Sati</i>	<i>Hedychium catium</i>	Rhizome	1 part
11.	<i>Yavani</i>	<i>Trachyspermum ammi</i>	Fruit	1 part
12.	<i>Sunthi</i>	<i>Zingiber officinale</i>	Rhizome	1 part
13.	<i>Guggulu</i>	<i>Commiphora mukul</i>	Resin	12 part
14.	<i>Ghrta</i>	-		6 part

Dose:- 2 tablets each tablets 500 mg.

Time:- After meal with warm water

Duration- 3 times/day

Route of administration- Oral

Table 2 Contains of *Masataila*(B.R)

	Name of Drug	Part used	Proportion
1	<i>Masa</i>	Seed	1 Parts

(*Phaseolasmungo*
Linn.)

2	<i>Saindhava</i>	-	16 Parts
3	<i>Taila</i>	-	4 Parts

Drug: *Masataila*

Dosage: 16 drops in each nostril

Time: After noon. once in a day

Route of administration: Nasal cavity



Duration of treatment: Every day for 15 days

CRITERIA FOR ASSESSMENT

The cardinal clinical manifestations, both subjective symptoms as well as objective

signs of frozen shoulder scored according to the severity and considered as the assessment criteria for the study

Criteria for pain assessment (VAS) visual analog scale

Visual Analog Scale (VAS)

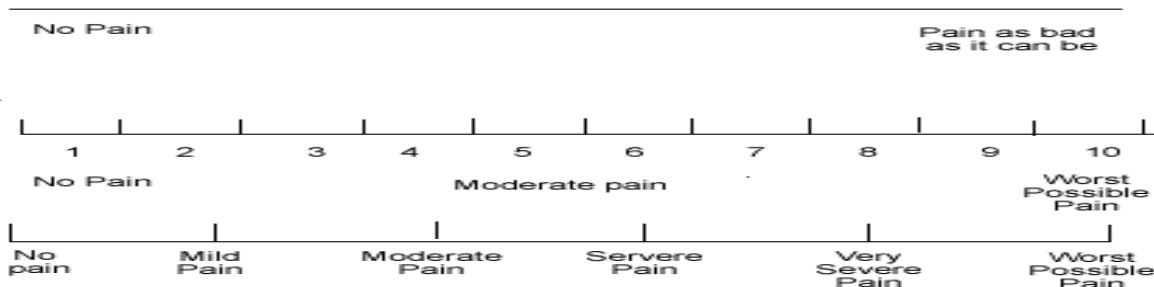


Table 3 Scoring pattern for pain

1.	No pain	0
2.	Mild pain	1-2
3.	Moderate pain	3-4

4.	Severe pain	5-6
5.	Very severe pain	7-8
6.	Worst possible pain	9-10

Table 4 Scoring pattern for Stiffness

Subjective parameter	Observations	Scale
<i>Stabdhata</i> (stiffness)	No stiffness	0
	Mild stiffness, particularly during shoulder movement able to continue routine work with difficulty.	1
	Moderate stiffness, unable to continue work with difficulty	2
	Severe stiffness, felt on movement and also at rest interfering routine work.	3

Table 5 Scoring pattern for shoulder joint movements

Objective parameter using Goniometer	Observation(in degrees)	Scale
Flexion	161-180	0
	141-160	1
	121-140	2
	<120	3
Extension	51-60	0
	41-50	1
	31-40	2
	<30	3
Abduction	161-180	0
	141-160	1
	121-140	2
	<120	3



Internal rotation	71-90	0
	51-70	1
	31-50	2
	<30	3
External rotation	71-90	0
	51-70	1
	31-50	2
	<30	3

Table 6 Criteria for total assessment of therapy

Marked Improvement	Above 75% to 100% relief in sign and symptoms
Moderately Improvement	More than 50% to 75% relief in sign and symptoms
Mild Improvement	25% to 50% relief in sign and symptoms
Unchanged	Less than 25% relief in sign and symptoms

RESULTS

Table 7 Comparative effect of signs and symptoms in patients of both the group

Signs and symptoms	Mean score		Overall S.D [#]	Degree of freedom	t value	p value
	Group A	Group B				
Pain	3.06	0.8	0.690	28	12.717	<0.001
Stiffness	1.8	0.73	0.636	28	6.49	<0.001
Flexion	1.85	0.78	0.593	27	6.98	<0.001
Extension	1.66	0.92	0.415	22	5.33	<0.001
Abduction	2	0.66	0.816	8	3.26	<0.001
Int.Rotation	1.46	0.8	0.775	26	3.07	<0.001
Ext.Rotation	1.5	0.83	0.485	12	8.73	<0.001

Table 8 Group- A: Effectiveness of *trayodasanga guggulu* and *Nasya karma with Masataila* in the management of *avabahuka* (frozen shoulder syndrome)

Signs and symptoms	Mean score			% Relief	Paired 't' test			
	BT*	AT**	D***		SD [#]	SE ^{##}	't'	P
PAIN	3.8	0.73	3.06	80.66%	0.79	0.21	14.36	<0.001
STIFFNESS	2.33	0.53	1.8	77.14	0.67	0.18	9.96	<0.001
R.O.M ⁺ (Flexion)	2.28	0.42	1.8571	84.52	0.53	0.14	12.52	<0.001
R.O.M. ⁺ (Extension)	2.11	0.44	1.66	78.94	0.5	0.17	9.42	<0.001
R.O.M ⁺ (Abduction)	2.28	0.28	2	87.5	0.81	0.33	6	<0.001
R.O.M. ⁺ (Int.Rotation)	1.92	0.46	1.43	76	0.62	0.19	7.66	<0.001
R.O.M. ⁺ (Ext.Rotation)	1.5	0	1.5	100	0.53	0.20	7.42	<0.001

Table 9 Group B: Effectiveness of *trayodasanga guggulu* in the management of *avabahuka* (frozen shoulder syndrome).

Signs and symptoms	Mean score			% Relief	Paired 't' test			
	BT*	AT**	D***		SD [#]	SE ^{##}	't'	P
PAIN	2.13	1.33	0.8	37.5	0.56	0.14	5.52	<0.001



STIFFNESS	1.46	0.73	0.73	50	42.25	0.153	4.78	<0.001
R.O.M⁺(Flexion)	1.71	0.92	0.78	45.23	30.95	0.11	6.90	<0.001
R.O.M.⁺ (Extension)	1.71	0.78	0.92	54.16	0.26	0.07	13	<0.001
R.O.M⁺ (Abduction)	1.33	0.66	0.66	50	0.51	0.21	3.16	<0.001
R.O.M.⁺ (Int.Rotation)	1.73	0.93	0.8	46.1	0.86	0.22	3.59	<0.001
R.O.M.⁺ (Ext.Rotation)	1.33	0.5	0.83	62.5	0.40	0.16	5	<0.001

BT*=Before Treatment;AT**=After Treatment;D***=Difference;SD[#]=Standard Deviation;SE^{##}=Standard Error;R.O.M⁺=Range of Motion

Table 10 Overall effect of treatment

Result	Group A		Group B	
	No. of patients	Percentage (%)	No. of patients	Percentage (%)
Marked improvement	10	66.67	0	0
Moderate improvement	05	33.33	8	53.33
Mild improvement	0	0	6	40
Unchanged	0	0	1	6.66

DISCUSSION

Results in both the groups are statistically significant. However, better results were obtained in the patients of group A than group B. It suggests that *nasya karma* along with oral medicaments is more effective than only oral medicaments in the patients of *avabahuka*. The *Nasya karma* especially exerts its effects on the *urdhvajatrugata pradesha*. All ingredients of *trayodasanga guggulu* work as *vatasamaka*, *vedana sthapana*, *sulahara*, *sothahara* properties. So it works on symptom index of *avabahuka* (frozen shoulder syndrome).

Possible *rasapanchaka* of *trayodasanga guggulu*:

Rasa : *tikta, katu, kasaya, madhura*

Guṇa: *laghu ruksa*

Virya: *usna*

Vipaka: *katu*

dosagnata: *kapha vatasamaka*

Compilation of the various prominent biopharmacological action of the ingredients of *trayodasanga guggulu* may be enlisted as under.

vedana sthapana, sulahara, sothahara, vranaropana, balya, dipana, anuloamana, tridosahara



These possible *rasapanchaka* of *trayodasanga guggulu* collectively execute the above enlisted various *karma* in the *khavaigunya* of *avabahuka* (Frozen shoulder syndrome).

As per *bhavaprakasa*, *vata vyadhi cikitsa prakarana* mentioned *trayodasanga guggulu* in *avabahuka chikitsa*.

Masa- *Masa* has *Madhur rasa*, *Guru* and *Snigdha Guna*, *Uṣṇa Virya* and *Madhur Vipaka*. Also it has *Vataghna*, *Samtarpaṇa*, *Brumhana*, *Vedanasthāpan*, *Balya*, *Sulaprasaman* and *Nadibalya* action. *Tila* works on *Vatavyadhi* by its *Vata-Kapha samaka* properties. *Caraka* also mentioned the role of *Masa saindhava tail nasya* in *vatavyadhi chikitsa*. *Bhāvaprakasa* also mentioned the use of *Masa rasa nasya* in *vata vyadhi chikitsa* for *avabahuka*. *abhisyandi karma* of *saindhava lavana* and *snigdha guna* of *tila taila* administered through *nasy karma* to initiate the synovial fluid formation in bursa of shoulder joint. It is not worthy that deminution in the quantity and quality of synovial fluid in bursa may causing increases friction in the shoulder joint and produce inflammation/capsulitis.

CONCLUSION

Both the treatment has significant effect when assessed individually with paired 't'

test. However, more percentile results were obtained in group A. During the testing of hypothesis (comparing the effectiveness of both the therapy) p value is less than 0.001 in all the parameter. Means, null hypothesis was rejected and alternate hypothesis accepted. It suggests that *nasya karma* along with oral medicaments is more effective than only oral medicaments in the patients of *avabahuka*.



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