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An open label single arm clinical study of *Dashamooladi Yamaka Pratimarsha Nasya* and *Prasaranyadi Kashaya in Apabahuka* (Frozen Shoulder)

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ABSTRACT

Background: *Apabahuka* is a *Vata Vyadhi* which affects *Amsa Sandhi* and causes *Amsa Bandha Shoshana. Prakupita Vata* causes *Kshaya* of *Shleshaka Kapha* and *Sira Sankochana* leading to *Bahupraspanditahara. Nasya* and *Uttarbhaktika Snehapana* are the indicated *Chikitsakrama* for *Apabahuka. Dashamooladi Yamaka Pratimarsha Nasya* and *Prasaranyadi Kashaya* are the indicated *Chikitsa Yoga* for *Apabahuka* in *Vatavyadhichikitsa*. Hence this study is intended to evaluate the same. **Objective:** To clinically evaluate the combined effectiveness of *Dashamooladi Yamaka Pratimarsha Nasya* and *Prasaranyadi Kashaya in Apabahuka* (Frozen Shoulder). **Methodology:** 36 subjects were administered with *Dashamooladi Yamaka Pratimarsha Nasya 2 Bindu* in each nostril after food morning and night and *Prasaranyadi Kashaya* 16ml 3 times a day on before food for a period of 14 days. Subjective and objective parameters were assessed by Constant Murley score. **Results:** Statistically significant ($P < 0.05$) improvement was observed in subjective parameters such as *Amsasandhi Shoola, Bahupraspanditahara.* With objective parameters like range of movement of shoulder significant change was observed. **Conclusion:** *Dashamooladi Yamaka* in the form of *Pratimarsha Nasya* and *Prasaranyadi Kashaya* orally together were found effective in the management of *Apabahuka*.

Key words: *Apabahuka, Frozen Shoulder, Dashamooladi Yamaka Pratimarsha Nasya, Prasaranyadi Kashaya.*

INTRODUCTION

Apabahuka has two words. *Apa and Bahuka. "Apa"* means *Viyoga* (dysfunction) & "*Bahuka*" means *Bahu.*[1] *Apabahuka* is caused by *Vata Prakopa* in *Amsa Desha. Prakupita Vata* causes *Shoshana* of *Amsa Bandha* and *Sankocha* of *Sira* of *Amsa Pradesha.*[2] This leads to *Stambha* and *Bahupraspanditahara.*[3] *Bahu* means *Koorparasya Urdhvabhaga* that is part above elbow. *Praspandana - Chalana, Chesta* or movement. *Vyana Vata* is responsible for *Cheshta* like *Prasarana, Akunchana, Vinamana, Unnamana and Tiryagagamana.*[4] *Hara* means loss of or impaired. Thus, *Bahupraspanditahara* means difficulty in movement or impaired or reduced range of movement of shoulder joint. *Sira Akunchana - Sira* is formed from *Snayu* and *Snehamsa* of *Medas. Sira* is responsible for *Akunchana* and *Prasarana* of *Sandhi.* In *Apabahuka Prakupita Vata* leads to *Sira Akunchana* in *Amsa Desha*. This leads to difficulty in *Akunchana* and *Prasarana* which results in *Bahuprasapaditahara*.

Apabahuka being a *Vatavyadhi, Samanya Vatavyadhi Chikitsa* is applicable. According to *Acharya Charaka*[5] and *Acharya Vagbhat,*[6] *Uttarabhaktika Snehapana* and *Nasya* are indicated in *Bahusheershagatavata. Nasya, Mardana, Bahuparivartanam, Shamana Aushadhi* and *Uttarabhaktika Snehapana* are mentioned in the management of *Apabahuka* in *Yogaratnakara.*[7]

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Frozen shoulder is estimated to occur in 2-5% of general population.[8] Every 5% of the consecutive new patients attend a clinic for Frozen shoulder. Diabetes mellitus is an independent risk factor for Frozen shoulder. Diabetic patients are 5 times more likely to develop it. The estimated prevalence is 13.4% in diabetic patients and 2-10% in non-diabetics. This tends to occur in patients of middle age and women. Frozen shoulder is a clinical condition characterized by painful restriction of both active and passive shoulder movements. Frozen shoulder has two causes. Shoulder and non- shoulder causes. Shoulder causes include bicipital tendinitis, fracture or dislocations of shoulder. Frozen shoulder has three stages, Stage of pain, Stage of stiffness and Stage of recovery.[9]

Materials and Methods

Source of data: Subjects of *Apabahuka* were selected from Out Patient and In patient department of Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Hassan.

Methods of collection of data

Screening

A screening form was prepared with all aspects of history, signs and symptoms of *Apabahuka*.

Diagnostic criteria

Diagnosis was made on the basis of *Samanya Lakshana* of *Apabahuka* viz. *Bahupraspanditahara, Amsa Sandhi Shoola* and symptoms of frozen shoulder.

Inclusion Criteria

1. Subjects aged between 30 and 70 years.
2. Subjects of either gender irrespective of caste, occupation and religion.
3. Subjects who are willing to participate and sign the informed consent form.

Exclusion criteria

1. Subjects presenting with fracture or dislocation of shoulder joint.
2. Uncontrolled Diabetes Mellitus and Hypertension.
3. Known case of neoplasm and infective condition.
4. Pregnant and lactating women.

Investigation

- X- Ray Shoulder joint - to rule out fracture
- HbA1c, if Diabetic

Ethical clearance and CTRI registration:

Ethical clearance was obtained from Institutional Ethics Committee. IEC No: SDM/IEC/78/2021. Trial was registered on www.ctri.gov.in with Registration No: CTRI/2022/08/044850 dated 19/07/2022

Study design

Study was an open label single arm clinical study on *Apabahuka* (frozen shoulder) (n=30) selected using the convenience (non-random) sampling technique with pre and post design conducted in tertiary *Ayurveda* hospital.

Dosage and Drug Administration

Dashamooladi Yamaka

Dosage: 2 Bindu each nostril (twice daily) after food

Route of administration: Nasal

Duration: 14 days

Prasaranyadi Kashaya

Dosage: 16 ml thrice a day before food

Route of administration: Oral

Duration: 14 days

Assessment Criteria

Subjective and objective parameters were assessed using Constant Murley Score.

a. Pain: (15 Points)

b. Activities of daily living: (20 Points)

- Sleep
- Normal daily living
- Normal recreation activity
- Hand comfort

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c. Movement: (40 Points)

- Flexion
- Abduction
- External rotation
- Internal rotation

d. Strength: (25 Points)

OBSERVATION

In the present study 67 subjects were screened, 36 subjects registered for the study, 30 subjects completed the study. Among 30 subjects maximum (n=14) were from the age group of 41-50 years and majority were males (n=19). 16 subjects were from middle lower-class group. Majority of them (n=32) had gradual onset. Diet wise distribution showed (n=22) had mixed diet. 18 subjects had disturbed sleep.

RESULTS

30 subjects were administered with *Dashamooladi Yamaka Pratimarsha Nasya* 2 *Bindu* each nostril after food morning and night and *Prasaranyadi Kashaya* 16ml 3 times a day before food for a period of 14 days. Paired t test was run on subjective and objective parameters and had shown significant improvement in symptoms like *Amsa Sandhi, Bahuprasapanditahara* and range of movement of shoulder joint.

Table 1: Paired T-test showing the combined effect of *Dashamooladi Yamaka Pratimarsha Nasya* and *Prasaranyadi Kashaya* on Part A (Pain)

Gross Score I	Gross Score J	Mean Diff. (I-J)	Std Deviation	Std Error Mean	T Value	Sig.	Remark
BT	7th day	-1.73	1.741	0.318	-5.45	0.001	S
7th day	AT	-2.86	1.717	0.313	-9.14	0.001	S
BT	AT	-4.60	2.554	0.466	-9.86	0.001	S

Paired T-test showed improvement in Part A (pain)with a mean difference of -1.733 between the 7th day and BT, -2.867 between 7th day and AT, and -4.600 between BT and AT was statistically significant with p< 0.05

Table 2: Paired T-test showing the combined effect of *Dashamooladi Yamaka Pratimarsha Nasya* and *Prasaranyadi Kashaya* on Part B (Normal activity, Recreational activity, Sleep, Painless activity level of shoulder)

Gross Score I	Gross Score J	Mean Diff (I-J)	Std Deviation	Std Error Mean	T Value	Sig.	Remark
BT	7th day	-2.10	2.186	0.399	-5.25	0.001	S
7th day	AT	-3.83	2.198	0.401	-9.55	0.001	S
BT	AT	-5.93	3.128	0.571	-10.3	0.001	S

Paired T-test showed improvement in Part B (Normal activity, Recreational activity, Sleep, Painless activity level of shoulder) with mean difference of -5.259 between 7th day and BT, -9.550 between 7th day and AT and -10.380 between BT and AT was statistically significant with p< 0.05.

Table 3: Paired T-test showing the combined effect of *Dashamooladi Yamaka Pratimarsha Nasya* and *Prasaranyadi Kashaya* on Part C (Flexion, Abduction, External rotation, Internal rotation)

Gross Score I	Gross Score J	Mean Diff. (I-J)	Std Deviation	Std Error Mean	T Value	Sig.	Remark
BT	7th day	-5.200	4.020	0.734	-7.08	0.001	S
7th day	AT	-4.066	4.050	0.739	-10.9	0.001	S
BT	AT	-13.26	6.136	1.120	-11.8	0.001	S

Paired T-test showed improvement in Part C (Flexion, Abduction, External rotation, Internal rotation) with mean difference of -7.084 between 7th day and BT, -10.907 between 7th day and AT and -11.842 between BT and AT was statistically significant with p< 0.05.

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Table 4: Paired T test showing the combined effect of *Dashamooladi Yamaka Pratimarsha Nasya* and *Prasaranyadi Kashaya* on Part D (Power)

Gross Score I	Gross Score J	Mean Diff. (I-J)	Std Deviation	Std Error Mean	T Value	Sig.	Remarks
BT	7th day	-1.33	1.625	0.296	-4.49	0.001	S
7th day	AT	-2.33	1.516	0.276	-8.42	0.001	S
BT	AT	-3.66	2.186	0.399	-9.18	0.001	S

Paired T-test showed improvement in Part D (Power)with mean difference of -4.492 between 7th day and BT, -8.429 between 7th day and AT and -9.184 between BT and AT was statistically significant with p< 0.05.

Table 5: Paired T test showing the combined effect of *Dashamooladi Yamaka Pratimarsha Nasya* and *Prasaranyadi Kashaya* on Total score

Gross Score I	Gross Score J	Mean Diff (I-J)	Std Deviation	Std Error Mean	T Value	Sig.	Remark
BT	Day 7	-10.40	7.793	1.422	-7.31	0.001	S
Day 7	AT	-17.10	7.043	1.285	-13.28	0.001	S
BT	AT	-27.50	12.555	2.292	-11.99	0.001	S

Paired T-test showed improvement in Total Score with mean difference of -10.400 between 7th day and BT, -17.100 between 7th day and AT and -27.500 between BT and AT was statistically significant with p< 0.05.

DISCUSSION

Effect of *Dashamooladi Yamaka Pratimarsha Nasya* and *Prasaranyadi Kashaya* on *Bahupraspanditahara*

Significant result was observed in range of active movements such as flexion, abduction, external rotation and internal rotation after the treatment.

Bahupraspanditahara is a symptom of *Apabahuka* where active movements are restricted due to stiffness of the shoulder joint. This may be due to increased *Sheeta* and *Ruksha Guna* of *Vata* and decreased *Snigdha Guna* of *Kapha*.

The combination of *Dashmooladi Yamaka* and *Prasaranayadi Kashaya* help in pacifying *Vata* and it normalises *Kapha.* Majority of the drugs have properties like *Snigdha Pichhila, Shlakshna* and *Guru Guna* which normalises the *Kapha Dosha* and along with these *Guna's Ushna Veerya* pacifies *Vata*.

Effect of *Dashamooladi Yamaka Pratimarsha Nasya* and *Prasaranyadi Kashaya* on *Amsa*

Statistically significant improvement was noticed in *Amsa Sandhi* after treatment using Paired t-test (P value <0.05).

Amsasandhi is manifested as a result of *Nidana* such as *Atibharavahana, Vishama Cheshta, Ativyayama* leads to *Vataprakopa* in *Amsa Pradesha* and causes *Amsa. Prasarini, Rasona, Bala, Masha, Shunthi* and *Dashamoola* have *Madhura Rasa* and *Madhura Vipaka. Tarpana* and *Brumhana* properties of this drugs helps in reducing *Amsasandhi* by pacifying *Vata*.

Discussion on Probable Mode of Action of Drug

Prasarani has *Guru Guna, Ushna Veerya* and it is *Balakaraka and Vatashamaka.* The drug has proven efficacy as an effective anti-inflammatory, analgesic activity.

Rasna has *Guru* and *Snigdha Guna, Ushna Veerya,* and is a potent *Vata Shamaka* drug. It is having *Shoolaghna* & *Shothahara* action which helps in reducing *Amsa Shoola*.[10]

Rasona has *Snigdha Guna* and *Ushna Veerya,* which helps in pacifying the *Vata*. It acts as *Shothahara, Shoolahara* and *Balya*.[11]

Shunthi has *Guru Guna, Ushna Veerya, Madhura Vipaka, Shophaghna, Shoolaghna, Agnivardhaka* and *Amapachaka* property, which help in reducing *Shoola* and *Shopha*.[12]

Masha has *Snigdha Guna, Ushna Veerya* which help in reduction of *Vata*. It is *Mamsabalaprada, Brumhaka, Balya, Tarpana* which helps in *Kapha Vardhana*.

Bala enlisted under *Brumhaneeya Mahakashaya* and is *Agrya* for *Vata Shamana*. It has *Madhura Rasa, Guru, Snigdha, Pichila Guna* which helps to pacify *Vata*.[13]

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Dashmoola has *Shotha-Shoolahara* and *Amapachana* properties and anti-inflammatory, analgesic effect which help in reducing *Amsa Sandhi Shoola.*

Discussion on mode of action of *Yamaka*

Tila Taila is *Brumhanakaraka* and *Vatahara*. *Vyavayi* and *Sookshma*, *Teekshna Guna* of *Tila Taila* help *Yamaka* to spread faster into *Sookshma Srotas*.[14] *Tarpana Karma* of *Tila Taila* can correct *Shleshaka Kapha* which is in *Kshaya Avastha*. *Ghrita* is *Yogavahi* and does *Agnideepana* and *Vatashamana*.[15] It has *Guru* and S*nigdha Guna* which helps in *Vata Shamana*. *Rasayana* and *Balya* properties of *Ghrita* helps in nourishing *Shleshaka Kapha*. Lipid-based formulations increase the intraluminal solubility of lipophilic drugs and enhance the drug absorption.[16]

Discussion on *Pratimarsha Nasya*

Auttarabhaktika Snehaprayoga is indicated in *Bahusheershagatavata. Apabahuka* being a condition with involvement of *Bahu, Dashamooladi Yamaka Nasya* was administered after food in the form of *Pratimarsha Nasya*. *Dashamooladi Yamaka Nasya* is indicated in the evening after food. *Bhuktabhakta* being a contraindication for *Nasya* in general, *Pratimarsha* mode of *Nasya* was done.

Probable mode of action - Vascular pathway- Highly vascularized nasal tissue makes effective and quick absorption of the drug administered through nose.[17] Neurological pathway - Chemoreceptors make up the olfactory nerve which end in the olfactory bulb. Bulbar olfactory pathway is made up of sensory neurons that project directly to the hypothalamus. Hypothalamus is responsible for regulating chemical mediators for pain. Therefore, *Nasya* may help in pain regulation in *Apabahuka* by acting upon hypothalamus.[18]

Conclusion

Dashamooladi Yamaka Pratimarsha Nasya 2 *Bindu* each nostril after food morning and night and *Prasaranyadi Kashaya* 16ml 3 times a day before food for a period of 14 days have shown significant results on subjective and objective parameters like *Amsashoola, Bahupraspanditahara* and range of movement of shoulder joint.

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