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An Open Label Single Arm Clinical Study on *Dashamooladi Yamaka Pratimarsha Nasya* and *Ashtavargam Kashaya* in *Vishwachi* (Cervical Radiculopathy)

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ABSTRACT

Background: *Vishwachi* is one among the 80 *Vatavyadhi*. *Lakshana* of *Vishwachi* are *Bahu Cheshtapaharana*, *Bahu Karma Kshaya*, *Stambha*, *Ruja*, *Toda*, *Spandana*, *Tandra*, *Gourava* and *Arochaka*. Cervical radiculopathy is a condition similar to *Vishwachi*, which results from compression of cervical nerve roots. This leads to neck pain radiating along the distribution of the affected nerve root, numbness, altered reflexes and weakness in the muscles of arm. **Objectives:** To evaluate the combined effectiveness of *Dashamooladi Yamaka Pratimarsha Nasya* and *Ashtavargam Kashaya* in *Vishwachi* (Cervical Radiculopathy). **Materials and methods:** 30 subjects fulfilling the inclusion criteria were administered with *Dashamooladi Yamaka Pratimarsha Nasya* in the dose of 2 *Bindu* twice daily after food and *Ashtavargam Kashaya*, 15ml thrice daily after food, for 14 days. *Ruja*, *Toda*, *Spandana*, *Sthambha*, *Tandra*, *Gourava*, *Arochaka*, *Bahukarmakshya*, *Bahucheshtapaharana* and Spurling test were assessed on 1 st day, 7th day and 15th day. Data were analyzed using appropriate statistical tests. **Results and conclusion:** Statistically significant ($P < 0.05$) improvement was observed in symptoms such as *Bahu Karmakshaya*, *Bahu Cheshtapaharana*, *Ruja*, *Toda*, *Spandana* and range of cervical movement. *Dashamooladi Yamaka Pratimarsha Nasya* and *Ashtavargam Kashaya* were found to be effective in the management of *Vishwachi*.

Key words: *Vishwachi*, Cervical Radiculopathy, *Dashamooladi Yamaka*, *Ashtavargam Kashaya*

INTRODUCTION

Vishwachi is one among the 80 *Vatavyadhi*. *Karma Kshaya* and *Cheshtapaharana* of *Bahu* are the symptoms of *Vishwachi*. It resembles *Gridhrasi* and is of two types - *Vataja* and *Vatakaphaja*. *Ruja*, *Stambha*,

Toda, *Spandana*, *Tandra*, *Gourava* and *Arochaka* are other symptoms of *Vishwachi*. There is similarity in the presentations of *Vishwachi* and Cervical radiculopathy.

Cervical radiculopathy is the result of degenerative changes such as cervical disc herniation and bone hyperplasia.^[1] It results from compression of cervical nerve roots leading to neck pain that may radiate to shoulder, arm, forearm and digits. Associated clinical features include numbness, altered reflexes and weakness in the muscles of arm. Prevalence of Cervical radiculopathy is around 3.5 per 1000 people.^[2] Annual incidence varies from 83 cases^[2] to 210 cases^[3] per 100,000 people. There is a recurrence rate of 32% over a period of 4.9 years.^[3] Peak incidence of Cervical radiculopathy is most frequently reported to occur in the fourth or fifth decade of life.^[4] Non surgical management comprises of acetaminophen, non-

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steroidal anti-inflammatory drugs, corticosteroid injections and cervical traction.

Vishwachi is a condition affecting *Bahu*. *Dhatukshaya* and resultant *Vata Prakopa* can be considered as the main factor leading to *Vishwachi*. *Sneha* helps in *Vata Shamana*. Administration of *sneha* in the form of *Nasya* is indicated in *Bahusheersagata Vata*.^[5] *Brimhana Nasya* with *Dashamooladi Yamaka*^[6] is indicated in *Vishwachi*. *Brimhana* helps in *Vata Shamana* and *Dhatu Poshana*. *Ashtavargam Kashaya* is *Vatahara*.^[7] Hence *Dashamooladi Yamaka Pratimarsha Nasya* and *Ashtavargam Kashaya* were chosen for the study.

OBJECTIVE OF THE STUDY

To evaluate the combined effectiveness of *Dashamooladi Yamaka Pratimarsha Nasya* and *Ashtavargam Kashaya* in *Vishwachi* (Cervical Radiculopathy).

MATERIALS AND METHODS

Source of data:

Subjects of *Vishwachi* were selected from Out Patient and In Patient Department of Sri Dharmasthala Manjunatheshwara Hospital, Hassan.

Diagnostic criteria:

Clinical features of *Vishwachi* and Cervical radiculopathy namely, *Bahu Cheshtapaharana*, *Bahu Karmakshaya* and radiating pain from neck and shoulder down to the arm were the criteria for diagnosis.

Inclusion criteria

1. Subjects between 30 - 70 years of age.
2. Subjects fit for *Nasya Karma*.
3. Subjects irrespective of gender, caste, creed, occupation, religion and socio economic status
4. Subjects who are willing to participate and ready to sign the informed consent form.

Exclusion criteria

1. Cases of uncontrolled diabetes mellitus, hypertension, impaired cardiac, renal, hepatic function and stroke.

2. Subjects having history of traumatic injury of cervical spine and cervical myelopathy.
3. Subjects who are known cases of neoplasm and infective disorders.
4. Pregnant women and lactating mothers.

Ethical clearance and CTIRI registration

Ethical clearance was obtained from Institutional Ethics Committee. IEC No: SDM/IEC/74/2021

Trial was registered on www.ctri.gov.in with Registration No: CTIRI/2022/05/042517 dated 12/05/2022

Study design: An open label, single arm, clinical study on *Vishwachi* (Cervical Radiculopathy) was carried out on 30 subjects, selected by convenience (non-random) sampling technique.

Intervention:

- *Ashtavargam Kashaya* Route of administration - Oral
- *Dashamooladi Yamaka* Route of administration - Nasal

Source and authentication of drug

- *Ashtavargam Kashaya* purchased from a GMP certified pharmacy was packed in 1 litre bottles at Sri Dharmasthala Manjunatheshwara College of Ayurveda Teaching pharmacy.
- Raw drugs for *Dashamooladi Yamaka-Dashamoola* and *Bala* were purchased from CKKM pharmacy. *Masha* was purchased from a local vendor and authenticated from the Department of Dravya Guna, SDM college of Ayurveda and Hospital, Hassan.

Method of preparation of *Dashamooladi Yamaka*

Dashamoola, *Bala* and *Masha*, in a quantity of 100grams each, were finely powdered for preparing *Kalka*. *Dashamoola*, *Bala* and *Masha*, in a quantity of 2 kilograms each were coarsely powdered and soaked in 48 litres of water. This was heated over mild fire and reduced to 12 litres. *Ghritha* and *Tila Taila* 1.5 litres each, were heated in mild fire. *Kalka* and *Kashaya* were

added to this and heated until the *Sneha Siddha Lakshanas* were obtained. *Dashamooladi Yamaka* was packed in 30ml bottles at Sri Dharmasthala Manjunatheshwara College, Teaching Pharmacy. Bottles were properly labelled with the name of the drug, reference, details of the manufacturer, batch number.

Treatment plan:

Ashtavargam Kashaya 15ml thrice daily after food and *Pratimarsha Nasya* with *Dashamooladi Yamaka*- 2 *Bindu* in each nostril, twice daily after food

Duration: 14 days.

Assessment criteria

Assessments were made based on the symptoms of *Vishwachi*^[8], such as *Ruja*, *Stambha*, *Toda*, *Spandana*, *Gourva*, *Arochaka*, *Tandra*, *Bahu Cheshtapaharana*, *Bahu Karma Kshaya*.^[9]

Table 1: Assessment parameters

SN	Parameter	Grade	Assessment
1.	<i>Ruja</i>	1	VAS 0 - No pain
		2	VAS 1-3 - Mild Pain
		3	VAS 4-7 - Moderate pain
		4	VAS 8-10 - Unbearable pain
2.	<i>Toda</i>	1	No pricking sensation
		2	Occasional mild pricking sensation
		3	Frequent pricking sensation
		4	Persistent pricking sensation
3.	<i>Spandana</i>	1	Absent
		2	Present
4.	<i>Gourava</i>	1	Absent
		2	Occasionally

		3	Daily, but not persistent
		4	Daily and persistent
5.	<i>Arochaka</i>	1	Absent
		2	Occasionally
		3	Frequent
		4	Persistent
6.	<i>Tandra</i>	1	Absent
		2	Present
7.	<i>Bahu Cheshtapaharana</i>	1	Absent
		2	Present
8.	<i>Bahu Karmakshaya</i>	1	Absent
		2	Present
9.	Spurling test	1	Negative
		2	Positive
10.	Neck -Range of Movements	(Measured using Goniometer)	

OBSERVATION

57 subjects were screened, 36 were enrolled and 30 subjects completed the study. 6 were drop outs. Majority among 36 subjects - 17 belonged to the age group of 30-40 years, 21 were females; 13 had schooling up to Secondary school education; 36 were married; 12 were homemakers; 16 each belonged to Upper Middle Class and Lower Middle Class category; 30 were from rural locality; 24 had gradual onset of symptoms; 28 followed mixed diet; 22 were observed to follow *Vishamashana*; *Chinta* was observed as a *manasika nidana* in 20; 22 were observed to have *Vishamagni*; 17 had disturbed sleep.

Statistical analysis was done using SPSS VER. 23

RESULTS

30 subjects were administered with *Dashamooladi Yamaka Pratimarsha Nasya* (2 *Bindu* each nostril twice

daily after food) and *Ashtavargam Kashaya* (15ml thrice daily after food) for 14 days.

Table 2: Results of Friedman test on *Ruja, Toda, Gourava* and *Arochaka*.

Parameter	N	Mean			Mean Rank			SD			X ²	Df	P Value	Remarks
		BT	D 7	AT	BT	D 7	AT	BT	D 7	AT				
<i>Ruja</i>	30	3.3	2.9	2.3	2.6	2.1	1.3	0.5	0.8	0.7	37.5	2	0.001	S
<i>Toda</i>		2.0	1.6	1.3	2.5	1.9	1.6	0.9	0.6	0.5	28.8	2	0.001	S
<i>Gourava</i>		2.3	1.9	1.6	2.5	1.9	1.6	1.3	0.9	0.8	24.3	2	0.001	S
<i>Arochaka</i>		1.1	1.1	1.1	2.0	1.9	1.9	0.6	0.4	0.4	2	2	0.4	NS

Table 3: Results of Mc Nemar test on *Spandana, Bahu Cheshtapaharana, Bahu Karmakshaya* and *Spurling* test.

Parameter	N	BT		D 7		AT		P Value BT-AT	Remarks
		Present	Absent	Present	Absent	Present	Absent		
<i>Spandana</i>	30	14	16	9	21	5	25	0.004	S
<i>Bahu Cheshtapaharana</i>		30	0	25	5	5	25	0.001	S
<i>Bahu Karmakshaya</i>		30	0	23	7	17	13	0.001	S
Spurling Test		15	15	15	15	9	21	0.031	S

Table 4: Results of Cochran's Q on *Tandra*.

<i>Tandra</i>	Mean Rank	N	Cochran's Q	Df	P Value	Remark
BT	28	30	4.0	2	0.14	NS
D7	28					
AT	30					

Table 5: Results of Repeated Measure ANOVA test on Neck - Flexion, Extension, Right and left rotation, Right and left lateral flexion

Parameter	N	Mean			Greenhouse- Geisser			Greenhouse- Geisser error df	Remark
		BT	D 7	AT	dF	F Value	P Value		
Neck flexion	30	65.2	68.9	72.3	1.9	23.2	0.001	56.2	S
Neck extension		40.8	42.5	45	1.8	13.8	0.001	53.2	S`

Neck Right Rotation	39.5	41.2	42	1.4	7.1	0.005	41.6	S
Neck Left Rotation	34.2	37.2	40.7	1.9	21.6	0.001	55.9	S
Neck Right Lateral Flexion	53.9	58.3	64.7	1.9	35.9	0.001	57.4	S
Neck Left Lateral Flexion	56.0	62.0	66.8	1.7	32.1	0.001	48.1	S

Friedman test on *Ruja*, *Toda* and *Gourava*; McNemar test on *Spandana*, *Bahu cheshtapaharana*, *Bahu karmakshaya* and Spurling test and Repeated Measure ANOVA test on Neck- Flexion, Extension, Right and left rotation, Right and left lateral flexion showed statistically significant improvement at $P < 0.05$.

DISCUSSION

Effect on *Ruja* and *Toda*

Statistically significant reduction was noticed in *Ruja* and *Toda* with $P < 0.05$. *Ruja* and *Toda* are *Lakshana* of *Prakupita Vata*. *Shoolahara* property of *Eranda*, *Shunthi*, *Nirgundi*, *Bilwa*, *Gambhari*, *Brihati*, *Gokshura*, *Masha* and *Lashuna* helps in reducing *Ruja* and *Toda*.

Effect on *Spandana*

Statistically significant reduction was observed in *Spandana* with $P < 0.05$. *Spandana* is *Kampa* or *Sphurana* caused by *Chala Guna* of *Vata*. *Dashamooladi yamaka* and *Ashtavargam Kashaya* are *Vata Shamaka* and can help in relieving *Spandana*.

Effect on *Gourava*

Statistically significant reduction was observed in *Gourava* with $p < 0.05$. *Gourava* is a *Kapha Vridhi Lakshana*. Majority of drugs in the intervention are *Vatakapahahara* & possess *Ushna Veerya*. This helps in pacification of *Kapha* and thereby reduction of *Gourava*.

Effect on *Stambha*, *Bahu Cheshtapaharana* and *Bahu Karmakshaya*

Stambha interpreted as stiffness of neck was assessed by measuring cervical range of movement using Goniometer. Statistically significant improvement was observed in Cervical range of movement, *Bahu cheshta* and *Bahu Karma* with $p < 0.05$.

Stambha is a *Saama Vata Lakshana*. *Bilwa*, *Shyonaka*, *Gambhari*, *Kantakari* and *Lashuna* possess *Pachana Karma*. *Ama Pachana* helps in relieving *stambha*.

Vyana Vata is responsible for body movements.^[10] *Aushadha Kala* for *Vyana Vata* is after food. Interventions were administered after food. This acts on *Vyana Vata* and helps in reducing *Stambha*, *Bahucheshtapaharana* and *Bahu Karmakshaya*.

Discussion on mode of action of *Pratimarsha Nasya*

Medicine administered through nostril, reaches *Sringataka marma*, spreads in *Murdha* and expels *Doshas* from *Uttamanga*.^[11] According to *Acharya Vagbhata*^[12], *Nasya* pacifies *Urdhwajatrugata Vikara*. *Jatru* is *Greeva Moola*. Hence the terminology *Urdhwajatru* includes *Greeva*. Pathology of Cervical radiculopathy lies in cervical vertebrae and intervertebral disc. Hence *Pratimarsha nasya* was helpful in pacifying symptoms of Cervical radiculopathy.

Snehaprayoga after food is indicated in *Urdhwajatrugata Roga* and *Auttarabhaktika Nasya* is indicated in *Bahu-Sheersha Gata Vata*. Hence *Snehaprayoga* in the form of *Auttarabhaktika Pratimarsha Nasya* with *Dashamooladi Yamaka* gets justified in *Vishwachi* where *Bahu* is affected. *Dashamooladi Yamaka Nasya* is indicated in the evening, after food. *Bhuktabhakta* being a contraindication for *Nasya* in general, *Pratimarsha Nasya* was chosen. *Pratimarsha Nasya* is free from *Yantrana* (restrictions with respect to time or regimen) or *Vyapat* (complications).^[13] It alleviates *Urdhwajatru Vikara* and is capable of strengthening *Greeva* and *Bahu*. *Nasya* done in the morning is capable of pacifying *Kapha* and that done in the evening is capable

of pacifying *Vata* and *Urdhwajatru Vikara*.^[14] Hence, two *Nasya Kala* chosen for the study can help in pacifying *Vata* and *Kapha* involved in *Vishwachi*.

Mode of action of Yamaka

Lipid form of medicine facilitates drug absorption.^[15] *Ghritha* is the best among *Sneha*. It does *Vatapitta Shamana*. *Ghritha* is *Yogavahi* and does *Agni Deepana*. *Tila Taila* is the best among *Taila*. It is *Vatakaphahara*. *Vyavayi* and *Sookshma*, *Teekshna Guna* of *Tilataila* help *Yamaka* to spread faster into *sookshma Srotas*. *Tarpana Karma* of *Tilataila* can correct *Asthidhatu* which is in *Kshaya Avastha*. It can pacify *Kevala Vata* as well as *Kapha anubandha Vata*. It is *Mamsa-Bala Sthairyakara*. *Ghritha* and *Taila* having *Brimhana & Balya Karma* help in relieving symptoms of Cervical radiculopathy which is caused by degenerative pathology.

Mode of action of drugs

Devadaru and *Nirgundi* are capable of doing *Koshthagata Ama Pachana*. *Eranda* does *Srotoshodhana*. *Bilwa*, *Agnimantha*, *Shyonaka*, *Gambhari* and *Kantakari* are capable of doing *Sthanika Ama Pachana*. These can relieve *Stambha* caused by *Saama Vata*. *Sookshma* and *Teekshna Guna* of *Eranda* and *Kantakari* help in transport of medicinal properties to minute channels of circulation. *Shunthi* in *Ashtavarga Kashaya* is capable of enhancing bioavailability of the intervention. *Balya Karma* of *Bala*, *Bilwa*, *Gokshura* and *Shalaparni* and *Mamsabalaprada* action of *Masha* are helpful in strengthening muscles of cervical region and relieving the symptoms. *Rasayana Karma* of *Gambhari*, *Gokshura*, *Shalaparni*, *Lashuna*, *Shunthi* and *Ghritha* helps in *Dhatuposhana*. This can help in slowing down the degenerative pathology in Cervical radiculopathy and correcting *Asthi Dhatu Kshaya* caused by *Vata Vridhi*.

The root extract of *Eranda*, ethanolic extract of *Shunthi*, Stem bark extract of *Devadaru*, ethyl extract of *Nirgundi*, Premanazole in *Agnimantha*, aqueous extract & Gangetin isolated from hexane extract of *Shalaparni* root have proved anti-inflammatory activity. Anti-inflammatory actions of drugs helps in relieving inflammation caused by acute disc herniation

and thereby relieving subsequent impingement on nerve root.^[16]

Vata and *Asthi* have *Asraya-Asrayi Bhava*.^[17] In *Vishwachi*, *Vata Prakopaka Nidana* leads to *Asthi Dhatu Kshaya*. This is comparable to degenerative pathology in Cervical radiculopathy. *Dashamooladi Yamaka* and *Ashtavargam Kashaya* through *Vata Shamana* action helps in correcting *Asthi Dhatu Kshaya* and thereby relieves symptoms of *Vishwachi*.

CONCLUSION

Administration of *Dashamooladi Yamaka Pratimarsha Nasya* and *Ashtavargam Kashaya* showed statistically significant results in *Ruja*, *Toda*, *Stambha*, *Spandana*, *Gourava*, *Bahucheshtapaharana* and *Bahukarma Kshaya*. Hence *Dashamooladi Yamaka Pratimarsha Nasya- 2 Bindu* twice daily after food and *Ashtavargam Kashaya - 15ml* thrice daily after food for 14 days is effective in the management of *Vishwachi* (Cervical Radiculopathy).

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