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A CLINICAL STUDY TO EVALUATE THE THERAPEUTIC EFFECT OF DASHAMULADHYA KASHAYA AND MAHAMASHA TAILA NASYA IN VISHWACHI W.S.R. TO CERVICAL SPONDYLOSIS"

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ABSTRACT

Neck is flexible part of the spinal vertebrae where the cervical vertebrae help in the movement of the neck in all possible direction. Neck also holds the whole weight of the skull. Hence cervical vertebrae are prone for degeneration. The degeneration may impact spinal nerves which pass through these cervical vertebrae from the brain stem to the periphery. As a consequence of compression in the spinal cord or nerve root at the level of cervical vertebrae due to various mechanical and degenerative pathology one may experience pain and stiffness in the neck along with radiating pain to arm which may be associated with numbness or tingling sensation and the condition is known as Cervical spondylosis *Vishwachi* is a *Shoola Pradana Vataja Nanathmja Vyadhi* where *Sira Kandara* and *Bahu* are affected in which pain from the neck radiates to one of the upper extremity. *Dashamuladhya Kashaya* and *Mahamasha Taila Nasya* are taken here for study. **Objectives:** To evaluate the efficacy of *Dashamuladhya Kashaya* and *Mahamashataila Nasya* in *Vishwachi* w.s.r Cervical spondylosis. It was an open labeled clinical study with pre and post test design. 30 patients suffering from *Vishwachi* (Cervical spondylosis) were selected from Sri Dharmasthala manjunatheswara hostipal of Ayurved,Udupi, Karanataka for the study. **Intervention:** The selected patients were administered with internal medication of *Dashamuladhya Kashaya* in

dose of 2 *pala (*96ml) after food and *Mahamasha Taila Nasya* was conducted for 7days. The study was conducted for 7 days and follow up for 7 days, making the total duration of 14 days. **Results:** On comparing the overall effect on symptoms, there was an overall 51.95% improvement in pain, 75% in stiffness, 88.88% improvement in tenderness, 68.3% improvement in range of movements, 62.22% in radiation of pain. On comparing the overall effect of treatment all the 30 patients had marked improvement within 75-100%. All these improvements when analyzed by statistical tests of significance proved highly significant results with $p<0.001$. **Conclusion:** from the statistical results obtained after analysis, it is concluded that *Dashamuladhya Kashaya* and *Mahamasha taila Nasya* is helpful in reducing the signs and symptoms of Vishwachi.

KEYWORDS: *Vishwachi,* Cervical spondylosis, *Dashamuladhya Kashaya, Mahamashataila, Nasya.*

INTRODUCTION

Changing the life style of human being in modern era has created several disharmonies in his biological system. As the progression of busy, professional and social life, improper sitting posture in offices, factories, school, colleges, as well as working at home, continuous and over exerting jerky movements during travelling and sports- all these factors create the undue pressure to spinal cord. This is true as far as *Vishwachi*[1] is concerned where trauma or any injury to *Nadi* of the neck region causing *Toda, Bahu Karma Kshaya* and *Stamba.* This particular pathology can be correlated to the cervical spondylosis in modern parlance.

Nasya karma, one amongst the *Panchakarma* carries very high importance as it deals with the organ of high importance, the *Shiras*. As it is told in the classics, our *Sharira* is divided into six parts *(Anga*), *Shiras* being the *Uttamanga* among six. *Acharyas* have given more importance to *Shiras* as it controls the whole body. *Nasya* not only plays a vital role in protection of *Shiras* but also in the *Urdhwajatru Pradesha*. *Nasya karma* also plays a vital role in maintaining and balancing *Tridosha* and thus promoting the health.

Cervical Spondylosis[2] is one of the degenerative conditions of the cervical spine. It is commonly seen in old age, but nowadays it is encountered in young and middle aged people. In males the prevalence is 96% by age 70 yrs, 94% in women older than 70 yrs.60-70% women and 85% of men show changes related with Cervical Spondylosis by the age 45.[3]

Cervical spondylosis for clinical identification can be compared with *Vishwachi, Manyastambha, Greevagraha* etc. all *acharyas* have highlighted the extensive utility of *Nasya Karma* in *Jatrurdhwaja Vata Vikaras.* Where *Nasya* could be effective, economical and affordable treatment modality. Administration of medicine through nearest routes being the best practice for yielding better results. *Kashaya* is one among the best shaman yoga with is more effective, thus considering the view in background, a clinical study of *Dashamuladhya Kashaya*[4] and *Mahamashataila*[5] *Nasya* in the management of *Vishwachi* (Cervical spondylosis) is taken.

MATERIALS AND METHODS

Source of data

The patients suffering from *Vishwachi* w.s.r to cervical spondylosis were selected for the study from OPD & IPD of Sri Dharmasthala Manjunatheshwara Ayurveda Hospital, Udupi. *Mahamasha Taila* and *Dashamuladhya Kashaya* were obtained from SDM Ayurveda Pharmacy, Kuthpady, Udupi.

Method of collection of data

The subjects suffering from *Vishwachi* w.s.r to cervical spondylosis were screened under strict diagnostic, inclusion and exclusion criteria and were selected for the study. Eligible subjects were invited to participate in the study after signing a detailed informed consent and registered for this clinical trial. Thus registered participants were treated with the medication as per the plan of intervention. The outcome measures were assesed at baseline, on Day 7 and Day 14th.

Design of the study: An open label single arm clinical study.

Intervention

- Dose: 1. *DashamuladhyaKashaya*- 96ml (2 pala)[6]

2. *Marsha Nasya* dose- 6 *Bindhu* (*Madhyamamatra)*[7]

- Form of trial drug: *Kashaya*, *Taila* for *Nasya.*
- Route of adminstration: *Kashaya*-Orally/*Nasyakarma*-into nostrils.
- Time of adminstration: *Kashaya* once a day, Night time After the food *Nasya*- morning time before food.[8]
- *Anupana* for *Kashaya*: *Taila* And *Ghritha* 10ml each (1 *karsha*)[9]
- Duration: *Nasya Karma* for 7 and *Dashamuladhya Kashaya* for 7days.

Follow up: 14th day follow up.

Total duration of the study: 7days Intervention and 7th day follow up total 14days.

Diagnostic criteria:

The diagnostic criteria includes the clinical presentation of *Vishwachi* w.s.r to Cervical Spondylosis i.e pain in the neck and stiffness, radiation of pain, degeneration of spine supported by X ray findings based on cervical degenerative index.

Inclusion criteria

- Patients presenting with *Lakshana* of *Vishwachi* (cervical spondylosis) supported with Radiological findings with X-ray.
- Patients of either sex aged between 16 to 70 years.

Exclusion criteria

- Patients showing the features of cervical spondylosis due to fracture and osteoporosis
- Sensory motor deficit corresponding to C1-C5 and C5 -T1
- Ankylosing spondylosis
- Rheumatoid Arthritis
- Motor neuron disease
- Metabolic and infectious bone disease
- Patients contraindicated for *Nasya*.[10]

Assessment criteria

The full details of history and physical examination of the patients will be recorded as per the pro forma. Clinical assessment will be done before treatment, during the treatment and at the end of the treatment. The assessment of pain can be done using treatment. The assessment of pain can be done using Visual Analouge Scale (VAS)[11] and assessment of the movement can be done with Goniometry, Neck Disability Index (NDI)[12] and Short Form (SF 12).[13] The laboratory investigations will be carried out before and after treatment.

Subjective parameters

- *Samyak Lakshanas* of *Nasya karma*[14]
- Neck stiffness/*Stambha*
- Neck pain/ *Ruk*
- Radiating pain to occipital frontal region, shoulder down to both arms

- Paraesthesia

Objective parameters

- Tenderness over cervical region
- Movements of neck painful/restricted
- Sensory loss in upper limbs
- Tone of hand muscles
- Reflexes of upper limbs

RESULTS

In the present clinical study, 30 patients were enrolled and efficacy of *Dashamuladhya Kashaya* and *Mahamashataila Nasya* w.s.r to Cervical spondylosis was studied. Statistical analysis of results was done using sigma stat software version 4.0 using paired 't' test and 'wilcoxon sign rank' test, the effect of treatment are as follows:

Effect on pain

The mean score of pain before treatment was 7.200 which were reduced to 3.467 after the intervention. Statistical analysis Z value is 4.853 and (P≤0.001), which was statistically significant change with 51.84% of improvement after treatment and 88.33% after follow up.

Table 1: Effect on pain.

Criteria	Time	Mean	±SD	±SE	median	Difference in mean	% improvement	Wilcoxon signed rank test	
Pain n=30	BT	7.200	0.997	0.182	7.00	3.733	51.84%	Z value	P value
	AT	3.467	1.008	0.184	3.50			4.853	≤0.001
	AF	0.84	0.874	0.160	1.00	6.36	88.33%		

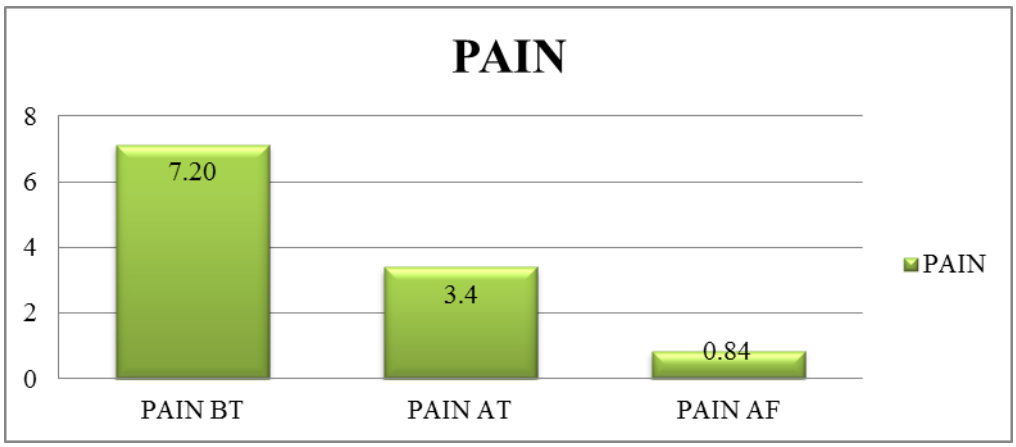

Figure 1: Effect on pain.

Effect on tenderness

The mean score of tenderness before treatment was 1.667which was reduced to 0.267 after the intervention. Statistical analysis Z= 4.949 and (P=<0.001), which was statistically significant change with 83.98% after treatment and 95.8% after follow up.

Table 2: Effect on tenderness.

Criteria	time	Mean	±SD	±SE	median	Difference in mean	% improvement	Wilcoxon signed rank test	
Tenderness n=30	BT	1.667	0.711	0.711	2	1.4	83.983%	Z value	P value
	AT	0.267	0.521	0.521	0			4.949	P≤0.001
	AF	0.0667	0.254	0.0463	0	1.6	95.8%		

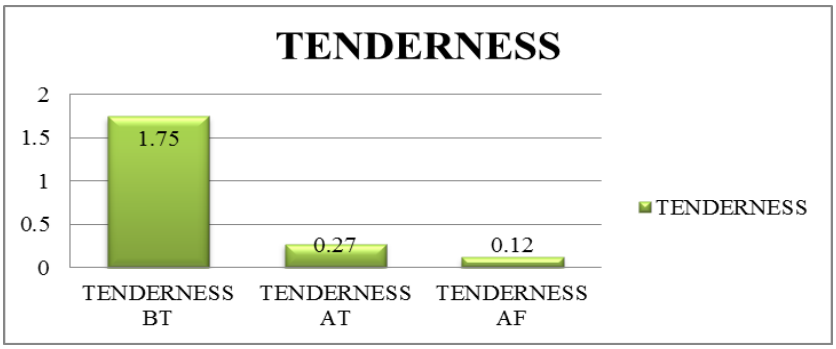

Figure 2: Effect on tenderness.

Effect on neck stiffness

The mean score of stiffness before treatment was 1.367 which was reduced to 0.4 after the intervention. Statistical analysis Z= 5.112 and (P=<0.001), which was statistically significant change with 70.73% after treatment and 98.53% after follow up.

Table 3: Effect on neck stiffness.

Criteria	Time	Mean	±SD	±SE	median	Difference in mean	% improvement	Wilcoxon signed rank test	
Stiffness	BT	1.367	0.490	0.0895	1.00	0.967	70.738%	Z value	P value
	AT	0.4	0.498	0.0910	00			5.112	P≤0.001
	AF	0.02	0.0	0.0	00	1.347	98.53%		

Figure 3: Effect on neck stiffness.

Effect on radiating pain

The mean score of radiating pain before treatment was 1.60 which was reduced to 0.60 after the intervention. Statistical analysis Z= 4.187and (P=<0.001), which was statistically significant change with 62.5% improvement after treatment and 98.3% after follow up.

Table 4: Effect on radiating pain.

Criteria	Time	Mean	±SD	±SE	median	Difference in mean	% improvement	Wilcoxon signed rank test	
Radiating pain	BT	1.60	0.621	0.113	2.0	1.0	62.5%	Z value	P value
	AT	0.60	0.498	0.091	1.0			4.187	P≤0.001
	AF	0.026	0.00	0.00	00	1.57	98.3%		

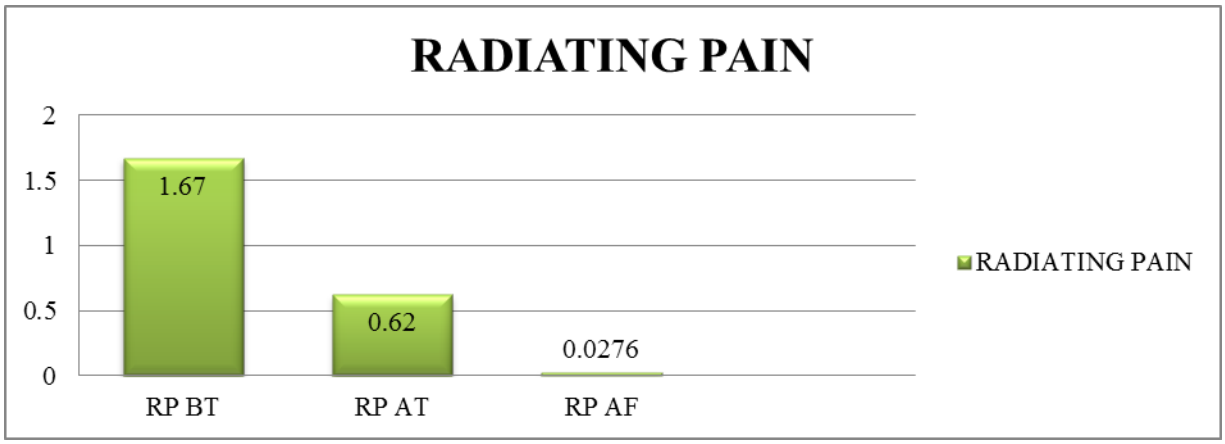

Figure 4: Effect on radiating pain.

Effect on flexion of neck

The mean score of flexion of neck before treatment was 32.133 which were increased to 38.667 after the intervention. Statistical analysis t ±13.44and (P=<0.001), which was statistically significant change with 20.33% improvement after treatment and 27.79% improvement after follow up in range of flexion.

Table 5: Effect on flexion of neck.

Criteria	Time	Mean	±SD	±SE	Difference in mean	% improvement	Paired t test	
Flexion of Neck	BT	32.133	3.711	0.678	6.534	20.33%	t value	P value
	AT	38.667	3.198	0.584			13.44	P≤0.001
	AF	44.500	1.526	0.279	12.37	27.79%		

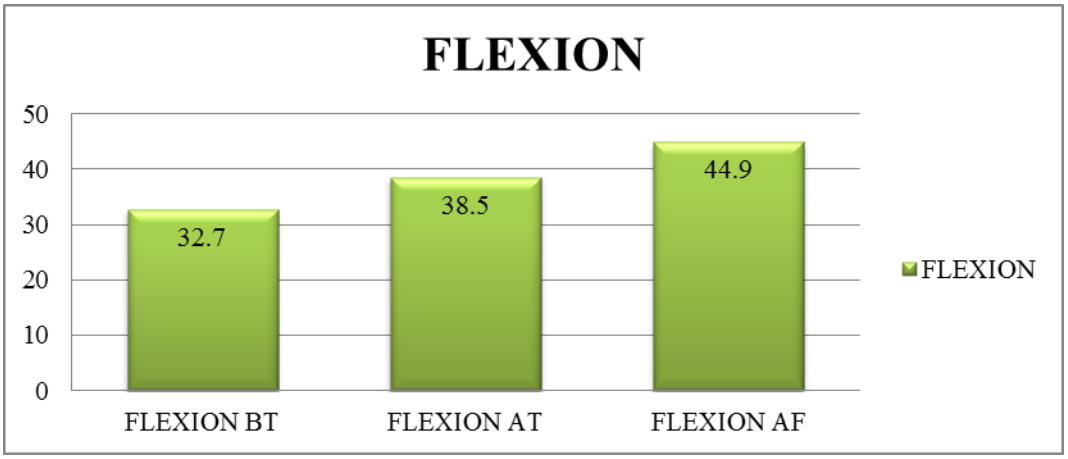

Figure 5: Effect on flexion of neck.

Effect on extension of neck

The mean score of extension of neck before treatment was 32.33 which were increased to 38.66 after the intervention. Statistical analysis t ±10.03 and (P=<0.001), which was statistically significant change with 20.33% improvement after treatment and 37.64% in range of extension after follow up.

Table 6: Effect on extension of neck.

Criteria	Time	Mean	±SD	±SE	Difference in mean	% improvement	Paired t test	
Extension of Neck	BT	32.33	3.40	0.622	6.34	20.33%	t value	P value
	AT	38.66	2.91	0.532			10.03	P≤0.001
	AF	44.50	1.52	0.279	12.17	37.64%		

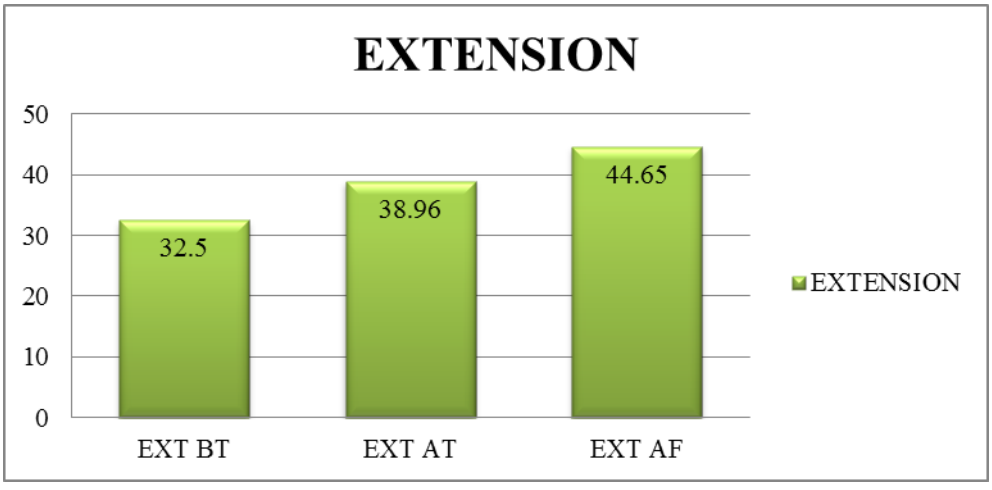

Figure 6: Effect on extension of neck.

Effect on lateral rotation of neck

The mean score of lateral rotation of neck before treatment was 27.00 which were increased to 33.66 after the intervention. Statistical analysis t ±10.26 and (P=<0.001), which was statistically significant change with 24.66% improvement after treatment and 51.85% in range of lateral rotation after follow up.

Table 7: Effect on lateral rotation of neck.

Criteria	Time	Mean	±SD	±SE	Difference in mean	% improvement	Paired t test	
Lateral rotation of Neck	BT	27.00	4.068	0.743	6.66	24.66%	t value	P value
	AT	33.66	3.198	0.584			10.26	P≤0.001
	AF	41.00	3.051	0.557	14	51.85%		

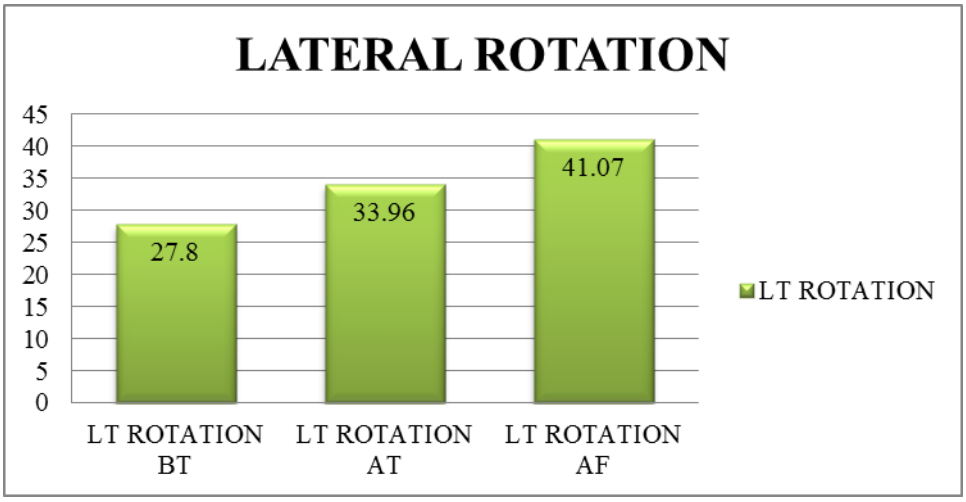

Figure 7: Effect on lateral rotation of neck.

Effect on neck disability index

The mean score of neck disability index before treatment was which was reduced to after the intervention. Statistical analysis Z= 4.794 and (P=<0.001), which was statistically significant change with 18.74% improvement after treatment and 80.50% after follow up.

Table 8: Effect on neck disability index.

Criteria	Time	Mean	±SD	±SE	Median	Difference in mean (BT-AT)	% improvement	Wilcoxon signed rank test	
Neck disability index n=30	BT	22.576	4.576	0.836	22.5	9.37	18.74%	Z value	P value
	AT	13.20	3.614	0.660	12.5			4.794	P≤0.001
	AF	4.400	1.632	0.298	4.0	18.17	80.50%		

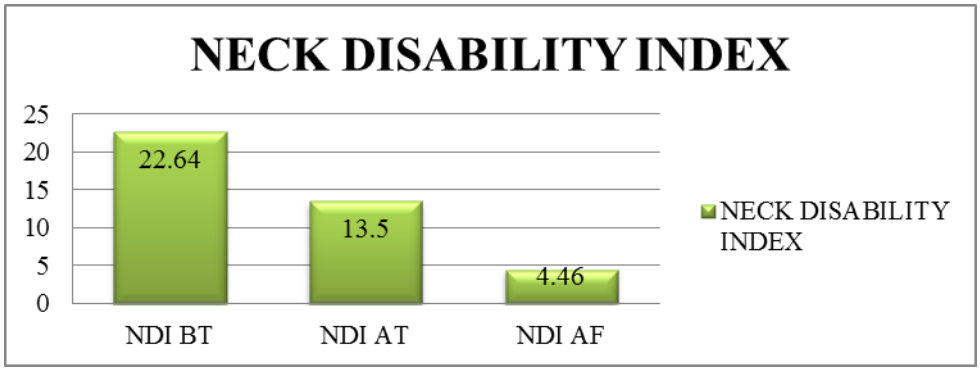

Figure 8: Effect on neck disability index.

Effect on SF-12 questionnaire

The mean score of SF-12 questionnaire before treatment was 31.60 which was reduced to 21.20 after the intervention. Statistical analysis Z= 4.800 and (P=<0.001), which was statistically significant change with 23.63% improvement after treatment and 54.24% after follow up.

Table 9: Effect on SF-12 questionnaire.

Criteria	Time	Mean	±SD	±SE	Median	Difference in mean	% improvement	Wilcoxon signed rank test	
								Z value	P value
SF-12 questionnaire n=30	BT	31.600	4.215	0.770	31.5	10.40	23.63 %	4.800	P≤0.001
	AT	21.20	3.872	0.707	20				
	AF	14.46	1.717	0.313	14	17.14	54.24%		

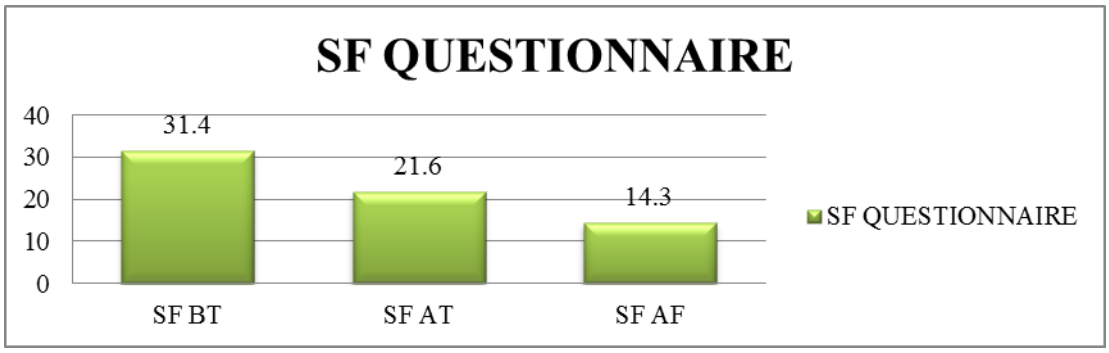

Figure 9: Effect on SF-12 questionnaire.

Over-all effect of treatment

By assessing the overall effect of *Dashamuladhya Kashaya* and *Mahamasha Taila Nasya* in *Vishwachi* among 30 patients, 67% i.e 20 patient showed moderate improvement and 13% i.e 4 patients showed good improvement and 20% i.e 6 patients showed average improvement.

Table 10: overall improvement of patients.

% of improvement	No. of patients	% of patients	comment
0%	0	0	Worsen
1%-25%	0	0	Poor improvement
26%-50%	6	20%	Average Improvement
51%-75%	20	67%	Moderate improvement
76%-100%	4	13%	Good improvement

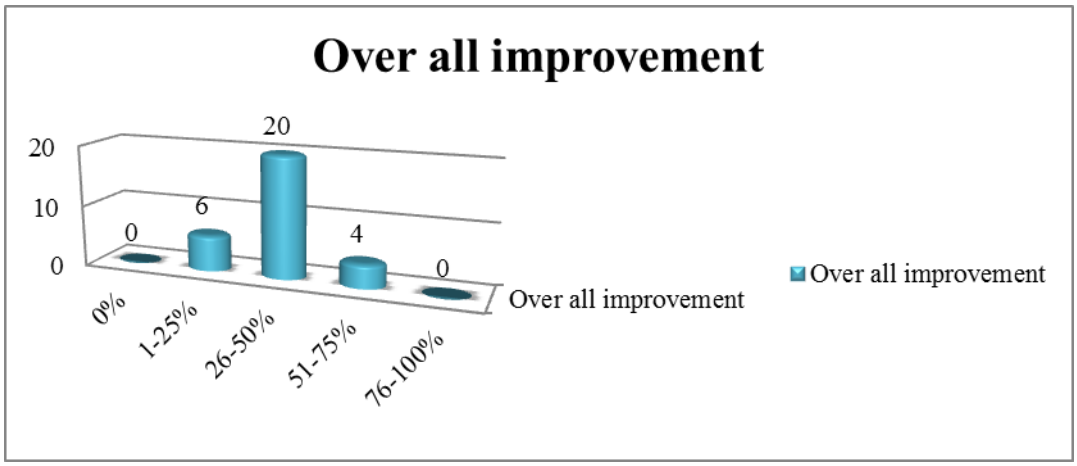

Figure 10: Overall improvement of patients.

DISCUSSION

Cervical spondylosis is one such condition where the degeneration of cervical vertebrae with some anatomical change takes place in the vertebrae resulting in compression of the nerve which causes the severe pain in neck with radiation to hands, restricted movements associated with numbness in upper limb which was much common in old age earlier is nowadays prevalent more in middle and young age too. *Vishwachi* is one such *vatavyadhi* where the symptoms can be correlated to cervical spondylosis where *ahara* and *vihara* plays a major role in *nidana*.*Vishwachi* is observed mainly due to *santarpanajanya, apatarpanajanya* and *abhighataja nidan* and *samprapti* where *rasa,rakta,meda,asthi,majjadhatus* are affected. Due to *rukshadhi ahara vihara* the *snigdha pradana majja medadi dhatu* are not nourished well and lead to *meda,mamsa,majja,kshaya* and *asthipurana karma* is hampered and *asthidhatu* becomes *sushira, durbala*. The *snayu* and *kandara* gets vitiated, hence the *lakshana's* like *bahukarma kshaya, ruk, toda,stambha* are seen.

The life style factors that are explained in table *vihara nidana*, where *ati vyayama* is contraindicated as excessive exercise leads to increase of *vatadosha* which in turn will lead to *Dhatukshayajanya Vatavyadhi*. Trauma can lead to inter vertebral disc prolapse or even fracture of cervical spine at extreme.

As far as etiopathology of *vishwachi* is concerned *vatavaigunya* is important. It essentially plays a role in the over stimulation of the nerve as experienced by severe pain in the course of affected part.

Snehana, svedana and *mrudushodhana* are the line of treatment in all the *vatavyadhi*. Even though *snayu* and *raktha* are involved as *dushya, agnikarma* and *siravyadha* are also the prime line of treatment. *Vagbhata* opines that *nasya karma* have the major benefit on *urdwajathrubhaga*. Hence the study with *mahamasha taila nasya* is taken in *vishwachi* along with *dashamuladhya kashaya* internally which consists of *dashamula, bala* and *masha* where most of the drugs were *vatakapha shamaka* having *madhura rasa* and *ushna virya* which is having *shoolahara* in *karma*.

Effect of drug in vishwachi

Mode of Action of nasya karma – As *mahamashataila* is selected as *brimhananasya* which nourishes the *dushya* involved in vitiation of *doshas.*

Through contemporary medicinal principles Effect of *Nasya* in Neuro-Enodocrinal and Nero-Psychological level.

The limbic system is concerned with multifunctional capabilities including behavioral aspect of human beings and control over endocrine secretions. The olfactory nerves and other adjacent nerves named as terminal nerves which run along the olfactory nerves are connected with limbic system of brain including hypothalamus. The experimental stimulation of olfactory nerve caused stimulation of certain cells of hypothalamus and amygdaloidal complex .The most probable way of action of the drug should be through olfactory pathways influencing hypothalamus, which in turn, causes the inhibition affect through the pituitary.

Mode of action of dashamuladhyakashaya

Dashamooladhyakashaya which was given internally had encouraging results are due to the combination of drugs that are having *VataKapha Hara*, *Shoolahara,Deepana, Pachana* and *Rasayana* properties. And it was given with *Anupana* as *Eranadatailaand ghrita* where *erandataila* acts as catalyst in bringing back the normalcy of vitiated *vatadosha* as it is best *vatashamaka.*

With this understanding the study is planned to evaluate the therapeutic effect of *Dashamuladhya kashaya* and *Mahamasha taila Nasya* in *Vishwachi* showed marked

improvement. The study gives more scope for further clinical studies in patients of *Vishwachi* and other *Vatavyadhi* too.

CONCLUSION

Thus it can be concluded with statistical proof that *Dashamuladhya Kashaya* and *Mahamasha Taila Nasya* is effective in reducing the signs and symptoms of *Vishwachi*/ Cervical spondylosis. The study did not show any adverse effects during the course hence proven the safety of drug.

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