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Clinical study on the combined effectiveness of Mashasaptaka Kwatha and Marsha Nasya with Mashasaptaka Taila in Pakshaghata (cerebrovascular accident-infarct)

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ABSTRACT

Background: Pakshaghata is one among Vataja Nanatmaja Vyadhis which are considered as Mahavyadhis. Pakshaghata can be correlated with Hemiplegia, the commonest pathology of which is cerebrovascular accident (stroke). Stroke is defined as sudden onset of neurologic deficit from vascular mechanism. 85% of all strokes are ischemic and 15% are hemorrhagic. Aims And Objectives: To evaluate the combined effectiveness of Mashasaptaka Kwatha and Marsha Nasya with Mashasaptaka Taila in the management of Pakshaghata (Cerebrovascular Accidentinfarct). Methods: Thirty diagnosed subjects of Pakshaghata (CVA due to infarct) were administered with Mashasaptaka Kwatha and Marsha Nasya with Mashasaptaka Taila for 7 days. The data of patients was recorded before and after treatment using an elaborate proforma. Assessment was done based on the primary and secondary outcome measures. For statistical analysis, Wilcoxon Signed Rank test, McNemar tests were used. Results: In this study it was found that there was statistically significant relief in the symptoms of Pakshaghata (Cerbrovascular accident-infarct). Conclusion: Relief in the symptoms was achieved by the drugs having properties such as Vatakaphahara, Anulomana, Brimhana, Srotoshodhana etc. Hence, Mashasaptaka Kwatha and Marsha Nasya with Mashasaptaka Taila for 7 days is effective in the management of Pakshaghata (Cerebrovascular accident-infarct).

Key words: Pakshaghata, Cerebrovascular Accident, Mashasaptaka Kwatha, Marsha Nasya.

INTRODUCTION

Vatavyadhi is considered to be one among the Ashtamahaqadas.^[1] Pakshaqhata is one among the 80 Vatajananatmaja Vikaras and is a Roga of Madhyamarogamarga.^[2] Gravity of the disease was perfectly judged by ancient physicians even the name

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given suggests the egregious nature of Pakshaghata. Pakshavadha is used synonymously with Pakshaghata. 'Vadha' means to assassinate and 'Ghata' means to strike hard and suddenly. Both the words suggest a sudden appearance of strong symptoms and sequel like Shiromarmaghata, Indriyanasha, Karmahani and even death.

The etiopathogenesis of Pakshaghata is explained in classics^[3] in which the vitiated Vata resides in one half of body and causes Shoshana of Sira and Snayu leading to loosening of joints. This in turn leads to symptoms like Cheshtanivrutti, Ruja and Vakstambha.^[4] Anya Dosha Anubandha Lakshanas are also explained.^[5]

CVA is not a disease in itself but is heterogeneous group of disorders. Hemiplegia is one of the most frequent and commonest clinical presentations of CVA.^[6] A stroke or cerebrovascular disease, is defined as an abrupt onset of neurological deficit that is

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attributed to a focal vascular cause. Stroke is the second major cause of death worldwide with 6.2 million dying from stroke in 2015, an increase of 830,000 since the year 2000.^[8] The world wide incidence has been quoted as 2/1000 population/annum; about 4/1000 in people aged 45-84 years.^[9] Over the last four decades the stroke incidence in low and middle-income countries has more than doubled. Community surveys in India have shown a crude prevalence rate for CVA in the range of 200 in 100,000 persons.^[10]

Eighty five percentages of stroke cases are due to cerebral infarction and fifteen percentages due to cerebral haemorrhage and 1.5 times more often in male than female,^[11] According to the India stroke fact sheet updated in 2012, the estimated age-adjusted prevalence rate for stroke ranges between 84/100,000 and 262/100,000 in rural and between 334/100,000 and 424/100,000 in urban areas.^[12]

The allopathic line of treatment for CVA is medical support, thrombolysis, antiplatelet agents, anticoagulation, neuroprotection and rehabilitation.^[13]

Pakshaghata Chikitsa explained by the classics mainly include Snehana, Swedana and Virechana.^[14] Detailed description of other line of treatment for Pakshaghata is also available such as Snehana, Swedana, Mruduvirechana, Mastishkya, Salvanaupanaha and Basti.^[15]

Mashasaptaka Kwatha is a multiherb decoction quoted to reduce the symptoms of *Pakshaghata* in 7 days.^[16] In this study it was administered orally and the *Taila* prepared out of the same formulation is used for *Nasya*.

Mashasaptaka kwatha is combination of Masha, Bala, Kapikacchu, Eranda, Rasna, Ashwagandha and Kattruna taken along with Hingu and Saindhava. Majority of drugs in this formulation possess Madhura Rasa and Ushna Veerya which are Vatashamaka. Masha, Bala and Hingu also possess Vedanashamaka property. Hingu and Saindhava being Teekshna and Sukshma would have aided in removing the Margavarna present in the Srotas while the drugs like Masha, Eranda, Kapikachu and Bala, being Brimhana and *Dhatuvardhaka* may have aided in relieving *Dhatukshaya*.

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OBJECTIVE

To assess the combined effectiveness of *Mashasaptaka Kwatha* in a dose of 30ml thrice after food with *Anupana* of *Hingu* and *Saindhava* and *Marsha Nasya* with *Mashasaptaka Taila* twice daily for a duration of 7 days in the management of *Pakshaghata* (Cerebrovascular accident-infarct).

MATERIALS AND METHODS

Source of data: Patients who attended the in-patient department of Kayachikitsa at Sri Dharmasthala Manjunatheswara Ayurveda Hospital, Hassan.

Method of collection of data: Data was collected using specially prepared case report form. The Demographic data of 34 enrolled patients of *Pakshaghata* such as age, gender, educational status etc. was collected.

Screening of the patient

Diagnostic criteria - subjects with classical features of *Pakshaghata*

- Cheshtanivritti
- Ruja
- Vaakstambha

Inclusion criteria

- Subjects who are conscious and oriented
- Subjects fit for Nasya
- Subjects of either gender
- Subjects aged between 30-80 years
- Subjects who are ready to participate and sign the informed consent form

Exclusion criteria

- Subjects with uncontrolled diabetes mellitus and uncontrolled hypertension
- Diagnosed cases of haemorrhagic stroke, intra cranial space occupying lesion, Congenital defects and carcinoma, Intra cranial infections.

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Pregnant women and lactating mother

Sampling technique - Convenient sample

Sample size - 34

Statistical method

Analysis Data is entered using SPSS 23 and data is analyzed. For significance of change in Nominal data, McNemar test was performed for significance of change in Ordinal data Wilcoxon signed rank test was performed.

Ethical consideration

IEC No- SDM/IEC/28/2020

CTRI No- CTRI/2021/01/030211

Study design

The study was open label, single arm, exploratory, prospective clinical on 34 patients of *Pakshaghata* selected using the convenience/ purposive (nonrandom) sampling technique with pre and posttest design conducted in a tertiary Ayurveda hospital attached to quarters in southern India.

Treatment plan

- Oral medication Mashasaptaka Kwatha 30ml tid A/F with Hingu (125mg) and Saindhav (350mg) as Anupana.
- 2. Procedure Marsha Nasya with Mashasaptaka Taila 8 Bindu, twice daily

Duration: 7 days

Source and authentication of raw drug

Required raw drug for the treatment were purchased from CKKM Ayurveda Pharmacy, Kerala, a GMP certified pharmacy and 1 drug was purchased from a local farm and authentication certificate was obtained from *Dravyaguna* Department of Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Hassan.

Assessment criteria

Assessment was done based on the improvement in the primary and secondary outcome measures after the administration of the medicine for 7 days.

Primary outcome measures

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Assessment was done based on the symptoms like *Cheshta Nivritti* (Table 1), *Vaakstambha* (Table 2), *Ruja* (Table 3).

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Secondary outcome measure

National Institute of Health (NIH) Stroke Scale, Modified Medical Research Council (MRC) Scale for Muscle strength.

Table 1: Cheshtha Nivritti Grading

Parameter	Grading	Observation			
Cheshta Nivritti	1	Normal			
	2	Needs minor help			
	3	Needs major help			
	4	Complete loss of function			

Table 2: Vakstambha Grading

Parameter	Grading	Observation
Vakstambha	1	Able to pronounce compound word
	2	Able to pronounce simple word but unable to pronounce compound words
	3	Slurred speech
	4	Aphasia

Table 3: Ruja Grading

Parameter	Grading	Observation
Ruja	1	No pain
	2	Mild pain occasionally
	3	Moderate tolerable pain
	4	Severe intolerable pain

RESULTS

34 patients were screened and enrolled in the clinical trial and 33 completed their course of treatment for 7 days and were assessed with before and after treatment. The socio demographic data of the patient's shows that average age of the patients enrolled in the

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study was from 51 to 60 and among the gender male were 23 in number (Table 4)

Table 4: Demographic data of 34 patients ofPakshaghata

Age in Years	No. of Patients	Percentage
30-40	3	8.8
41-50	10	29.4
51-60	6	17.6
61-70	14	41.2

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71-80	1	2.9
		-

The effectiveness of the drug imperatively evaluated with improvement in *Cheshta Nivrutti, Vaaksthambha, Ruja* and NIH stroke scale, which showed improvement among the patients.

The primary outcome measure was assessed by *Chesta Nivritti, Vaaksthambha* and *Ruja. Cheshta Nivritti* was improved in 19 patients, *Vakstambha* was improved in 13 patients and *Ruk* was improved in 18 patients. Statistically Wilcoxon signed rank test showed significant p value see table number 1: primary outcome measures.

Table 5: Wilcoxon Signed rank test showing the effect of Mashasaptaka Kwatha and Mashasaptaka Taila on primary
outcome measures

Primary outcome measure	Negative ranks			Positive ranks			Ties	Tot al	z	Р	Remarks			
	N	MR	SR	N	MR	SR								
Chestanivrittii AT-BT	19	10.0	190.0	0	.00	.00	14	33	-4.264	<0.05	S			
Vakstambha AT-BT	13	7.00	91.00	0	.00	.00	20	33	-3.606	<0.05	S			
Ruja AT-BT	18	9.50	171.0	0	.00	.00	15	33	-4.243	<0.05	S			
MR = Mean Rank, SR = Sum of	Ranks,	S= Significar	MR = Mean Rank, SR = Sum of Ranks, S= Significant, NS = Non Significant											

The secondary outcome measures was assessed by Wilcoxon signed rank test for muscle power of both upper and lower limbs statistically test showed significant value and there was improvement after the treatment. NIH stroke scale showed significant improvement in motor arm drift, motor leg drift and dysarthria see table number 3 NIH stroke scale.

Table 6 : NIH Stroke scale parameters

Negative ranks			Posi	Positive ranks		Ties	Total	z	Р	Remar ks
N	MR	SM	N	MR	SM					
14	7.5	105.0	0	.00	.00	19	33	-3.742	.000	S
28	14.5	406.00	0	.00	.00	5	33	-4.88	.000	S
29	15.0	435.00	0	.00	.00	4	33	-4.893	.000	S
12	6.50	78.00	0	.00	.00	21	33	-3.357	.001	S
	N 14 28 29	N MR 14 7.5 28 14.5 29 15.0	N MR SM 14 7.5 105.0 28 14.5 406.00 29 15.0 435.00	N MR SM N 14 7.5 105.0 0 28 14.5 406.00 0 29 15.0 435.00 0	N MR SM N MR 14 7.5 105.0 0 .00 28 14.5 406.00 0 .00 29 15.0 435.00 0 .00	N MR SM N MR SM 14 7.5 105.0 0 .00 .00 28 14.5 406.00 0 .00 .00 29 15.0 435.00 0 .00 .00	N MR SM N MR SM 14 7.5 105.0 0 .00 .00 19 28 14.5 406.00 0 .00 .00 5 29 15.0 435.00 0 .00 .00 4	N MR SM N MR SM SM <td>N MR SM N MR SM SM<td>N MR SM N MR SM SM SM $^{-1}$ $^{-1}$</td></td>	N MR SM N MR SM SM <td>N MR SM N MR SM SM SM $^{-1}$ $^{-1}$</td>	N MR SM N MR SM SM SM $^{-1}$

MR = Mean Rank, SR = Sum of Ranks, S= Significant, NS = Non Significant

Table 7: Wilcoxon Signed rank test showing the effect of Mashasaptaka and Mashasaptaka Taila on Muscle power.

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Muscle power	Negative ranks			Positiv	Positive ranks			Total	z	Ρ	Rem arks
	N	MR	SR	P MR SR							
UL-Proximal AT- BT	0	.00	.00	31	16.00	496.00	2	33	-4.936	.000	s
UL -Distal AT-BT	0	.00	.00	31	16.00	496.00	2	33	-4.936	.000	s
LL- Proxi mal AT- BT	0	.00	.00	31	16.00	496.00	2	33	-4.933	.000	s
LL- Distal AT- BT	0	.00	.00	31	16.00	496.00	2	33	-4.933	.000	s
MR = Mean Rank, SR = Sum of Ranks, S= Significant, NS = Non Significant											

DISCUSSION

Statistically significant improvement was found in muscle strength and consequently motor arm, motor leg and *Cheshta nivrutti* after treatment. Wilcoxon signed rank test (P value>0.05) showed improvements in mean after treatment.

All the ingredients of the *Kwatha* are *Vatahara*. *Tila Taila* used as base oil for *Sneha Nasya* is best *Vatahara Sneha* and thereby improves the *Bala*. *Sneha* may have helped in nourishing the *Gritakaram Majja* as *Samanyo Vridhikaranam* thereby regaining motor function.

Cheshta Nivrutti is also as a result of the Shoshana of Sira and Snayu by Rukshateekshna Nidana Sevana, Dhatukshaya etc. The Ruksha Guna of Vata may have been combated by the Snigdha Guna present in the ingredients of Kwatha as well as by the Sneha. Ashwagandha, Bala, Masha, Kapikacchu does Vatanulomana which helps in corrects the flow of Vayu. They also possess Karma like Balya, Brimhana, Nadibalya, Dhatuvardhaka, Ojovardhaka and Rasayana which would have improved the nourishment of the muscles leading to improved activity.

Motor activities of the body are attributed to the normal functioning *Vyana*. *Hridaya* is the seat of *Vyana Vayu*. *Kattrina* and *Hingu* are *Hridya* and *Hridaya Srotoshodhaka* respectively aiding in removing any *Avarana* present and thereby facilitating unobstructed flow of *Vyana*. Loss of functions of *Udana* such as maintenance of *Prayatna, Urja* and *Bala* as well as loss of function of *Vyana* like *Gati, Apakshepana, Utkshepa* presents as *Cheshta Nivritti* in *Pakshaghata. Oushadha Sevana Kala* advised for *Vyana Vata* and *Udana Vata* is after food, morning and evening respectively. The medicine is administered in this *Kala*. This would have helped in improving the deranged *Vyana* and *Udana*.

The importance of *Hetu* and *Sthana* for the correct diagnosis and accordingly planning the treatment is mentioned in *Vatavyadhi*.

Targeting the *Sthana: Sthana* in case of *Pakshaghata* can be considered as *Shiromarma* and *Hetus* are multifaceted. *Shiras* is the *Sthana* of *Prana Vayu* which nourishes all the other types of *Vata*. As *Nasa is Shiraso Dwaram, Nasya* acted as the appropriate route of drug administration.

Research findings on ingredients w.r.t. enhancing locomotion: The results of a study showed that *Withania somnifera* has neuroprotective potential in both pre and post-stroke treatment paradigms in a mouse model of focal ischemia. In addition to the infarct volumes, WS also showed a definite trend in improving the locomotor activities of mice subjected to ischemia, which was an important finding vis-a-vis the functional recovery following stroke. *Rasna* contains chemical components such as pluchine, flavonoids, quercetin and isorhamnetin. Previous studies have revealed that Pluchine acts as CNS stimulant, has

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neuroprotective and neuromodulatory action. Flavonoids have both antioxidant and antithrombotic property. Quercetin, attenuate severe neurological deficits and reduces infarct volume. Isorhamnetin improves blood brain barrier function. In a previous study, root extract has effect on locomotor activity and pentobarbital induced sleep, social isolation-induced aggressive behavior, motor coordination in the rotarod test.^[17]

Effect on Vakstambha and dysarthria

Statistically significant improvement was noticed in *Vakstambha* and dysarthria after treatment. Wilcoxon signed rank test (P value=.005) showed improvements in mean after treatment.

Vaksanga occur due to affliction of Udana Vayu. Nasa is one of the site of Udana Vayu. The Nasya Karma is indicated in Vakgraha, Gadgadatva etc. Nasya administered using Mashasaptaka Taila which have Indriyabalakara and Tridoshahara and Vatakaphashamaka properties respectively would have helped in improving speech.

In Swarabheda Chikitsa, Vatakaphahara line of treatment is mentioned. The cumulative effect of Mashasaptaka Kashaya is also Vatakaphahara.

Samana Avruta Prana causes Gadgada and Mookatva. Rasna, Eranda, Kattruna, Hingu and Saindhava have Deepana, Pachana and Vatanulomana effect which might have helped in removing the Avarana. Kaphavruta Udana causes Vak Graha. Tila Taila, Hingu, Saindhava are Vyavayi, Vikasi and Teekshna. By virtue of this, it acts as Margavaranahara and Kapha Nisaraka leading to the normal Gati of Udana and Pranavata. Oushadha Sevana Kala advised for Udana Vata that is evening after food was adopted in order to improve the function of Udana.

Effect on *Ruja*: Statistically significant improvement was noticed in *Ruk* after treatment. Wilcoxon signed rank test (P value=.000) showed improvements in mean after treatment. *Ruja* is caused by the *Laghu*, *Ruksha* and *Ashukari Guna* of *Vata Dosha*. *Masha*, *Bala*, *Rasna* and *Hingu* and *Saindhava* has *Shoolaprashamana* and *Vedanasthapana* properties by virtue of *Guru Snigdha* and *Ushna Guna*.

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Effect on Facial Palsy: The deviation of angle of mouth and obliteration of naso labial fold is due to facial weakness on the affected side due to corrupted nerve supply. Vaktrardhvakra occur due to aggravation of Chala Guna of Vata, which is responsible for 'Anavasthitatva'. Mukhabhyanga done with Tila Taila as Purva karma of Nasya isVvatahara and Dadyakara. Nasya due to its therapeutic effect as well as pharmacological effect of Mashasaptaka Taila and oral intake of Mashasaptaka Kwatha helps to combat it by its Shodhana, Snehana Balya, Brinhaniya, Nadibalya and Sthairyakara properties.

Mode of action of drug: Most of the drugs in Mashasaptaka Kwatha are having Sniadha, Guru Guna, Ushna Veerya, and Vata Shamaka properties. All the above properties are very useful to alleviate the Vata which is aggravated by Dhatukshaya, Vata Prakopaka Ahara & Vihar, Abhighata etc. Tikshna, Sukshma, Vyavayi Guna and Ushna Veerya (Properties of drugs and Til Taila) remove the Avarana of Vayu and retain its normal Gati. Balya, Brimhaniya properties of drugs can nourish and increase the tone of Dhatus. Ushna Veerya, Tikshna-Sukshma Guna of Taila & Drugs which is administered by Nasya Karma (Target to site), remove the Mamsadi Dushya Samurcchana with Dosha. Nasya is directly affect the site i.e., Murdha where Khavaigunya takes place. ("Nasa Hi Shiraso Dvarum")

Mode of action of Nasya: Nasa being gateway to Shirah, the drug administrated through nostrils reaches Shringataka, a Siramarma by Nasa Srota and spreads in the Murdha (~Brain), taking routes of Netra (Eyes), Shrotas (Ears), Kantha (Throat) and stretches the morbid Doshas from Urdhwajatru and expels them from Uttamanaa. The nasal route of drug administration helps in by passing the hepatic first pass mechanism and drug degradation, leads to rapid drug absorption and quick onset of action. The blood brain barrier is highly permeable for lipid and lipid soluble substances. Therefore, these substances can pass easily through the blood brain barrier and can exert their actions. Certain lipids are used for providing energy to nervous tissues. Nasya acts at the level of blood circulation, lymphatic channel including CSF,

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causes neuroendocrinal and neurovascular stimulation and also acts at neuropsychological levels

CONCLUSION

Mashasaptaka Kwatha with Hingu and Saindhava as Anupana and Marsha Nasya with Mashasaptaka Taila was found beneficial in subjects of Pakshaghata. It showed improvement in primary outcome measures such as Cheshta Nivrutti, Vakstambha and Ruk in subjects of Pakshaghata with p value < 0.05. In this study, maximum improvement was found in "Cheshta Nivritti" followed by "Ruk" and then Vak Stambha". It showed improvement in the NIH stroke scale parameters with p value < 0.05. No adverse drug reactions were reported during the study. Research hypothesis was thus accepted.

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