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An open label single arm prospective clinical study in the management of *Pakshaghata* (CVA due to infarct) with *Maharasnadi Kashaya* and *Shunti Churna*

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A B S T R A C T

Pakshaghata is one among 80 *Vata Namathmaja Vyadhi*. In *Pakshaghata* vitiated *Vata* resides in one half of body and causes *Vishoshana* of *Sira* and *Snayu* leading to loosening of joints results into manifestation of symptoms like *Cheshta Nivrutti, Ruja* and *Vakstambha*. *Pakshaghata* can be correlated to stroke or CVA. The study aims to evaluate the combined effectiveness of *Maharasnadi Kashaya* with *Shunti Churna* as *Anupana* in management of *Pakshaghata* (CVA due to infarct). The open label prospective clinical study was conducted among the 32 patients of *Pakshaghata* by convenient sampling method at a tertiary Hospital Sri Dharmasthala Manjunatheshwara College of Ayurveda & Hospital, Hassan, Karnataka from December 2018 to December 2019. The effectiveness of the drug 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 "*Ruk*" followed by "*Cheshta Nivrutti*" and then "*Vak Stambha*". Hence this drug is more effective in "*Saruja Pakshaghata*" hence; it showed improvement in the NIH stroke scale parameters with p value < 0.05. The combined effectiveness of *Maharasnadi Kashaya* with *Shunti Churna* as *Anupana* in management of *Pakshaghata* (CVA due to Infarct) is proved.

Key words: *Pakshaghata, Cerebro Vascular Accident* (CVA due to Infract), *Maharasnadi Kashaya, Shunti Churna.*

INTRODUCTION

Pakshaghata is a *Vatavyadhi* classified under *Astamahagada.*[1] It is *Vata Pradhana Tridoshaja Vyadhi*, in which among *Vata - Prana, Udana, Vyana, Apana,* in *Pitta - Ranjaka*, *Aalochaka*, and *Pachaka* and in *Kapha - Avalambak, Bodhak, Tarpak* are associated.[2] *Pakshaghata* is included in 80 *Vata Namathmaja Vyadhi.*[3] *Pakshaghata* is caused by *Dhatukshayajanya* and *Margavaranjanya*. The aggravated *Vata* perfuse through *Urdwa, Adhah* and *Tiryak Ghata Dhamanis.*[1] In *Pakshaghata* vitiated *Vata* resides in one half of body and causes *Vishoshana* of *Sira* and *Snayu* leading to loosening of joints resulting in symptoms like *Cheshta Nivrutti, Ruja* and *Vakstambha.*[4]

Pakshaghata can be correlated to stroke or CVA. In 1970, the World Health Organization defined stroke as 'rapidly developed clinical signs of focal (or global) disturbance of cerebral function, lasting more than 24 hours or leading to death, with no apparent cause other than of vascular origin.[5] The signs and symptoms of stroke are sudden numbness or weakness in the face, arm, or leg, especially on one side of the body , confusion, difficulty speaking, or difficulty in understanding speech, trouble seeing in

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one or both eyes, trouble in walking, dizziness, loss of balance, or lack of coordination, severe headache with no known cause. According to CDC stroke can be classified into 3, they are ischemic stroke, cerebral stroke and transient ischemic attack.[9]

World stroke organization report of 2018 gives the data of annual risk of stroke inclusive of all risk combined accounts for 88.8%. Metabolic blood systolic high pressure, high body mass index, high fasting plasma glucose, high total cholesterol and low glomerular filtration rate accounts for 72.1%. Behavioral factors such as smoking, poor diet and low physical activity accounts for 66.3%. Of all hypertension solely contributes 57.3% of risk of stroke.[6]

Annually five and half million people die of stroke. 53% and 47% die each year of stroke in male and female respectively. Less than 44 years of age 4% all death and fewer than 70 years of age 39% of all deaths are from stroke.[7] According Indian statistics 7,00,000 populations is affected by stroke every year. 10% recover completely, 25% live with minor impairment, 40% live with moderate to severe impairment, 10% require care in hospital and 15% die shortly after the stroke.[1]

Acharya Charaka describes the treatment of *Pakshaghata* is *Swedana, Snehana* and *Virechana.*[2] In modern science treatment for stroke is thrombolysis, antiplatelet agents, anticoagulation, neuroprotector and rehabilitation.

According to *Sharangdhara Samhita*, *Maharasnadi Kashaya* with *Shunti Churna Anupana* is used to treat *Pakshaghata.*[8] *Maharasnadi Kashaya* is a formulation comprising of 26 drugs which is contribution of *Sharangdhar Samhita*. As per the claim of classical textbook it is indicated in treatment of *Pakshaghata* along with *Shunti Churna Anupana*. This contains *Tikta Rasa, Katu Vipaka, Ushna Veerya* and *Guru, Snigdha Guna, Vatakapha Shamaka, Rasayan, Deepana, Hrudya, Medhya Karma.* Therefore this study intends to evaluate the combined effectiveness of *Maharasnadi Kashaya* with *Shunti Churna* as *Anupana* in management *Pakshaghata* (CVA due to infarct).

MATERIALS AND METHODS

Study setting

Out Patient Department of Sri Dharmasthala Manjunatheshwara Ayurveda College & Hospital, Hassan, Karnataka, India.

Study population

Patients with *Pakshaghata Lakshana*

Study period

December 2018 - December 2019

Inclusion criteria

Chesta Nivritti, *Vaaksthambha* and *Ruja.*

Subjects aged between 30yrs - 75yrs.

Pakshaghata associated with disease like controlled Diabetes Mellitus, Hypertension, Hyperlipidemia (Any of these or all of these).

Those who are ready to sign the informed consent form.

Exclusion criteria

- Known case of HBsAg, HIV, Carcinoma, Renal disorders, COPD.

- History of evidence of Intra Cranial Infection - Encephalitis, Meningitis, Cerebral Tumor, Cerebral Abscess.

- Congenital Defects - Diffused Sclerosis, Cerebral Agenesis.

Sampling technique

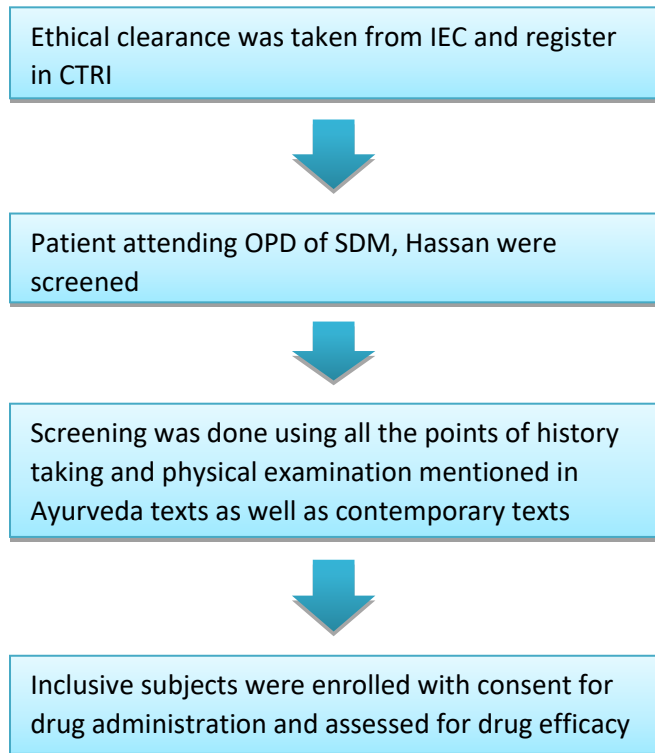Convenient sample

Sample size - 32

Statistical method/ analysis

Data is entered using SPSS 20 and data is analysed.

For significance of change in Nominal data McNemar test was performed

For significance of change in Ordinal data Wilcoxon signed rank test was performed

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Data collection method

Ethical clearance was taken from IEC and register in CTRI

Patient attending OPD of SDM, Hassan were screened

Screening was done using all the points of history taking and physical examination mentioned in Ayurveda texts as well as contemporary texts

Inclusive subjects were enrolled with consent for drug administration and assessed for drug efficacy

Ethical consideration

IEC No- SDM/IEC/62/2018-19

CTRI No- CTRI/2019/04/018440

Intervention

An intervention was planned to administer *Maharasnadi Kashaya* 50ml with *Shunti Churna Anupana* 1½ grams twice daily after food for 7 days which was prepared in teaching Pharmacy of SDM College of Ayurveda, Hassan.

Grouping

62 patients who attended OPD were screened, among them 32 patients were included in the study and administered the drug.

Source and authentication of the drug

Maharasnadi Kashaya raw drug was purchased from CKKM pharmacy, Kerala and *Shunti Churna* was purchased from Sri Dharmasthala Manjunatheshwara Ayurveda pharmacy, Hassan.

RESULTS

32 patients were screened and enrolled in the clinical trial completed their course of treatment for 7 days

was assessed with before and after treatment. The socio demographic data of the patient's shows that average age of the patients enrolled in the study was from 51 to 60 and among the gender male were 26 in number see table number 1 patient characteristic.

Table 1: Patient characteristic

Age	Frequency (N=32)	Percentage
Less than 40	3	9.4%
41-50	7	21.9%
51-60	13	40.6%
61- 70	6	18.8%
Above 70	3	9.4%
Gender		
Male	26	81.3%
Female	6	18.8%

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 24 patients *Vakstambha* was improved in 11 patients and *Ruk* was improved in 28 patients. Statistically Wilcoxon signed rank test showed significant p value see table number 2primary outcome measures.

Table 2: Primary outcome measures

Primary outcome measures	Negative ranks			Positive ranks			Ties	Total	Z Value	P Value	Remarks
	N	MR	SR	N	MR	SR					
Cheshta Nivritti	24	12.50	300.0	0	.00	.00	8	32	-4.735	.000	S

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	N	MR	SR	N	MR	SR	Ties	Total	Z Value	P Value	Remarks
BT-AT											
Vakstambha BT-AT	11	6.00	66.00	0	.00	.00	21	32	-3.317	.01	S
Ruk BT-AT	28	15.36	430.0	1	5.00	5.00	3	32	-4.803	.00	S

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 3: NIH stroke scale

NIH stroke scale	Negative ranks			Positive ranks			Ties	Total	Z Value	P Value	Remarks
	N	MR	SR	N	MR	SR					
Motor arm BT-AT	30	15.50	465.0	0	.00	.00	2	32	-5.108	.000	S
Motor leg BT-AT	26	13.50	351.0	0	.00	.00	6	32	-4.689	.000	S
Dysarthria BT-AT	6	3.50	21.00	0	.00	.00	26	32	-2.449	.014	S

DISCUSSION

The combination of 26 drugs in *Maharasnadi Kashaya* contains *Tikta Rasa, Katu Vipaka*, *Ushna Veerya* and *Guru, Snigdha Guna, Vatakapha Shamaka, Rasayana, Deepana, Hrudya* and *Medhya Karma*. *Acharya Vagbhata* in *Ashtanga Sangraha* has opined that any treatment should be given for 7 days, if there is no improvement in this duration then other *Chikitsa* should be opted once the power of the first *Chikitsa* subsides.[10] If there is mild improvement in the treatment to get maximum benefit treatment should be continued.[10] Hence *Maharasnadi Kashaya* with *Shunti Churna* is administered for 7 days. *Rasna* has *Usna, Tikshna Guna, Guru, Vatakaphashamak* and *Pachak* it opens all micro channels and reaches cellular level to show its neuro generative anabolic and adaptive effect.[11] *Shunti, Nagara, Pippali, Haritaki,Chavya, Musta, Prativisha, Dhanyaka* and *Sahachara* acts as *Deepana* and *Pachana*. *Bala, Eranda, Haritaki, Punarnava, Guduchi, Vriddadharu, Ashwagandha, Shatavari* and *Pippali* act as *Oja Vardhaka, Rasayana, Balya, Vrushya, Brmhana, Smirti Prada, Medhya, Nadi Balya* and *Pushtikara*.

Cheshta Nivritti

Statistically significant improvement was noticed in Cheshta *Nivritti* after treatment. Wilcoxon signed rank test (P value = 0.000) showed improvements in mean after treatment. *Cheshta Nivritti* is manifested due to the *Vyana Vata Prakopa*. The *Sthana* of *Vyana Vata* is *Hrudaya*. The combination of drugs such as *Bala, Vasa, Nagara, haritaki, Guduchi, Dhanyaka, Gokshura* and *Kantakari* acts as *Hrudya* and *Vata Pradhana Tridoshahara*. Hence these drugs act on *Vyana Vata* to reduce *Cheshta Nivritti*.[12] Another cause of *Cheshtanivritti* is *Shoshana* of *Sira* and *Snayu, Rasna's Guru Snigdha Lakshana* may help to reduce the same.[13]

Rasna contains chemical components such as pluchine, flavonoids, quercetin and isorhamnetin. Pluchine acts as CNS stimulant, neuro protective action, neuro modulatory and pyramidal neurons.[14] Flavonoids have both antioxidant and antithrombotic property.[15] Quercetin, attenuate severe neurological deficits and reduces infarct volume. Isorhamnetin improves blood brain barrier function.[16]

Cheshta Nivritti is due to *Shoshana* of *Sira* and *Snayu* which are *Upadhatus* of *Rakta Doshas*. *Rakta Prasadaka* and *Deepana Pachana* drugs such as *Vasa, Shunti, Gokshura, Guduchi, Kantakari, Vacha, Pippali,*

Haritaki, Nagara, Punarnava, Shatavari, Kritamala drugs nourishes *Rakta* and its *Upadhatus.*

Vak Stambha

Statistically significant improvement was noticed in *Vak Stambha* after treatment. Wilcoxon signed rank test (P value = 0.001) showed improvements in mean after treatment*. Kaphavrutaudana* causes *Vak Stambha. Rasna, Devadaru, Shati, Nagara, Vacha, Chavya, Vriddadharu, Shatapushpa, Ashwagandha, Pippali, Sahachara, Kantakari* and *Bruhati* might have acted as *Margavaranahara* and *Kapha Nisaraka* leading to the normal *Gati* of *Udana* and *Pranavata*. *Vacha* and *Kantakari* which is *Swara Krut* and *Kanthya* (euegnol and asarone) improved the speech.

Ruk

Statistically significant improvement was noticed in *Ruk* after treatment. Wilcoxon signed rank test (P value = 0.000) showed improvements in mean after treatment. *Ruk* is caused by *Vata Dosha* which is counteracted by the *Vata Shamaka Dravyas* like *Rasna, Eranda*, *Gokshura, Haritaki, Ashwagandha,* and *Shunti*. *Rasna, Eranda, Shati, Shatapushpa, Kritamala, Sahachara, Bruhati* are *Shoola Prashamana Dravyas* (lupenol, strearic acid, quercetin etc.).[17]

CONCLUSION

The Combined effect of *Maharasnadi Kashaya* with *Shunti Churna Anupana* showed improvement in primary outcome measures such as *Cheshta Nivritti*, *Vakstambha* and *Ruk* in subjects of *Pakshaghata* with p value < 0.05. In this study, maximum improvement was found in "*Ruk*" followed by "*Cheshta Nivritti*" and then "*Vak Stambha*". Hence this drug is more effective in "*Saruja Pakshaghata*". It showed improvement in the NIH stroke scale parameters with p value < 0.05. Adverse drug reactions were not reported during the study. The combined effectiveness of *Maharasnadi Kashaya* with *Shunti Churna Anupana* in management of *Pakshaghata* (CVA due to Infarct) is proved.

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