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An open label single arm prospective clinical study on *Vatagajankusha Rasa* with *Pippali Churna* and *Manjishta Kwatha* as *Anupana* in *Pakshaghata* (CVA due to Infarct)

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A B S T R A C T

Background: *Pakshaghata* is one among the 80 *vataja nanatmaja vikara* and is a *roga* of *madhyama roga marga*. *Vatavyadhi* is considered to be one among the *ashta mahagadas*. *Vatagajankusha rasa* is a combination of *vyosha, bhasmas, vatsanabha, karkatasringi, haritaki* etc. It has v*atakaphahara, vikasi, vyavayi, rasayana* etc properties. It is said to be effective in treating *pakshaghata* in 7 days if given along with *Pippali churna* and *Manjishta kwatha.* **Aims and Objectives**: To evaluate the efficacy of *Vatagajankusha rasa* with *Pippali churna* and *Manjishta kwatha* as *anupana* in the management of *pakshaghata* (CVA due to infarct). **Methodology:** Among 32 registered patients, 30 completed the course of treatment. They were administered with *Vatagajankusha rasa* 1 tablet (125 mg) after food with *anupana* 3gm *Pippali churna* and 15 ml *Manjishta kwatha* twice daily (morning and evening) for a period of 7 days. Nominal & ordinal data were analysed using non parametric tests like McNemar and Wilcoxon's signed rank tests respectively. **Result:** There was statistically significant improvement in the primary and secondary outcome measures (p<0.05 was observed)*.* **Conclusion:** *Vatagajankusha rasa* with *Pippali churna* and *Manjishta kwatha* as anupana is effective in the management of Pakshaghata (CVA due to infarct).

Key words: *Pakshaghata, CVA, Vatagajankusha Rasa.*

INTRODUCTION

Pakshaghata is one among the 80 *Vataja Nanatmaja Vikara* and is a *Roga* of *Madhyama Roga Marga.*[1] *Vatavyadhi* is considered to be one among the *Ashta Mahagadas.*[2] The etiopathogenesis of *Pakshaghata* is explained in classics[3] in which the vitiated *Vata* resides in one half of body and causes *Vishoshana* of *Sira* and *Snayu* leading to loosening of joints leading to symptoms like *Cheshta Nivrutti, Ruja* and *Vakstambha.*[4] *Anya dosha anubandha lakshana* are also explained.[5]

Cerebrovascular Accident (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] The World Health Organization (WHO) defines CVA as "the rapidly developing clinical symptoms and/or signs of focal disturbance of cerebral function, with symptoms lasting more than 24 hours or leading to death with no apparent cause other than that of vascular origin.[7]

There are many risk factors for CVA including hypertension, diabetes, hyperlipidemia etc. All these are very common in the present era in mid aged people mainly due to unhealthy food habits and sedentary life style.

CVA is the second major cause of death worldwide. The world wide incidence has been quoted as 2/1000

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population/annum; about 4/1000 in people aged 45-84 years.[8] The prevalence of stroke in India shows a huge variation of 147-922/100,000 across diverse community-based studies.[9] Eighty five percentages of stroke cases are due to cerebral infarction and fifteen percentages due to cerebral hemorrhage and 1.5 times more often in male than female.[10] 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.[11]

The allopathic line of treatment for CVA is medical support, thrombolysis, antiplatelet agents, anticoagulation, neuroprotection and rehabilitation.[12] *Pakshaghata chikitsa* explained by the classics mainly include *Snehana, Swedana* and *Virechana.*[13] Detailed description of other line of treatment for *Pakshaghata* is also available such as S*nehana, Swedana, Mrudu Virechana, Mastishkya, Salvana Upanaha* and *Basti.*[14]

Vatagajankusha Rasa is a combination of *Vyosha, Bhasmas, Vatsanabha, Karkatasringi, Haritaki* etc.[15] of which *shunti, maricha, pippali* works as *deepana* and *ama pachana. Vatsanabha* has the properties like *vikasi, vyavayi, yogavahi*; which makes it easy to digest along with all the drugs present in *Vatagajankusha Rasa*. It opens all the micro channels and easy to reach on cellular level. *Haritaki, Agnimantha, Karkatashringi* work as *deepana, Vatanulomaka, kapha nissaraka, Vatashamaka*. All *bhasmas* does *agni deepana* and work as balya, *Rasayana, Vata pradhana tridosha shamaka.*[16] In this way the combination of these drugs acts in the management of *Pakshaghata*.

OBJECTIVE

To evaluate the efficacy of *Vatagajankusha Rasa* with *Pippali Churna* and *Manjishta Kwatha* as *Anupana* in the management of *Pakshaghata* (CVA due to infarct)

MATERIALS AND METHODS

Source of data: Patients who attended the out-patient department of Kayachikitsa at Sri

Dharmasthala Manjunatheswara College of Ayurveda and Hospital, Hassan.

Method of collection of data

32 patients (Table 1) were screened and selected based on the screening form prepared. Data was collected using specially prepared case report form. The demographic details of 30 enrolled patients of *Pakshaghata* such as age, gender, educational status etc are represented in table below (Table 1).

Table 1: Demographic detail of 30 patients of *Pakshaghata*

Geographic Observation	Predominance	No of Patients (%)
Age	61-70 years	10 (33.33%)
	51-60 years	8 (26.66%)
Gender	Male	26 (86.66%)
Educational Status	Primary school	11 (36.66%)
Marital Status	Married	29 (96.66%)
Smoking	Present	20 (66.66%)
Alcoholism	Present	20 (66.66%)

The observations related to the disease details of the 30 patients of *Pakshaghata* are represented in table below (Table 2)

Table 2: Observations related to disease

Cheshta nivrutti	Present	30 (100%)
Vakstambha	Present	22 (73.33%)
Ruk	Present	28 (93.33%)
K/C/O Hypertension	Present	15 (50%)
K/C/O Hypertension and Diabetes Mellitus	Present	13 (43.33%)

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Diagnostic Criteria

An elaborate proforma incorporating all the points of history taking and physical examinations mentioned in Ayurveda texts as well as in modern sciences was prepared. In this, special provision was made for *Jnanendriya* and *Karmendriya pareeksha* along with central nervous system examination (Sensory, Motor, Cranial nerve and Autonomic dysfunctions).

Inclusion Criteria

- *Pakshaghata* (CVA due to infarct) after the acute stage

- Caused by most prevalent disease like Diabetes Mellitus, Hypertension, Hyperlipidemia (Any of these or all of these)

- GCS more than 8

- Either gender

- Patients aged between 30-75 years

- Those who are ready to sign the informed/oral consent form

Exclusion Criteria

- *Pakshaghata* complicated with heart disease, uncontrolled diabetes

- Systemic disorders like CHD,CRF,CLD

- History of HIV,HBSAG, Carcinoma

- Pregnant women and lactating mother

- H/O Intra cranial infection- encephalitis, meningitis

- Cerebral tumor, cerebral abscess

- Congenital defects- diffused sclerosis, cerebral agenesis

- Marked impaired mental function

Ethics

Ethics clearance was obtained from Institutional Ethics Committee before initiation of the study (IEC No: SDM/IEC/16/2017-2018).

Study design

The study was open label, single arm, exploratory, prospective clinical on 30 patients of *Pakshaghata* selected using the convenience/ purposive (non-random) sampling technique with pre and post test design conducted in a tertiary Ayurveda hospital attached to quarters in southern India.

Intervention

Medicines - *Vatagajankusha Rasa* with *Pippali churna* and *Manjishta kwatha* as *anupana*

Source and authentification of drug:

- *Vatagajankusha Rasa* (125mg each) tablets were purchased from VIRGO Pharmacy, Gujarat, which is a GMP certified pharmacy.

- Powdered *Pippali* was purchased from Sri Dharmasthala Manjunatheswara College of Ayurveda and Hospital pharmacy, Udupi, which is a GMP certified pharmacy.

- Raw drugs for *Manjishta kwatha* were procured from Kajrekar pharmacy, Belagavi and were authenticated at Dravyaguna department of Sri Dharmasthala Manjunatheswara College of Ayurveda and Hospital, Hassan.

Method of preparation of *Manjishta Kwatha*

Roots of *Manjishta* were cleaned and dried. They were coarsely powdered, weighed as per formula and then mixed well. 4 parts of water added to 1 part of *Manjishta* coarse powder, boiled and reduced to 1/4th part. Prepared *kwatha* was packed in 210 ml bottles and labeled with name of the drug, reference, details of the manufacturer, batch number.

Treatment plan

Vatagajankusha Rasa tablet of 125 mg after food with 3 gm *Pippali churna* and 15ml *Manjishta kwatha* as *anupana* twice daily.

Duration: 7 days

Assessment criteria

Primary outcome measures

Assessment was done based on the improvement in the symptoms like *Cheshta nivrutti*, *Vakstambha*, *Ruk* after the administration of the medicine for 7 days

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and also based on the improvement in the secondary outcome measures.

Table 3: *Cheshta Nivrutti* grading

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

Table 4: *Vakstambha* grading

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

Table 5: *Ruk* grading

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

Secondary outcome measures:

National Institute of Health Stroke Scale (NIHSS)

OBSERVATIONS AND RESULTS

In the present study, among the 40 patients screened, 32 patients were registered of which 30 have completed their course of treatment.

The effect of therapy in 30 patients of *Pakshaghata* is shown in the table below:

Wilcoxon Signed Rank test was applied to note the significant changes in primary outcome measures with significant level at P value < 0.05 (Table 6).

Table 6: Effect of therapy on primary outcome measures

Primary outcome measures	Negative ranks			Positive ranks			Ties	Total	Z Value	P Value	Remarks
	N	MR	SR	N	MR	SR					
Cheshta nivrutti BT-AT	20	10.50	210.0	0	.00	.00	10	30	-4.300	.000	S
Vakstambha BT-AT	12	6.50	78.00	0	.00	.00	18	30	-3.464	.01	S
Ruk BT-AT	26	13.50	351.0	0	.00	.00	4	30	-4.604	.000	S

In 30 enrolled subjects, impairments were observed in the NIH Stroke Scale parameters like motor arm drift, motor leg drift and dysarthria. All other parameters of NIH Stroke Scale were found to be normal in the subjects.

Wilcoxon Signed Rank test was applied to note the significant changes in NIH Stroke Scale parameters with significant level at P value < 0.05 (Table 7).

Table 7: Effect of therapy on NIH Stroke Scale parameters.

NIH stroke scale	Negative ranks			Positive ranks			Ties	Total	Z Value	P Value	Remarks
	N	MR	SR	N	MR	SR					
Motor arm BT-AT	26	13.50	351.0	0	.00	.00	4	30	-4.767	.000	S
Motor leg BT-AT	25	13.00	325.0	0	.00	.00	5	30	-4.716	.000	S

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Dysarthria BT-AT	5	3.0	15.00	0	.00	.00	25	30	-2.236	.025	NS

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

DISCUSSION

Statistically significant improvements were observed in the primary and secondary outcome measures with administration of *Vatagajankusha Rasa* with *Pippali churna* and *Manjishta kwatha* as *anupana*. Assessment of these parameters was done after 7 days of treatment.

Statistically significant improvement was noticed in *cheshta nivrutti* after treatment. Wilcoxon signed rank test (P value=0.000) showed improvements in mean after treatment.

Cheshta nivrutti is manifested due to the *vyana Vata prakopa*. *Vatsanabha, Pippali*, *Manjishta, Haratala* pacify *Prakupita Vyana Vata* by *Snigdha Guna, Ushna Virya* and *Madhura Vipaka*. *Haritaki* which is *Laghu*, *Ushna*, *Madhura* and *Tridoshahara* does the *Vata anulomana*. *Oushadha sevana kala* advised for *vyana Vata* is morning after food. So the medicines are given in this *kala*.[17]

Another cause for *Cheshta Nivrutti* is the *Shoshana* of *Sira* and *Snayu* by *Ruksha-Teekshna Ahara Sevana*, *Dhatukshaya*. These are the *upadhatus* of *Raktadhatu*. *Manjishta* and *loha bhasma* are *rakta pRasadaka* which nourishes the *rakta* and its *upadhatus* by *tikta-madhura Rasa*, *madhura vipaka* and *guru guna*.

Statistically significant improvement was noticed in *vakstambha* after treatment. Wilcoxon signed rank test (P value=.001) showed improvements in mean after treatment.

Samana avruta prana causes *gadgada vakya* and *mookatva*. *Kaphavruta udana* causes *vak graha*. *Agni sameepastha samana Vata* is pacified by *agnideepana* drugs such as *pippali, shunti, tankana, agnimantha* etc having *katu Rasa*, *katu vipaka* and *ushna virya*.

Vatsanabha has *vyavayi*, *vikasi* and *yogavahi* properties by which it does *kapha nisarana* and clears *Margavarana*. *Manjishta* is "*swara krut*", it improves the speech.

Oushadha sevana kala advised for *udana Vata* is after food. So the medicines are given in the evening after food.[18]

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* due to *laghu guna*, *darunata*, *ashukaritwa*. *Loha bhasma* and *Manjishta* does *Vata shamana* by *guru guna*, *madhura Rasa* and *ushna veerya*.

Haritaki is *Vatanulomaka* and brings *Vata* in its normal path thereby reduces *ruk*. *Pippali* and *shunti* are included in *shoola prashamana dashemani* due its *ushna veerya* and *snigdha guna*. *Vatsanabha* is *rujapaha* due to its *vyavayi*, *vikasi* and *yogavahi* properties thus relives *ruk*.

Probable mode of action of *Vatagajankusha Rasa*

According to *Rasa Ratna Samuchhaya*, after *marana*, *bhasma* becomes microfine particles that easily absorb into the body along with *Rasa dhatu*. Such absorbed *bhasmas* provide nourishment to the body and cures all types of diseases.[19]

Absorption into gut

After *marana* the particle size of the *bhasma* reduces into the size of "platelets" (1.5 чм) and it can be absorbed through the gap junctions and epithelial tissues in middle gut.

Entry to the blood stream

Particles penetrate the intestinal barrier either by endocytosis, phagocytosis or persorption and transit to the blood stream.

Crossing blood-brain barrier

When a particle penetrates into the blood stream, perhaps tagged by and adjuvant with *yogavahi* properties, it reaches the specific target area.

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Microfine particles with increased bio availability, cross the blood-brain barrier and act as neuro-protectants.[20]

Mode of action of different ingredients

- The combination of *Rasa oushadhis* act as *kapha-Vata pradhana tridosha hara*. They increase the *jataragni* and works as *balya* and *Rasayana*

- *Shunti*, *maricha*, *pippali* work as *deepana*, *pachana*. It improves digestion thereby improves the overall nourishment of the body

- *Vatsanabha* has *vikasi*, *vyavayi* and *yogavahi guna* which make it easy to be digested. It opens all the micro channels and reaches cellular level

- *Karkatasringi*, *haritaki* and *agnimantha* work as *agni deepaka*, *Vatanulomaka*, *kapha nisaraka* and *Vata shamaka*

- *Pippali* is *kapha-Vata hara* and *urdhwa bhaga hara dravya* due to which it can improve the brain functions. It is of *madhura vipaka* and *ushna veerya* which counteracts *Vata dosha*. It is *Rasayana*.

- *Manjishta* is *pitta-kapha shamaka* due to which it can counteract the *pitta* or *kapha anubandha* with *Vata*. It is *rakta pRasadaka* which improve the blood circulation. It is *swara krut*.

CONCLUSION

Administration of *Vatagajankusha Rasa* with *Pippali churna* and *Manjishta kwatha* as *anupana* for 7 days shown statistically significant improvement in the clinical features of *Pakshaghata* namely – *cheshta nivrutti*, *vakstambha* and *ruk.* Statistically significant improvement was observed in the NIH Stroke Scale parameters like motor arm drift and motor leg drift. There was no statistically significant improvement in dysarthria. The study showed more improvement in "*ruk*" followed by "*cheshta nivrutti*" and then "*vakstambha*". Hence administration of *Vatagajankusha Rasa* (125 mg) twice daily with *Pippali churna* (3 gm) and *Manjishta kwatha* (15 ml) as *anupana* after food for 7 days is effective in the management of *Pakshaghata* (CVA due to infarct).

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