

## TREATMENT OF HEMIPLEGIA WITH VARAHI KANDA –AN OPEN LABEL SINGLE ARM CLINICAL STUDY TO INVESTIGATE THE EFFECT OF VARAHI KANDA RASAYANA IN MARGAVARANAJA PAKSHAGHATA / VASCULAR STROKE

Annapoorna Acharya<sup>\*1</sup>, G. Shrinivasa Acharya<sup>2</sup>, Shailesh Y.<sup>3</sup> and Shrilatha Kamath T.<sup>4</sup>

<sup>1</sup>Final year PG Scholar, <sup>2</sup>Ex Principal, <sup>3</sup>Assistant Professor, <sup>4</sup>Professor and HOD  
Department of Kayachikitsa and Manasaroga, Sri Dharmasthala Manjunatheshwara College  
of Ayurveda, Udupi, Karnataka.

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### \*Corresponding Author

**Dr. Annapoorna Acharya**

Final year PG Scholar  
Department of Kayachikitsa  
and Manasaroga, Sri  
Dharmasthala  
Manjunatheshwara College  
of Ayurveda, Udupi,  
Karnataka.

### ABSTRACT

*Pakshaghata* is a *vatavyadhi*, and a large group of populations are affected by this disease globally and rather than younger people, older people are more susceptible. *Pakshaghata* is one among the 80 *nanathmaja vatavyadhi*.<sup>[1]</sup> There are 3 distinct *nidana* for the *pakshaghata*, they are *dhatukshaya*, *margavarana* and *swakopa*.<sup>[2]</sup> *Margavarana* refers to the obstruction of the *raktamarga*. Prime causative factors for *margavarana* is *santarpanajanya nidana* which leads to *dhamani pratichyaya* ends up in *pakshaghata*. This unique pathology is understood with thrombo embolism of the vessels supplying the brain. Further this pathology can result in hemiplegia when one half of the body is involved. *Margavarana* is the resultant of the *santarpanajanyanidanasevana*.<sup>[3]</sup> The pathophysiological sequel to this *nidanasevana* is *dhamanipratichyaya* which can be understood as

the atherosclerosis of the vessel in modern parlance which is the precursor of the stroke syndrome. The treatment of this dreaded disease includes immediate intervention in terms of the thrombolization, blood thinner and so on for which very minimum population may have access and still the reversal of pathology is under query. So an effective alternate treatment is the need of hour. *Rasayana* is one of the best line of treatment in such conditions, among which *varahi kanda rasayana* is the best choice. Hence an effort is made in 30 patients treated with *varahi kanda rasayana* in *margavarana* *pakshaghata*/vascular stroke.

**KEYWORDS:** *Margavranaja Pakshaghta, dhamanipaticaya, varahi kanda Rasayana.*

## INTRODUCTION

It does not matter how slowly we go as long as we do not stop. Many disorders immobilize the patients and we doctors make a constant effort to increase the quality of life of the patients. *Pakshaghata* (stroke) is one such disorders which immobilize the patient and is a challenging task for the doctors.

In the present world scenario due to indulgence in faulty food habits and erroneous life style there is occurrence of different diseases specifically *Vatavyadhi* (disorders caused by vitiation of vata), it limits the person's ability for free mobility due to its crippling nature. In general, *Vatavyadhi* obtain clinical importance by the severity of disability caused by the illness, chronic course of the disease and partial recovery by employing the most effective treatment. This *Vatavyadhi* is said to be caused by either of the influence of *nidana* (causative factors), *dhatukshaya* (emaciation) or *margavarana* (metabolic disorders). Thus developed disease may present in three forms like *kevala vatavyadhi*, *samsrushta vatavyadhi* and *avaranaja vatavyadhi* (types of *vatavyadhi*). The diseases in which the invariable involvement of the morbid *vata dosha* are referred as *kevala vatavyadhi* and those in which the morbid *vata dosha* is associated with *kapha* and *pitta dosha* come under *samsrushta vatavyadhi*.

The *Vatavyadhi* in which the pathology of *avarana* is involved is referred as *avaranaja vatavyadhi*.<sup>[4]</sup> This *avarana* is a complex pathological process which generate wide spectrum of diseases. *Avarana* pathology is unique for the causation of the *Vatavyadhi*, as it does the obstruction to the passage of bodily elements and it suppress the normal body functions of the *vata dosha*. Further the *avaranaja vatavyadhi* can be explained under three categories as *margavarana*, *dosha avarana* (*avarana* among the *doshas*), and *anonya avarana* (*avarana* among the types of *vata*).

The type of *Vatavyadhi* which is initiated as a result of obstruction of the channels refers to *Margavaranaja vatavyadhi*.<sup>[5]</sup> The *marga* refers to *srotas*<sup>[6]</sup> or the channels of the body which carry the micronutrients or they can be considered as the micro and macro circulatory system of the body.<sup>[7]</sup> *Marga* here denotes *rasarakta marga* and the obstruction in this passage predisposes the morbidity of the *vata dosha*. The pathology of *Margavarana* can occur at different locations based on the *khavaigunyata* (empty, disease prone space) and it causes

multitudes of *Vatavyadhi* with the involvement of *kapha* and *pitta dosha* located at the site of *Margavarana*.<sup>[2]</sup>

The *vata dosha* gets vitiated by the excessive indulgence in its own etiological factors. Similarly, the excessive consumption of nutritive food in combination with lack of physical activity causes the morbid accumulation of *kapha* and *medas* in the liquid *rasa* and *rakta dhatu*.<sup>[5]</sup> This morbid accumulation is termed as *Shonita abhishyandana* or *amarasa*.<sup>[8]</sup> This abnormality in the liquid *dhatu* silently eventuate *Dhamani pratichaya*.<sup>[9]</sup> This *Dhamani pratichaya* terminally instigate the obliteration of the vessels causing *Margavarana*. The vitiated *vata dosha* by its own etiological factors will get further vitiated when there is obstruction in its normal course. When this pathology of *Margavarana* occurs in the *shiro marma pradesha*, it leads to a set of syndromes which include *manyasthambha* (neck stiffness), *ardita* (facial palsy), *shwasa* (breathing difficulties), *moha* (darkness around eyes), *chesta nashi* (loss of movements), *hanugraha* (lock jaw)<sup>[10]</sup> etc. Among these *Pakshaghata* is the most common illness. Spontaneous onset of the symptoms is the characteristic feature of *Margavarana*. The symptoms of *chesta nivrutti* (loss of movements), *achetana* (hemi sensory deficit), *toda* (pricking pain), *shula* (pain), *ruja* (pain), *sankocha* (spasticity), involving the left or right half of the body along with *vaksthambha* (dysarthria) characterises the clinical presentation of *Pakshaghata*.<sup>[11]</sup>

These symptoms parallels with clinical presentation of ischemic stroke syndrome. Cerebrovascular accidents are considered as the most common cause of physical disability and deaths worldwide. It is worth mentioning here that stroke is established as the second leading cause of death all over the world causing around 6.2 million deaths in 2011.<sup>[12]</sup> Recent population study reveals the incidence of this disease in India is around 119-145/100000<sup>[13]</sup> and it represents 1.2% of total deaths in India. Due to serious disability and risk of fatal outcome, energetic treatment at the outset is mandatory. This present clinical study was carried out on 30 patients with *varahi kanda rasayana*. It is one of the best drug of choice in *vatavyadhi* and an effort is made to prove the same.

## MATERIALS AND METHODS

The patients with confirmed diagnosis of *pakshaghata* / vascular stroke having stable general condition will be recruited for the study from OPD & IPD of Sri Dharmasthala Manjunatheshwara Ayurveda Hospital, Udupi. The aqueous extract of *varahi kanda*

(*Dioscorea bulbifera*) in capsule form will be obtained from Sri Dharmasthala Manjunatheshwara Ayurveda Pharmacy, Kuthpady, Udupi.

### Design of the study

- Study Type : Interventional
- Estimated enrolment : 30 patients suffering from pakshaghata
- Sampling method : Non-probability sampling
- Allocation : Non randomized
- Endpoint Classification : Efficacy Study
- Intervention Model : Single group assignment
- Masking : Open Label
- Primary Purpose : Treatment

### Method of collection of data

The subjects suffering from vascular stroke confirmed by radiological examination will be screened with due consideration of inclusion as well as exclusion criteria and will be registered for the study after signing the detailed informed consent. Thus registered patients will be treated with varahi kanda rasayana as per the protocol. The primary as well as secondary outcome measures are assessed at baseline and again after the completion of the course of varahi kanda rasayana.

### Intervention

Aqueous extract of Varahi kanda rasayana is obtained in the 500 mg capsule form for the rasayana schedule as detailed below.<sup>[11]</sup>

Day	Medication	Timing	Anupana
Day 1	20 ml eranda taila	early morning before food	Warm water 150 ml
Day 2	Rasayana - 04 cap	early morning before food	Warm milk 150 ml
Day3	Rasayana - 08 cap	early morning before food	Warm milk 150 ml
Day4	Rasayana - 12 cap	early morning before food	Warm milk 150 ml
Day 5 to day 30	Rasayana - 16 cap	early morning before food	Warm milk 150 ml

The duration of varahi kanda rasayana is 30 days and is followed by another 30 days of follow-up period. The total duration of the study is 60 days.

### Data analysis

**Primary outcome measures:** 1. Change in mean muscle power score of the upper limb from base line at fingers, wrist, elbow and shoulder [time frame day 1 and day 30] (the muscle power is graded as 0=no contraction; 1=flicker or trace of contraction; 2=active movement with gravity eliminated; 3=active movement against gravity; 4= active movement against gravity and resistance; 5= normal power) 2. Change in mean muscle power score of the lower limb from base line at toes, ankle, knee and hip [time frame day 1 and day 30] 3. Change in the total score of Stroke Specific Quality of Life Scale from base line [Time Frame: Day 0 to Day 30].<sup>[11]</sup>

**Secondary outcome measures:** 1. Change in the average hand Grip strength from base line [Time Frame: Day 0 to Day 30] The hand grip strength will be measured by using the sphygmomanometer. 2. Change in mean score of Spasticity of bilateral upper and lower extremities measured with Modified Ashworth Scale from base line [time frame day 1 and day 28] (The Modified Ashworth scale (MAS) measures resistance during passive soft-tissue stretching and is used as a simple measure of spasticity. The Statistical analysis was done based on Sigma Stat Statistics software version 3.5. Paired 't' test for continuous data & Wilcoxon Signed Rank Test for ordinal data.

### OBSERVATIONS

Distribution were done based on Demographic data, Personal history, Physical status, Dashavidha pariksha, Disease history, area affected and signs & symptoms of margavarajanaya pakshaghata. In the current study conducted on 30 patients, maximum of 11(33.33%) patients belonged to the age group of 56-60 years. majority of 83.33% of the subjects were males. 96.67% of the patients registered for the study belonged to Hindu religion and among them 41.67% belonged to lower class status. Similarly, 33.33% of patients completed their high school education. 80% of patients were skilled workers. 90% of the subjects under study were married. 60% of the patients belonged to rural community. 73.33% had a mixed dietary habit. 56.67% of patients had a regular bowel habit and 33.33% had constipated bowel. 76.67% had regular micturition urge and 20% had incontinence in the urination. 7.81% were addicted to alcohol, 10.94% addicted to cigarette. 63.33% had their BMI between 18.5 – 24.9 and 16.67% had it between 25-29.9%. Maximum of the patients of

this study, belonged to *Dwandaja prakruti*. Amongst them maximum of 36.67% had *Vatapittaja prakruti* and 43.33% had *Vata kaphaja prakruti*. Among the 30 patients, maximum of 86.67% had *madhyama sara*. With regards to *Satmya*, 83.33% of patients in the study were found to have *Madhyama satmya*. On assessment of *Satva*, it was found that majority of 66.67% had *Madhyama satva*. The assessment of *Samhanana* of all the patients revealed that 86.67% had *Madhyama samhanana*. 90% had *Madhyama pramana*. On assessment of the *Ahara Shakti* it was revealed that 86.67% had *Madhyama ahara abhyavaharana Shakti*. 80% had *Madhyama ahara jarana Shakti*. 80% had *Avara vyayama Shakti*. Maximum of 56.67% had a history of hypertension. 66.67% of the subjects were under medication for the diabetes mellitus. 63.33% had left side affected and 36.67% had it on right side of the body. 53.33% have onset of stroke at day time. 6.67% had aphasia and 93.33% had dysarthria. 100% had the symptoms of affliction of facial nerve and spinal accessory nerve. 53.33% had the infarct involving the MCA territory. *Gouravata* was present in 96.66% of patients, 16.66% had *Shotha* and 10% had *Sheetata*. 6.66% had symptom of *Daha*, 63.33% had *Toda* and 63.33% had *Ruja* and 6.66% had *santapa*.

## RESULTS

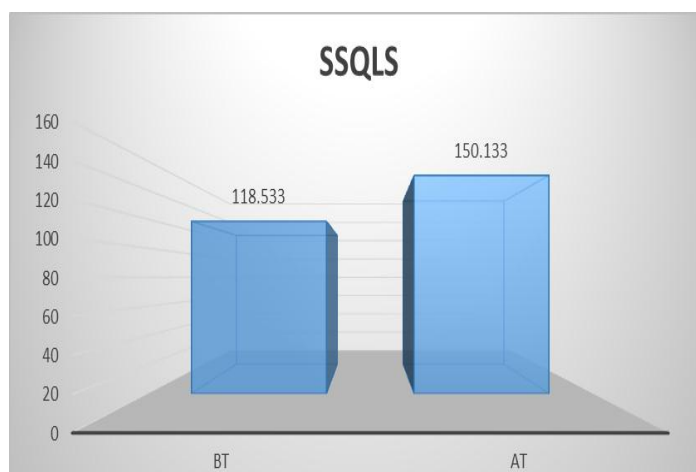
Sl. no.	Outcome measures	Percentage improvements
1	Abduction of upper arm	76.97%
2	Flexion of forearm at elbow	76.97%
3	Extension of forearm at elbow	75.01%
4	Wrist flexion	122.79%
5	Palmar abduction of thumb	122.79%
6	Finger abduction and adduction	122.79%
7	Hip flexion	95.55%
8	Hip extension	88.51%
9	Hip abduction	88.51%
10	Hip adduction	86.55%
11	Knee extension	86.55%
12	Knee flexion	73.16%
13	Ankle dorsiflexion	74.57%
14	Ankle plantarflexion	82.35%
15	Hand grip strength	76.97%
16	Spasticity	75.01%

Assessment of the Stroke Specific Quality of Life Scale before and after treatment showed that there is moderate improvement in the mean score which was 118.53 before treatment has improved to 150.13 after the treatment with about 26.65% improvement. This analysis done

using Wilcoxon Signed Rank test showed that Varahi Kanda Rasayana has a role in improving the quality of life of the stroke patients.

### Effect of treatment on SSQLS

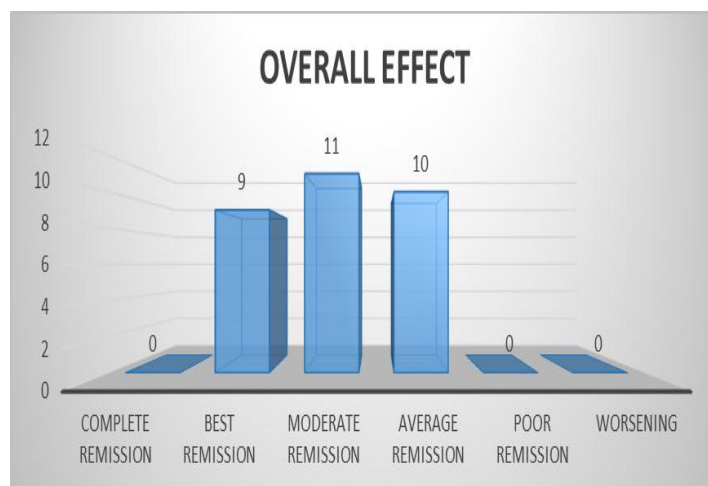
SSQLS (Range)	Mean score		Difference in Means	% Improvement	Wilcoxon Signed rank test		
	BT ( $\pm$ SE)	AT ( $\pm$ SE)			SD	Z value	p value
49-245	118.53 (4.677)	150.13 (4.555)	-31.6	26.65%	BT-25.615 AT-24.951	4.783	<0.001



The overall effect of varahi kanda Rasayana in patients suffering from the margavarana pakshaghata/ ischaemic stroke was assessed by percentage of improvement in the summation of mean score of muscle power, muscle spasticity, hand grip strength, stroke specific quality of life scale, pulse rate, heart rate, weight and blood pressure. Complete remission was not recorded in any of the scores. Study revealed that 36.66% of patients had moderate remission and 30% patients had best remission. Also 33.33% patients had average remission.

Extent of change	Change category	No. of patients	% of patients
100% improvement	Complete remission	0	0
Improvement from 76 to 99%	Best remission	9	30
Improvement from 51 to 75%	Moderate remission	11	36.66
Improvement from 26 to 50%	Average remission	10	33.33
Improvement from 1 to 25%	Poor remission	0	0
Worsening	Worsening	0	0





## DISCUSSION

*Rasayana* is one of the best ways to cure as well as prevent diseases. It has also been mentioned as *jara vyadhi nashana* meaning it is best in cases of disorders of the old age (geriatrics). *Naimittika Rasayana* is the one which directly acts on the cause of the disease. As mentioned in the classics it given in *vardhamana* dosage as mentioned above. Firstly, starting with 20ml *eranda taila* in early morning empty stomach for the purpose of *koshta shodhana*, without which *rasayana* action will not be fulfilled. *Eranda taila* is selected as it is easily available and is best *vatahara*. *Varahi kanda* possesses the *madhura rasa* (sweet taste) which does *poshana* (Nourishment) to the body and the *katu rasa* (pungent) which removes the excess of *vata* in the body. it is *laghu* (light) in nature which makes it easy to digest and also has *snigdha* (unctuous) properties which tackles the vitiated *vata* in old age. Again the *ushna veerya* and *katu vipaka* tackles the excess *vata* and *kapha* in the body. It has the *prabhava* of the *rasayana* and *vrushya* action, which directly acts on the disorder.

Though *santarpana* nidana predisposes the *Margavarana* and which in turn causes *Shiromarmabhighata*. The resulting illness *Pakshaghata* which is considered as the *paratantra vyadhi* is having the symptoms of the vitiated *vata dosha*. The immediate treatment of *Pakshaghata* should be concentrated mainly in tackling the morbidity of the vitiated *vata dosha*. *Bahya senhana*, *abhyantara snehana*, *virechana*, *basti*, *shamana*, *brihmana* and *rasayana* form the complete treatment of *Pakshaghata*. Enough clinical studies have been done on different modalities of treatment of *Pakshaghata*.

Among these *shamana rasayana* form the sheet anchor in mitigating the vitiated *vata dosha* and the *jara vyadhi*. *Varahi kanda* is the ideal prescription in this regard. The *rasayana*, *balya* and *vata shamaka* action of the drug helped in counteracting the symptoms of *Pakshaghata*.



The improvement recorded in this study is also statistically highly significant. Also this treatment has not given complete relief from the symptoms. This indicates that the same treatment may be more effective in different dosage pattern for a longer duration of period. Thus this clinical trial paves way for newer clinical studies in proving the effect of *Varahi kanda rasayana* in patients suffering from *Pakshaghata*.

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