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AN OPEN LABEL CLINICAL STUDY EVALUATING THE EFFECT OF *SHAMANA SNEHANA* WITH *SHATAPAKI KSHEERABALA TAILA* IN *MARGAVARANAJA PAKSHAGHATA*/ISCHEMIC STROKE

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ABSTRACT

Background: *Shamana snehana* form the sheet anchor of treating chronic debilitating disorder like *Pakshaghata*. *Ksheerabala bala taila* is the ideal prescription in this regard and the fortification of the same as *Shatapaki Ksheerabala taila* is used, thereby enhancing the therapeutic efficacy. This study is planned to evaluate the effect of *Shatapaki Ksheerabala taila* in the patients suffering from *Pakshaghata.* **Objectives:** To evaluate the therapeutic effect of *Shatapaki Ksheerabala taila* in reducing the symptoms of *Margavaranaja Pakshaghata*/Hemiplegia due to ischemic stroke and to measure the improvement in the health related quality of life attained following the medication. **Study design:** Study Type: Interventional; Allocation: Non randomized; End point classification: Efficacy study; Intervention Model: Single group assignment; Masking: Open label; Primary purpose: Treatment. **Setting:** 30 patients selected from OPD & IPD of Sri Dharmasthala Manjunatheshwara College of Ayurveda & Hospital, Udupi. **Intervention:** Oral administration of *Shatapaki Ksheerabala taila* in a dose of 24 ml in the morning in empty stomach about half an hour before breakfast along with 150 ml of warm water. **Outcome measures:** The efficacy of the treatment was assessed based on the primary and secondary outcome measures which are Muscle power of upper and lower limb, Muscle Spasticity of upper and lower limb, Pain, Berg balance scale and Stroke specific quality of life scale at a time frame of Day 0 and Day 28. Wilcoxon Signed Rank test was used to assess the statistical analysis of the data. **Results:** *Shatapaki Ksheerabala taila* is found to be effective in the remission of the symptoms of *Margavaranaja Pakshaghata* as evidenced by statistically significant reduction in the symptom score of primary and secondary outcome measures. **Conclusion:** *Shatapaki Ksheerabala taila* is proved to be efficacious in reducing the symptoms of *Margavaranaja Pakshaghata* and hence improving the Quality of Life.

KEYWORDS: *Margavaranaja Pakshaghata*; Ischemic stroke; *Shatapaki Ksheerabala taila*.

INTRODUCTION

In general, *Vatavyadhi* obtain clinical importance by the severity of disability caused by the illness, chronic course of the disease as well as partial recovery by employing the most effective available treatment. These diseases are popularly known as *nanatmaja vatavyadhi*. These diseases may be caused either by the *dhatukshaya* or due to the *margavarana*. *Apatarpana nidana* causes the *dhatukshaya* and then lead to the *vatavyadhi*. Contrary to this *santarpana nidana* through the accumulation of *kapha* and *medas* obliterates the *srotas* and thereby pilot the pathology of *vatavyadhi*. To be more clear, excessive consumption of nutritive food in combination with lack of physical activities causes morbid accumulation of the *kapha* and *medas* in the liquid *rasa* and *rakta dhatu*.[1] This morbid accumulation is termed as *amarasa* or *shonita abhishyndana*.[2] Again, this morbid *kapha* and *medas* in the *rasa* and *rakta dhatu* tend to adhere to the wall of the *dhamani* reducing the lumen of vessels. Thus formed thickening of the *dhamani*, its tortuosity, reduced compliance and hardening eventuates the condition of *Dhamanipratichaya*.[3] This *Dhamanipratichaya* terminally instigate the obliteration of the vessels known as *Margavarana*. Spontaneous development of symptoms for no apparent reason is the characteristic feature of *vatavyadhi* caused by *Margavarana*. This pathology of *Margavarana* when involves the *shiromarma* the patient may suffer from set of syndromes that include Emprosthotonus, Facial paralysis, Squint, Confusional state, Paresis/Paralysis, Aphasia, Dysarthria, Aphonia, Dysphonia etc.[4] Among

these *Pakshaghata* is the most common illness. The symptoms of *cheshtanivrutti, toda, shula, ruja,* and *sankocha* involving right or left half of the body added with *vakstambha* characterises the clinical presentation of *Pakshaghata*.[5] More to add, these symptoms parallels with the clinical picture 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.[6]

Margavarana causes *vatavyadhi* including *Pakshaghata*. *Dhamanipratichaya* is the causative illness and known as *svatantra vyadhi. Pakshaghata* is the resulting illness and is known as *paratantra vyadhi*.[7] Though *Pakshaghata* is regarded as *paratantra vyadhi*; due to the serious disability and risk of fatal outcome of *Pakshaghata*, energetic treatment of *Pakshaghata* at the outset is mandatory. *Snehana, svedana, shodhana, brimhana* and *rasayana* form the crux of treating *Pakshaghata.* Among these *shamana snehapana* form the sheet anchor of treating any *vatavyadhi* and *Pakshaghata* in particular. *Kshirabala taila* is the ideal prescription in this regard and the fortification of the same in the form of *Shatapaki kshirabala taila* thereby greatly enhancing the therapeutic efficacy.

Enough clinical studies have been done on different modalities of treatment of *Pakshaghata.* The therapeutic effect of *snehapana* in patients suffering from *Pakshaghata* is yet to be explored. *Shatapaki ksheerabala taila* is the fortified *taila* preparation and claimed to be very effective in different *Vatavyadhi* [8] including *Pakshaghata*. Thus this clinical study is intended to explore the clinical efficacy of *Shatapaki ksheerabala taila* in patients suffering from *Margavaranaja Pakshaghata*/ Hemiplegia due to Ischemic stroke.

Objectives of the study

- To evaluate the therapeutic effect of *Shatapaki ksheerabala taila* in reducing the symptoms of *Margavaranaja Pakshaghata*/Hemiplegia due to ischemic stroke.
- To measure the improvement in the health related quality of life attained following the medication with *Shatapaki ksheerabala taila*.

MATERIALS AND METHODS

Source of data

The patients suffering from *Margavaranaja Pakshaghata*/Hemiplegia due to ischemic stroke were selected for the study from OPD & IPD of Sri Dharmasthala Manjunatheshwara Ayurveda Hospital, Kuthpady, Udupi. The *Shatapaki ksheerabala taila* was obtained from Sri Dharmasthala Manjunatheshwara Ayurveda Pharmacy, Kuthpady, Udupi.

Method of collection of data

The subjects suffering from *Margavaranaja Pakshaghata*/Hemiplegia due to ischemic stroke were screened under strict diagnostic, inclusion and exclusion criteria and selected for the study. Eligible subjects were then invited to participate in the study after signing a detailed informed consent and then registered for this clinical trial. Thus registered participants were treated with the medication as per the plan of intervention. The outcome measures were assessed at baseline and after the completion of the *Shamana snehapana* with *Shatapaki ksheerabala taila*.

Design of the study

- Study Type: Interventional
- Allocation: Non randomized
- Endpoint Classification: Efficacy Study
- Intervention Model: Single group assignment
- Masking: Open Label
- Primary Purpose: Treatment

Intervention

Recruited subjects were treated with oral administration of *Shatapaki ksheerabala taila* in a dose of 24 ml in the morning in empty stomach about half an hour before breakfast along with 150 ml of warm water. This medication was continued for 28 days.

Duration of study

The study included 28 days of medication with *Shatapaki ksheerabala taila* followed by another 28 days of follow up period. Total duration of study was 56 days.

Diagnostic criteria

- Clinical diagnosis of *Margavaranaja Pakshaghata*, as evidenced by acute onset of *cheshtanivrutti, toda, shula, ruja,* and *sankocha* involving right or left half of the body. This may be associated with *vakstambha.*
- Clinical diagnosis of ischemic stroke evidenced by abrupt onset of focal neurological deficits that may include hemiparesis, monoparesis, hemi sensory deficits, dysarthria, facial droop, aphasia and sudden decrease in the level of consciousness etc.
- Radiological diagnosis of ischemic stroke by CT or MRI head.

Inclusion criteria

- Diagnosed cases of *Margavaranaja Pakshaghata*/Hemiplegia due to ischemic stroke as per the diagnostic criteria.
- Patients stabilised for seven days after the ischemic stroke.
- Total duration of the disease not greater than two years.
- Absence of any severe cognitive impairment such that patient is unable to provide details for assessing outcome measures.
- Men and non-pregnant, non-lactating women.

- Ages eligible for the study: ≥ 16 years and ≤ 70 years (adult, senior).
- Both participant and caregiver are willing and able to provide informed consent.

Exclusion criteria
- Stroke due to haemorrhagic cause.
- Hemiplegia due to other causes like malignancy, intracranial infections, degenerative lesion, space occupying lesions, metabolic encephalopathy, cerebral haemorrhage.
- Patients with cognitive deficits associating the stroke that impede understanding of study protocol.
- Presence of seizure disorders associating the stroke syndrome or history of epilepsy.
- Pregnant women or female intending to become pregnant.
- Coexisting vascular dementia.
- Patients with uncontrolled diabetes and hypertension.

Assessment criteria
Assessment was done on the basis of Primary & Secondary outcome measures before and after the treatment.

Primary outcome measures
- Change in mean score of muscle power of the upper limb from base line [Time frame Day 1 and Day 28]
- Change in mean score of muscle power of the lower limb from base line [Time frame Day 1 and Day 28]
- 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
- Change in mean score of pain from base line [Time frame Day 1 and Day 28]

Secondary outcome measures
- Change in the total score of Berg Balance Scale from the base line [Time Frame: Day 1 and Day 28].
- Change in the total score of Stroke Specific Quality Of Life Scale from base line [Time Frame: Day 1 and Day 28].

Investigations
1) Blood investigations – TC (Total count WBC), DC (Differential count WBC), ESR (Erythrocyte sedimentation rate), Hb% (Haemoglobin %) RBS (Random blood sugar), Fasting lipid profile
2) HbA1c in diabetic patients
3) ECG
4) Radiological study: CT/MRI Head if needed

Statistical test
The statistical software package for the analysis of the parameters was sigma stat 3.5 version. The primary outcome measures and secondary outcome measures were assessed statistically and the observations were recorded before and after the treatment. The Mean, Percentage, S.E and the p value were calculated from the observation recorded using Wilcoxon signed rank test for ordinal data.

OBSERVATIONS
The current clinical study among 30 patients revealed that maximum of 23.33% patients belonged to the age group of 56-60 years with a Male predominance of 80%. 93.33% of the patients registered for the study belonged to Hindu religion and 60% of the patients belonged to Rural community due to geographical predominance. In view of the observations made on disease history 36.67% of patients had a previous history of stroke and 20% had a family history of stroke. 66.67% had a history of HTN and 50% had history of Diabetes mellitus. 30% of patients had both histories of HTN and Diabetes mellitus which are the risk factors of stroke. Among the 30 subjects, affected side was right for 53.33% and left for the remaining. 53.33% had the onset of stroke at Day time and only 30% of patients had Aphasia. Dysarthria was present in 43.33% of patients, 86.67% had affliction of Facial nerve and 73.53% had the affliction of Spinal accessory nerve. In this clinical trial maximum of 53.33% had MCA territory infarct. The details are included in Table No.1.

Table 1: Observations.

Observations in demographic data				Variable	Detail	No.	%
Variable	**Detail**	**No.**	**%**				
Age Group	30-35	1	3.33	***Satva***	*Pravara*	5	16.7
	36-40	1	3.33		*Madhyama*	20	66.7
	41-45	5	16.7		*Avara*	5	16.7
	46-50	3	10	***Samhanana***	*Pravara*	7	23.3
	51-55	2	6.66		*Madhyama*	19	63.3
	56-60	7	23.3		*Avara*	4	13.3
	61-65	6	20	***Pramana***	*Pravara*	5	16.7
	66-70	5	16.7		*Madhyama*	22	73.3
Gender	Male	24	80		*Avara*	3	10
	Female	6	20	***Vyayama shakti***	*Pravara*	0	0
Religion	Hindu	28	93.3		*Madhyama*	9	30

	Muslim	2	6.67		*Avara*	21	70
	Christian	0	0	***Ahara Abhyavarana Shakti***	*Pravara*	4	13.3
	Jain	0	0		*Madhyama*	20	66.7
Educational Status	Un educated	2	6.67		*Avara*	6	20
	Illiterate	3	10	***Ahara Jarana shakti***	*Pravara*	3	10
	Primary	8	26.7		*Madhyama*	21	70
	High school	8	26.7		*Avara*	6	20
	Junior college	1	3.33	***Vaya***	*Bala*	0	0
	Graduate	6	20		*Madhyama*	17	56.7
	Post graduate	2	6.67		*Vriddha*	13	43.3
Socio Economic Status	Lower class	0	0	**Observations in disease history**			
	Lower middle class	6	20	**H/o previous stroke**	Present	11	36.7
	Middle class	16	53.3		Absent	19	63.3
	Upper middle class	8	26.7	**Family h/o stroke**	Present	6	20
	Upper class	0	0		Absent	24	80
Occupation	Desk work	4	13.3	**H/o HTN**	Present	20	66.7
	Field work	17	56.7		Absent	10	33.3
	Student	0	0	**H/o DM**	Present	15	50
	Domestic work	5	16.7		Absent	15	50
	Retired	4	13.3	**H/o HTN & DM**	Present	9	30
Marital status	Single	1	3.33		Absent	21	70
	Living relationship	0	0	**Affected side**	Right	16	53.3
	Married	27	90		Left	14	46.7
	Divorced	0	0	**Time of onset**	Day time	16	53.3
	Widow	2	6.67		Night time	14	46.7
Habitat	Urban	12	40	**Observations in clinical presentation of symptoms and signs of *Pakshaghata*/ischemic stroke**			
	Rural	18	60	**Aphasia**	Present	9	30
Observations on personal history					Absent	21	70
Diet	Veg	7	5	**Dysarthria**	Present	13	43.3
	Mixed	23	8		Absent	17	56.7
Bowel habits	Regular	17	56.7	**Affliction of cranial nerves**	Facial nerve	26	86.7
	Constipated	10	33.3		Spinal accessory nerve	22	73.5
	Incontinence	3	10		Hypoglossal nerve	5	16.7
Micturition	Regular	23	76.7	**CT/MRI Brain area of infarct**	Mca territory	16	53.3
	Scanty	0	0		Pca territory	4	13.3
	Incontinence	6	20		Aca territory	3	10
	Feeling of retention	1	3.33		Corona radiata	7	23.3
Addiction	Cigarette smoking	7	23.3		Lentiform nucleus &Caudate nucleus	5	16.7
	Tobacco chewing	7	23.3		Basal ganglia	8	26.7
	Alcohol	11	36.7	***Gouravata***	Present	22	73.3
	Nil	14	46.7		Absent	8	26.7
Observations in *Dasha vidha pariksha*				***Shotha***	Present	9	30
Prakruti	*Vatapittaja*	10	33.3		Absent	21	70
	Vatakaphaja	9	30	***Sheetata***	Present	12	40
	Pittakaphaja	11	36.7		Absent	18	60
Sara	*Pravara*	3	10	***Daha***	Present	8	26.7
	Madhyama	23	76.7		Absent	22	73.3
	Avara	4	13.3	***Toda***	Present	7	23.3
Satmya	*Pravara*	1	3.33		Absent	23	76.7
	Madhyama	27	90	***Ruja***	Present	7	23.3

	Avara	2	6.67		Absent	23	76.7
				Shula	Present	16	53.3
					Absent	14	46.7

RESULTS AND DISCUSSION

In the present clinical study, mean initial score of Muscle power in Upper limb with respect to movements of Shoulder, Elbow, Forearm, Wrist was 2.767, 2.733, 2.733, 2.700 which has improved to 4.067, 4.033, 4.067, 4.067 respectively after the treatment with a p value of <0.001 is statistically significant. The mean scores of Muscle power in Lower limb with respect to movements in Hip, Knee, Ankle before treatment was 2.633, 2.667, 2.600 which got improved to 3.867, 3.933, 3.800 respectively after the treatment and is statistically significant. With regard the effect of the treatment on the Muscle Spasticity in Upper limb showed that the mean initial score of Muscle Spasticity with respect to movements of Shoulder, Elbow, Forearm, Wrist were1.200, 1.450, 1.583, 1.617 which has reduced to 0.667, 0.700, 0.900, 0.967 respectively after the treatment which is again a statistically significant result. Similarly, the mean scores of Muscle spasticity in Lower limb with respect to movements in Hip, Knee, Ankle before treatment was 1.100, 1.183, 1.117 which got reduced to 0.550, 0.567, 0.500 respectively after the treatment with a p value of < 0.001. While assessing the change in the Pain on affected side showed marked remission with its initial mean score 4.067 came down to 1.733 after treatment was also found to be statistically significant. The mean score of the Berg Balance Scale had a statistically significant improvement as it's mean score was 27.367 prior to the treatment got improved to 41.167 after the treatment. The mean scoring of Stroke Specific Quality of Life Scale before and after treatment showed that there is moderate improvement, the score was 120.467 before treatment had improved to 161.933 after the treatment with about 34.41% improvement and it is also statistically significant. Thus by assessing all these measures it is evident that Shatapaki ksheerabala taila has efficaciously reduced the symptoms of Margavaranaja Pakshaghata and also contributed in improving the quality of life. The details are included in Table No.2.

Table 2: Results.

Outcome		**Mean score**		**Difference in Means**	**%**	**Wilcoxon Signed rank test- P**
		BT (±SE)	AT (±SE)			
Muscle power with respect to movement	Shoulder	2.767(0.223)	4.067 (0.143)	-1.300	46.98%	<0.001
	Elbow	2.733(0.209)	4.033(0.155)	-1.300	47.56%	<0.001
	Forearm	2.733(0.214)	4.067(0.159)	-1.333	48.77	<0.001
	Wrist	2.700(0.215)	4.067(0.159)	-1.367	50.62%	<0.001
Muscle power with respect to movement	Hip	2.633(0.222)	3.867(0.178)	-1.233	46.82%	<0.001
	Knee	2.667(0.200)	3.933(0.179)	-1.267	47.50%	<0.001
	Ankle	2.600(0.207)	3.800(0.194)	-1.200	46.15%	<0.001
Spasticity with respect to movement	Shoulder	1.200(0.160)	0.667(0.132)	0.533	44.41%	<0.001
	Elbow	1.450(0.150)	0.700(0.139)	0.750	51.72%	<0.001
	Forearm	1.583(0.122)	0.900(0.136)	0.683	43.14%	<0.001
	Wrist	1.617(0.121)	0.967(0.146)	0.650	40.19%	<0.001
Spasticity with respect to movement	Hip	1.100(0.136)	0.550(0.105)	0.550	50%	<0.001
	Knee	1.183(0.0943)	0.567(0.117)	0.617	52.15%	<0.001
	Ankle	1.117(0.112)	0.500(0.117)	0.617	55.23%	<0.001
Pain (Range)	0-10	4.067(0.303)	1.733(0.318)	2.333	57.36%	<0.001
Berg Balance scale	**Range** 0-56	27.367**(**2.733**)**	41.167**(**2.196**)**	-13.80	50.42	<0.001
SSQLS	**Range** 49-245	120.467(5.454)	161.933(6.059)	-41.46	34.41%	<0.001

DISCUSSION

The management of *Pakshaghata* in the literature includes both internal and external medications. The internal medications are classified as the ones causing Purification, Pacification, Nourishment and Rejuvenation. The choice of the purification depends on the location, severity of *dosha* vitiation along with association of other *dosha*. After the purification the medicines for the pacification of the vitiated *dosha* are given. These are called *shamana* medicaments which are continued till the reduction in the symptoms. External and internal *snehana* and *svedana* are considered as the best procedures for the mitigation of the *vata dosha*. Thus the *snehana* and *svedana* are continued till the complete reduction of the symptoms. In case of internal *snehapana*, *achapeya* and *vicharana sneha* is considered as the best. But due to its palatability and administration in higher dose, patients will find it hard to take and it make practically difficult in *Pakshaghata* patients. So the next superior medicament which can mitigate the *vata dosha* is the *shamana snehapana*. This type of *snehapana* differ from the *acha peya*, in its dosage and

time of administration. The *shamana snehapana* is administered in the *anna kala* or the time of intake of food in empty stomach and only moderate dosage of the *sneha* is given which make it easier for the patients to intake. *Taila* is considered as the best in mitigating *vata dosha*. There are innumerable *taila* formulations mentioned in literature for the same. *Ksheerabala* is one such *taila yoga* which is said to be effective in all types of the *vata roga*. It is considered as *rasayana* which comprises of ingredients like *ksheera, bala moola* and *tila taila* which possess *balya, vata shamana, vyavyayi* and *vikasi* properties. This facilitate to remove the obstruction in the minute channels. The drug *Shatapaki ksheerabala taila* is prepared by doing the *paka* for 100 times and each time fresh *kalka, kwatha* and *ksheera* are used.

In the present study *Shatapaki ksheerabala taila* was administred in the form of *shamana snehapana* in a dose of 24 ml in the morning, in empty stomach about half an hour before breakfast along with 150 ml of warm water. This medication was continued for 28 days.

Sneha kalpana is considered to be the best way to extract the lipid soluble active principles from the drugs. Thus it enhances the drug absorption. So during the process of boiling the active principles from the drugs are moving to the liquid media. To extract the more number of active principles we need more amount of liquid media. So we require more time for the evaporation of the excess water molecules. The rationality behind the of *avartita sneha kalpana* is the same. *Avartana* means repetition, here the *sneha dravya* is undergoing repeated processing with the *kalka dravya* and *drava dravya*. By the continuous processing of the formulation, we can see there will be loss in the quantity of *sneha*. The advantages of *avartana* procedure by which we can reduce the dosage of administration, it will be quick in the action, having utmost therapeutic efficacy, it can act even on minute channels of the body and it will be easier for administration. This view can be supported with the ability of lipid soluble solutes and the free fatty acids to diffuse across the blood brain barrier.

Shamana snehapana is the type of *snehapana* selected for the study as for its practical convenience. *Shamana snehapana* is administered in the *annakala*, usually in the morning or evening hours when proper hunger is developed. The criteria for the selection of morning hours is, as it is said that the medicaments administered in the morning empty stomach will have the maximum therapeutic efficacy due to higher degree of absorption.

The dosage of *snehapana* is fixed based on the time taken for the digestion of *sneha*, and its superior dosage is digested in 24 hours, moderate dosage in 12 hours and lowest dosage is digested in 6 hours. According to it, the conventional dosage of *snehapana* is considered to be largest dosage of 48g, moderate 36g and the smallest dose be 24g.[9] This dosage of the snehapana depends upon the *agni, kosta, desha, kala, vyadhi* and *roga bala* and the dosage of *avaritita sneha* will be considerably reduced as it possesses more active principles than a normal *sneha kalpana*. Considering that, the dosage adopted in this study is the lowest dosage i.e., 24gms which is empirical and rational. The *anupana* for the *sneha kalpana* differs from the type of *sneha*, for *ghrita ushna jala* and for *taila yusha* is told. But among these, *ushna jala* is considered to be best in any *snehapana*. *Ushna jala* by virtue of its *agnideepaka* property help in the easy digestion of the *sneha dravya*.[10] So luke warm water was advised as *anupana* for the study. The dosage of *anupana* as per Sharangdhara goes like three *pala* for *vataroga*.[11] which come approximately 150ml, which is selected for the study.

The *Shatapaki ksheerabala taila* is a *rasayana yoga* for all sorts of *vataroga*. The *rasayana* medicaments are best administered for a period of one *masa* for their therapeutic efficacy. Hence the period of 28 days is selected for the study.

On the other hand, various pharmaceutical invitro and invivo studies are conducted on the drugs Sida cordifolia and Sesamum indicum. Sida cordifolia is proved to be having antioxidant, lipid peroxidation inhibitory, hypolipidemic, analgesic and anti-inflammatory activities. Water infusion and ethanolic extract of Sida cordifolia have antioxidant activity tested by two methods; 2,2'-azinobis-3-ethyl-benzothiazoline-6-sulfonic acid (ABTS+) radical cation decolorization assay and inhibition of lipid peroxidation of rat brain homogenate by the plant infusion.[12] There will be oxidative stress and formation of free radicals during cerebral ischemia. Thus Sida cordifolia helps in treating the inflammatory pathology and act as a nerve tonic by preventing the irreversible damage of neurons. Sesamum indicum is reported to be having the anti-oxidant and free radical scavenging activities which help in reversing the disease progress.[13]

While analysing the results of the present study, the improvement in the muscle power and reduction in the muscle spasticity can be justified by the *balya, brihmaniya*, and *vatashamaka* properties of *Balamoola* and the *vataghna* property of *Tila taila* together. This fact is further supported by cross referring a research study where in the antioxidant, inhibitory action on lipid peroxidation and free radical scavenging activities of the drugs were established. *Balamoola* is a drug which have significant effect on the vitiated *vata dosha* by virtue of its *vatahara* property and *Tila* is considered to be having *vedanasthapana* action. This change is supported by the anti-spasmodic, analgesic and anti-inflammatory activity of *Balamoola*. Thus the efficacy of *Shatapaki ksheerabala taila* in reducing the pain is justified. The improvement observed in the scoring of the Berg balance scale and Stroke specific quality of life scale can be justified by the *rasayana, balya* and *vatashamana* properties of the *Balamoola*, *Tila taila* and *Ksheera* with

their effect in mitigating the vitiated *vata dosha* and nourishing the depleted *dhatu*.

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*. 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 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 *Shatapaki ksheerabala taila* in patients suffering from *Pakshaghata*.

CONCLUSION

Shatapaki ksheerabala taila was found to be effective in reducing the symptoms of *Margavaranaja Pakshaghata* and improving the muscle power and strength of the body. It also helped in improving the quality of life of the patients. The same has been supported strongly by the positive statistical tests. Further clinical trial need to carried out with more number of subjects with an increased time frame for a better proof of the complete efficacy of *Shatapaki ksheerabala taila.*

REFERENCES

1. Sushruta. Sushruta Samhita with Nibandha Sangraha commentary of Dalhana. Acharya Jadvji Trikamji editor. Varanasi: Chaukhambha Sanskrit Sansthan; Reprint edition, 2012; 822: 73.
2. Agnivesha. Charaka Samhita with Ayurveda Dipika commentary of Chakrapanidatta. Acharya Jadavaji Trikamji editor. Varanasi: Chaukhambha orientalia; Reprint edition, 2011; 738: 149.
3. Agnivesha. Charaka Samhita with Ayurveda Dipika commentary of Chakrapanidatta. Acharya Jadavaji Trikamji editor. Varanasi: Chaukhambha orientalia; Reprint edition, 2011; 738: 115.
4. Agnivesha. Charaka Samhita with Ayurveda Dipika commentary of Chakrapanidatta. Acharya Jadavaji Trikamji editor. Varanasi: Chaukhambha orientalia; Reprint edition, 2011; 738: 717.
5. Agnivesha. Charaka Samhita with Ayurveda Dipika commentary of Chakrapanidatta. Acharya Jadavaji Trikamji editor. Varanasi: Chaukhambha orientalia; Reprint edition, 2011; 738: 619.
6. Kasper Dennis L, Hauser Stephen L, Jameson Larry J, Fauci Anthony S, Longo Dan L, Loscalzo Joseph. Harrison's principles of internal medicine (Vol2). 19th ed. New York: Mcgraw Hill publications, 2015; 2770-2559.
7. Vridhha Vagbhata. Astanga Samgraha with Shashilekha commentary by Indu. Sharma Shivprasad editor. 3rd ed. Varanasi: Chawkhambha Sanskrit Series Office, 2016; 965: 173-74.
8. Vagbhata. Astangahrdayam with Sarvangasundara commentary of Arunadatta & Ayurvedarasayana commentary of Hemadri. Paradakara Harishastri editor. 10th ed. Varanasi: Chaukhambha Orientalia, 2014; 956: 732.
9. Sharma Priya Vrat editor. Cakradatta. Varanasi: Chowkhambha Krishnadas Academy, 2012; 620: 604.
10. Agnivesha. Charaka Samhita with Ayurveda Dipika commentary of Chakrapanidatta. Acharya Jadavaji Trikamji editor. Varanasi: Chaukhambha orientalia; Reprint edition, 2011; 738: 83.
11. Parashuram Shastri Vidyasagar editor. Sarngadhara Samhita. Varanasi: Chaukhamba Surbharati Prakashan, 2006; 398: 178.
12. Auddy B, Ferreira M, Blasina F, Lafon L, Arredondo F, Dajas F, Tripathi PC, Seal T, Mukherjee B. Screening of antioxidant activity of three Indian medicinal plants, traditionally used for the management of neurodegenerative diseases. Journal of ethno pharmacology [serial online]. 2003 Feb; 84(2-3): 131-8. [cited 2020 Mar 10]. Available from: URL: https://www. ncbi.nlm.nih. gov/ pubmed/12648805.
13. Luciana de Almeida Vittori Gouveia, Carolina Alves Cardoso, Glaucia Maria Moraes de Oliveira, Glorimar Rosa, Annie Seixas Bello Moreira. Effects of the Intake of Sesame Seeds (Sesamum indicum L.) and Derivatives on Oxidative Stress: A Systematic Review. Journal of medicinal food [serial online], Apr 2016; 19(4): 337-345. [cited on 2020 Mar 15]. Available from: URL: https: // www. researchgate.net/publication/301287947_ Effects_ of_the_ Intake_of _Sesame_ Seeds_Sesamum _indicum_L _and _Derivatives _on _ Oxidative _Stress_A_Systematic_Review.