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Research Article

A PROSPECTIVE CLINICAL OBSERVATIONAL STUDY ON PROTOCOL BASED SUSHRUTAS *AVASTHANUSAR* MANAGEMENT OF *PAKSHAGATA* (ISCHEMIC STROKE)

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ABSTRACT

Stroke is one amongst the leading cause of death and disability, and the treatment so far has no promising results. Even though ample research is being carried out for alleviating the disease and new avenues are being explored in acute management followed by physical rehabilitation and physiotherapy etc, yet the disease have not been dominated and remain incurable with minimal residual disability. *Pakshaghata* treatment schedule adopted according to the stage i.e. in acute stage the immediate aim is to maintain the lifestyle and to prevent the further complications treatment based on *Avastha* helps in reversal of pathology, so here protocol is developed which is already being followed giving promising results in acute conditions need to be documented. **Objective:** The study was undertaken to assess the efficacy of *Avasthanusar chikitsa* in the management of Ischemic stroke (*Pakshagata*). **Methods:** 10 patients of acute ischemic stroke directly coming to Sushrut Ayurveda Hospital were enrolled after confirming the CT/MRI as per diagnostic criteria and those who were fitting in inclusion criteria. All the 10 patients underwent the whole treatment protocol according to *Avastha* but the time, medicines were totally individualized. **Results:** 1. In *Pitta samasargaja avastha*, Glass gow coma scale showed 91.49 % improvement which was highly significant. 2. In *Kapha samasrgaj avastha* NINDH stroke scale and Barthel index showed significant improvement of 83.7%. 3. In *Vataja samsargaja avastha* modified Rankin scale and 10 meter walk test showed 72.5% & 86.21% improvement respectively which was highly significant. **Conclusion:** In *Pittasamsargaja avastha* when presenting symptoms are *Mada, Murcha* and *Akashepaka* the both *Dosha* and *Vyadhi viparita chikitsa* is done simultaneously by *Teekshana nasya* and *Sheeta upakramas*, Once *Pittaja laxanas* are reduced *Kapaha/ Amahara Chikitsa* is done, in *Vata Samsargaja Chikitsa Brihmana Chikitsa* is done.

INTRODUCTION

Stroke is the 3rd major cause of death and functional disability in the world[1]. it is defined as a syndrome of rapid onset of cerebral deficit and frequent outcome of stroke is hemiplegia and stroke may be either from an ischemic or a hemorrhagic pathological process, the treatment so far has no promising results.

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The contemporary drugs only assuage the symptoms temporarily and the underlying pathology goes on progressively to worsen the condition. only ample research is being is done to overcome th disease and new avenues are being explored, Followed by physical rehabilitation, physiotherapy, yet the disease have remained incurable. To add it up, the adverse effects poses distant threat to the well-being by hampering the quality of life explored for treating early ischemic injury by thrombolytic agents, Neuro protectants, anti oxidants[2], etc. Followed by physical rehabilitation, physiotherapy etc., yet the disease haven pose distant threat to the well-being especially hampering the quality of life.

Not only of treatment of hemiplegia but management of acute stroke is well explained in *Ayurvedic* research literature which is brought about by various treatment modalities adopted according to stage wise.

Panchakarmas therapeutics like Nasal instillation (*Nasya*), Enema (*Basti*), Purgation (*Virechan*), Massage (*Abhyanga*), Medicated paste application (*Lepa*) forms a very important part of the treatment plan for Hemiplegia and their application wholly depends presenting stage of patient.

There is need for *Ayurvedic* protocol devolpment and its driven clinical trails is beginning to be felt in professional *Ayurvedic* circle because in the recent times under the influence of biomedical treatment strategies, *Ayurvedic* researchers have tended to reduce their holistic and individual specific management strategies to uniform treatments mimicking allopathic treatments under the mistaken belief that research designs based on classical Ayurvedic protocols are not researchable

Hence this observational study was undertaken that showed 2 to 3 folds of motor and functional recovery within 2 weeks which itself takes 3 to 4 months in contemporary medical management and complete depent by the end of 3- 4 weeks.

AIM AND OBJECTIVES

- To assess the efficacy of *Avasthanusara chikitsa* in the management of Ischemic stroke (*Pakshagata*).

MATERIAL AND METHODS

- The study is Registered under Clinical Trials Regestery of India with no

  Ctri Reg No- CTRI/2017/01/011540
- Ethical clearance was obtained from Institutional Ethical Committiee, The consent for the study was taken prior enrolment by the patient relatives.
- Source of data- The patients were enrolled from OPD/IPD of Sushruta Ayurveda Hospital, Puttur Dakshina Kannada.

Diagnostic Criteria

- Karmahani of ardha kaya (loss of functions of unilateral side of the body).
- CT scan/ MRI to confirm the diagnosis

Inclusion criteria

1. Presenting with classical signs and symptoms of *Pakshaghata* selected.
2. Clinical diagnosis of ischemic stroke, confirmation by CT.
3. Aged between 30 and 80 years.
4. Patients presenting with Akshepaka avastha will also be considered

Exclusion criteria

1. Hemorrhagic hemiplegia
2. CO-existing terminal diseases
3. Tuberculosis/Encephalities/Abscess
4. Chronicity of more than one month
5. Trauma
6. Neoplasms
7. Patients received rtPA

Assesment criteria for observations

The parameters assessement was obsereved at every *Avastha* to and in between *Avastha chikitsa* till the end of *Vata samsargaja chikitsa* at 0th day, stage 1, stage 2, stage 3.

1. Glass gow coma scale
2. Stroke scale of NIH
3. Modified Rankin score
4. Barthel index
5. 10 meter walk test
6. BP and Pulse monitored on hourly basis

Table 1: Assessment Parameters

S. no	Parameters	0th day		End of stage 1	End of stage 2	End of stage 3
1	Glass gow coma scale[3]	BT	AT			
2	Stroke scale of NIH [4,5]					
3	Modified Rankin score[6]					
4	Barthel index[7]					
5	10 meter walk test[8]					
6	BP and Pulse on hourly basis					

Treatment Protocol

Table 2: For *Pitta Samsargaja Avastha*

Lakshanas	Treatment	Duration	Criteria assessed at the end of treatment
	Himadhara *(Dhanyaka+Amalaki)* for 20min		

Mada, Murcha, Santapa	***Talam*** with *Shatdouta gritha* and *Manjistadi choorna*	3 times a day with interval of 1 *Yama* repeated for 3 days	Till regain of consciousness and improvements in movements of arms 3 or maximum 7days
	Sheeta alepa with *Shatdouta gritha* all over the body		
	Teekshna nasya *(Yasti + Pippali + Maricha + Hingu + Saindhava)* each 1 pinch mixed with *Ksheera* 8 drops in each nostrils		
	Sarpipana *Kalyankagrita/Mahatiktaka grita* 450ml after *Nasya* in morning with *Shunti Swarasa* as *Anupana*		
	***Mridu virechana* 30ml** *Gandharava Hastadi Eranda Taila* 30ml + *Ksheera* On 4th day		

Table 3: Stage 2- *Kaphaja Samsargaja Chikitsa*

Lakshanas	**Treatment**	**Duration**	**Criteria assessed at the end of treatment**
Shaitya, Gurutwa, Stamba, Ama	***Ruksha lepa/Agni lepa*** *(Nirgundi + Maricha + Lavanga + Lashuna + Tulasi + Agnimantha + Kola)* 1 time a day	7 days *Basti* will be given on same day/ alternate day	
	Dhara *(Dhanyaka + Ammalaki)*		
	Sarvanga abhyanga with *Sarshapa taila* before giving *Basti*		
	Niruha- *Maha Manjistadi kashaya basti/ Dasmoola plain kashaya basti* 500ml ***Basti: Anuvasana-*** *Brihat Saindhava taila 100ml*		

Table 4: Stage 3- *Kevala Vataja Chikitsa*

Lakshanas	**Treatment**	**Duration**
Ruja, Sankocha, Karmahani	***Shirodhara*** with *Bala taila* for 30minutes	Maximum for 7 Days
	Sarvanga abhayanga with *Ksheer bala taila*	
	Basti: ***Niruha-*** *Manjistadi kashaya basti* 500ml ***Anuvasana Basti****- Narayana taila* 100ml	
	Upanaha to affected limbs *(Devadaru + Rasna + Takra+ Saindava + Godhuma) / Sastika shali pinda sweda*	

Statistical Analysis

- The result of the treatment were assessed during regular intervals of the treatment All the available data was statically analysis by applying ''paired T test'' The calculated value was compared with tabulated value and the Sequel assessed at various probabilities The results obtained were interpreted as :- Significant -$p < 0.05$

OBSERVATION AND RESULTS

Table 5: Observation showing Sex and Age incidence

Sex	**No. of patients**	**Percentage**
Male	6	60%
Female	4	40%

Age Group	**No. of patients**	**Percentage**
40-50 Years	0	0%
51-60 Years	7	70%
61-70 Years	3	30%

Table 6: Effect on Glasgow coma scale

Symptom	Measures		AT	%	S.D (+.)	S.E (+.)	t value	p value
Glasgow coma scale	0 day BT	5.7	14.1	40.43	1.350	0.450	1.532	0.1602
	0 day AT	6.8		48.23	1.494	0.498	6.0	0.0002
	End of stage1	11.6		82.27	1.434	0.478	2.632	0.0277
	End of stage 2	12.9		91.49	1.033	0.344	6.127	0.0002

This study consisting of 10 patients of with **Glass gow coma scale** revealed the result

Statistical analysis showed that the mean score which was 5.7 in before treatment, was increased to 14.1 with 91.49% improvement.

Table 7: Effect on Stroke Scale

Stroke Scale	Measures			%	S.D (+.)	S.E (+.)	t value	p value
	0 Day							
	17.8	End of stage 1	12.9	27.53	4.795	1.598	3.23	0.0103
		End of stage 2	7	60.67	2.781	0.927	12.28	0.0001
		AT	2.9	83.71	2.961	0.987	15.91	0.0001

Statistical analysis showed that the mean score which was 17.8 in before treatment, was reduced to 2.9 with 83.71% improvement

Table 8: Effect on Modified Ranking scale

Modified Ranking scale	Measures			%	S.D (+.)	S.E (+.)	t value	p value
	0 Day							
	4	Stage 1	3.7	7.50	0.483	0.161	1.96	0.08 NS
		Stage 2	2.8	30.00	0.422	0.141	9.00	0.0001
		Stage 3	2.1	47.50	0.568	0.189	10.58	0.0001
		AT	1.1	72.50	0.568	0.189	16.16	0.0001

Statistical analysis showed that the mean score which was 29.5 in before treatment, was increased to 83 with 81.93% improvement, and there is a highly statistically significant change.

Table 9: effect on 10 meter walk test

Symptom	Measures		AT	%	S.D (+.)	S.E (+.)	t value	p value
10 meter walk test	0 day	0.5	2.90	0.00	0.316	0.105	29.00	0.0001
	Stage 1	0.9		31.03	0.471	0.157	13.42	0.0001
	Stage 2	1.8		62.07	0.486	0.165	11.00	0.0001
	Stage 3	2.5		86.21	0.516	0.172	2.45	0.0368

Statistical analysis showed that the mean score which was 0.5 in before treatment, was increased to 2.90 with 86.21% improvement

Table 10: Effect on Blood pressure

	Measures				% of Relief		S.D (+.)		S.E (+.)		t value		P value
	0 Day BT	SP	0 Day BT	DP	SP	DP	SP	DP	SP	DP	SP	DP	
0 day AT	158	148	102	94	6.33	7.84	6.667	6.325	2.22	2.10	4.74	4.00	0.0001 0.0031
Stage 1		148		90	6.33	11.7	12.47	6.325	4.15	2.10	2.54	6.00	0.0137 0.0002

Stage 2		146		89	7.59	12.7	14.75	9.487	4.91	3.16	2.57	4.33	0.0302 0.0019
Stage 3		139		88	12.0	13.7	12.86	10.75	4.28	3.58	4.67	4.12	0.0012 0.0026

Statistical analysis showed that the mean score which was 158/102 in before treatment, was reduced to 139/88 after treatment

DISCUSSION

The total outcome all the treatment procedures of all *Avasthas* showed significant improvement in individual parameters, the whole results can be concluded by taking the following proven studies in the management of acute stroke.

The outcome of this protocol is compared to outcome measures of various studies referred from standard journals to know the efficacy of protocol on factors like:

1. Time
2. Motor recovery
3. Quality of life

Pitta Samsargaja Avastha

In *Pitasamsargaja avastha chikitsa* following treatment procedures were carried out and their effect on individual parameters will be discussed *Sheeta dhara, Sheeta lepa, Teekshna nasya, Sarpipana, Virechana.* During the course of *Pittaja samsargajavastha chikitsa* following parameter showed prominent improvement

Glass gow coma scale- Major improvement with statistical significant change with p value <0.05, this may be justified by *Vyadhi* and *Dosha vipeerita chikitsa*, as the presentation is unconsciousness or altered consciousness with or without convulsions.

It can be correlated as *Mada, Murcha* and *Akshepaka* which can be considered as *Pittaja pradhana avastha*[9] where in *Pitta hara chikista* should be adopted first. But the *Samprati* is because of *Tamo avarana* in *Sanjna vaha srotas* causing *Pitta vrudhi* so as a measure for *Samprapti vighatana* both *Avarana hara* and *Pitta hara chikitsa* should be carried simultaneously. Which is very much similar occlusion by Thrombus or Emboli causing infarct causing blood deprivation to some part of brain area with complete or partial death of that area cells. Discussing about management strategies include recanalisation and increasing neuroplasticity by administration of rTPA or anti platelets drugs. This can be considered as *Avarna hara chikista.*

In *Akshepaka avastha* the treatment should be done for the same, which includes *Teekshna nasya, Dhara* and *Lepa* and *Sarpi pana*[10].

Action of *Teekshna Nasya*

Nasya done with *Teekshna ushna* drugs immediately clears the obstruction and thus establish recanalisation improving the flow to blood to blood deprived area, sometimes cells adjacent to the infact area may be partially dead by the irritation of the *Ushna teekshna guna* of *Dravya* enhances the neuroplasticity action in brain cells irritation leading to increase in blood pressure thus flushing the flow of blood to penumbra also encourages the collateral flow to reaching penumbra so that to save dying brain tissues.

Action of *Sheeta Upakarmas*

By the application of *Sheeta upakramas* the neural activity is reduced which in turn reduces the increased blood flow causing regulation of Blood pressure.

All these drugs are having *Sheeta guna* and *Stamba* is the *Guna* of *Sheeta dravya*[11] so by the *Stamba guna* the nerve cell life is sustained for more longer period even with less blood supply and *Manjistadhi choorna* with *Shatadhouta grita* applied on head helps in reducing cerebral edema helps in reducing the inflammation thus developing of function loss can be limited.

Sarpipana

The pathophysiology of seizures after stroke is not completely understood but several mechanisms are hypothesized, Discussing about management by Ayurveda various therapeutic procedures are explained which includes *Pravara matra sarpipana*[12], the patients soon after the administration of *Teekshna nasya* could regain consciousness due to local irritant action of drug followed by which *Sarpi* is administered in *Pravara matra* that prevents the further spread of *Vata.*

Ghrita kalpanas also can be considered as high ketogenic diet (Ramchandra P. Babar et al; Concept of Medicated Ghee (*Ghrita Kalpana*)[13] in the Management of Epilepsy (*Apasmara*), different *Gritha* can be used based on *Dosha avastha* as a vehicle to prevent seizures.

Mridu Virechana

Virechana is the prime treatment module explained for *Pittaja* disease, acute stroke conditions may be considered as *Samsargaja avastha* either *Pitta avarana* or *Kapha avarana* of *Vata.* In case of *Samsargaja dosha*, i.e., if *Vata* is affected by *Pitta* and *Kapha* both, then *Pitta* should be controlled first[14] and for controlling *Pitta*. Hence in *Doshanubandhita*

Pakshaghata Virechana can be considered as a treatment which is done once the patient is stable after *Teekshna nasya.*

Kapha Samsarga Avastha

In *Kapha samsargaja avastha chikitsa* following treatment procedures were carried out and their effect on individual parameters will be discussed.

Sarvanga abhyanga (Rooksha), Agnilepa, Kaphara basti:

Nirooha- *Manjistadi kashaya basti*

Anuvasana basti- *Brihat sainadavadi taila*

During the course of *Kapha samsargaja avastha* parameters showing prominent improvement and from the results it is found that

1. NIH stroke scale- Significant improvement
2. Barthel index- significant improvement

Discussion on *Kaphasamsargaja Chikitsa*

Here treatment like *Kaphara abhyanga, Basti* and *Agni lepa* was planned were in it helps in *Ama pachana* as well as *Raktaprasadana* by the *Basti* planned.

Once the *Ama* which is causing spasticity and in such conditions with *Kapha* involvement correction of *Agni* is necessary, *Vata* gets provoked mainly by the *Sheeta Guna* having close relationship with the *Ap Mahabhutha. Aama* which has similar properties like that of *Kapha* has a close relation with *Ap Mahabhuta*. Drugs having *Ushna, Tikshna*, and *Ruksha* qualities which are quite opposite to the qualities of *Aama* and *Kapha* have the capacity to increase the *Agni* disseminate the *Aama* and correct the status of *Ap Mahabhuta*.

Thus it can be said that drugs used in *Agnilepa*[15] get absorbed through the skin and produce action according to the property of the medicine i.e., *Kapha Vata Shamana* and does the *Agni Depana, Ama Pacana* and *Srothoshodhana*

Vataja Samsargaja Avastha

In *Vata samsargaja avastha chikitsa* following treatment procedures were carried out and their effect on individual parameters will be discussed *Sneha abhyanga, Brihmana basti, Shirodhara, Upanaha.*

During the course of *Vataja samsargaja avastha* parameters showing prominent improvement and from the results it is found that

1. 10 meter walk test- significant improvement
2. Modified Rankin scale- significant improvement

Discussion on *Vatasamsargaja Chikitsa*

Abhyanga, Shastika shali pinda sweda, Basti, upanaha done *with Vatahara / Brihmana taila* helps in nourishing the degenerated tissues whereas *Swedana like Shastika Shaali Pinda Swedana* also improves the tone of the body.[16] *Swedana Karma* increases the metabolic activity which in turn increases the oxygen demand and blood flow. This vasodilatation stimulates the superficial nerve ending causing a reflex dilatation of the arterioles. Due to the effect of heat on the sensory nerve ending there will be a reflex stimulation of sweat glands in the areas exposed to heat. This rise in temperature induces muscle relaxation and increases the efficacy of muscle action as the increased blood supply ensures the optimum condition for the muscle contraction.

Abhyanga softens the skin, gives soothing effect, allows free movement, reduces the spasticity and rigidity in joints as well as muscles, improves blood circulation to the muscles and relieves the pain. In the long term, muscle wasting may also be prevented.

All these therapies are similar to strategies in rehabilitation after stroke to compensate for sensory, perceptual and motor loss given in post stroke conditions.

Hence *Dosha-Avasthanusar* adopted *Chikitsa* in patients showed maximum improvement in acute presentation of stroke.

CONCLUSION

By this observational study it is noted that protocol derived from *Acharaya Sushruta Avasthanusar chikitsa* principles is more effective in the treatment of Ischemic stroke (*Pakshagata*).

- Conscious is regained well by the end of *Pitta samsargaja chikitsa* i.e., within 3-4days, which itself take long time in the management of acute stroke in ICU setups.
- Motor parameters in Neurological mapping showed 2 to 4 folds of improvement.
- Finer movements restored slowly compared to gross motor function improvement and complete recovery of motor functions by the end of *Vatasamsargaja chikitsa.*

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