JAHM
EISSN: 2321 - 1563
Jour. of Ayurveda & Holistic Medicine
Volume- II, Issue- IX
Research

CLINICAL STUDY ON THE EFFICACY OF RASAYANA IN THE MANAGEMENT OF MARGAVARANAJANYA PAKSHAGHATA (ISCHAEMIC STROKE)

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ABSTRACT:

Background: Ayurvedic literature highlights the symptoms of *Pakshaghata* as *chesta nivritti* either in *vama or dakshina parshwa* along with *ruja* and *vakstambha*. *Pakshaghata* (Hemiplegia) being one of the 80 *nanatmaja vata vyadhi* can occur either due to *dhatukshaya* or *margavarana.* General *vatavyadhi chikitsa* is best achieved through *snigdha sweda* and *mridu shodhana*. But the specific treatment for margavarana is achieved through *anabhishyand isnigdha dravya* and *srotoshuddi kara chikitsa.* Untreated *margavarana* in due course can result in other diseases like *hridroga, vidradhi, pleeha* etc. WHO defines Stroke, as rapidly developing clinical signs of focal disturbance of cerebral function lasting more than 24 hours. Here patients with *Pakshaghata* due to *margavarana/* ischaemic stroke were selected for the study. **Materials and methods**: This study is a single group with pre and post test design wherein 50 patients fulfilling the diagnostic criteria of *Pakshaghata/* Ischaemic stroke was selected and were subjected to *nitya virechana* and *Shasthi shali pinda sweda* for 7 days followed by *Shilajathu-loharasayana* in a dose of 6 g. OD with milk before food was administered for a period of 28 days**. Results:** Statistically highly significant results were found in muscle strength, finger and toe movements, hand grip and foot pressure (p= <0.001). **Discussion:** It was found that the response of the therapy was statistically significant with P value < 0.001 in terms of symptoms of *Pakshaghata.*

Key Words: *Pakshaghata, Margavarana*, Ischemic stroke.

INTRODUCTION:

Pakshaghata (Hemiplegia) being one amongst 80 *Vataja nanatmaja vyadhi*[1] can be manifested either due to *dhatukshaya or margavarana*. [2] The cardinal features of *Pakshaghata* includes *chestahani, ruja, vakstambha, hasta pada samkocha*.[3]*Sandhi bandha vimoksha* can also be associated in some situations.

In current system of medicine, Stroke is said to be the major cause of adult disability due to both debilitating initial symptoms and in many cases severe long term impairment in activities such as walking and speech.[4] This occurs suddenly with the onset of weakness, numbness, paralysis, slurred speech, aphasia, problems with vision and other manifestations of a sudden interruption of blood flow to a particular area of brain. Involvement of ischemic area determines a type of focal deficit.

Stroke runs as 3rd leading cause of death. 14% of those who have a first stroke or TIA (transient ischemic attack) will have another stroke within one year.[5]Dyslipidaemia, persistent accelerated hypertension is the risk factors for stroke. Recurrent strokes often have a higher rate of death and disability because of parts of brain already injured by original stroke.[6] Our classics quotes the *kapha* and *medo avarana* in *raktamarga* related to *shiras* resulting in precipitation of *Pakshaghata.* Based on the pathogenesis of *pakshaghata* the line of treatment has to be planned. In this case, the line of treatment told for avarana as well as for vata dosha is given prime importance.

With the above said gravity of problem the treatment told for *margavarana janya pakshaghata*/ischaemic stroke is being planned as a rational approach which will prevent the repeated attacks of the disease. In the present study *snigdha sweda* along with *mridu virechana* is planned as an initial treatment which is followed by *Rasayana chikitsa* in the form of *shilajathu-loharasayana*[7]mentioned in the same context.

OBJECTIVES:

To evaluate the combined effect of *nitya virechana,*

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Access this article online: www.jahm.in

Received on: 17/11/14, Revised on: 21/11 /14, Accepted on: 10/12 /14

Shasthi shali pinda sweda along with *shilajathu-loharasayana* in patients of *pakshaghata* due to *margavarana.*

MATERIALS AND METHODS:

Study design: Clinical study with pre and post test design.

Sample size: 50 patients

Source: Diagnosed case of *Pakshaghata* due to *margavarana/*Ischaemic stroke from OPD and IPD of Shri Dharmasthala Manjunatheshwara Ayurveda and Hospital, Udupi, India.

Institutional ethical clearance no.
SDMCAU/ACA15/EC27/09-10.

Medicine: Drugs required for *Shashti shali pinda sweda,* for *nitya virechana* with *eranda taila* (oil of *Ricinus communis*)*, shunti qwatha churna, (*Decoction powder of *gingiber officinale*) for *swedana bala mula kwatha churna* (Decoction powder of *Cida cordifolia*) and *shilajatu-loha rasayana* was prepared at Shri Dharmasthala Manjunatheshwara Ayurveda Pharmacy, Kuthpady, Udupi.

Diagnostic criteria

- Patients with clinical manifestation of *Pakshaghata* / stroke syndrome
- CT scan head confirming Ischemia/infarction.
- Carotid Doppler confirming atherosclerosis.

Patients fulfilling the following inclusion criteria of *Pakshaghata* of either sex, irrespective of their economical status, educational status, caste were selected for the study.

Inclusion criteria

- Patients fulfilling diagnostic criteria.
- Patients between the age group of 16-70yrs.
- Patients after the stroke onset of 15 days upto 1 year.
- Patients who are fit for *nitya virechana* and *pinda sweda*.

Exclusion criteria

- Patients with altered state of consciousness.
- Patients of stroke syndrome other than thrombo-emobolic factor.
- Patients with other systemic illnesses.

Investigations

- Routine haematological such as Hb% TC, DC, ESR, RBS.
- Biochemical: Blood urea, Serum creatinine, Lipid profile.
- Routine and microscopic analysis of Urine.
- C.T. Head and Carotid Doppler study.

Intervention

All the 50 selected patients were treated with initial 7 days of *nitya virechana with Eranda taila* (oil of *Ricinus communis*) – 20ml, *shunti kashaya* (*Zingiber officinale*) – 20ml at 7.00 am followed by *sarvanga abhyanga* with *Mahanarayana taila*[8]and *Shashti shali pinda sweda.*

After completion of initial 7 days of treatment, they were administered with *Shilajathu-loharasayana*[9] in a dose of 6 g. with milk at 7 am daily for a period of 28 days.

Follow up period: 30 days

Total duration of the study: 65 days.

Observation during the initial 7 days includes initial onset of *Vega* (~onset) and total number of *Vegas* and assessment of *samyak swinna laxanas*. [10]

Assessment criteria

Each patient was assessed before the treatment, daily during the initial 7 days of *nitya virechana* and *shashti shali pinda sweda* course and also assessed after the completion of *rasayana* course. Overall assessment was done during the follow up period.

Subjective and Objective parameters were assessed statistically.

Subjective parameters

- Assessment of *Nitya virechana* and *Samyak swinna laxanas.*
- Assessment of symptoms of *Pakshaghata*.

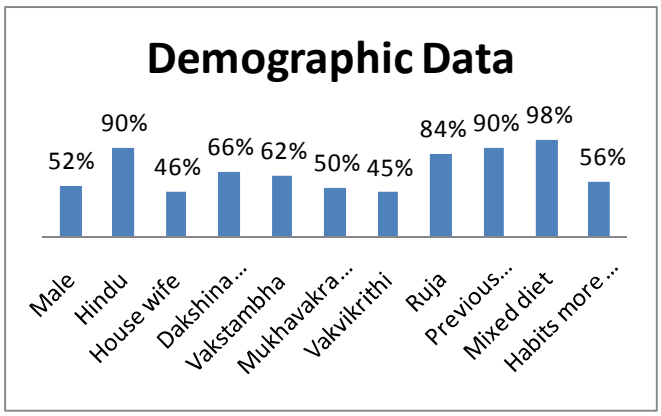
Objective parameters

- Muscle strength, Finger movements, Toe movements, Sitting from lying down, Standing from sitting, Paper holding in finger, disturbance of speech, Muscle tone, Hand grip power test, Foot pressure, walking time.
- Assessment of Carotid Doppler study in terms of PSV ratio in ICA / CCA.and EDV ratio in ICA/ CCA both in Right and left carotid arteries.

OBSERVATIONS AND RESULTS:

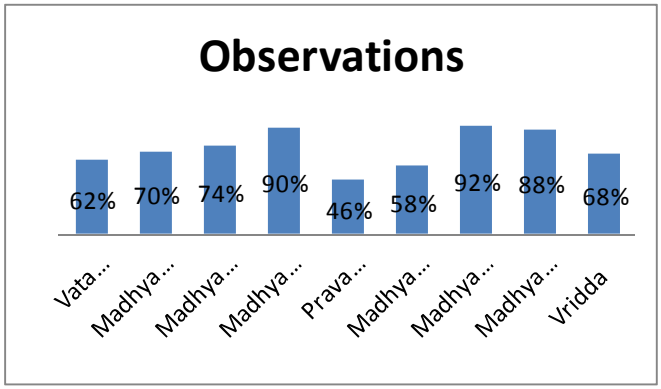
The present study is a single blind with Pre andPost test design wherein the effect of the treatment on different parameters were assessed initially before treatment, during initial 7 days of treatment and after 28 days of course of rasayana treatment. Paired ‘t’ test was used to compare the results.

Fig. 1: Depicting demographic data of 50 patients of *Pakshaghata*.



The above chart depicts maximum incidences of demographic data along with observations amongst 50 patients of *Pakshaghata*. 52% patients were males, 90% were belonging to hindu religion, 46% of patients were house wives, 66% of patients were affected in *dakshina parshwa* (rt. half of the body), 62% patients were not having *vakstambha*, 50% of patients had *mukha vakratha*, 45% patients had *vakvikrithi* (dysarthria, indistinct speech) 84% patients had *ruja* (pain in the affected side), 90% patients did not had previous stroke attacks, 98% patients were taking mixed diet, 56% patients had more than one habit.

Fig. 2: Depicting maximum incidences of observations amongst 50 patients of *Pakshaghata*.

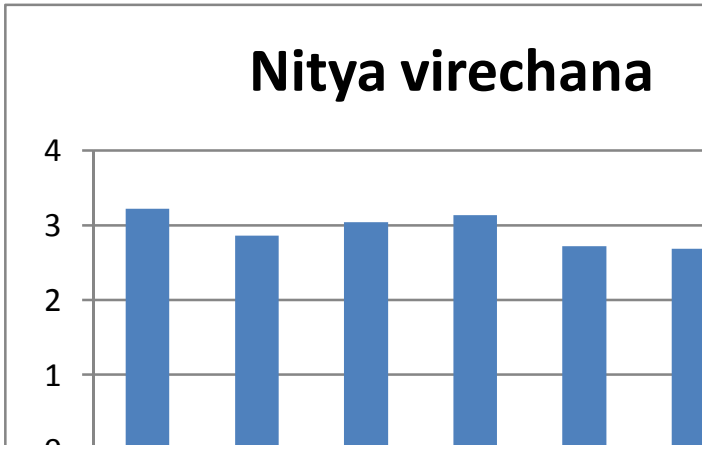


Amongst of 50 patients, 62% were with *vata pitta prakrithi*, 70% were having *madhyama sara*, 74% with *madhyama samhanana*, 90% with *madhyama pramana*, 46% with *pravara sathmya*, 58% were with *madhyama satwa* 92% with *madhyama Ahara shakthi*, 88% with *madhyama vyayama shakthi*, 68% were *vayovridda*.

Table 1: Mean average of *Nityavirechana.*

Nitya virechana (Average mean)	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Rasayana group	3.22	2.86	3.04	3.14	2.72	2.68	2.7

Fig. 3: Depicting mean average of *Nityavirechana*.



The above chart depicts the average mean score of *nityavirechana* amongst 50 patients. The day one average score was 3.22, on 2nd day -2.86, day 3 was 3.04, day 4 was 3.14,day 5 was 2.72,day 6 was 2.68, day 7 was 2.7.

RESULTS:

Patients were assessed before the treatment and after the completion of treatment in terms of different assessment parameters and they were recorded in proforma.

To all those assessable parameters statistical tests were applied to check the level of significance. Paired 't' test were applied to compare within the group.

Table 2: Effect of treatment on muscle strength within the groups.

Gr.	B.T.	A.T.	Diff.	%	S.D.	S.E.	T	p
1	2.600(1.161)	3.160(1.037)	0.56	21.53	0.76	0.108	-5.209	<0.001

The mean score of muscle strength amongst 50 patients: B.T. was 2.6 which has increased to 3.16 A.T. with a mean difference of 0.56. The change that occurred with the treatment is greater than would be expected by chance; there is a statistically significant change (P = <0.001)

Table 3: Effect of treatment on in finger movements within the groups.

Gr.	B.T.	A.T.	Diff	%	S.D.	S.E.	t	p
1	1.70 (1.594)	2.00 (1.565)	0.300	17.64	0.580	0.0821	-3.656	<0.001

The mean score of finger movements amongst 50 patients: B.T. was 1.7 which has increased to 2.0 A.T. with a mean difference of 0.3. The change that occurred with the treatment is greater than would be expected

by chance; there is a statistically significant change (P = <0.001)

Table 4: Effect of treatment on toe movements within the groups.

Gr.	B.T.	A.T.	Diff	%	S.D	S.E.	t	p
1	1.660 (1.479)	2.000 (1.485)	0.340	20.48	0.626	0.0886	-3.839	<0.001

The mean score of toe movements amongst 50 patients: B.T. was 1.66 which has increased to 2.0 A.T. with a mean difference of 0.340. The change that occurred with the treatment is greater than would be expected by chance; there is a statistically significant change (P = <0.001)

Table 5: Effect of treatment on sitting from lying down posture within the groups:

Gr.	B.T.	A.T.	Diff	%	S.D.	S.E.	t	p
1	0.660 (0.479)	0.480 (0.505)	0.180	27.27	0.438	0.0619	2.909	0.005

The mean score of sitting from lying down posture amongst 50 patients: B.T. was 0.66 which has reduced to 0.48 A.T. with a mean difference of 0.18. The change that occurred with the treatment is greater than would be expected by chance; there is a statistically significant change (P =0.005)

Table 6: Effect of treatment on standing from sitting posture within the groups.

Gr.	B.T.	A.T.	Diff	%	S.D.	S.E.	t	p
1	0.760 (0.476)	0.580 (0.575)	0.180	23.68	0.438	0.0619	2.909	0.005

The mean score of standing from sitting posture amongst 50 patients: B.T. was 0.76 which has reduced to 0.58 A.T. with a mean difference of 0.18. The change that occurred with the treatment is greater than would be expected by chance; there is a statistically significant change (P =0.005**)**

Table 7: Effect of treatment on paper holding in fingers within the groups.

Gr.	B.T.	A.T.	Diff	%	S.D.	S.E.	t	p
1	0.660 (0.772)	0.860 (0.808)	0.200	30.3	0.404	0.0571	- 3.500	0.001

The mean score of Paper holding in fingers amongst 50 patients: B.T. was 0.66 which has increased to 0.86 A.T. with a mean difference of 0.20. The change that occurred with the treatment is greater than would be expected by chance; there is a statistically significant change (P =0.001**)**

Table 8: Effect of treatment on speech disturbance within the groups.

Gr.	B.T.	A.T.	Diff	%	S.D.	S.E.	t	p
1	0.940 (1.300)	0.760 (1.117)	0.180	19.14	0.482	0.0682	2.641	0.011

The mean score of speech disturbance amongst 50 patients: B.T. was 0.94 which has reduced to 0.76 A.T. with a mean difference of 0.18. The change that occurred with the treatment is greater than would be expected by chance; there is a statistically significant change (P =0.011**)**

Table 9: Effect of treatment on muscle tone within the groups.

Gr.	B.T.	A.T.	Diff	%	S.D.	S.E.	t	p
1	1.140 (1.143)	1.020 (0.979)	0.120	10.52	0.385	0.0545	2.201	0.032

The mean score of muscle tone amongst 50 patients: B.T. was 1.14 which has reduced to 1.020 A.T. with a mean difference of 0.120. The change that occurred with the treatment is greater than would be expected by chance; there is a statistically significant change (P =0.032**)**

Table 10: Effect of treatment on hand grip within the groups.

Gr.	B.T.	A.T.	Diff	%	S.D.	S.E.	t	p
1	20.060 (32.962)	28.600 (35.341)	8.540	42.57	7.357	1.040	-8.208	<0.001

The mean score of hand grip amongst 50 patients: B.T. was 20.06 which has increased to 28.6 A.T. with a mean difference of 8.54. The change that occurred with the treatment is greater than would be expected by chance; there is a statistically significant change (P =<0.001)

Table 11: Effect of treatment on foot pressure within the groups.

Gr.	B.T.	A.T.	Diff	%	S.D.	S.E.	t	p
1	13.360 (13.987)	23.700 (15.838)	10.340	77.39	6.160	0.871	-11.870	<0.001

The mean score of foot pressure amongst 50 patients: B.T. was 13.36 which have increased to 23.70 A.T. with a mean difference of 10.340. The change that occurred with the treatment is greater than would be expected

by chance; there is a statistically significant change (P =<0.001)

Table 12: Effect of treatment on walking time within the groups.

Gr.	B.T.	A.T.	Diff	%	S.D.	S.E.	t	p
1	19.500 (23.392)	33.800 (24.023)	14.300	73.33	36.645	5.182	-2.759	0.008

The mean score of walking time amongst 50 patients: B.T. was 19.50 which haveincreased to 33.80 A.T. with a mean difference of 14.30. The change that occurred with the treatment is greater than would be expected by chance; there is a statistically significant change (P =0.008)

Table 13: Effect of treatment on PSV ratio (Rt. ICA/CCA) within the groups.

Gr.	B.T.	A.T.	Diff	%	S.D.	S.E.	t	p
1	0.885 (0.416)	1.106 (0.528)	0.221	24.97	0.392	0.0555	-3.983	<0.001

The mean score of PSV ratio of Rt. Internal carotid artery / Common carotid artery amongst 50 patients: B.T. was 0.885 which has increased to A.T. was 1.106 with a mean difference of 0.221. The change that occurred with the treatment is greater than would be expected by chance; there is a statistically significant change (P =<0.001)

Table 14: Effect of treatment on PSV ratio (Lt. ICA/CCA) within the groups.

Gr.	B.T.	A.T.	Diff	%	S.D.	S.E.	t	p
1	0.966 (0.649)	1.383 (1.036)	0.417	43.16	0.456	0.0645	-6.472	<0.001

The mean score of PSV ratio of Lt. Internal carotid artery/ Common carotid artery amongst 50 patients: B.T. was 0.966 which has increased to A.T. was 1.383 with a mean difference of 0.417 The change that occurred with the treatment is greater than would be expected by chance; there is a statistically significant change (P =<0.001)

Table 15: Effect of treatment on EDV ratio (Rt. ICA/CCA) within the groups.

Gr.	B.T.	A.T.	Diff	%	S.D.	S.E.	t	p
1	0.856 (0.401)	1.003 (0.474)	0.146	17.05	0.368	0.0520	-2.815	0.007

The mean score of EDV ratio of Rt. Internal carotid artery / Common carotid artery amongst 50 patients: B.T. was 0.856 which has increased to A.T. was 1.003 with a mean difference of 0.146.The change that occurred with the treatment is greater than would be expected by chance; there is a statistically significant change (P =0.007).

Table 16: Effect of treatment on EDV ratio (Lt. ICA/CCA) within the groups.

Gr.	B.T.	A.T.	Diff	%	S.D.	S.E.	t	p
1	0.979 (0.860)	1.297 (1.152)	0.317	32.37	0.353	0.050	-6.346	<0.001

The mean score of EDV ratio of Internal carotid artery/ Common carotid artery amongst 50 patients: B.T. was 0.979 which has increased to A.T. was 1.297 with a mean difference of 0.317. The change that occurred with the treatment is greater than would be expected by chance; there is a statistically significant change (P =<0.001)

DISCUSSION:

***Nityavirechana*:** As the *mridushodhana* becomes of the line of treatment in *vatavyadhi,* trial drug *Erandataila* along with *shuntikashaya* in a dose of 20ml each early in the morning in empty stomach had promising effects. The vega started within 10 min. to half an hour in majority whereas in some it was delayed for 3 to 4 hours. Some patients had pain in abdomen during the onset of vega. Many complained griping pain in the abdomen. Minimum *vega* noted was one and maximum 10. This can be due to nature of koshta in the patient. As the dose was fixed in all patients those who had *mridukoshta* resulted in maximum *vega* throughout the week, and those with *krurakoshta* had minimum of one vega. Those with *madhyama koshta* had 3 to 6 vegas within a day. Few patients had no vegas at all throughout the day. But none had other complications. Hence the drug is found to be very safe and effective in patients of *pakshaghata* which can be safely administered for a period of 7 days. Through this treatment *vatanulomana* was achieved.

***Shashti Shali pinda sweda*:** In the present study*, snigdha sweda* was administered. Selected patients are subjected to *abhyanga* with *mahanarayana taila* followed by *Shashti shali pinda sweda* for a period of 7 days. During these days, subjective as well as objective parameters of *samyak swinna laxanas* were assessed. Majority of the patients had *sheeta vyuparama* during initial day of *swedana*, whereas *shula vyuparama* was found after 3 to 4 days of *swedana*. Majority could appreciate the *samyak swinna laxanas* during 7 days of treatment. *Twak mardavata* was observed in majority of patients. None had untoward symptoms. But some experienced coldness after *Shashti shali pinda sweda*, may be due to the paste which was smeared on the body after *swedana.* Hence adviced to take hot water

bath using bengal gram powder soon after completion. Patients were adviced to follow rules and regimens of *swedana.*

Rasayana therapy: The selected patients were administered with *shilajathu -loha rasayana* in a dose of 6g. OD with milk after 7 days of initial treatment. This was administered for a period of 28 days. The patients could tolerate the above dose without any side effects. After administrations of the medicines the patients were advised nill by mouth for 2 hours.

Clinical study after the treatment proved highly significant results in muscle strength, finger and toe movements, hand grip and foot pressure. (p= <0.001) No much statistical significant results were encountered in muscle tone and foot pressure.

Carotid doppler study after the treatment revealed highly significant results in PSV ratio (Peak systolic velocity) of rightand left ICA/CCA (Internal carotid artery / common carotid artery)and also in EDV ratio (end diastolic velocity) left. ICA/CCA. (Internal carotid artery / common carotid artery)

Mode of action of the therapy:

Pakshaghata due to *margavarana* characterised by *chestahani, ruja, vakstambha, hasta pada samkocha, Sandhi bandha vimoksha* were improvised after a course of *shasthi shali pinda sweda* due to *ushna*, *snigdha*, *sukshma*, *guru* property.

Role of *nitya virechana* was to attain *vatanulomana* in patients of *pakshaghata* which even acted as *mridu shodhana* in such patients. Hence those patients who had *adhmana, shula* in lower abdomen along with constipation got relieved. Total improvement was proved with highly significant results in muscle strength, finger and toe movements, hand grip and foot pressure.

Shilajathu -loharasayana reduces *kapha* and *medas* by virtue of its *ruksha, lekhana guna*. Hence in *margavarana janya pakshaghata* because of *kapha* and *medo avarana* in *raktamarga* got reduced significantly which was evidenced from the changes that are noticed in peak systolic velocity and also in end diastolic velocity of blood flow in carotid doppler study. Hence the combined effect of the therapy was highly effective in patients of *Pakshaghata.*

CONCLUSION:

The present study to assess the efficacy of *shilajathu-loha-rasayana* in *margavarana janya-pakshaghata* revealed that there are highly statistical significant results (p=<0.001) obtained in majority of the parameters assessed in 50 patients with a total duration of the study as 65 days. The study also proved the highly significant results in PSV and EDV ratios of ICA/CCA.

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Cite this article as: Rajalaxmi M.G., G. Shrinivasa Acharya. Clinical Study on the Efficacy of Rasayana in the Management of Margavaranajanya Pakshaghata (Ischaemic Stroke). *J of Ayurveda and Hol Med (JAHM)*.2014;2(9):16-21.

Source of support: Nil, Conflict of interest: None Declared.