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A CLINICAL STUDY TO EVALUATE THE EFFICACY OF PAYASERAṆḌA TAILAM VIRECANA AND YOGAVASTI IN PAKṢĀGHĀTA W.S.R TO ISCHEMIC STROKE

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ABSTRACT

In modern world, changing life style leads to vitiation of Vāta, chief among Tridoṣas and dynamic entity of life and locomotion. Pakṣāghāta took a prime position among all other 80 types of Vāta Vyadhis. Hemiplegia also caused by a wide spectrum of disease processes like CVA, infective disorders of brain tissue, tumors, trauma etc. CVA is a 3rd most common cause of death in the world, after Cancer and Ischemic disease. It is mainly two types Ischemic and Hemorrhagic. Ischemic is due to lack of blood flow and Hemorrhagic is due to bleeding. About 80% of all ischemic strokes are mainly due to Cerebral Infarction. In Ayurveda the symptoms of Pakshaghata as loss of function either in rt or lt side along with pain and aphasia/dysarthria.[1] In present clinical study the panchakarma treatments as follows Snehapāna, Abhyaṉga, Svedana, Virecana karma, Saṃsarjana krama and then Yoga Vasti. Virecana is a process by which the vitiated dosha are expelled through the adhomarga. Basti therapy covers more than half of the treatment of all the disease. Considering both line of treatments, present study was planned study the efficacy of Virecana & Basti in Pakshaghata affected patients. Present study was undertaken on 60 patients of Pakṣāghāta Patients were randomly selected from the OPD and IPD of S.V. Āyurvedic Hospital, T.T.D, Tirupati. **Statistical Analysis:** The results are subjected to ANOVA followed by Turkey multiple comparison test of 60 patients in group. The values of $p<0.001$ were highly significant.

KEYWORDS: Pakṣāghāta, Virecana, yogavasti, ischemic stroke.

INTRODUCTION

Pakṣāghāta (Hemiplegia) being one amongst 80 Vataja nanatmaja vyadhi.[2] The cardinal features of Pakṣāghāta includes chestahani, ruja, vakstambha, hasta pada samkocha Sandhi bandha vimoksha.[3] The condition similar to Pakṣāghātain modern science is Hemiplegia. Hemiplegia is caused by a variety of clinical conditions like cardiovascular disease, trauma, brain tumor and abscess, syphilis, meningitis, etc. Among these vascular accident or stroke is the commonest cause of hemiplegia[4]. CVA.is a 3rd most common cause of death in the world, after Cancer and Ischemic disease. It is mainly two types-Ischemic and Hemorrhagic.[5] About 80% of all ischemic strokes are mainly due to Cerebral Infarction. Among stroke survivors almost 50% will experience some disability. Annual incidence of Stroke is estimated between180 to 300.[6] The prevalence of completed stroke and hemiplegia due to any cause is 56.9 per 1,00,000 and the high incidence of hemiplegia in the young has been pointed out, the prevalence rate per 1,00,000 population in 68.5 in male and 44.8 in female.[7]

According to W.H.O 15 million people suffers from stroke worldwide each year, of these 5 million die and another 5million are permanently disabled. As per recent survey it is estimated that by the year 2015 India will report 1.6 million cases of stroke annually, of them at least 1/3 of will be disabled. Whereas diagnostic part of Pakṣāghāta (hemiplegia) is strong in modern science, there as no complete cure is available till today now. Modern science also believes that the brain tissues once damaged cannot be regenerated by any therapies, which leads to permanent neurological deficit. Hence the disease has a poor prognosis, making the person disabled dependent. In Modern medicine, management of Hemiplegia the therapies are more rehabilitative in nature. So the groups of patient suffering from Pakṣāghāta usually approach Āyurvedic Hospitals.

The panchakarma therapeutic modalities included in the present study are Snehapāna, Abhyaṇga and Svedana, Virecana with Payas Erandatailam[8] and main modality as Yoga Vasti with Balā tailam[9] and Mahārāsnādi Quātha churnam.[10] The Vasti has got important place in Pañcakarma therapy because of its wide and effective use and also it is said to be Ardha Cikitsā.[11]

Sixty patients of Pakṣāghāta were registered for clinical study from the O.P.D. of Dept. of Pañcakarma of S.V. Āyurvedic College and Hospital, irrespective of sex, caste, religion.

A detailed history taking and physical examinations were carried out in these patients. Relevant data along with the elaborated assessment of functional disability, pain,

neurological deficit, motor system assessment are collected on Before treatment and After treatment, After one month follow up after completion of treatment in the specially designed case Proforma.

MATERIALS AND METHODS

It's a open, non group, non randomized clinical trial. Total 60 patients were selected from OPD of of Dept. of Pañcakarma of S.V. Ayurvedic College and Hospital Tirupati. Study was approved by Institutional Ethics Committee with approval no IES/SVAYC/15/PK/38 dated 26-03-2015. All the patients were given an information sheet stating all the details of the study protocol, benefits of the trial and do's and don'ts to be followed by patient.

i. Inclusion Criteria

- Age between (20 – 65yrs).
- Patients of unilateral motor deficit either right or left half of the body.
- With or without higher cerebral functions deficit such as Aphasia or dysarthria or visual field defect.
- With or without Ataxia or Vertigo or diplopia.
- Duration 2 months to 2 years.

ii. Exclusion Criteria

- Hemorrhagic stroke
- Hepatitis
- Uncontrolled Hypertension
- Uncontrolled IIDM
- Malignant conditions,
- Severe Metabolic Disorder
- Traumatic injuries
- Unconscious patients
- Space occupying lesions
- Malignant conditions
- Parkinsonism
- Syphilis

Investigations

- Haemogram

- Routine Urine examination
- Lipid profile
- Serum Creatinine
- Blood urea

Assessment criteria

1. Higher mental function
2. Cranial nerve examination
3. Motor system examination

a. Muscle bulk

b. Tone.

c. Power.

d. Gait.

e. Reflexes.

4. Sensory system examination
5. Barthel Index [Activities of Daily Living (ADL) Score]
6. Glasgow coma scale

Assessment are collected on Before treatment and After treatment, After one month follow up after completion of treatment in the specially designed case Proforma.

Duration of treatment: 27-31 days.

Drug administration

In 60 patients Virecana karma with Eranda taila 20ml- 60ml and milk (20ml) has been given after abhyantara samyaka snehana with Rasnadi ghritam to be continued till the samyak Snigda lakshanas achieved, after that sneh abhyangam and bhaspa swedam for 3 days. Basti karma with Mahārāsanādi kvātha Cūrṇam Niruhana Basti (dose960 ml) and Balā Tailam Anuvasan Basti (dose 120 ml) in the form of yoga vasti which has been given after smayaka snehana (external) and swedana.

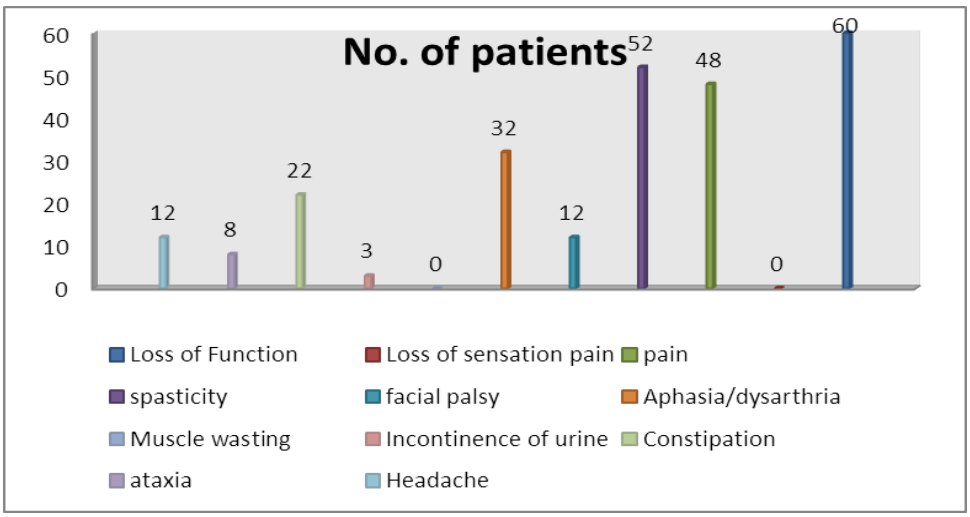
Statistical Analysis

The results are subjected to ANOVA followed by Turkey multiple comparison test of 60 patients in group. The values of $p<0.001$ were highly significant Values are expressed in

Mean Mean ±SD, MD of 60 patients. Comparison between before treatment and immediately after treatment, before treatment and after one month follow up.

OBSERVATION AND RESULTS

Statistical analysis in regards to age, sex, marital status, and dietary habit etc. of 60 patients who are included in the study. It was found that 27% patients belonged to the age group of 41-50 and 51-60 years. Out of the registered patients, 70% patients were of male gender. Religion wise 70% patients were observed to be Hindu religion. Out of all patients registered 76.6% were literate. 86.6% patients were married. Out of 60 patients50% patients were field worker with physical labour, 60% patients were belonging to Jāṉgala Deśa, 93.33% patients were consuming mixed diet. 53.3% of patients are with medium built. 43.3% patients were addicted of smoking and alcohol. 66.6% of patients possessed emotional stress. 63.3% patients were of Vāta-Kapha Prakṛtī. 46.6% patients were of AvaraSatva. 80% in Avara Vyāyāma śaktī. others 80% with left half of body. On observation of the duration of illness, 33.3% patients were of 7 months – 12months chronic, 30% patients had that of DM and HTN both. On observation of Level of consciousness of disease it was found that 93% or fully conscious, On observation of Level of orientation of disease it was found that 93% or normally, Symptomatology observed in the present study Loss of function, was observed in all the patients. 86.6% presented with spasticity, 80% presented with pain, 20% presented with facial palsy; aphasia/dysarthria was featured in 53.3%. No one was presented with loss of sensation and muscle wasting while ataxia was found in 13.33%. and headache in 20% of patients. Only 3patients (5%) suffered with incontinence of urine. patient 36.6% patient of presented with constipation.



Graph No-1 Distribution of patients according symptom wise.

Table No-1 Showing effect of Payaseranda tailam Virecana and Yogavasti on subjective parameters & objective parameters before treatment and immediately after treatment.

	Mean ± SD		MD	Q	P value	Remarks
	0-DAY	Immediately After treatment				
Aphasia/Dysarthria	2.33±1.130	2.916±0.8886	0.5833	4.074	P<0.001	***
Barthel index	53.3±11.11	65.7 ±9.60	12.4	9.271	P<0.001	***
Pain	1.81±0.85	1.21±0.92	0.600	5.330	P<0.001	***
Finger movement upperlimb	1.16±084	2.38±0.738	1.217	12.206	P<0.001	***
Lowerlimb	1.46±1.737	2.54±2.162	1.080	4.121	P<0.05	*
Ability to lift hand	1.75±1.019	3.133±0.9107	1.383	11.34	P<0.001	***
Wrist dorsiflexion	1.2±1.448	2.4±2.252	1.200	4.678	P<0.01	**
Wrist Plantar flexion	1.6±1.773	2.86±2.446	1.260	4.442	P<0.01	**
Elbow Flexion	2.66±1.768	4.66±2.248	2.000	7.588	P<0.001	***
Elbow Extension	2.4±1.923	4.26±2.558	1.86660	5.995	P<0.001	***
Shoulder Abduction	2.3±1.608	3.79±1.531	1.490	7.718	P<0.01	**
Shoulder Flexion	2.27±2.603	2.91±2.686	0.640	2.147	P>0.05	Ns
Shoulder Extension	2.0±1.114	2.26±1.113	0.2600	1.808	P>0.05	Ns
Knee flexion	4.2±2.656	6.2±2.370	2.00	6.356	P<0.001	***
Knee extension	4.34±2.784	6.2±2.484	1.860	5.566	P<0.001	***
Hip Abduction	3.66±1.583	5.26±1.856	1.600	7.550	P<0.001	***
Hip Flexion	2.8±1.349	4.26±1.874	1.460	6.807	P<0.001	***
Hip Extension	3.4±1.303	5.34±2.816	1.940	8.160	P<0.01	**
Ancle dorsiflexion	1.37±1.217	1.91±1.600	0.540	2.999	P>0.05	Ns
Ancle Plantar flexion	1.57±1.251	2.21±2.487	0.640	2.772	P>0.05	Ns
	Mean ± SD		MD	Q	P value	Remarks
	0-DAY	Immediately After treatment				
Muscle tone Upper limb	2.3±1.094	2.21±0.993	0.0833	0.62	P>0.05	Ns
Muscle tone Lower limb	2.3±1.094	2.21±0.993	0.0833	0.62	P>0.05	Ns
Muscle power upper limb	2.65±1.039	3.4833±0.8535	0.833	7.142	P<0.001	***
Muscle power lower limb	2.6±1.077	3.25±0.7946	0.650	5.451	P<0.001	***
Biceps reflex	5.14±1.137	5.061±1.1.143	0.07900	0.5364	P>0.05	Ns
Triceps reflex	4.7±1.105	4.8±1.243	0.1000	0.6286	P>0.05	Ns
Supinator reflex	4.2±1.517	4±1.486	0.2000	1.036	P>0.05	Ns
Knee reflex	4.54±1.461	4.86±1.456	0.3200	1.699	P>0.05	Ns
Ancle reflex	5.00±1.948	4.86±1.943	0.1400	0.5577	P>0.05	Ns
Sitting from lying down	1.5833±1.013	2.9±0.8577	1.317	11.24	P<0.001	***
Standing from sitting	1.766±1.140	2.933±0.8610	1.167	9.291	P<0.001	***
Walking capacity	1.7±1.280	2.816±0.9828	1.117	8.128	P<0.001	***
Walking stairs	1.4±1.404	2.06±1.230	0.6600	3.913	P<0.05	*

Table No-2 Showing Effect of Payaseranda tailam Virecana and Yogavasti on subjective parameters & objective parameters before treatment and after one month follow up.

Aphasia/ Dysarthria	Mean ± SD		MD	Q	P value	Remarks
	0-DAY	After one month follow up				
Aphasia/ Dysarthria	2.33±1.130	3.1±0.8377	0.7667	6.182	P<0.001	***
Barthel index	53.3±11.11	72.5 ±10.35	19.1	14.311	P<0.001	***
Pain	1.81±0.85	0.9±0.83	0.91	8.143	P<0.001	***
Finger movement Upper limb	1.15±08402	2.5±0.724	1.333	13.376	P<0.001	***
Finger movement Lower limb	1.46±1.737	2.54±2.162	1.080	4.121	P<0.05	*
Ability to lift hand	1.75±1.019	3.266±0.8995	1.517	12.43	P<0.001	***
Wrist Dorsiflexion	1.2±1.448	2.54±2.162	1.340	5.224	P<0.01	***
Wrist Plantar flexion	1.6±1.773	3.6±2.314	2.000	7.051	P<0.01	***
Elbow Flexion	2.66±1.768	4.86±2.080	2.200	8.346	P<0.001	***
Elbow Extension	2.4±1.923	5.34±2.662	2.940	9.476	P<0.001	***
Shoulder Abduction	2.3±1.608	3.76±1.334	0.8600	4.455	P<0.01	**
Shoulder Flexion	2.27±2.603	3.05±1.417	0.780	2.616	P>0.05	Ns
Shoulder Extension	2.0±1.114	2.26±1.114	0.2600	1.808	P>0.05	Ns
Knee flexion	4.2±2.656	6.46±2.27	2.26	7.182	P<0.001	***
Knee extension	4.34±2.784	6.4±2.486	2.060	6.164	P<0.001	***
Hip Abduction	3.66±1.583	5.74±1.461	2.080	9.815	P<0.001	***
Hip Flexion	2.8±1.349	4.86±1.717	2.060	9.604	P<0.001	***
Hip Extension	3.4±1.303	3.6±1.923	0.200	0.8413	P>0.05	Ns
Ancle dorsi flexion	1.37±1.217	1.57±1.339	0.200	1.111	P>0.05	Ns
Ancle Plantar flexion	1.57±1.251	1.97±1.359	0.400	1.732	P>0.05	Ns
Musle tone Upper limb	2.3±1.094	2.1±0.9863	0.200	1.51	P>0.05	Ns
Muscle tone Lowr limb	2.3±1.094	2.1±0.9863	0.200	1.51	P>0.05	Ns
Muscle power Upper limb	2.65±1.039	3.633±0.8018	0.9833	8.428	P<0.001	***
Muscle power Lower limb	2.6±1.077	3.33±0.8766	0.7333	6.150	P<0.001	***
Biceps reflex	5.14±1.137	5.06±1.143	0.0800	0.5432	P>0.05	Ns
Triceps reflex	4.7±1.105	4.74±1.337	0.0400	0.2514	P>0.05	Ns
Supinator reflex	4.2±1.517	4±1.486	0.2000	1.036	P>0.05	Ns
Knee reflex	4.54±1.461	4.54±1.461	0.000	0.000	P>0.05	Ns
Ancle reflex	5.00±1.948	4.86±1.943	0.1400	0.5577	P>0.05	Ns
Sitting from lying down	1.5833±1.013	3.066±0.8410	1.483	12.66	P<0.001	***
Standing from sitting	1.766±1.140	3.0166±0.8924	1.250	9.955	P<0.001	***
Walking capacity	1.7±1.280	2.95±0.8911	1.250	9.099	P<0.001	***
Walking stairs	1.4±1.404	2.06±1.230	0.6600	3.913	P<0.05	*

Note

S.D-Standard deviation, **M.D**-Mean difference**, NS**- Non significant, **p-Value**: Indicates significance of treatment on specific symptoms, Significant - * $p < 0.05$, Highly Significant - ** $p < 0.01$, Extremely Significant - *** $p < 0.001$.

DISCUSSION

- Among 60 patients 50% of patients found to be in the age group between 41-60 years. Ācārya Suśruta has stated that Parīhānī Kāla of Madhyama Avasthā sets in at the age group of 40-70 years.[12] This is Vāta Prakopa Kāla and beginning of the ageing process and degenerative changes. This leads to Kṣaya of Śārīra Bala and all the dhātus and results in Vāta prakopa The males (70%) are more affected with the Pakṣāghāta. Males having more stressful background in their professional life and in intellectual fields, which can lead to HTN and stroke.
- More number of patients (63.33%) were doing field work. Stress was observed in 93.33% of patients. Atī vyāyāma, Rātri jāgarana, Alpāśana, financial crises and mental stress may be the cause of prevalence of disease in field workers leads to Vāta prakopa.[13]
- Maximum number of patients presented with avara Satva (46.33%) and Avara Vyāyāma śaktī (80%). This highlights towards weak mental and physical contribution leading to doṣic imbalance.
- In 80% of patients of Pakṣāghāta was left half of body was affected. 43.3% of patients had past history of illness of DM&HTN. These addictions affect the Agni along with increase in Rūkṣa, Vyavāyi, Vikāsi Guna of Vāta. They also suppress the immune modulatory mechanism and provoke Vāta. In long run these addictions may be a cause of Ojo kṣaya and leads to neurological disorders. Modern textual references also quote smoking, consumption of alcohol, etc. to be grave risk factors for stroke.
- Maximum patients (33%) had a chronicity of 7-12 months, This shows that the gradual change in the trend and awareness of people to the benefits of authentic Pañcakarma therapy of Āyurveda in early stage of disease.
- Among the symptoms, no one presented with sensory loss and wasting. Incontinence found in only 3(5%) patients and Ceṣṭa nivṛttī found in all 60 patients, Saṉkoca found in 52 patients.
- Among higher mental functions only 4(7%) were presented with drowsiness & decreased orientation(space/time/memory), after treatment they are also showed improvement consciousness and orientation this shows clinically good sign.
- Remaining 56(93%) are fully consciousness & and orientation also good. Glasgow coma scale shows insignificant in this study.
- Speech aspect improved but it is not up to the mark. The mean score of aphasia/dysarthria was 2.33, 2.91 and 3.1 shows mild changes in value but statistically significant results.

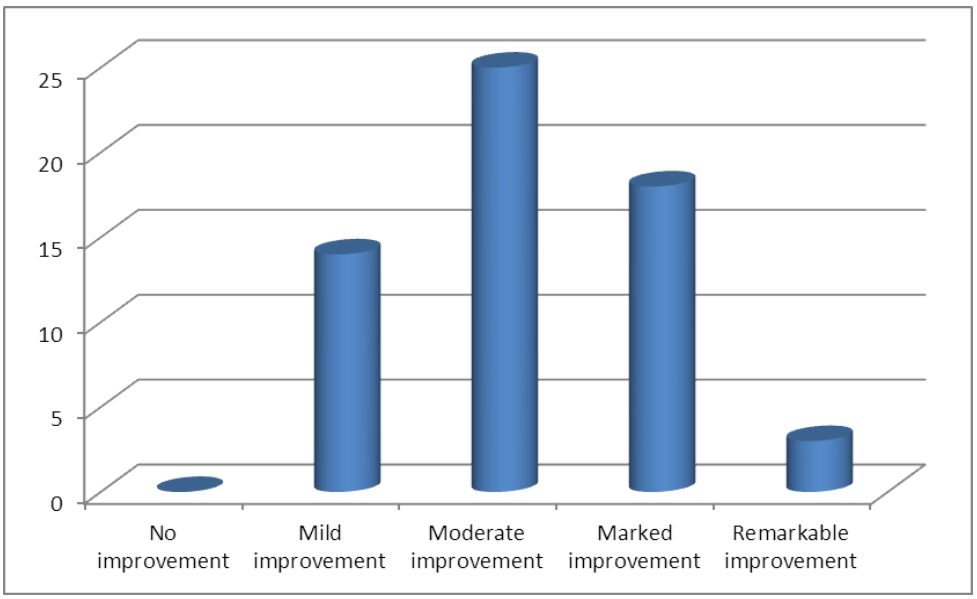
- Barthel Index includes score of activities of daily livings as feeding, bathing, personal toilet etc. The mean score of Barthel Index was 53.3, 65.7and 72.5 on before treatment, after treatment and after one month follow up respectively, shows highly significant results.
- Motor parameters in neurological examination showed significant improvement clinically it is a good sign.
- Finer movements restored very slowly and percentage of improvement is comparatively less to that of gross.
- Reflexes remain unchanged throughout the procedure but after the treatment there was relief in clonus. This shows least change in mean score but 'p' value was non-significant statistically.
- There is marked relief in sitting from lying down, standing from sitting and in walking capacity, this indicates highly significant result ($p < 0.001$). On 0 day, after treatment and after one month follow up.
- Prior Virecana karma Snehapāna done with Rāsnādighṛtam[14] was commenced in progressively for 3 to 7 days, It should be continued till the Samyaka Snigdha Lakṣanas are achieved.
- After Snehapāna Abhyaṉgam and Bhāspa Swedam done with Balā tailam for 3days prior to Virecana karma and patient is advised to take Pitta Vardaka ahara during this period.
- The Virecana drug was given after the completion of the Kapha Kāla, i.e., between 7- 9 Am. Patients were directed to take Uṣṇa jala after every 20-30 minutes. After appearance of Samyak Virecana lakṣanas, Drava and Uṣṇa Āhāra is advised from the noon of the same day or when he/she feels hungry and then patients advised to take rest.
- As per the Śuddhi of the patients, they were kept on Saṃsarjana krama as given in the classics for reviving the strength of Agni then finally resumed to normal diet.
- Yoga Vasti has to be started after 7 days, from the first day of Saṃsarjana krama.
- Virecana is a line of treatment in the management of Pakṣāghāta. In Vāta vyādhi most of the authors mentioned mṛdu Virecana.[15]
- This may help in both Vātānulomana as well as smooth excretion of mala. The sneha Virecana clears obstruction in the Srotas and relieves Vāta vitiation very quickly. Virecana given with help of mild drugs added with unctuous ingredients help in the elimination of morbid material and produces beneficial effects.[16]

- So Payaseraṇḍa taila help in the elimination of morbid dosha and produce beneficial effects.
- Out of 60 patients, 60% patients experienced Madhyama vegās(10—20), 25% patients manifest Pravara vegās (20-30) and 15% patients with Avara vegās(1-10) but overall patients having Laingikiśuddhi.
- Cakrapāṇi described, Virecana is given before the administration of Vasti. If Vasti is given without proper purification it becomes ineffective.
- Virecana can prove to be very effective in Pakṣāghāta. Virecana removes the Āvarana of Vāta, so that Vāyu performs its functions normally.
- Virecana imparts strength to the body and stabilizes all the dhatus. Hence present study we have choosen Virecana karma with Payas Erandatailam in Pakṣāghāta.
- In the Present study yoga vasti given with Balā tailam for Anuvasana Vasti and Mahā Rāsnādikvātha Cūrnam for Niruha Vasti for 8 days. After the completion of Samsarjana Krama. ParīhīraKāla should be followed for double the days of Vasti. In Yoga Vasti this regimen has to be follow for the 16 days.
- Balā tailam is the best for curing Vātika diseasesand it is used for Pāna, Abhyanga, Vasti.
- Balā Taila Anuvasana promotes strength, complexion etc the brimhana nature of Balā taila which helpful Akarmanyata, balahāni in Pakṣāghāta.[17]
- Maha Rāsnādi kvātha Niruha causes Srotosuddhi. This indicates that Srotośodhaka property of Nirūha Vasti clears Āvarana of the disease.
- Āvarana is main causative factor in the pathophysiology of Pakṣāghāta. This indicates that Srotośodhaka property of Nirūha Vasti clears Āvarana of the disease.[18]
- Of all the therapeutic measures suggested for Vāta disorders, Anuvāsana Vasti and Nirūha Vasti treatment for Vātik disorders because immediately after entering the Pakwāśaya, they strike at the very root of morbid Vāta and when it is overcome in the Pakwāśaya even the entire morbid Vāta dwelling in the other parts of the body could be alleviated.[19] As Vāta is the main doṣa in the pathogenesis of Pakṣāghāta, so the Nirūha and AnuvāsanaVasti mainly help in Saṃprāptī vighatanam.
- The Vīrya of Vasti administered in to the Pakvāśaya reaches the whole body through the channels (srotas), as the water when poured at the root of the tree reaches the whole plant.[20] Thus the active principles of the drug used in the Vasti will reach the entire body and show the desired effect.

- Caraka opines that there is no other measure than using Snēha to counteract Vāta. He also described the benefits of Anuvāsana Vasti as it gives pleasure to mind and enhances complexion and digestive fire.[21]
- Out of 60 patients 95% experienced Samyak yoga lakshanas of Vasti, 5% with Ayoga lakshanas of Vasti, no one presented with Atiyoga lakshanas.
- In Pakṣāghāta functional ability of the patients and the quality of life will be improved by the cumulative effect of (Virecana & Vasti treatments) which is confirmed by the response noted in patients.
- Properly administered Virecana karma does Sroto vishuddi, Laghuta, improves the intellect and mental status. It increases strength of indriyas, stabilizes all the seven dhatus, thus provides strength of Indriyas and power to the body.[22]
- The main cause of Pakṣāghātais vitiated Vāta and the choice of treatment of Vāta Doṣa is Vasti and on the other hand Āvarana is main causative factor in the pathophysiology of Pakṣāghāta.

Table No. 3- Overall effect of therapy.

Sr. no.	GRADE	No. OF PATIENTS	%
1	No improvement (0%)	0	
2	Mild Improvement (1% - 25%)	14	
3	Moderate Improvement (26% - 50%)	25	
4	Marked Improvement (51% - 75%)	18	
5	Remarkable Improvement (76% - 100%)	3	



Graph No-2 Showing overall assessement percentage of clinical trial.

CONCLUSION

Payas eranda taila Virecana and yoga vasti improves the signs and symptoms of Pakṣāghātaas well as the activities of daily livings there by making better quality of life of the patients. Present work concludes combined use of Virecana and yogavasti is a better therapy module in improving the disability in hemiplegic patients when compared with other contemporary rehabilitative therapies.

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