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 samsargaja avastha, Glassgow coma scale showed 91.49 % improvement which was highly significant. 2. In Kapha samsargaja 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 Pitta 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 world11, 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.

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 oxidants21, 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 devolopment 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 Committee, The consent for the study was taken prior enrolment by the patient relatives.

| 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 monitored on hourly basis |         |                |                |                |

Treatment Protocol

| Lakshanas | Treatment | Duration | Criteria assessed at the end of treatment |
|-----------|-----------|----------|------------------------------------------|
| Himadhara | (Dhanyaka+Amalaki) for 20min |          |                                          |
Sori Ashwini et al. Study on Protocol Based Sushrutas Avasthanusar Management of Pakshagata

Table 3: Stage 2- Kaphaja Samsargaja Chikitsa

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

Table 4: Stage 3- Kevala Vataja Chikitsa

| Lakshanas         | Treatment                                                                 | Duration   |
|-------------------|---------------------------------------------------------------------------|------------|
| Ruja, Sankocha,   | Shirodhara with Bala taila for 30minutes                                   | Maximum for 7 Days |
| Karmahani         |                                                                           |            |
| 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%        |
This study consisting of 10 patients of with Glassgow 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.

| Symptom                  | Measures | %   | S.D (+) | S.E (+) | t value | p value |
|--------------------------|----------|-----|---------|---------|---------|---------|
| Glasgow coma scale       | 0 day BT | 5.7 | 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 stage 1 | 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  |

Table 7: Effect on Stroke Scale

| Stroke Scale | Measures | %   | S.D (+) | S.E (+) | t value | p value |
|--------------|----------|-----|---------|---------|---------|---------|
| 0 Day        | 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                  | 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 | %   | S.D (+) | S.E (+) | t value | p value |
|--------------------------|----------|-----|---------|---------|---------|---------|
| 10 meter walk test       | 0 day    | 0.5 | 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          | 158     | 148     | 102     | 94      | 6.33    | 7.84    | 6.667   | 6.325   | 2.22    | 2.10    | 4.74    | 4.00    | 0.0001  | 0.0031  |
|          | SP          | 148     | 90      | 117     | 12.47   | 6.325   | 4.15    | 2.10    | 2.54    | 6.00    | 0.0137  | 0.0002  |

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| 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 samsargavastha 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 virepirita 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 in 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 chikista 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 rtTPA or anti platelets drugs. This can be considered as Avarana 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 usha drugs immediately clears the obstruction and thus establish recanalisation improving the flow to blood to blood deprived area, sometimes cells adjacent to the infarct 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 dravyag[11] so by the Stamba guna the nerve cell life is sustained for more longer period even with less blood supply and Manjistadh choorana 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 sarpi pana[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 (Apsarmara), different Ghrita 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 Doshanubandhta
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 salnadavadi 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 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 Vataja 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. 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-Avasthanasar 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 Avasthanasar 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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Cite this article as:
Sori Ashwini, Ravishankar Pervaje Ravishankar, Prasad B S. A Prospective Clinical Observational Study on Protocol Based Sushrutas Avasthanusar Management of Pakshagata (Ischemic Stroke). International Journal of Ayurveda and Pharma Research. 2021;9(7):15-21. https://doi.org/10.47070/ijapr.v9i7.1954

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

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