

## CLINICAL TRIAL OF NASYA KARMA WITH MAHANARAYANA TAILA IN PAKSHAGHATA/ ISCHEMIC STROKE

<sup>1</sup>K Nishanth Pai, <sup>2</sup>G. Usha Patil,

1. MD(Ayu), Senior Consultant & Administrator, SDM Ayurveda Hospital, Udupi.
2. Associate Professor, Dept. of Dravyaguna SJSCH, Chennai

Corresponding Author: [nishanthpaik@gmail.com](mailto:nishanthpaik@gmail.com)

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## INTRODUCTION

Compared to other Panchakarma procedures, Nasya karma is used widely in various disease conditions as the procedure's duration is less compared to other Panchakarma Procedures. Nasya Karma is a commonly performed procedure for head and neck diseases. Nevertheless, Nasya Karma is also indicated daily for the maintenance of health. However, the effect may vary individually. This issue may be due to the non-uniformity of the dosage. To address this issue, clinicians often prefer to go with the minimum dosage of the dravya used for the Nasya karma. More doses of Nasya karma are needed to achieve the desired effect, but this undoubtedly increases the possi-

bility of local irritation of the nasal cavity and pharynx and rarely causes any complications.

Pakshaghata is equated with a Cerebrovascular Accident, which commonly occurs due to the reduced or absence of the blood supply to a part of the brain. It most commonly occurs due to Atherosclerosis of the arteries(1). Studies have shown that Nasya Karma is beneficial in various disorders that involve the head and neck(2). The conditions may vary from simple rhinitis to that of a Cerebrovascular Accident. Of Course, the drugs used, and the formulation may vary depending on the condition. However, the mechanism of delivering the drug to the system remains the

same. However, some untoward procedure symptoms have been identified, including sneezing, eye irritation, and headache.

Given that the route of administration of Nasya karma differs from that of other Panchakarma Procedures, the influence of the Nasya Karma is distinct in various conditions. However, the drug absorption area is smaller than other Panchakarma procedures. Thus, we designed this trial to investigate the effects of standardised Nasya Karma with specific oils used in Vatavyadhi, Mahanarayana Taila on Pakshaghata/ Ischemic Stroke. Considering that other Taila has been used widely in Pakshaghata, we postulated that Mahanarayana Taila, which is not used in Nasya Karma but has been mentioned in Vatavyadhi, may also have a similar or more significant effect than conventional Taila(3).

#### Materials and methods

##### Trial design

The study's purpose was to assess the effects of Nasya karma with Mahanarayana Taila on Pakshaghata/ Ischemic Stroke. This clinical trial was conducted between July 2024 and December 2024. The Consolidated Standards of Institution performed all methods. Written informed consent was obtained from all participants.

##### Participants

**Inclusion criteria:** (1) abrupt onset of focal neurological deficits that may include hemiparesis, hemi sensory deficits, dysarthria, facial droop and aphasia. (2) Radiological confirmation by CT or MRI head suggests Ischemia/infarction. (3) Fully conscious. (4) Age 16–70 years, Gender was not limited. (5) Duration ranged between  $\geq 7$  days  $\leq 2$  Years. (6) Non-pregnant,/non-lactating (7) RBS - 79-160 mg/dl; HbA1c:  $<7.0\%$

**Exclusion criteria:** (1) Hemorrhage / SOL / infections / degeneration . (2) Age less than 16 and more than 70 years. (3) Patients with BP  $\geq 180/110$  mm hg. (4) Semi-Conscious/Unconscious. (5) RBS  $> 160$  mg/dl & HbA1c  $> 7.0\%$ .

##### Enrolling and intervention

Participants were recruited after fulfilling the Inclusion and Exclusion Criteria. On the day before the

procedure, the investigator explained the research process and obtained the consent of patients and their families to sign the informed consent form when the participant could not. Participants are then given the prescription of Mahanarayana Taila for Nasya. This will be taken for the next seven consecutive days to the Panchakarma Theatre, wherein the procedure of the Nasya karma is carried out under the supervision of the Investigator. The Blood Pressure, Heart rate and Pulse Rate are monitored before the start of the Procedure and after the completion of the Procedure. The Procedure was carried out in three steps the 1)Purva karma (Preoperative Process) 2) Pradhana karma(Operative Procedure) and 3)Paschat karma(Postoperative Procedure. Purva karma Includes the education the participant regarding the process and benefits of the Nasya karma by the researcher, Then the Sthanika Abhyanga (Localized massage) to face with same given Taila Followed by Sthanika Sweda(Localized Steaming with Towel Dipped in the Hot Water) and patting over the face without touching the surface of the skin. 2) Pradhana karma is to instill 10ml of the Taila to each nostril. 3) Paschat karma is to massage again without applying the oil on the face and giving the Localized steam with the Towel.

##### Outcomes

The primary endpoint of this study was the change in Muscle Strength, stroke-specific quality Of Life Scale, Hand Grip strength & Berg Balance Scale. The secondary outcomes were Weight, BP, Heart rate, and Pulse. Other outcome measures include adverse reactions such as 1)Mild adverse events (s) reported which subside with or without medication, 2)Moderate to severe adverse event(s) reported which subside with or without medication and do not necessitate stoppage of study treatment and 3) Severe adverse event(s) which necessitate stoppage of study and Overall Improvement in Parameters.

##### Statistical methods

The sample size calculation was done using an online sample size calculator.<sup>1</sup>Considering the population size of 100,000, with a 95% confidence level and 9.6% margin of error, and assuming the population

portion to be 40%, the sample size for the study was 20. Participants were recruited after fulfilling the Inclusion, exclusion, and Diagnostic criteria.

### Results

#### Participants and follow-up

Between July 2024 and December 2024, we selected 20 participants after meeting the inclusion criteria. Twenty patients were selected for Mahanarayana Taila Nasya. No patients dropped out of the trial and were lost to follow-up.

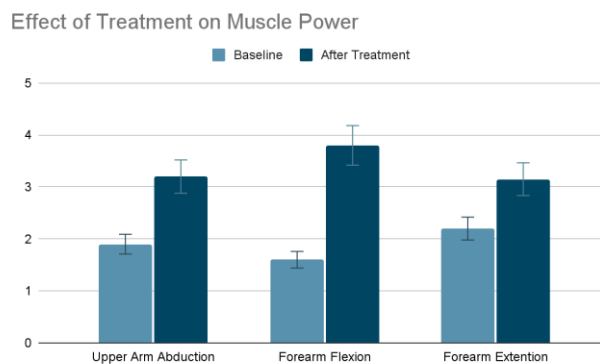
#### Primary and secondary outcome analysis

In the present study, 20 patients of Margavarajanya Pakshaghata were treated with Mahanarayana Taila Nasya. It was an open-label clinical trial with assessments before and after treatment. The treatment's effect was assessed regarding primary and secondary outcome measures. The statistical analysis was done using GraphPad Prism Software.

#### EFFECT OF TREATMENT ON MUSCLE POWER

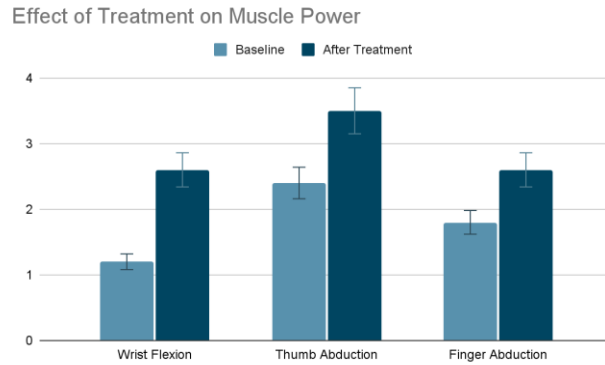
The effect of the treatment on muscle power was assessed, and the results showed that the mean difference in muscle power score with respect to movements of Abduction of upper arm, Flexion of forearm at Elbow, and Extension of Forearm at elbow was 1.9, 1.6, and 2.2, respectively, which improved to 3.2, 3.8, and 3.15, respectively.

With mean difference of 1.3, 1.3, 1.250 after the treatment. The statistical analysis by adapting the Paired 't' test showed a statistically significant change with  $p = <0.001$ . This analysis shows the significance of Mahanarayana Taila Nasya on improving the Muscle power of the upper arm with 26%, 26%, and 25% improvement in the Abduction of the upper arm, Flexion of the forearm at the Elbow, and Extension of the Forearm at the elbow, respectively.



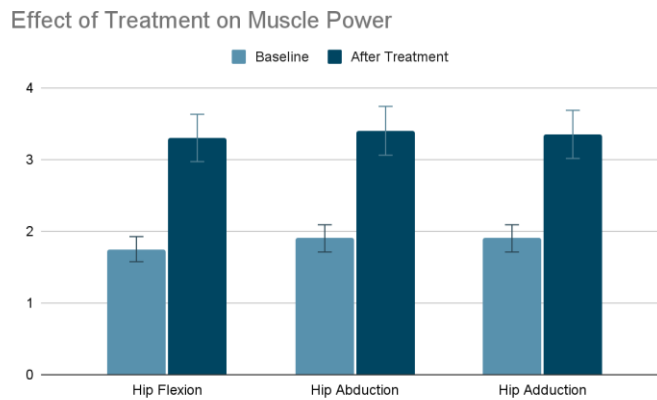
The effect of the treatment on the muscle power was assessed and the results showed that the meaning of the difference in score of muscle power with respect to movements of Wrist flexion, Palmar abduction of thumb, Finger abduction and adduction were 1.2, 2.4, 1.8 which has improved to 2.6, 3.5, 2.6 respectively

after the treatment. The statistical analysis by adapting the Paired 't' test showed a statistically significant change with  $p = <0.001$ . This analysis shows the significance of Mahanarayana Taila Nasya on improving the Muscle power of the upper arm with approximate 45% improvement in the Wrist flexion, Palmar abduction of thumb, Finger abduction and adduction, respectively, from the Baseline.



The effect of the treatment on muscle power was assessed. The results showed that the difference in score of Hip flexion, Hip extension, Hip abduction, and hip adduction were 1.75, 1.9, 1.9 & 1.9, which has improved to 3.3, 3.4, 3.4 & 3.35, respectively, with a mean difference of 1.55, 1.5, 1.5 & 1.450 after the treatment. The statistical analysis by adapting the Paired ‘t’ test showed a statistically significant

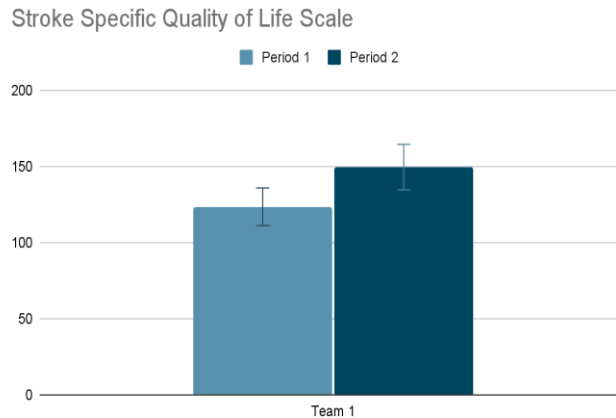
change with  $p = <0.001$ . This analysis shows the significance of Mahanarayana Taila Nasya on improving the Muscle power of the upper arm with 31%, 30%, 30%, & 29% improvement in the Hip flexion, Hip extension, Hip abduction, and hip adduction from the Baseline.



The mean scores of Muscle power concerning Knee extension, Knee flexion, Knee flexion, Ankle dorsiflexion, and Ankle plantarflexion were 1.9, 2.0, 1.95 & 1.95, which has improved to 3.35, 3.35, 3.3 & 3.3, respectively, with a mean difference of 1.45, 1.35, 1.35 & 1.35 after the treatment. The statistical analysis by adapting the Paired ‘t’ test showed a statistically significant change with  $p = <0.001$ . This analysis shows the significance of Mahanarayana Taila Nasya on improving the Muscle power of the upper arm with 29%, 27%, 27%, & 27% improvement in the Knee extension, Knee flexion, Ankle dorsiflexion, and Ankle plantarflexion from the Baseline.

#### EFFECT OF TREATMENT ON STROKE-SPECIFIC QUALITY OF LIFE SCALE

Assessment of the Stroke Specific Quality of Life Scale before and after treatment in a study sample of 20 showed moderate improvement in the mean score, which was 123.5 before treatment and improved to 149.45 after treatment, with about 10.6% improvement. This analysis, done using the Wilcoxon Signed Rank test, showed that Mahanarayana Taila nasya has a role in improving the quality of life of stroke patients.



## DISCUSSION

The results of our study revealed that Mahanarayana Taila Nasya have improved in all Assessment Parameters. In addition, there is a statistically significant improvement in the Stroke Specific Quality of Life Scale. Thus, Mahanarayana Taila Nasya can be considered a standard treatment that can be conventionally used in the Stroke(Pakshaghata) treatment protocol, especially in the Margavarana variety. Margavarana can cause Dhatukshaya in the distal part of the avarana. Hence, Brihmana has to be the line of treatment, which will be Hetu and vyadhi Vipareeta. Achieving the same can be done in many ways; one will be Snehana, which will have Brahmana property. Again, the mode of administration of the brahmana could be in many ways, like Basti, Snehapana, Abhyanga, etc. Pathology involves the Head region, and Urdhva Jatrugata Vikara Nasya can be considered best. It is also considered Uttamanga, and Nasya Karma is considered best in removing morbid dosha(4).

Administering the Nasya, not only the Asannamarga for the disease, but also seats for all the nerves originating from the brain and running to the periphery. Hence, the administration of the Nasya karma can be justified in Margavarana Janya Pakshaghata. As for the mode of action of the Mahanarayana Taila, the drugs with which Mahanarayana Taila is processed such as Bilva (Aegle marmelos), Ashwagandha (Withania somnifera) Brihati (Solanum indicum), Gokshura (Tribulus terrestris) Patha (Oroxylum indi-

cum) Bala (Sida cordifolia) Paribhadra ( Erythrina variegata), Kantakari (Solanum xanthocarpum), Punarnava (Boerhavia diffusa), Atibala (Abutilon indicum), Agnimantha (Premna corymbosa), Prasari (Paederia foetida), Patala (Stereospermum suaveolens) Taila – Oil of Sesamum indicum and many other drugs for the Paste for the process(5).

The above drugs are considered as either Kapha Vatahara and Balya, which is by its Karma and guna and is considered as beneficial in Vata Kapha Vyadhi. The Pakshaghata here taken is Margavarana variety. Here, Margavarana refers to the obstruction of the artery by atherosclerotic plaque, which may develop in that area or be an embolus occluding the artery. In these conditions, the Nasya is the nearest route of administration to where the pathology is present. The drugs are specific to the pathology of the Margavarana, and the result is the Pakshaghata(6). In other words, the Nasya Karma with Mahanarayana Taila is beneficial in the Stroke specifically occurring with the pathology of Arterial occlusion.

This study concluded that 20 subjects diagnosed with Margavarana variety Pakshaghata were administered with Mahanarayana Taila Nasya for a period of 7 days, and there was 25.5% improvement in the motor functioning of the Shoulder and arm, 45% improvement in the Movement of the wrist and fingers, 29% Improvement in the motor functioning of the Lower Limb, and 10.6% Improvement in the Stroke-Specific Quality of Life Scale.

### Limitations

(1) In this study, functional benefits and quality of life were assessed, but structural changes could not be elicited as radiological brain imaging was not affordable to all.

(2) Although this study verified that 10ml of Mahanarayana Taila Nasya gives a good result in terms of functional improvement, it remains uncertain whether the recommended classical dosage can achieve the best effect with less or no adverse reactions, which needs further investigation.

(3) In this study, although 7 days of Nasya karma were administered, the duration can also be increased to investigate further improvement in functional impairment. The results of this study may have some limitations in delivering more benefits, possibly because the sample size taken may not be sufficient to justify a larger population.

Therefore, a larger, multicenter, and sufficiently powered trial is needed to assess the results definitively.

### CONCLUSION

In patients of Margavarajanya Pakshaghata undergoing Nasya Karma with Mahanarayana Taila for 7 days after Mahanarayana Taila Mukhabhyanga followed by Sthanika Sweda with hot water showed improvement in Muscle power of Upper and Lower limb and also Stroke Specific Quality of Life Scale, which is conducive to improving patient satisfaction with Mahanarayana Taila Nasya with no adverse effects can be considered under standard management protocol for Margavarajanya Pakshaghata. However,

er, for patients with other varieties of the Pakshaghata, such as Dhatu Kshayaja or Abhigataja. Further Study can be considered to investigate the effect of the Nasya Karma in such conditions.

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