



NASAL INSTILLATION OF MEDICATED OIL (NASYA) SADBINDU TAILA IN PARKINSON'S DISEASE – A CASE SERIES

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ABSTRACT

Parkinson's disease (PD) is the second most common neuro-degenerative disease which affects about 1% of the elderly population worldwide. It is a progressive neuro-degenerative condition with cardinal features like bradykinesia, rigidity, tremor and postural stability. The current mainstay of treatment revolves around the oral administration of levodopa. Even though levodopa provides significant relief from bradykinesia and rigidity, it produces certain side-effects like levodopa induced dyskinesia and fatigue. Ayurveda is most often sought after by patients with a hope of obtaining relief from symptoms or the side effects of conventional medication. Nasya is a unique mode of medicine administration through the nose which is used in the management of a varied spectrum of diseases. Ayurveda considers nose as the gateway to the brain and higher centres. Hence, nasya is used as a treatment mode in PD. This case series is a prospective pre and post-test of the nasal instillation of medicated oil Sadbindu taila in 4 subjects for a period of 7 days. The nasal administration of medicated oil produced significant results in freezing, facial expression, rigidity and postural stability and bradykinesia. This case series contributes to the evidence regarding the utility of panchakarma like Nasya in the treatment of neuro-degenerative conditions.

KEYWORDS: Parkinson's disease (PD), Sadbindu taila, Nasya, Nasal instillation.

INTRODUCTION:

The lack of a permanent cure for neuro- degenerative disease and its effect on the quality of life and burden on caretakers often forces patients to seek alternative medicine.¹ Parkinson's disease is the second most common neurodegenerative disease that affects mobility in addition to the classical triad of bradykinesia, rigidity and tremor.² Levodopa, the gold standard of PD management offers satisfactory relief to the motor symptoms of PD along with monoamine oxidase inhibitors.³ However, certain non- motor symptoms like sialorrhea, sleep disturbances may also be experienced in PD which significantly affects the QOL. The prolonged administration of levodopa poses a threat of developing dyskinesia and motor fluctuations with on and off periods.⁴ Due to these limitations, Ayurveda physicians are approached by PD patients for either exclusive management or an integrated approach.⁵ Case reports on the effective use of Nasya with various medicated oils have reported encouraging results in tremor, bradykinesia and rigidity. However, the results varied with different medication in individuals with disease of varied duration. Sadbindu taila was selected because of its proximity in treating the diseases of head and the rasayana property of certain ingredients.⁶ In the present study, a case series of four participants with PD who responded to Nasya with Sadbindu taila is presented.

Case I:

A 60 year old male who was a manual labour presented with complaints of tremor in both hands, difficulty to walk, reduced facial expression, difficulty in handling utensils and change in handwriting since 3 years. He often faced difficulty in speech and was asked to repeat sentences. He was on anti - parkinsonism medication since 3 years. His quality of life was affected as he was unable to leave his home for more than 30 minutes and stopped socializing. He also complained of constipation, disturbed sleep and urinary urgency. He was a beedi smoker (discontinued 10 years ago) and there was no known case of PD in his family.

Case II:

A 62 year old female known case of diabetes mellitus presented with the complaints of difficulty to walk and stand up, loss of facial expression and unclear speech since 8 years. She was on allopathic treatment for Parkinson's disease but got no relief from her symptoms. In addition to these symptoms, she also had a long history of low back ache which did not respond to treatment. She also complained of constipation and experienced emotional stress due to her inability to perform activities of daily living and the progression of her condition. Due to her dependency on caretakers for daily activities, quality of life was minimal. No member in the family was affected with IPD.

Case III:

A 56 year old male working as an automobile technician presented with stiffness and tremor in right leg, slowness in movements and difficulty to walk since 4 years. There was also episodes of occasional tremor in right hand. He was on allopathic medication for Parkinson's disease since 4 years. He also complained of nocturnal micturition (3-4 times/night). He also had a history of smoking. The patient reported of renal dysfunction, but no reports were available. There was no positive history of family member affected with IPD.

Case IV:

A 52 year old male working as an accountant complaining of stiffness of left arm and leg and occasional difficulty in initiating speech since 3 years. He was on anti- parkinsonism medication since 3 years. Anxiety regarding the progression of the condition increased the tremor. The patient also felt depressed occasionally due to loss of speed and dexterity in daily activities. He had a history of Bell's palsy 7 years ago which resolved after allopathic treatment. He also had a history of hemorrhoids, which aggravated during intake of spicy food and non- vegetarian diet. There was no IPD affected family member.

Table 1: Clinical Examination

Systemic examination	Case 1	Case 2	Case 3	Case 4
Higher mental functions	Alert, cooperative. Speech – soft voice, clear.	Alert, cooperative. Mood – depressed Speech – unclear, mild slurring. Tone and volume less.	Alert, cooperative. Reduced facial expression Speech – occasional word finding difficulty	Alert, cooperative. Speech – clear, coherent, relevant Reduced tone, volume and speed.
Cranial nerves	Intact	Intact	Intact	Intact
Muscle tone	Left upper and lower limb-rigid –grade 2	Left upper and lower limb – rigid-grade 2	Right upper limb and lower limb – cog wheel rigidity	Left lower limb- rigid- grade 2
Coordination	Finger nose test- slow on left Disdiadochokinesis- left	Finger nose test – slow on left Disdiadochokinesis – left	Finger nose test- slow on the right Disdiadochokinesis – right upper limb	Disdiadochokinesis – left upper limb
Cerebellar signs	Absent	Absent	Absent	Absent
Extrapyramidal signs	Tremor at rest- both hands	Tremor at rest –right hand	Tremor at rest- right lower limb	Absent

Posture	Stooped	Stooped	Erect	Stooped
Gait	Short steps with forward propulsion	Unable to walk without support, small steps, tendency to fall	Reduced arm swing (R) No festination	Reduced arm swing (L), dragging of left leg. No freezing/ no falls
Sensory system	Intact	Intact	Intact	Intact

Assessments and investigations:

The patients were assessed using Section II and III of Unified Parkinson's Disease Rating Scale (UPDRS) and Parkinson's Disease Questionnaire 39 (PDQ39) for quality of life. The assessments were done at baseline (0th day) and after the completion of intervention (8th day).

Method of intervention:

All the four participants were examined for fitness for Nasya. This included checking patency of nasal pathways and strength of respiratory muscles. The by stander was also educated regarding the procedure and the number of days of intervention and the pre and post assessments. The medicine was procured from a GMP certified manufacturer and kept in air tight containers away from direct sunlight. The procedure was performed by a doctor who was an expert in Panchakarma at the Nasya theatre at Vaidyaratnam P S Varier Ayurveda College Hospital, Kottakkal. Nasya was done for seven consecutive days in the morning between 7:00am- 8:00 am. The patient was given instructions not to take food in the morning before Nasya and not to do head bath for seven days. He/she may take body bath in warm water one hour after Nasya. They were advised not to take curd, milk, banana, fish, meat and fried foods.

Purvakarma (preparatory procedures):

The patient was subjected to oil application with gingelly oil on head, face, ears,

neck, shoulders, back of neck and upper back for 10 minutes. The patient's eye was covered using damp cotton pad and tied with a clean cloth so as to protect during sudation. Then the patient was made to sit on a stool and the physician performed sudation on the face, chest and upper back till the patient started to sweat. Then he/she was made to lie on a droni with neck extended and head tilted backwards.

Nasya (procedure):

The medicine was measured and transferred into a sterilized gokarna. The medicine was administered in the right nostril first and then in the left nostril. After the medicine was instilled, gentle massage was done on the face, shoulders and feet. The patient was asked to rub both palms together. The patient was asked not to swallow the medicine that was drained into the mouth and spit it by gently rising from the droni.

Paschat karma (post- operative procedures):

The patient was asked to lie in the droni for a period of 100 matra and continue spitting till the medicine is completely expelled. After that, dhumapana (medicated smoke) was done using hardiradi varti and kabala with lukewarm water. The head of the patient is covered with a towel and is asked to take rest for an hour ensuring that there is no exposure to winds.

Patient characteristics:

Table 2: UPDRS 2- Activities of Daily Living

	Case 1			Case 2			Case 3			Case 4		
	BT	AT	% of change*	BT	AT	% of change*	BT	AT	% of change*	BT	AT	% of change*
Speech	2	1	50%	2	1	50%	0	0	-	1	1	-
Salivation	1	0	100%	1	1	-	0	0	-	0	0	-
Swallowing	0	0	-	0	0	-	0	0	-	0	0	-
Handwriting	3	3	-	2	2	-	0	0	-	1	1	-
Cutting food and handling utensils	2	2	-	4	3	25%	1	1	-	1	1	-
Dressing	2	2	-	3	2	33.3%	1	0	100%	1	1	-
Hygiene	2	2	-	3	3	-	1	1	-	0	0	-
Turning in bed and adjusting bed clothes	1	1	-	4	3	25%	0	0	-	0	0	-
Falling	0	0	-	0	0	-	0	0	-	0	0	-
Freezing when walking	2	1	50%	2	1	50%	2	1	50%	0	0	-
Walking	2	2	-	3	2	33.3%	2	1	50%	1	1	-
Tremor	3	2	33.3%	3	3	-	2	2	-	1	1	-
Sensory complaints	2	1	50%	3	1	66.6%	0	0	-	1	1	-

*Percentage change was calculated as difference in the individual score compared to baseline score multiplied by 100

Table 3: UPDRS 3- Motor Examination

	Case 1			Case 2			Case 3			Case 4		
	BT	AT	% of change*	BT	AT	% of change*	BT	AT	% of change*	BT	AT	% of change*
Speech	2	1	50%	1	1	-	0	0	-	1	1	-
Facial expression	3	2	33.3%	3	2	33.3%	2	1	50%	1	1	-
Tremor at rest	3	3	-	3	3	-	3	2	33.3%	1	1	-
Action or postural tremor of hands	3	3	-	3	3	-	2	0	100%	0	0	-
Rigidity	3	2	33.3%	3	3	-	2	1	50%	1	0	100%
Finger taps	2	1	50%	3	3	-	1	0	100%	0	0	-
Hand movements	2	1	50%	2	2	-	2	1	50%	1	1	-
Rapid alternating movements of hand	2	2	-	2	1	50%	2	0	100%	2	1	50%
Leg agility	1	1	-	2	1	50%	1	1	-	1	1	-
Arising from chair	2	1	50%	4	2	50%	1	0	100%	0	0	-
Posture	3	2	33.3%	2	2	-	1	1	-	1	1	-
Gait	2	1	50%	3	2	33.3%	1	1	-	1	1	-
Postural stability	1	1	-	3	2	33.3%	1	0	100%	0	0	-
Body bradykinesia and hypokinesia	3	2	33.3%	4	3	25%	2	1	50%	2	1	50%

*Percentage change was calculated as difference in the individual score compared to baseline score multiplied by 100

Table 4: PDQ 39 scores

Domain	Case 1			Case 2			Case 3			Case 4		
	BT	AT	% of change*	BT	AT	% of change*	BT	AT	% of change*	BT	AT	% of change*
Mobility	50	42.5	15%	100	97.5	2.5%	27.5	20	28%	30	15	50%
Activities of daily living	62.5	45.8	27%	87.5	83.3	4.8%	8.3	4.1	50%	0	0	-
Emotional well being	16.6	12.5	25%	54.16	41.6	18.4%	8.3	4.1	50%	41.6	25	40%
Stigma	43.7	37	14%	37.5	37.5	-	43	31	29%	25	18.7	25%
Social support	0	0	-	0	0	-	0	0	-	16.66	16.66	-
Cognition	37.5	25	33.3%	6.25	6.25	-	12.5	6.25	50%	0	0	-
Communication	25	16	33.6%	16.6	8.33	50%	0	0	-	16.6	8.33	50%
Bodily discomfort	33.3	25	25%	41.6	41.6	-	0	0	-	0	0	-

*Percentage change was calculated as difference in the individual score compared to baseline score multiplied by 100

Table 5: Treatment protocol

Nasya with sadbindu taila

	Case 1	Case 2	Case 3	Case 4
Day 1	1 ml	1 ml	1 ml	1 ml
Day 2	2 ml	2 ml	2 ml	2 ml
Day 3	2 ml	2 ml	2 ml	2 ml
Day 4	2+1 ml	2+1 ml	2+1 ml	2+1 ml
Day 5	2+2 ml	2+1 ml	2+1 ml	2+1 ml
Day 6	2+2 ml	2+2 ml	2+2 ml	2+2 ml
Day 7	2+2 ml	2+2 ml	2+2 ml	2+2 ml

OBSERVATIONS AND RESULTS:

The patients were assessed after treatment for changes in activities of daily living, motor functions and quality of life after completion of the treatment procedure. 50% change in speech was seen in case I and II whereas no change was seen in case IV. Salivation recovered completely in case I. There was 25% improvement in cutting food and handling utensils in case II. The third case showed 100% change in dressing and the second case showed 33.3% improvement. Only the second case showed 25% improvement in turning bed and adjusting bed clothes. Except for the last case, all of the patients showed 50% change in freezing when walking after treatment. Walking showed 33.3% change in the second case and 50% change in the third case. Sensory complaints reduced by 50% in the first patient and by 66.6% in the second patient. No change was observed in the handwriting of the participants.

Speech improved by 50% in the first patient and facial expression improved by 33.33% in the first two patients and 50% in the third patient. Both rest tremor and action tremor showed a 33.3% change after treatment in the third case only. The fourth patient showed 100% change in rigidity and the third patient showed 50% change, but the first patient had only a 33.3% improvement. Finger taps and hand movements improved by 50% in the first and the third patient. Rapid alternating movements of hand showed a 100% change in the third patient and 50% change in the second and fourth patient. Only the second patient had a 50% change in leg agility, while others had no change. A 100% change in arising from chair was observed in the third patient and 50% change in first and second patients. Posture improved by 50% in the first patient and gait improved by 50% in the third case and 33.3% in the second case. Bradykinesia improved by 50% in the third and fourth case, only 33% and 25% changes were observed in the first and second cases respectively.

The quality of life was assessed using the PDQ39 questionnaire which consists of eight domains. Mobility improved by 50% in the fourth patient and by 28% in the third patient. The changes in the first two patients were less than 20%. In the domain activities of daily living, there was 50% improvement in the third patient and 27% improvement in the first patient. Emotional well-being improved by 50% in the third patient, 40% in the fourth patient and 25% in the first patient. Even though there was a change in the second patient's emotional well-being, it was less than 20%. Stigma experienced by the patients reduced during the period of intervention by an average of 24% in all subjects. Changes in cognition were reported by the first and third patient at 50% and 33.3% respectively. Communication improved by 50% in the second and fourth patients and by 33.3% in the first patient. Bodily discomfort improved by 25% in the first patient only.

DISCUSSION:

In the above case series, cardinal changes ($\leq 50\%$) were observed in speech, salivation, freezing, dressing and sensory symptoms in UPDRS Section II. On comparison with the administration of Mulakadi taila, better results were obtained in speech and dressing in the current trial.⁷ However, no changes in handwriting were noted in the current case series whereas 46% change was observed in the trial with Mulakadi taila. Quite interestingly, none of the participants in the Mulakadi taila nasya trial reported sensory symptoms. In this case series, cardinal changes were observed in facial expression, rigidity, finger taps, rapid alter-

nating movements, postural stability and bradykinesia. However in the trial with Mulakadi taila nasya, the changes were less than 50% in these domains. In the current case series, no significant changes were obtained in rest tremor and action tremor, except in one case. This finding is not in cue with that of the trial with Mulakadi taila nasya and Jyotismati taila nasya.⁸ A significant change ($\leq 50\%$) was observed in the domain communication and emotional well-being on assessment of quality of life.

Nasya is a unique mode of Panchakarma that utilizes the nasal route of drug administration.⁹ It is widely used in the management of diseases affecting the nervous system and degenerative conditions. Parkinson's disease occurs due to the degeneration of dopaminergic neurons in the substantia nigra pars compacta causing symptoms like tremor, bradykinesia and rigidity. The use of lipids as a drug delivery system administered via the nose to target brain cells is of increasing interest among researchers.¹⁰ Hence, medicines administered through this route may serve as a potential therapeutic agent to arrest the progression of diseases like PD. In addition to this, lipid mediated drug delivery enables to cross the blood-brain barrier which is otherwise impermeable to medicinal molecules. The size of the molecules also plays an important role in the treatment of diseases of higher centre. Molecules less than 400 Da can cross the blood brain barrier and create effective pharmacological action.¹¹ In this case series, the use of Nasya with Sadbindu taila proved to be effective in reducing the cardinal symptoms like bradykinesia, rigidity, freezing and speech.

Nasya is intended to remove the toxic materials and microscopic cellular debris from the head by use of appropriate medicines in the form of oil, powders and fresh extracts. The actions of nasal instillation of medicated oil varies with the formulation. Certain drugs like vidanga (*Embelia ribes*) and sigru (*Moringa oleifera*) act as sirovirechana (removal of cellular debris and toxic metabolites from head).¹² However the use of drugs like bala (*Sida cordifolia*) and satavari (*Asparagus racemosus*) confer nourishment to cells that have lost vitality while administered nasally. This enables the use of nasal instillation of medicated Ayurveda oil for multiple purposes. In degenerative conditions like Parkinson's disease, there is a need to repair cell damage as well as remove the accumulated toxic proteins. Hence, nasya acts as a modality to address both cell repair and clearance of debris.

The pathophysiology of Parkinson's disease can be compared to that of kapha avarana vata resulting in speech and movement disorders along with loss of higher mental functions like memory.¹³ Prana vayu, udana vayu and samana vayu play an important role in motor functions, speech and memory. The malfunctioning of vata dosa occurs either due to degeneration or due to avarana.¹⁴ In PD, both pathologies can be seen as there is loss of striatal dopaminergic neurons and abnormal accumulation of α -synuclein proteins.¹⁵ The loss of mobility in PD is not confined to the gait and hand movements but also intestinal motility. Retrospective studies of PD individuals point out the onset of constipation decades before the onset of motor symptoms.¹⁶ This shows that there is derangement of apana vayu also during the course of the disease. Nasya serves as a mode to rectify the kapha avarana in the siras.

Sadbindu taila is a unique formulation consisting of herbs like vidanga, eranda that provide the benefit of removal of toxic metabolites and other herbs like bringaraja, yastimadhu that nourish cells that are depleted due to degeneration. The formulation also contains Tagara that is known to possess anti anxylotic and sleep inducing properties.¹⁷ Researches indicate the cytoprotective effect of Valeriana officinalis on an in vitro model of Parkinsonism.¹⁸

CONCLUSION:

The use of levodopa for therapeutic management in PD is inevitable. However, there is a need to look beyond the supplementation of levodopa due to its limitations and delayed side-effects. The use of nasal drug delivery system to target the cells of the brain and modify disease progression by using Ayurveda principles and treatment modalities offers new age solutions to individuals affected with PD. This case series provides evidence to the effect of Nasya with Sadbindu taila in reducing difficulty in speech, increase in salivation, bradykinesia and freezing

during walking. Changes in the domains of quality of life such as mobility, communication and emotional well-being renders promising results in PD therapy. Further studies in animal models to delineate the exact mechanism of nasal medication is required to provide stronger evidence. The role of pratimarsha nasya in prevention and palliative management of PD also needs to be investigated as there is no permanent cure for the disease currently.

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