Journal of Ayurvedic and Herbal Medicine

Research Article

J. Ayu. Herb. Med.
2016; 2(3): 67-72
May- June

www. ayurvedjournal.com

Comparative study of efficacy of 'Mulakadi taila'-Basti and Nasya in management of Kampavata w.s.r. to parkinson's disease

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ABSTRACT

Tremors, bradykinesia and rigidity are the cardinal symptoms of Parkinson's disease. The symptoms of the disease are bothersome to the patient because they affect the quality of life of the Patient. The main line of treatment in Parkinson's disease is administration of drugs affecting the dopaminergic system. Although they significantly reduce the presenting symptoms they cannot prevent the progression of the disease. Thus, there remains a need for a therapy which would also slow down disease progression and improve quality of life. The trail was undertaken to study the comparative efficacy of 'Mulakadi Taila' Basti and Nasya in management of Kampavata (Parkinson's disease) by giving Mulakadi Taila Basti and Nasya in two groups of Patients. Mulakadi Taila from Gadanigraha is selected because Chikitsa siddhanta says that Vataja disorders can be treated with Sneha (Taila) incorporated with Vatahara dravyas. The principle constituents of this very balanced formulation are all Vata-shamak, Vatakapha-shamak or 'Tri-Doshaghna', and especially indicated in Vata disorders. The clinical assessment was done using Modified Universal Parkinson's Disease Rating Scale. All symptoms were given scoring depending upon their severity from 0 to 4. The scores were subjected to 't' test and it suggests significant difference after the treatment. Overall the results are a little better with Basti group. But, both the groups have their own areas of strength over the other group in certain symptoms. Hence, by changing the Mode of administration the treatment can be tailor-made as per the requirements of individual Patient. So far, our experience with treatment has been good and the results are encouraging.

Keywords: Mulakadi Taila, Basti, Nasya, Kampavata, Parkinson's Disease.

INTRODUCTION

Parkinson's disease belongs to the group of extra pyramidal neurological disorders [1]. It is a chronic progressive disorder in which idiopathic Parkinsonism (variable combination of Tremor, Rigidity and Bradykinesia) occurs, with a characteristic disturbance in Gait and Posture. 1 to 2 per 1000 of general population and 1 per 100 among people older than 65 years; (approximately 6.3 million people) are affected by Parkinson's disease worldwide.

Tremors at rest had been first mentioned as an independent clinical entity by Madhavakar in Madhav Nidanam in the 7th century. He states that the tremors in the whole body and head caused by *Vata* are called *'Vepathu'. 'Kampavata'* was first described in Basavarajiyam with cardinal symptoms as *Hastapadatale Kampa, Dehabhramana Deenata and Ksheenamati* [2].

Parkinson's disease is caused by an idiopathic degeneration of dopamine-producing cells in the substantia nigra [3]. The main line of treatment in Parkinson's Disease is administration of drugs affecting the dopaminergic system. These drugs significantly reduce the presenting symptoms but cannot prevent the progression of the disease. Also they have limitations regarding dosage and have their own side-effects. Thus there remains a need for a therapy which would also slow down disease progression and improve quality of life.

Application of Ayurvedic principles on the pathology involved, reveal a distinct vitiation of *Vata-dosha.* The cardinal symptoms of Bradykinesia, Rigidity, Tremors and Speech defects indicate an involvement of *Vyana* and *Udana Vayu; Majja, Mamsa, Meda* and *Rasa* are the *dhatus* involved with *Upa-dhatu Snayu;* the type of *Srotodushti* involved is *'Sanga'.* This multi-factorial vitiation of V*ata* can be possibly normalized using the golden standard of V*ata* treatment – the '*Basti Chikitsa'. 'Basti'* is stated to be *'Ardha Chikitsa'* or *'Sarva Chikitsa';* capable of curing half or all of the curable diseases [4].

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Nasya is an intranasal drug therapy, wherein medication is administered through the nasal route [5]. *'Shiras'* or the *'Uttamanga'* i.e. the *'Mastishka'* is the chief seat of *Prana Vayu* and the *Udana Vayu* as well as the *Indriyas* , and the nose is said to be a doorway to it [6]. Hence, drug given by nasal route is known to be highly efficient on the central nervous system.

'Mulakadi Taila' is a formulation mentioned in 'Gadanigraha' is said to treat *'Kampa'* along with other *Vatavyadhis* [7]. The principle constituents are *'Bal Mulak', Amlakanji, Dadhi* and *Godugdha* which are all *Vata-shamak, Vatakapha-shamak* or *'Tri-Doshaghna'*, and especially indicated in *Vata disorders* [8]. This combination when administered by the route of *Basti* acts directly on the *Vata dosha*, whereas given by means of *Nasya* is potent to act directly on *'Shiras'* (*Uttamanga*) i.e. Central Nervous System.

The interest of this study is oriented in analyzing the effects of *'Mulakadi Taila'* on *'Kampavata'* and also which route of administration of the formulation is more beneficial for the same. *Kampavata* can be limited by progressive, graded nourishment of all the seven *dhatus,* inclusive of the *Majja dhatu*. *'Rasayana Chikitsa'*or the rejuvenation therapy; which can potentially revert or stall or delay the degenerative changes of aging; is a unique stronghold of Ayurveda [9]. Ayurveda is currently being viewed as a source of a disease modifying drugs and formulations. *Naimittik Rasayana* or the anti-degenerative treatment in Ayurveda has drawn considerable attention of the world. Thus, this is a potent therapy which may delay the rate of disease progression.

AIMS & OBJECTIVES:

1. To evaluate the clinical efficacy of *'Mulakadi Taila'- Basti* and *Nasya* in the management of *Kampavata* w.s.r. to Parkinson's disease.

2. To compare effect of *Basti* and *Nasyakarma* in the management of *Kampavata* and to observe their probable mechanism of action.

3. To establish a potent modality for Parkinson's disease by application of Ayurved *Chikitsa Siddhanta*.

MATERIAL & METHOD

Title of study: Comparative study of efficacy of *'Mulakadi taila'-Basti* and *Nasya* in management of *Kampavata* w.s.r. to parkinson's disease.

Type of Study: Open (Non blind) comparative clinical study.

Place of study: Panchkarma Dept., K.G.M.P. Ayurveda Mahavidyalaya & Hospital, Mumbai.

No. of patients: 10 (5 in each group) well diagnosed & established patients of Parkinson's disease from IPD & OPD of Department of Panchakarma.

Drug, Dosage and Duration: *Mulakadi taila* as stated in Gadanigraha are mentioned in Table 1.

Table 1: Drug, Dosage and Duration in Group A and Group B Patients
Institutional Ethical committee clearance reference number of trail :- KGMP/MUHS/PG (Dissertation/thesis)/1069 dated 3.12.2011

Group	GROUP A- Mulakadi Taila Basti	GROUP B- Mulakadi Taila Nasya
No of patient	5	5
Dose	60 ml/day X 16 days [10]	5ml/day in each nostril X 16 days[11,12]
Time	*Pratahpashchatbhukta* 12:30-13:30	*Pratahkala* 06:30-10:00
Procedure	Basti (rectal route)	Nasya (intranasal drug therapy)

Table 2: Ingredients of *Mulakadi taila* as described in Gadanigraha.

Contents with latin name	*Matra* in text	Metric system (approx.)
Mulak Rasa -Raphanus Sativus	*1 Aadhak*	3720 ml.
Dadhi -Cow's milk curd	*1 Aadhak*	3720 ml.
Amlakanji -Sour gruel	*1 Aadhak*	3720 ml.
Ksheer -Cow's milk	*1 Aadhak*	3720 ml.
Til Taila -Sesamum indicum	*1 Aadhak*	3720 ml.
Rasna -Pluchea lanceolata	*1 pala*	48 gm.
Bhallatak -Semicarpus anacardium Linn.	*1 pala*	48 gm.
Saindhav -Sodii Chloridum	*1 pala*	48 gm.
Pippali -Piper longum	*1 pala*	48 gm.
Gajapippali -Scindapsus officinalis	*1 pala*	48 gm.
Bala -Sida cordifolia	*1 pala*	48 gm.
Ativisha -Aconitum heterophylum	*1 pala*	48 gm.
Shunthi -Zinziber officinale	*1 pala*	48 gm.
Chitrak -Plumbago zeylanica	*1 pala*	48 gm.
Vacha -Acorus calamus	*1 pala*	48 gm.
Gokshur -Tribulus terrestris Linn.	*1 pala*	48 gm.

Drug Profile:

Mulakadi taila as stated in Gadanigraha was prepared as per standard *Tailpaka vidhi.*

The ingredient of *Mulakadi taila* are mentioned table 2.

INCLUSION CRITERIA

1) Age group : Between 40 to 80 years

2) Gender : No barrier

3) Race & Religion : No barrier

4) Well diagnosed and established case of Parkinson's disease.

5) Willing to give informed written consent.

EXCLUSION CRITERIA

1) Parkinsonism other than Parkinson's disease

2) Any other neurological disease

3) Hepatic Diseases

4) Cardiac Disorder

4) Koch's Disease

5) Metabolic disorders

6) Pregnancy

ASSESSMENT PARAMETER

Objective Assessment: Parkinson's disease does not have objective parameter of assessment, therefore assessment of efficacy depends entirely on clinical findings.

Subjective assessment: Gradation as 'Modified Universal Parkinson's Disease Rating Scale'.

OBSERVATIONS AND RESULTS

I. PRE-TREATMENT AND POST TREATMENT OBSERVATIONS WITH GROUP – A

Table 3: Showing pre-treatment and post treatment observations with group - A.

	GROUP A-BASTI											
	PRE - TREATMENT						**POST-TREATMENT**					
	1	2	3	4	5	TOTAL	1	2	3	4	5	TOTAL
I. DISORDERS OF COGNITION & MEMORY												
1. Intelectual impairment	0	1	1	2	0	4	0	0	1	1	0	2
2. Thought disorder	1	1	2	1	1	6	1	1	1	1	0	4
3. Depression	2	3	1	3	1	10	1	1	1	3	1	7
4. Loss of Memory	2	2	2	2	1	9	2	1	1	1	1	6
II. AFFECTED ACTIVITES OF DAILY LIVING												
5. Salivation	2	2	3	2	1	10	1	0	1	1	0	3
6.Swallowing	1	1	2	0	0	4	0	0	1	0	0	1
7. Handwriting	2	2	3	2	2	11	2	1	2	1	1	7
8. Cutting Food & handling Utensils	1	1	2	2	1	7	1	1	1	1	0	4
9. Dressing	2	1	2	3	1	9	1	1	1	2	1	6
10. Hygiene	2	1	2	2	1	8	1	0	1	1	0	3
11. Turning in bed, Adjusting bed clothes	1	1	3	1	1	7	1	0	1	0	0	2
12. Walking	2	2	3	2	2	11	1	1	1	1	1	5
13.Sensory complaints related to Parkinson's Disease	0	0	0	0	0	0	0	0	0	0	0	0
III. MOTOR EXAMINATION												
14. Bradykinesia	3	2	3	3	2	13	2	1	2	2	1	8
15. Posture	2	1	2	3	1	9	1	0	1	1	0	3
16. Postural Stability	1	0	1	2	1	5	0	0	1	1	0	2
17. Rigidity	2	3	3	2	2	12	1	1	2	1	1	6
18. Gait	3	2	3	3	1	12	1	1	2	2	1	7
19. Falling	0	0	0	0	0	0	0	0	0	0	0	0
20. Freezing while walking	1	1	2	1	0	5	1	0	1	0	0	2
21. Tremors at rest	1	2	2	2	1	8	1	1	0	1	1	4
22. Action Tremors	2	2	3	3	2	12	1	1	1	2	1	6
23. Speech	2	2	2	3	2	11	2	1	1	2	1	7
24. Facial Expression	2	2	2	3	1	10	2	1	1	2	1	7
25. Finger taps	1	1	2	2	1	7	0	0	1	1	1	3
26. Hand Movements	2	1	3	3	2	11	1	1	2	2	1	7
27. Arising from Chair	2	2	3	2	2	11	0	1	1	1	1	4
28. Rapid Alternating Movements of Hand	2	2	3	2	2	11	1	1	1	1	1	5
TOTAL	44	41	60	56	32	233	26	17	30	32	16	121
COMPLICATIONS OF THERAPY												
Dyskinesia	0	0	3	0	0	3	0	0	1	0	0	1
Anorexia	0	0	1	2	0	3	0	0	0	0	0	0
Nausea, Vomitting	0	0	0	0	0	0	0	0	0	0	0	0
Insomnia/ Hypersomnolence	1	2	1	2	1	7	0	1	1	1	1	4
Symptomatic Orthostasis	0	0	0	0	0	0	0	0	0	0	0	0

II. PRE-TREATMENT AND POST TREATMENT OBSERVATIONS WITH GROUP B

Table 4: Showing pre-treatment and post treatment observations with group - B

GROUP B-NASYA												
MODIFIED. UPDRS	**PRE-TREATMENT**						**POST- TREATMENT**					
PATIENTS	1	2	3	4	5	TOTAL	1	2	3	4	5	TOTAL
1. Intelectual impairment	1	0	1	2	0	4	1	0	1	1	0	3
2. Thought disorder	2	1	2	2	2	9	1	0	1	1	1	4
3. Depression	2	2	2	3	3	12	1	1	1	1	1	5
4. Loss of Memory	1	0	1	2	2	6	1	0	1	1	1	4
5. Salivation	1	2	1	1	2	7	0	1	0	0	0	1
6.Swallowing	2	0	2	1	0	5	1	0	1	0	0	2
7. Handwriting	3	3	3	2	2	13	1	3	1	1	1	7
8. Cutting Food & handling Utensils	1	1	1	1	1	5	1	1	1	1	0	4
9. Dressing	2	3	2	1	1	9	1	2	1	1	1	6
10. Hygiene	2	3	2	1	1	9	1	2	1	1	0	5
11. Turning in bed, Adjusting bed clothes	2	3	2	1	1	9	1	1	1	0	0	3
12. Walking	3	3	3	2	2	13	2	2	2	2	1	9
13.Sensory complaints related to Parkinson's Disease	0	0	0	0	0	0	0	0	0	0	0	0
14. Bradykinesia	2	2	2	1	1	8	1	1	1	1	0	4
15. Posture	2	1	2	1	2	8	1	1	1	1	1	5
16. Postural Stability	1	2	1	0	1	5	1	1	1	0	0	3
17. Rigidity	2	3	2	2	2	11	1	2	1	1	1	6
18. Gait	3	3	3	1	2	12	1	2	1	1	1	6
19. Falling	0	2	0	0	0	2	0	0	0	0	0	0
20. Freezing while walking	1	2	1	1	1	6	1	1	1	0	0	3
21. Tremors at rest	2	2	2	2	2	10	1	1	1	1	1	5
22. Action Tremors	2	3	2	3	2	12	1	1	1	2	1	6
23. Speech	2	3	2	2	2	11	1	2	1	1	1	6
24. Facial Expression	2	1	2	1	2	8	1	1	1	1	1	5
25. Finger taps	1	2	1	1	1	6	1	1	1	0	1	4
26. Hand Movements	1	2	1	2	2	8	1	1	1	1	1	5
27. Arising from Chair	2	2	2	2	2	10	1	1	1	1	1	5
28. Rapid Alternating Movements of Hand	3	3	3	2	2	13	2	2	2	1	2	9
TOTAL	48	54	48	40	41	231	27	31	27	22	18	125
COMPLICATIONS OF THERAPY												
Dyskinesia	0	0	0	0	0	0	0	0	0	0	0	0
Anorexia	0	1	0	2	1	4	0	0	0	0	1	1
Nausea, Vomitting	0	0	0	0	0	0	0	0	0	0	0	0
Insomnia/ Hypersomnolence	2	2	2	3	3	12	1	1	1	1	1	5

III. PRE AND POST TREATMENT OBSERVATION WITH *MULAKADI TAILA* IN BOTH – GROUP A & B.

The results obtained and statistical processing is as follows in table 5.

Mulakadi Tail in *Basti* form was administered in Group A and in *Nasya* form in the second Group B. The drug administered in both the routes provided significant improvement in majority of cardinal and associated signs and symptoms of *Kampvata*.

Mulakadi Tail has properties like *Katu-Madhur Rasa, Madhur Vipak* and *Ushna Veerya*. *Sneegdha Guna* and *Strotoshodhan, Vibandhagna*, Probable *Balya, Brimhana, Rasayan* and *Vrishya*, these properties alleviate vitiated *Vata* and due to *Katu pradhan Rasa* it acts as a *Kaphahara*. As *Vata* is main culprit in the pathogenesis of *Kampavata*, and that tremor is due to vitiation of *Vata,* specially that of *Vyan Vayu* by its *Chal Guna* and probably, due to *Avarana* of Kapha and/or *Dhatukshaya*, the formulation that holds Anti *Vata- Kapha* properties like *Mulakadi Tail* is desirable. The drug works against both *Avarana* and *Dhatukshya* pathology. This is a very rare property because properties of drug that act against *Avarana* and those acts against *Dhatukshaya* are seldom similar.

Table 5: Pre and Post treatment observation with *Mulakadi Taila* in both – Group A & B.

	PRE T/T	POST T/T		GROUP A		PRE- T/T	POST- T/T		GROUP B
	Grp.A	Grp.A	D	d/PRE*100		Grp. B	Grp. B	D	d/PRE*100
	TOTAL	TOTAL		In %		TOTAL	TOTAL		In %
1. Intelectual impairment	4	2	2	50		4	3	1	25
2. Thought disorder	6	4	2	33.34		9	4	5	55.55
3. Depression	10	7	3	30		12	5	7	58.33
4. Loss of Memory	9	6	3	33.34		6	4	2	33.33
5. Salivation	10	3	7	70		7	1	6	85.71
6.Swallowing	4	1	3	75		5	2	3	60
7. Handwriting	11	7	4	36.36		13	7	6	46.15
8. Cutting Food & handling Utensils	7	4	3	42.85		5	4	1	20
9. Dressing	9	6	3	33.34		9	6	3	33.33
10. Hygiene	8	3	5	62.5		9	5	4	44.44
11. Turning in bed, Adjusting bed clothes	7	2	5	71.42		9	3	6	66.67
12. Walking	11	5	6	54.54		13	9	4	30.76
13.Sensory complaints related to PD	0	0	0			0	0	0	
14. Bradykinesia	13	8	5	38,46		8	4	4	50
15. Posture	9	3	6	66.67		8	5	3	37.5
16. Postural Stability	5	2	3	60		5	3	2	40
17. Rigidity	12	6	6	50		11	6	5	45.45
18. Gait	12	7	5	41.66		12	6	6	50
19. Falling	0	0	0	0		2	0	2	100
20. Freezing while walking	5	2	3	60		6	3	3	50
21. Tremors at rest	8	4	4	50		10	5	5	50
22. Action Tremors	12	6	6	50		12	6	6	50
23. Speech	11	7	4	36.36		11	6	5	45.45
24. Facial Expression	10	7	3	30		8	5	3	37.5
25. Finger taps	7	3	4	57.17		6	4	2	33.33
26. Hand Movements	11	7	4	36.37		8	5	3	37.5
27. Arising from Chair	11	4	7	63.63		10	5	5	50
28. Rapid Alternating Movements of Hand	11	5	6	54.54		13	9	4	30.77
TOTAL	233	121	112	48.0686		231	125	106	45.88

Mulakadi Tail probably helps to tackle the *Avarana* owing to its *Tikshana* and *Laghu* Properties. Thus, it becomes *Sookshma strotogami* and act on deep seated *Doshas.*

d = difference in signs and symptoms scoring Pre –Treatment and Post- Treatment

d/Pre*100= relief percentage in signs or symptoms

T/T= Treatment

If $H_o = \mu_1 = \mu_2$ i.e., There is no result in the symptoms after treatment. We have to reject H_o, if $t_{cal} > t_{tab}$ for 5% error, i.e., $t_{cal} > 2.05$

t_{cal} for these symptoms is 11.7967 for Group A and 11.325 for Group B. Therefore Hypothesis is rejected. Thus, it is statistically proven that this treatment shows results for symptoms of *Kampavata*.

DISCUSSION

Parkinson's disease is a highly specialized area where the defined role of Ayurveda is not clearly known to the us. Most patients approach to the doctors of Indian system of medicine with a hope that their disease will be cured. Unregulated tall claims fuel this false perception creating a difficulty in explaining realistic outcome of the treatments to the patients. Due to an apparent lack of complete remission in the primary motor symptoms specially tremors and bradykinesia, the other possible long term benefits that the hebal medicine would provide are not known to all. With lack of proper understanding of the disease and with an attitude to expect complete or near complete cure, patient many a time fail to follow up and thus do not derive of the other benefits offered by the system.

As stated earlier, the contemporary medicines definitely have their limitations in treating such challenging ailments. There is a definite need to reduce dyskinesias, and wearing off associated with Levodopa treatment and to improve non motor clinical features specially, constipation, hallucinations, depression etc and advocate agents that would confer neuro protection which is a challenging task for Ayurveda researchers too.

As of now, the clinical trial has been conducted in 10 patients. *Basti* and *Nasya* were given to 5 patients in each group with appropriate *Purvakarma* as mentioned in texts for 16 days. Patients were assessed during and after treatment on the basis of the signs & symptoms of *Kampavata* (Parkinson's Disease).

Symptoms better managed in *Basti* Group: Intellectual impairment, Freezing while walking, Rigidity, Activities of daily living, Hand Movements, Rapid alternating movements of hands, Finger taps, Posture etc.

Symptoms better managed in *Nasya* Group: Speech, Depression, Thought Disorder, Bradykinesia, Postural Tremors, etc.

Probable Mode of Action

Mulakadi Taila from Gadanigraha is selected because *Chikitsa siddhanta* says that *Vataja* disorders can be treated with *Sneha (Taila)* incorporated with *Vatahara dravyas*. The principle constituents of this very balanced formulation are *'Bal Mulak', Amlakanji, Dadhi* and *Godugdha* which are all either *Vata-shamak, Vatakapha-shamak* or *'Tri-Doshaghna'*, and especially indicated in *Vata* disorders.

It is a very balanced formulation wherein the drastic effects of one drug is counter-corrected by the opposite properties of the other, making it fit for wide usage in many Vataja Disorders along with *Kampavata* as stated in the text. It has *Rasayana karma* which can potentially reverse or delay the degenerative changes that are the indispensible part of this disease. Thus this can be a neuro protective therapy which may delay the rate of its progression. There is possible role of *Naimittik Rasayanas* in preventing and reversing complications, and potentially reduce the rate of neurological degeneration in *Kampavata* (Parkinson's Disease). Its role in reducing the symptomatic manifestation of the disease and improving quality of life of the patient is also very important.

LIMITATIONS OF STUDY

Small Sample Size and Less Significant improvement in the para meters observed are the obvious limitation of present study.

For the said trail, patients were approached at support group meetings of 'Parkinson's Disease and Movement Disorder Society- Mumbai' held regarding possibility in Ayurveda for management of Parkinson's disease. It was noticed that though patients were very curious to find out if there exists cure for disease in other system of medicine. Thus, opting for Ayurveda treatment is by and large the choice of patients themselves or by the close relatives.

Further, unfortunately, the patients who were enrolled for the study, were not aware about the Ayurveda treatment modalities like Enema (Basti) or Intranasal drug therapy (Nasya). They had to be convinced regarding scope of Basti and Nasya treatment. Furthermore, the time and economical commitment of 16 days treatment on working days, travelling within the city in public transport in spite of their crippling disease needed constant motivation and support from the family members, such were the constraints of the outpatient administrations. In case of admitted patients, the daily bed charges added on to additional economical burden. Also, patients with Hoehn Yahr staging 4 and above needed full time attendant to stay with them. Arranging for the attendant was not feasible due to lack of supportive manpower and extra money for the same. This further, limited the sample size of patients in the study.

Most of the patients in this study were retired people having meager income or pension, while few others were totally dependent on their family. This, further posed a problem of initial unwillingness in few, while others demanded miraculous outcomes of the treatment, having incurred the expenses. Such cases needed constant counseling and motivation while promoting only realistic possible expectations from the treatment intervention. In the presence of cognitive impairment and anxiety disorder, repetitive explanations and attempt to allay fears of the recruited patients had to be done.

CONCLUSION

Both the groups have their own areas of strength over the other group in certain symptoms. Hence, by changing the mode of Administration the treatment can be tailor-made as per the requirements of individual Patients.

The clinical improvement provided by *Mulakadi Taila Basti* and *Nasya* reveals new availability in the management of *Kampavata*, so that the Quality of Life of the patients can definitely improved. As per our experience we have seen significant results. We recommend that this procedure should be done in cycles & should be further evaluated scientifically using the principles of neurology.

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HOW TO CITE THIS ARTICLE

Shukla Mukesh B., Dwivedi Amarprakash P. Comparative study of efficacy of 'Mulakadi taila'-Basti and Nasya in management of Kampavata w.s.r. to parkinson's disease. J Ayu Herb Med 2016;2(3):67-72.