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A Randomised Clinical Trial to Evaluate the Role of *Guduchyadi Niruha Basti* in Effective Management of Parkinsonism

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ABSTRACT

Parkinsonism is typically considered a chronic progressive neuro-degenerative movement disorder. Prevalence of Parkinsonism is noted to be 41 people per 100,000 in the fourth decade of life. Men are 1.5 times more prone to have Parkinsonism than women. In the recent times it was seen that Constipation is an early indicator and a common symptom which might be a possible cause for Parkinsonism. One of the very important concepts quoted in our text is the Concept of avarana, where gati, the unique feature of Vata is obstructed by Kapha dosha, thus leading to the disease. The best modality for such a disease condition explained by our Acharyas is the Basti chikitsa. After registration with C.T.R.I. (CTRI/2018/09/015592), Guduchyadi Niruha Basti was administered to the patients in a yoga basti course, a total of 23 patients diagnosed with Parkinsonism were subjected to the basti treatment & assessment was done using parameters laid by Movement Disorder Society's Parkinson's disease Rating Scale. Significant reversal of symptoms was seen in the patients subjected to the study. An overall 85% improvement in the patient considering the parameters of the MDS-UPDRS scale used for assessment was noted. The cardinal symptoms like masked facial expressions, salivation, depression, stupor, gait disturbances, constipation, hallucinations and sleep disturbances, changes in the handwriting, confidence showed highly significant changes both clinically and statistically. Thus from the data harvested through the clinical trial clearly proves that there was definite activity of Guduchyadi Niruha Basti in the effective treatment of Parkinsonism

KEYWORDS

Parkinsonism, Guduchyadi Niruha Basti, Constipation, Avarana Concept



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INTRODUCTION

Parkinsonism is defined as a progressive disease of the nervous system marked by rigidity, tremor, and hyperkinesia, bradykinesia, akinesia with secondary manifestation like defective posture, abnormal Gait and mask face¹. A calculable seven to ten million individuals worldwide have Parkinson's disease. Prevalence of Parkinsonism is noted to be 41 people per 100,000 in the fourth decade of life². The incidence of the disease, or the rate of newly diagnosed cases, generally increases with age. When cardinal motor signs (bradykinesia, rest tremor, and rigidity) required for the diagnosis of Parkinsonism appear, about 58–64% of dopaminergic neurons in the substantia nigra (SN) have been lost and striatal dopamine content has been reduced by about 60–80%³. The non-motor Symptoms in Parkinsonism include Constipation, Loss of Smell (Anosmia), Mood Disturbances like Depression, Anxiety, Restless-Legs Syndrome, Pain, Apathy, and Fatigue⁴. The only treatment that is present in the modern sciences is dopamine supplementation and administration of laxatives in an event of constipation or symptomatic approach. Ayurveda on the other hand deals Parkinsonism in a completely unique way.

The best modality for the treatment of Vata Dosha explained by our Acharyas is the Basti chikitsa, and is said to be, “Basti Vataharanam Shreshtham” or Bastitantranam, Vataharanam, Paramaoushadi, Ardha chikitsa⁵. This basti is having activity from head to toe i.e. Apaadamastaka. Further Acharya Sushruta has added, a Vaidya can treat multidimensional variety of diseases right from eka doshaja to sannipataja variety with basti chikitsa owing to its therapeutic effect and the drug combinations.

In Ayurveda Parkinsonism can be correlated with various disorders predominantly pertaining to the vitiation of vata and kapha dosha, wherein Avarana is present in relation with Marma, Asthi, and Sandhi is involved directly/indirectly, as it is considered as a vatavyadhi, the line of treatment for the above said revolves around Niruha basti/Rasayana chikitsa. If patient is already on allopathic medication; this treatment regimen even proves effective in controlling the side effects of allopathic medications and is able to minimize the dosage of allopathic medications.

MATERIALS AND METHODS

Source of data:

A total of 23 patients diagnosed as Parkinsonism were randomly selected and



subjected for the study from OPD / IPD of Shri Dharmasthala Manjunatheshwara Ayurveda Hospital, Kuthpady, Udupi. Before starting the trial, the trial was registered with the **Clinical Trials Registry-India (CTRI) prospectively**, i.e. before the enrolment of the first participant, with CTRI REGISTRATION NO: CTRI/2018/09/015592⁶

Method of Data Collection:

It is an open label clinical study, where a total of 23 patients of either sex were randomly selected. A detailed proforma was prepared considering all points pertaining to history, signs, symptoms and examinations as mentioned in our classics and allied sciences to confirm the diagnosis.

Inclusion criteria:

- 1) Patients fulfilling the criteria of diagnosis of Parkinsonism.
- 2) Patients who are fit for Niruha Basti.

Exclusion criteria:

- 1) Previous diagnosed or known cases of Secondary Parkinsonism, Parkinson plus syndrome, Brain tumour were excluded
- 2) Patients who are unfit for Niruha basti were also excluded from the study

Study design:

This is a randomised open label clinical study with pre-test and post-test design where a total of 23 patients diagnosed as Parkinsonism of either sex were selected randomly. All the patients fulfilling the

inclusion criteria will be subjected to Guduchyadi Niruha Basti⁷, in a yoga basti course.

Duration of Study:

Duration of treatment: 08 days

Duration of follow up: 16 days

Total duration of study: 24 days

Intervention:

Poorva karma:

Preparation of the medicine:

All the raw drugs for the basti and for Abhyanga and Swedana were procured from S.D.M. Pharmacy, Udupi. And Guduchyadi Niruha Basti was prepared freshly every day.

Pradhan Karma:

Starting from the day of admission until day of discharge, the patient was prescribed with 10gms of Avipattikara choorna with hot water as a purgative and a laxative effect, every night. In a YOGA BASTI course, starting with anuvasna basti on day of admission, three Guduchyadi Niruha Basti were given in a dose of 810 ml with enema-can on 2nd, 4th, 6th day morning after about 7 am in empty stomach along with 5 matra basti with murchita tila taila in a dose of 30 ml with syringe and catheter on 1st, 3rd, 5th, 7th, 8th days in the afternoon immediately after food.

Assessment criteria:

- a) The Samyaka niruda lakshanas were assessed after the administration of



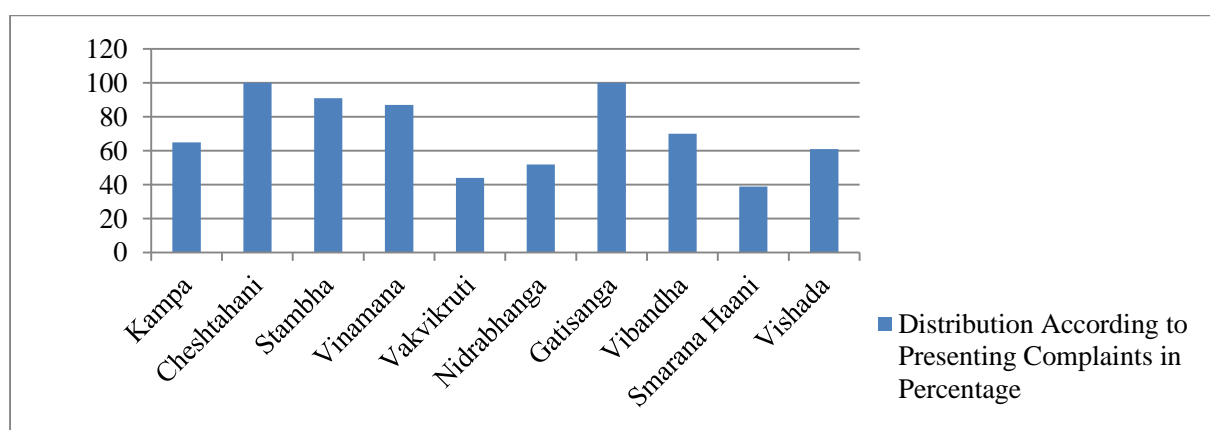
Guduchyadi niruha basti, Similarly Samyak anuvasita lakshanas were assessed after the administration of Anuvasana Basti.

b) The result was assessed on the basis of signs and symptoms of Parkinsonism and with the help of scoring through the Movement Disorder Society-Unified Parkinson's Disease Rating Scale⁸ (MDS-UPDRS) before treatment, after the treatment and on the day of follow-up.

c) Wilcoxon Rank Test was performed over the observed data and the results were calculated using the GraphPad-Instat Software.

OBSERVATIONS:

Distribution According to the Presenting complaints



Graph 1 Distribution According to Presenting Complaints

In the above mentioned graph no.1, distribution according to the presenting complaints has been graphically presented

in percentage. In table no.1 its statistical values have been explained through which the graph was derived.

Table 1 Distribution According to Presenting Complaints

Symptoms	No of patients	%
Kampa	15	65
Cheshtahani	23	100
Stambha	21	91
Vinamana	20	87
Vakvikruti	10	44
Nidrabhanga	12	52
Gatisanga	23	100
Vibandha	16	70
Smarana Haani	9	39
Vishada	14	61

RESULTS

All the results were analysed using the WILCOXON RANK TEST. The results of

the study conducted over 23 patients diagnosed as Parkinsonism with

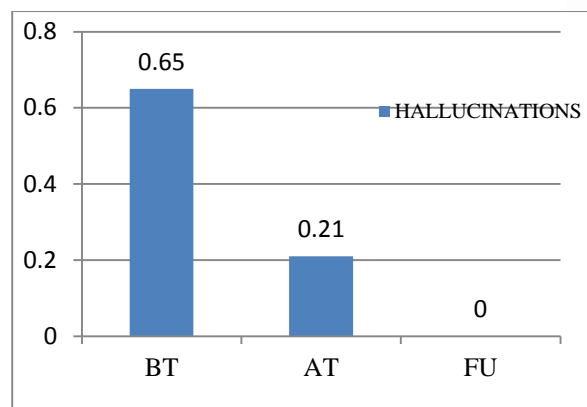


Guduchyadi Niruha Basti using the MDS-UPDRS are as follows:

BT - Before initiation of Guduchyadi niruha Basti

AT - Immediately after completion of the Basti

FU – During follow-up visit after 16 days of Basti karma.



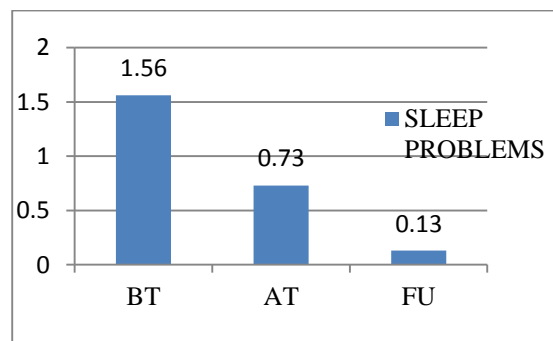
Graph 2 Effect of Basti on Hallucinations

Table 2 Effect of Basti Karma on Hallucinations

N	BT		Diff	%	Wilcoxon rank test				
	Mean				SD	SEM	P	Significant	
23	0.65	AT	0.21	0.43	66.15	0.42	0.87	0.0156	S
		FU	0.00	0.65	100	0.00	0.00	-	-

In table no 2 and graph no 2, the mean score observed before the treatment was 0.65, after treatment that score reduced to (which reduced after treatment to) 0.21, further reduced to 0 after the follow up. The effect of Guduchyadi Niruha Basti showed 66.15% improvement after the basti karma and after follow up showed 100% improvement. Statistically there was significant improvement after treatment

whereas after follow-up and clinically the patient had extremely significant results in Hallucinations.



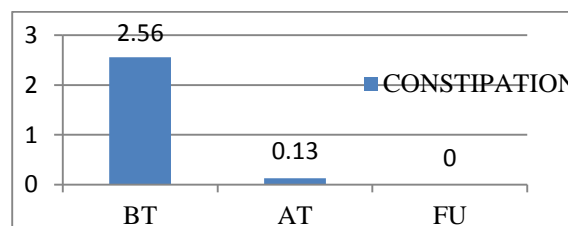
Graph 3 Effect of Basti on Sleep Problems

Table no: 3 Effect of Basti Karma on Sleep problems

N	BT		Diff	%	Wilcoxon rank test				
	Mean				SD	SEM	P	Significant	
23	1.56	AT	0.73	0.82	53	1.01	0.21	0.0005	ES
		FU	0.13	1.43	92	0.34	0.07	0.0005	ES

In Table no.3 and Graph no 3, the mean score observed before the treatment was 1.56 which was reduced after treatment to 0.73, further reduced to 0.13 after the follow up. The effect of Guduchyadi Niruha Basti showed 53% improvement after the basti karma and after follow up showed 92% improvement. Statistically and

clinically, there was very significant improvement both after treatment and after the follow-up in sleep problems.



Graph 4 Effect of Basti on Constipation

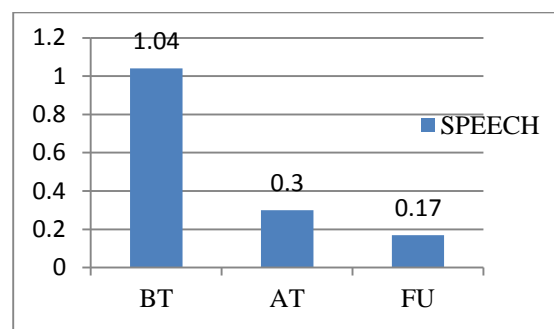


Table 4 Effect of Basti Karma on Constipation

N	BT Mean		Diff d	%	Wilcoxon rank test				
					SD	SEM	P	Significant	
23	2.56	AT	0.13	2.43	94	0.34	0.07	<0.0001	ES
		FU	0	2.56	100	0.00	0.00	--	--

In table no.4 and graph no 4, the mean score observed before the treatment was 2.56 which was reduced after treatment to 0.13, further reduced to 0 after the follow up. The effect of Guduchyadi Niruha Basti showed 94% improvement after the basti karma and after follow up showed 100% improvement. Statistically there was extremely significant improvement after treatment whereas after follow-up

statistically didn't show any result, but clinically the patient had extremely significant results in Constipation.



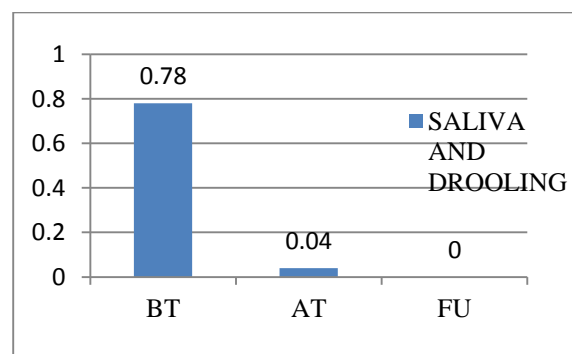
Graph 5 Effect of basti on Speech

Table 5 Effect of Basti Karma on Speech

N	BT Mean		Diff d	%	Wilcoxon rank test				
					SD	SEM	P	Significant	
23	1.04	AT	0.30	0.73	70	0.87	0.18	0.0001	ES
		FU	0.17	0.86	83	0.83	0.17	0.0001	ES

In the table no.5 and graph no 5, the mean score observed before the treatment was 1.04, after treatment the score reduced to (which reduced) 0.30, further reduced to 0.17 after the follow up. The effect of Guduchyadi Niruha Basti showed 70% improvement after the basti karma and after follow up showed 83% improvement. Statistically and clinically, there was extremely significant improvement both

after treatment and after the follow-up in Speech.



Graph 6 Effect of Basti on Saliva And Drooling

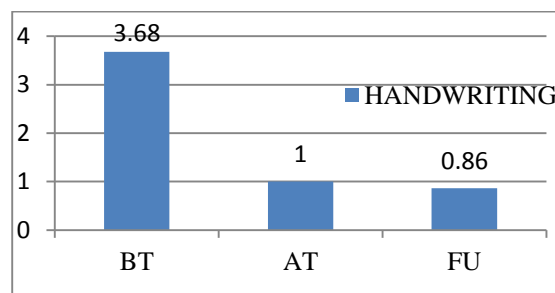
Table 6 Effect of Basti Karma on Saliva & Drooling

N	BT Mean		Diff d	%	Wilcoxon rank test				
					SD	SEM	P	Significant	
23	0.78	AT	0.04	0.73	93	0.20	0.04	0.03	S
		FU	0	0.78	100	0	0	--	--



In the table no.6 and graph no 6, the mean score observed before the treatment was 0.78, after treatment the score was reduced to 0.04 and further reduced to 0 after the follow up. The effect of Guduchyadi Niruha Basti showed 93% improvement after the basti karma and after follow up showed 100% improvement. Statistically and clinically there was significant

improvement after treatment in saliva & drooling.



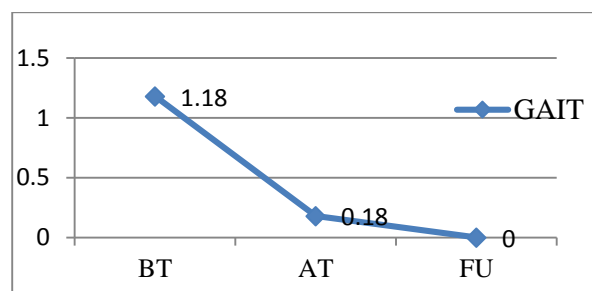
Graph 7 Effect of Basti on Handwriting

Table 7 Effect of Basti Karma on Handwriting

N	BT		Diff	%	Wilcoxon rank test			
	Mean				SD	SEM	P	Significant
23	3.68	AT	1	2.68	0.30	0.06	<0.0001	ES
		FU	0.86	2.81	0.35	0.07	<0.0001	ES

In the table no.7 and graph no 7, the mean score observed before the treatment was 3.68 which reduced after treatment to 1.00, further reduced to 0.86 after the follow up. The effect of Guduchyadi Niruha Basti showed 72% improvement after the basti karma and after follow up showed 76% improvement. Statistically and clinically, there was extremely significant

improvement both after treatment and after the follow-up in Handwriting of the patient



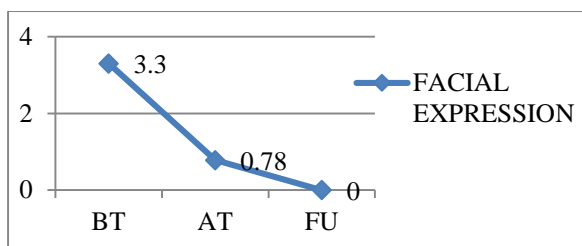
Graph 8 Effect of Basti on Gait

Table 8 Effect of Basti Karma on Gait

N	BT		Diff	%	Wilcoxon rank test			
	Mean				SD	SEM	P	Significant
23	1.18	AT	0.18	1.00	0.50	0.10	<0.0001	ES
		FU	0	1.18	0.00	0.00	--	--

In the table no.8 and graph no 8, the mean score observed before the treatment was 1.18 which reduced after treatment to 0.18, further reduced to 0 after the follow up. The effect of Guduchyadi Niruha Basti showed 84% improvement after the basti karma and after follow up showed 100%

improvement. Statistically there was extremely significant improvement after treatment whereas after follow-up statistically didn't show any result, but clinically the patient had extremely significant results in gait.



Graph 9 Effect of Basti on Facial Expression

In table no 9 and graph no 9, the mean score observed before the treatment was 3.30

Table 9 Effect of Basti Karma on Facial expression

N	BT		Diff d	%	Wilcoxon rank test			
	Mean				SD	SEM	P	Significant
23	3.30	AT	0.78	2.52	0.42	0.08	<0.0001	ES
		FU	0	3.30	0.00	0.00	--	--

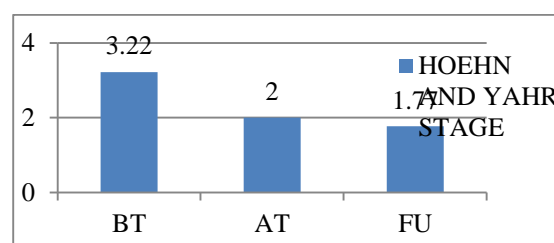
Statistically there was extremely significant improvement after treatment whereas after follow-up statistically didn't show any result, but clinically the patient had extremely significant results in Facial Expression.

Table 10 Effect of Basti Karma on HOEHN & YAHR Stage

N	BT		Diff d	%	Wilcoxon rank test			
	Mean				SD	SEM	P	Significant
23	3.22	AT	2	1.22	0.53	0.11	<0.0001	ES
		FU	1.77	1.45	0.75	0.16	<0.0001	ES

In the table no 10 and graph no 10, the mean score observed before the treatment was 3.22 which reduced after treatment to 2.00, further reduced to 1.77 after the follow up. The effect of Guduchyadi Niruha Basti showed 37% improvement after the basti karma and after follow up showed 45% improvement. Statistically and clinically, there was extremely significant improvement both after treatment and after

which reduced after treatment to 0.78, further reduced to 0 after the follow up. The effect of Guduchyadi Niruha Basti showed 76% improvement after the basti karma and after follow up showed 100% improvement.



Graph 10 Effect of Basti on HOEHN AND YAHR Stage

the follow-up in Hoehn and Yahr Staging of the disease

DISCUSSION

Most of the patients, i.e. 52% patients had constipation as the first symptom, whereas for 48% of the patients for whom constipation wasn't the first symptom, were involved in the study. A lot of studies have been done to identify the cause of Parkinsonism or to find a pre-marker for the



early diagnosis of the disease. **History of long standing Constipation could be one of those early signs or markers that can be used to say a person might be susceptible to Parkinsonism in the long run.**⁹ According to Ayurveda, vit-sanga, Vibandha, vit-Graha, etc is various symptoms explained in various contexts of vata Vyadhis and kapha prakopa lakshanas. **Which could mean Ayurveda knew about this disorder long before James Parkinson, just with different nomenclature,** we can come to a conclusion that the relationship of enteric nervous system and Parkinsonism is definite. The “Second Brain of the Body” is attributed to the enteric nervous system for several such reasons. Enteric nervous system has the ability to operate autonomously. Its connection with the CNS is through the Para-sympathetic pathway (vagus nerve) and the sympathetic pathway (through prevertebral ganglia). But there have been studies that show even when the vagus nerve is severed the enteric nervous system keeps working efficiently. About 30 neurotransmitters have been identified in the enteric nervous system that are identical to those found in the CNS like acetylcholine, dopamine, and serotonin. More than 90% of the body's serotonin lies in the gut, and about 50% of the body's

dopamine also can be found in the gut, this is currently being studied to detail our understanding about its utility in the functioning of the brain. ENS is known as the Brain of the Gut¹⁰, due to the similarities it shares with the CNS. Constipation can be considered as one of the major presenting complaints of a lot of patients, due to the GI dysfunction, long before the motor complications set in. Also irregular functioning of colon leads to the irregular bowel movements resulting into accumulation of faeces in the colon. As both digested and undigested food passes to the small intestine from the stomach, only the nutrients are absorbed in small intestine, and the rest of the matter is passed on to the large colon, which contains dead cells, unwanted toxins, undigested food, microbes etc but due to improper emptying of colon, this matter gets stagnated and begins to putrefy. Eventually these toxins start affecting the body. Guduchyadi Niruha Basti begins its Action by regulating the peristalsis of the colon and helps the body for easier evacuation. Niruha basti acts both in the therapeutic effect as well as brings about a cleansing effect in the body. The toxins accumulated in the colon are diluted due to the osmotic water retention done by the niruha basti and are passed on to the rectum for evacuation. The stagnation



of toxins is reduced. This improves the colon's health bringing about harmony in the structures of the colon. Guduchyadi Niruha Basti is a Yavana basti, meaning it has a unique role of (उभयार्थकारी) i.e. शोधन and बृंहण. As Guduchi is the major active ingredient of the basti it is named as Guduchyadi Niruha Basti. The pathology of Kaphavrutta-Vyana revolves around avarana by kapha over the Vata dosha. This Guduchyadi Niruha Basti brings about vilayana of kapha dosha; while preparing the Basti firstly, Madhu is added to the basti which has the properties like Kaphaharana, Lekhana, Shodhana, Deepana, Marganusari and Yogavahi. This will help the Stroto shodhana with the help of Lekhaneeya drugs in the Kalka as well as the avaapa, namely, Gomutra, Amla Kanji, and Shukta.

Tikshnata of the basti owing to its ingredients here might cause vata prakopa, to tackle this use of two sneha dravyas i.e. ghrita and taila has been mentioned by Acharya Sushruta. The kwatha dravya like Dashamoola, Guduchi, Bala, Triphala, Rasna all these are having rasayana property. The neuro-degeneration and further damage to the neurons can thus be reduced by

the use of these dravyas. The pathophysiology of Parkinsonism according to ayurveda revolves around avarana, which includes both vata and kapha dushti. By the time the patients come to the Ayurvedic physicians; most of them develop the full blown symptoms of Parkinsonism. Thus this basti will help to pacify both the vata dosha and the kapha dosha. By the virtue if the drugs used in the basti it will have both systemic as well as the symptomatic effect.

CONCLUSION

History of long standing Constipation could be one of those early signs or markers that can be used to say a person might be susceptible to Parkinsonism in the long run. Ayurveda knew about this disorder long before James Parkinson, just with different nomenclature. After analysing the data it is difficult to conclude at a definitive decision that type of diet plays an important role in relation with Parkinsonism. And we can conclude that Mandaagni is the prime reason for any disease pathology to occur which might be true in case of Parkinsonism also. Kaphavrutta vyana may be the more apt diagnosis correlation with Parkinsonism.



There was 85% improvement in the patient, considering all the parameters of the MDS-UPDRS scale used for assessment. Thus we can say that this particular Guduchyadi Niruha Basti has Antiparkinsonian activity and might be the choice of basti for the management of Parkinsonism.



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