ejpmr, 2016,3(7), 546-554.

SJIF Impact Factor 3.628

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

Research Article

ISSN 2394-3211

EJPMR

OPEN LABELLED CLINICAL TRIAL TO ESTABLISH THE STANDARD TREATMENT PROTOCOL FOR PARKINSON'S DISEASE (KAMPAVATA).

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Article Received on 18/05/2016 **Article Revised on 07/06/2016** **Article Accepted on 28/06/2016**

ABSTRACT

Background: Parkinson's disease (*Kampavata*) is a neurodegenerative condition which affects the basal ganglia and which presents with differing combinations of bradykinesia, rigidity, tremor and loss of postural reflexes also commonly observed in geriatric population. Researches conducted so far in the field of this disease in both Ayurveda and contemporary systems of medicine, it still remains the established risk factor for the geriatric population after the age of 50 years. Till date there is no definite curative treatment available in modern medicine. **Aims:** To access the clinical efficacy of the developed treatment protocol. **Material and methods**: In this trial, ten patients having sign and symptoms of PD were subjected to open labelled clinical trial with developed treatment protocol and internal medication. Assessment was done on the basis of relief in sign and symptom of disease. Effect of therapy on Hoehn & Yahr's Staging System was also evaluated by means of statistical analysis. **Results**: Developed protocol showed statistically significant changes in sign and symptoms. Moderate improvement was seen in majority of the patients belonging to stage 3 while marked improvement was seen in all patients in stage 4 of PD. Overall effect of the therapy provided marked improvement in majority of the patients. **Conclusion**: The study establishes that the developed treatment protocol has definite role in the management of PD and it also helps to improve the quality of life of the patients.

KEYWORDS: Parkinson's disease, Ayurveda, Protocol, Kampavata, Neurodegenerative disorder.

INTRODUCTION

The neurological disorders that are observed in geriatric population are often degenerative in nature.[1] Amongst them Parkinson's disease (PD) is a neurodegenerative condition which affects the basal ganglia and which presents with differing combinations of bradykinesia (***Chestasanga***), rigidity (***Stambha***), tremor (***Kampa***) and loss of postural reflexes.[2] Even after the researches conducted so far in the field of PD *(Kampavata)* in both Ayurveda and contemporary systems of medicine, it still remains the established risk factor for the geriatric population after the age of 50 years. The prevalence of PD is about 0.3% of the whole population in industrialized countries and has an annual incidence of 0.2/1000. Its prevalence rises from 1% in those over 60 years of age to 4% of the population over 80. Caring for this increasing elderly population can be challenging as 80% of elderly Indians live in rural areas, 73% are illiterates, 60% are women and 60% live below the poverty line.[3] Few Indian neuro-epidemiological studies have estimated the load of neurological diseases.[4,5,6] Neurological disorders cause significant morbidity, mortality, disability, socioeconomic losses and reduce the quality of life.[7] So for these reasons it is necessary to improve the quality of life of the patient and to relieve the socioeconomic, emotional and mental burden on the patients as well as family members of patients. Though in the past 35 years the pattern of the disease has changed with the arrival of some modern drugs but till date there is no definite curative treatment available in modern medicine.

Aims and Objectives

To access the clinical efficacy of the developed treatment protocol.

MATERIALS AND METHODS

Total ten patients, from the outpatient and inpatient department of Kayachikitsa Department, Institute of Postgraduate Teaching and Research in Ayurveda Hospital, Jamnagar, Gujarat, were registered in this open labelled clinical trial. A prior written informed consent was taken from and every patient. Clinical study was started after getting clearance from Institutional Ethics

Committee (No. PGT/7/Ethics/2013–2014/1767) and study was also registered under Clinical Trial Registry of India (CTRI/2014/08/004894).

Inclusion criteria

Patients of both sexes who met the diagnostic standards of PD aged between 25 to 80 years were included in this study. Participants were included on the basis symptoms like bradykinesia (***Chestasanga***), rigidity (***Stambha***), tremor (***Kampa***) and signs like micrographia, pill rolling movements, rhombergism, propulsion test and glabellar tap test.

Exclusion criteria

Patients who are suffering from repeated strokes with stepwise progression, repeated head injury, definite encephalitis, more than one affected relative, presence of cerebral tumour, uncontrolled Diabetes Mellitus, having a past history of atrial fibrillation, acute coronary syndrome, myocardial infarction, stroke or severe arrhythmia in last 6 months are excluded.

Treatment Protocol

Acharya Vangasena for the first time described the complete line of management of Kampavata which includes Abhyanga, Swedana, Nasya, Basti, Shirobasti & Virechana.[8] A good result can be provided in the management of Kampavata if complete management is planned instead of single therapy like Nasya or Basti. Considering this line of management mentioned by Acharya Vangsena, the treatment protocol with some modifications as per the advice from Ayurveda experts was planned which is mentioned in table 1.

Criteria for assessment

The improvement in the patients was assessed mainly on the basis of relief in the signs and symptoms of the disease. The details of the scores adopted for the symptoms, signs and associated symptoms in this study are as shown in figures 1,2 & 3 respectively.

Criteria for the total effect of the therapy

For the assessment of the total effect of therapy the criteria shown in table no.2 were taken into consideration.

Statistical analysis

Wilcoxon matched-pair signed-rank test and paired t-test were used to assess results using GraphPad Instat 3.1software (GraphPad Software Inc., California, USA).

Observation

Total 10 patients of PD were registered for the present study, out of which 9 patients have completed the full course of treatment and 1 patient left the treatment due to his job transfer to other city. Most of the patients in the study were having *Vata-kapha prakriti* (body constitution) (Figure-4). The maximum patients in the study were aged above 50 and were living in urban areas (Figure-4). Most of the patients were found addicted to tea and taking *Katu rasa* predominant diet (Figure-4). In *Aaharaj Nidana* (unwholesome diet), maximum patients were found of taking *Viruddha* and *Ruksha Guna* (incompatible diet) predominant diet while in *Viharaj Nidana* (unwholesome regimen), *Diwaswapna* (day sleeping), *Ratrijagaran* (late night awakening) and *Vegasandharan* (suppression of natural urges) were found to be predominant (Figure-5). *Chinta* (stress) and *Krodha* (anger) were observed as *Manasika Nidana* (psychological factor) in maximum patients (Figure-5). *Vata* and *Pitta dosha* vitiation was found in maximum patients (Figure-6). *Kampa*, *Chestasanga*, *Stambha* and *Gati vikriti* were found as cardinal symptoms in majority of the patients (Figure-7). Signs of PD like Micrographia, Rombergism, Pill-rolling movements and Propulsion test were present in majority of the patients (Figure-8). *Vibandha* (constipation), *Gurugatrata* (heaviness in the body), *Angamarda* (bodyache) were found as associated symptoms in majority of the patients (Figure-9).

RESULTS

Statistically significant result was found in the symptom of PD like Kampa, Stambha, *Gativikriti* (Figure-10)(Table-3) and *Chestasanga* viz.- Reduced Pin picking test, Reduced Buttoning time test, Reduced Rapid alternating movement test and Reduced Chest expansion (Figure-11) (Table-3). In signs of PD, statistically significant results were found in Micrographia, Rombergism, Pill-rolling tremors, Propulsion test and Glabellar tap test (Figure-12) (Table-4). In case of associated symptoms, the therapy provided significant relief in *Gurugatrata*, *Angamarda* and *Katishula* (Figure-13) (Table-5). Moderate improvement was seen in majority of the patients belonging to stage 3 while marked improvement was seen in all patients in stage 4 of PD (Table-6). Overall effect of the therapy provided marked improvement in majority of the patients (Table-7).

Table-1: Showing the developed treatment protocol.

Days		Medication & Procedure	Dose	Adjuvant	Time	Purpose
First 3 days	01	Sunthi Siddha Jala	100 ml	---	Early morning empty stomach	Dipana-Pachana
	02	Eranda Bhristha Haritaki Powder	6 g	Luke warm water	At night before sleep	Kostha shuddhi
Next 7 days		Mashadi Taila	40 ml	Luke warm water	Early morning empty stomach	Snehana
Next 8 days	01	Sarvanga Abhayga with	Q.S	---	Early morning	External

		Mashadi Taila				oleation
	02	Sarvanga Swedana		---	Early morning	Sudation
	03	Marsha Nasya with Mashadi Taila	6-6 drops	---	Early morning	
Next 21 days		Tritiyabaladi Yapana Basti	Upto 960 ml	---	Early morning	Rasayan
Next 1 month	01	Ashwagandha Powder- + Kapikacchu Powder + Sunthi Powder -	2 g. 4 g 1 g.	Milk	Twice a day after food	Medhya Rasayan

Kampa - Tremor

No tremors	0
Unilateral slight tremor present at rest, decreased by action, increases by emotions and stress and disappears during night	1
Bilateral tremor	2
Tremors not violent but present in less number of organs mentioned below	3
Bilateral violent tremors along with tremors in tongue and/or in eyelids, lips and not suppressed or diminished by willed movement	4

Gati Vikriti – Gait disorder

Can walk brisk without aid.	0
Can walk without assistance slowly but with shuffling gait.	1
Can walk without assistance slowly with shuffling with retropulsion/propulsion.	2
Can walk slowly but need substantial help, shuffling with retropulsion, propulsion with lack of associated movements.	3
Unable to raise from bed and to walk without assistance.	4

Stambha - Rigidity

No rigidity	0
Cog-wheel rigidity feebly present and on continuous examination vanishes	1
Rigidity demonstrable in one of major joints.	2
Patients sits properly but cog-wheel rigidity demonstrable in all major joints, slow eye ball movements without staring appearance.	3
Marked rigidity in major joints of limbs, patient maintains abnormal sitting postures, stared eyes.	4

Vaka Vikriti – Speech disorder

Normal speech.	0
Variable tone of voice, slight slurring of speech.	1
No echoing, dysarthria present but speech is clearly understandable, monotony present.	2
Monotonous voice, split consonance but understandable, speaks freely with examiner.	3
Incomprehensive words, monotonous voice, echoing, speaks only on insistence of examiner.	4

Figure-1:

Picking of pin test for Bradykinesia

No slowness	0
Mild slowness	1
Moderate slowness	2
Marked slowness	3

Chest expansion

Normal (> 2 cm.)	0
Mild deformity (1 – 2 cm.)	1
Moderate deformity (0.5 – 0.9 cm.)	2
Severe expansion deformity (<0.5 cm.)	3

Buttoning time

Normal (<25 seconds)	0
Mild slowness (25 – 40 seconds)	1
Moderate slowness (40 – 60 seconds)	2
Extreme slowness (Above 60 seconds)	3

Walking time

Normal (20 – 25 seconds)	0
Mild slowness (26 – 40 seconds)	1
Moderate slowness (41 – 60 seconds)	2
Extreme slowness (Above 60 seconds)	3

Marie sign

Normal (Above 20 blinks/min.)	0
Mild slowness (15 – 20 blinks/min.)	1
Moderate slowness (10 – 14 blinks/min.)	2
Extreme slowness (<10 blinks/min.)	3

Rapid alternating movements

Inactivity or extreme slowness of movement.	0
Slowness of movement.	1
Normal movement.	2

Figure-2:

Mala Vibangha - Constipation

Stool passes as per normal schedule - Normal	0
Passes stool with strain, sometimes takes purgative.	1
Passes stool after more than 24 hours, frequently takes purgative.	2
Passes stool after gap of one day, normal purgatives does not work.	3

Gurugatrata

No feeling of heaviness – Normal.	0
Occasional feeling of heaviness not affecting the daily routine.	1
Frequent feeling of heaviness mildly affecting the daily routines.	2
Feeling of heaviness throughout the day moderately affecting the daily routines.	3
Feeling of heaviness throughout the day. Daily routines are totally hampered.	4

Katishoola – Backache.

No Backache – Normal.	0
Occasional backache.	1
Relieves by medicine.	2
Dependent on analgesics (pain killers).	3

Mutra Daha – Burning micturation.

No burning – Normal.	0
Occasional burning micturition.	1
Occasional burning micturition, required treatment.	2
Constant burning micturition required treatment	3
Constant severe burning micturition but did not show relief even after treatment.	4

Angamarda - Bodyache

No Pain – Normal.	0
Generalized pain of and on during the day.	1
Generalized pain/ache during most part of the day not affecting any work	2
Generalized pain pain/ache throughout the day but person is able to do normal routine.	3
Generalized (sarvanga) bodyache/pain enough to affect routine work for all the day.	4

Figure 3:

Table-2: Showing criteria for the assessment of total effect of therapy.

Complete Remission	100% relief in sign, symptom and clinical test was considered as cured.
Markedly Improved	More than 75% but less than 100% average relief shown by the patients in their symptom and clinical tests were taken under the markedly improved category.
Moderately Improved	51% to 75% average relief shown by the patients in their symptom and clinical tests were taken under the moderately improved category.
Mildly Improved	26% to 50% average relief shown by the patients in their symptom and clinical tests were taken under the mild improved category.
Unchanged	Relief found between 0 to 25 % is taken under unchanged category.
Deterioration	Increase in the signs and symptoms or appearance of new symptom during the therapy was taken as deterioration.

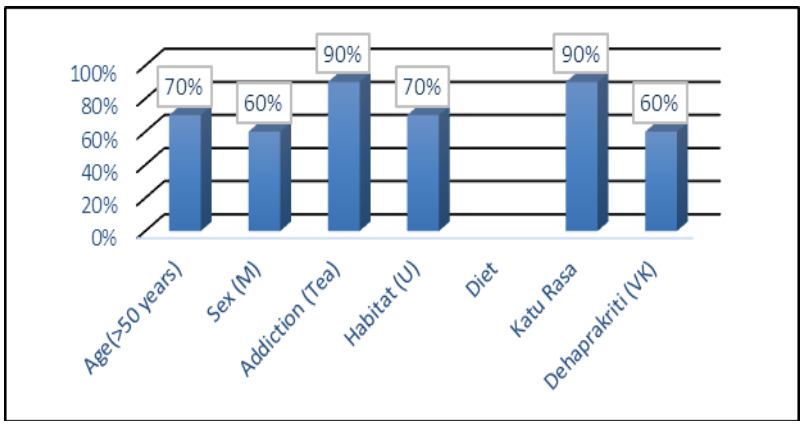

Figure-4: Showing general observation related to Age, Sex, Addiction, Habitat, Diet and Prakriti.

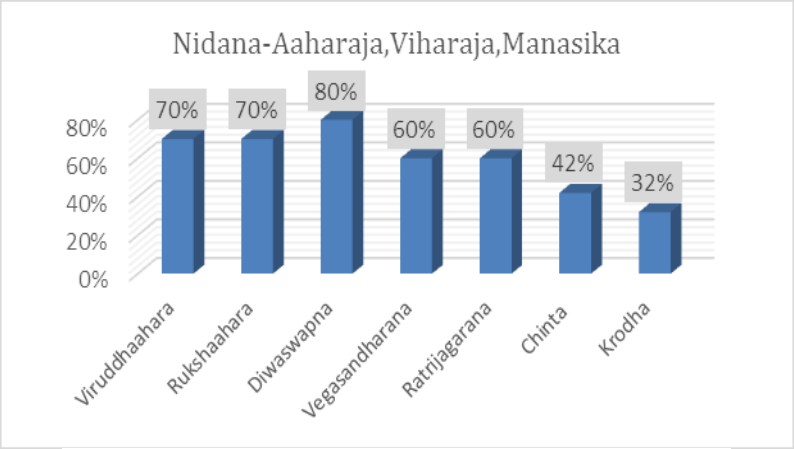

Figure-5: Showing Nidana(causes) found in patients of PD.

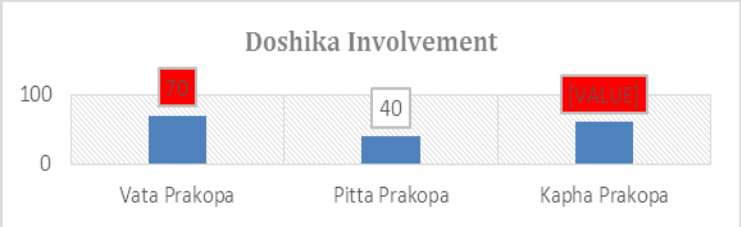

Figure-6: Showing Doshika involvement in patients of PD.

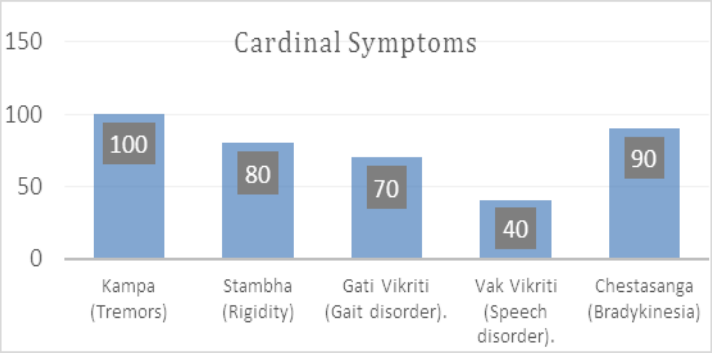

Figure-7: Showing cardinal symptoms found in patients of PD.

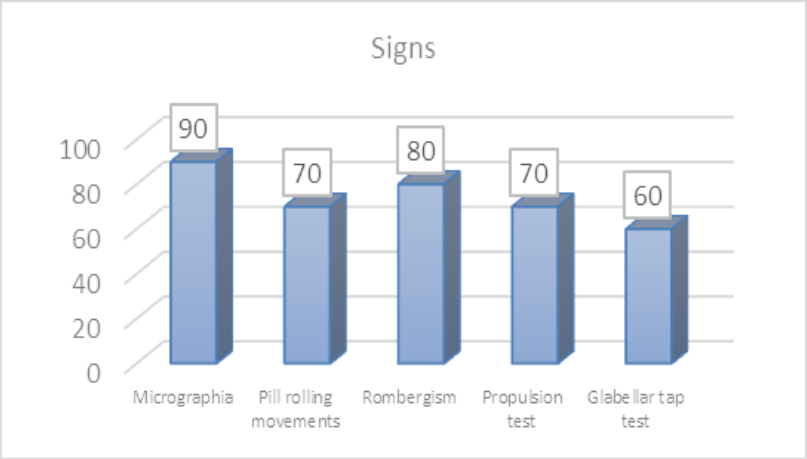

Figure-8: Showing signs found in patients of PD.

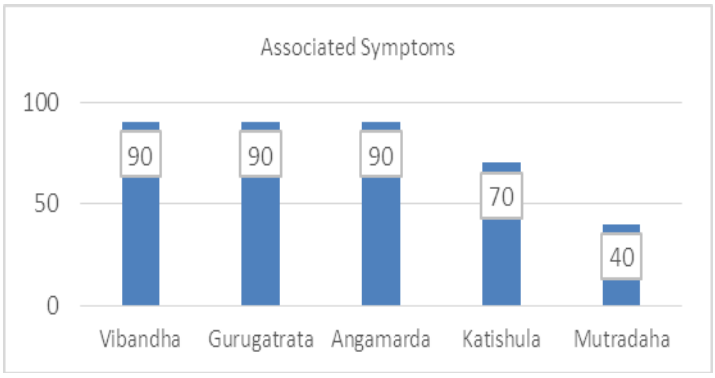

Figure-9: Showing associated symptoms found in patients of PD.

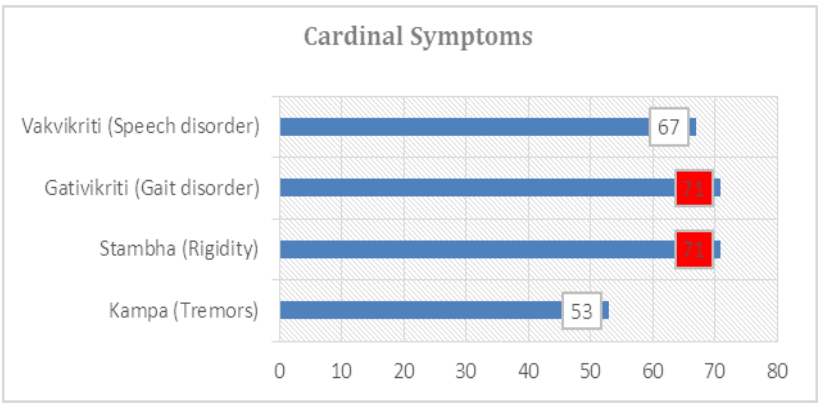

Figure-10: Showing effect of therapy on cardinal symptoms of PD.

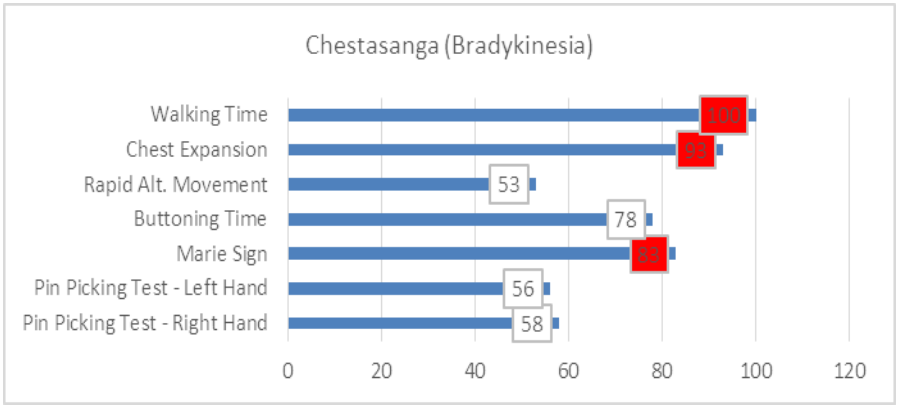

Figure-11: Showing effect of therapy on symptom of chestasanga.

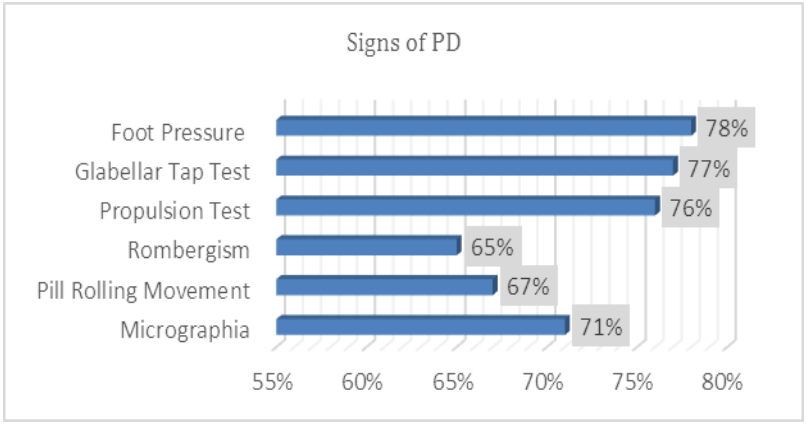

Figure-12: Showing effect of therapy on signs of PD.

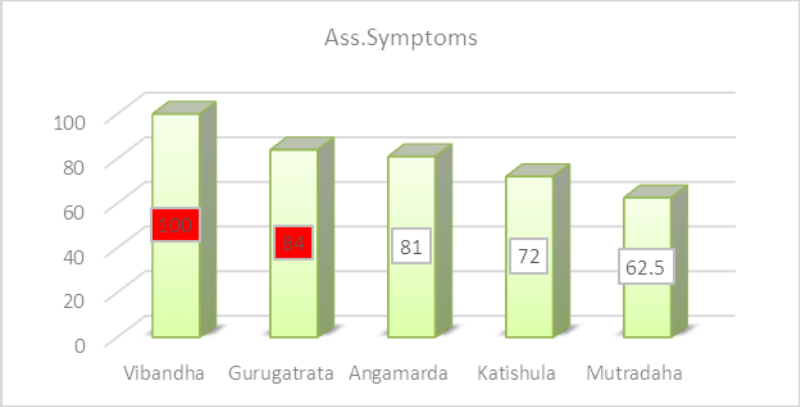

Figure-13: Showing effect of therapy on associated symptom of PD.

Table-3: Effect of therapy on Symptoms of PD.

Symptoms	N	Mean		Diff of mean	SD		SE		%	W	T+	T-	P
		BT	AT		BT	AT	BT	AT					
Kampa	09	3.33	1.44	1.89	0.7071	0.5270	0.2357	0.1757	53.13	45	45	0	0.0039
Stambha	08	2.333	0.667	1.666	1.225	0.7071	0.4082	0.2357	71.43↓	36	36	0	0.0078
Gati-vikriti	07	1.556	0.444	1.112	0.8819	0.5270	0.2940	0.1757	71.43↓	28	28	0	0.00156
Vak-vikriti	04	1	0.33	0.67	1.323	0.500	0.4410	0.1667	66.67↓	10	10	0	0.1250
Chestasanga													
Pin-picking test – Right	09	2.88	1.22	1.66	0.33	0.4410	0.11	0.1470	57.69	45	45	0	0.0039
Pin-picking test – left	09	2.77	1.22	1.55	0.4410	0.4410	0.1470	0.1470	56	45	45	0	0.0039
Marie sign	05	0.667	0.111	0.556	0.7071	0.333	0.2357	0.1111	83.33	15	15	0	0.0625
Buttoning time	09	2	0.44	1.56	0.8660	0.5270	0.2887	0.1757	77.78	45	45	0	0.0039
Rapid alternating movements	09	0.88	1.88	1	0.6009	0.33	0.2003	0.11	52.94	-36	0	-36	0.0078
Chest expansion	08	1.556	0.111	1.445	0.7265	0.3333	0.2422	0.1111	92.86	36	36	0	0.0078
Walking time	09	0.667	0	0.667	0.50	0	0.1667	0	100	--	--	--	--

Table-4: Effect of therapy on Signs of PD.

Sign	N	Mean		Diff of mean	SD		SE		%	W	T+	T-	P
		BT	AT		BT	AT	BT	AT					
Micrographia	09	2.667	0.777	1.89	0.5000	0.4410	0.1667	0.1470	70.83	45	45	0	0.0039
Pill rolling movements	07	2	0.667	1.33	1.225	0.500	0.4082	0.1667	66.67	28	28	0	0.0156
Rombergism	08	2.222	0.778	1.44	0.9718	0.4410	0.3239	0.1470	65	36	36	0	0.0078
Propulsion test	07	1.889	0.444	1.44	1.167	0.5270	0.3889	0.1757	76.47	28	28	0	0.0156
Glabellar tap test	06	1.44	0.33	1.11	1.130	0.500	0.3768	0.1667	76.92	21	21	0	0.0313

Table-5: Effect of therapy on associated symptoms of PD.

Associated symptoms	N	Mean		Diff of mean	SD		SE		%	W	T+	T-	P
		BT	AT		BT	AT	BT	AT					
Vibandha	09	2.556	0	2.556	0.5270	0	0.1757	0	100	--	--	--	--
Gurugatrata	09	2.778	0.444	2.334	0.4410	0.5270	0.1470	0.1757	84	45	45	0	0.0039
Angamarda	09	2.889	0.556	2.333	0.6009	0.5270	0.2003	0.1757	80.77	45	45	0	0.0039
Katishoola	07	2	0.556	1.444	1.225	0.5270	0.4082	0.1757	72.22	28	28	0	0.0156
Mutradaha	04	0.889	0.333	0.556	1.167	0.500	0.3889	0.1667	62.5	10	10	0	0.1250

Table-6: Effect of therapy on Hoehn & Yahr's Staging System.

Stage of PD	No. of Patients	Marked improvement	Moderate Improvement	Mild Improvement	Deteriorated
3	05	00	80%	20%	00
4	04	100%	00	00	00

Table-7: Overall effect of therapy on patients of *Kampavata* (Parkinson's disease).

Overall Effect	No. of patients	Percentage
Complete remission	00	00
Markedly improved	05	55.56%
Moderately improved	03	33.33%
Mild improvement	01	11.11%
Unchanged	00	00
Deteriorated	00	00

DISCUSSION

Tremors are produced by *Vata Prakopa* especially of *Vyana Vayu* by its *Chala Guna* and probably due to *Swa-Nidanena Prakopa of Vata and Avarana by Kapha.* The relief provided by this therapy on symptom of *Kampa* amounted to 53.13 % which was statistically highly significantn (Table-3). *Dipana Pachana* with *Sunthi Siddha Jala* improves the vitiated *Agni* and also conveys about *Amapachana* which further eliminates *Srotorodha* and interrupts the process *Avarana*. This may help to bring vitiated *Vata* and *Kapha Dosha* back to regularity thus sinking the symptom of *Kampa* i.e tremor. Further *Snehapana* together with *Abhyanga* and *Swedana* also helps to back the vitiated *Vata Dosha* by way of its *Snigdha Guna and Ushna Guna* to its usual state. *Yapana Basti* possesses *Snigdha*, *Madhura*, *Tikta Rasa* and also having *Brimhana*, *Balya* and *Rasayana* property. So due to all these qualities, it might have alleviated *Vata* and might have broken *Avarana of Kapha* which shows relief in *Kampa*. *Acharya Charaka* has mentioned "*Mardavam Snigdhata Cha Ange*[9]," in context of *Samyaka Sniggdha Lakshanas* which can be proved in this case. While describing the *Samyaka Sweda Lakshana Acharya Charaka* has mentioned *Stambha-Gaurava-Nighrahe and Mardave*[10] which is well observed in the patients. The relief provided in the symptom of Stambha was statistically significant (Table-3). This observation also goes well with textual statement that *Basti* is advised for *Stambha* and *Sankocha.*[11] This improvement in *Stambha* indicates towards breaking of *Avarana* of *Vyana* by *Kapha*, It may be due to improvement in function of *Snayu* and on increased *Shlakshna* properties of *Mamsavaha Srotas*. This also suggests the effect of therapy on alpha and gamma motor neurons which helps in reduction of rigidity. The relief provided by the therapy on the symptom of *Gativikriti* was significant (Table-3). *Gativikriti* (Gait disorder) may be due to rigidity and bradykinesia which is commonly found in the patients of PD. As a result of effect of the therapy there may be breaking of the *Avarana* process of *Kapha* on *Vyana* and *Udana* which may be the cause for rigidity and bradykinesia. Effect of therapy on *Chestasanga* (bradykinesia) is also promising due to combined effect of therapy as discussed above. Effect of therapy on signs of PD are noted improving with this protocol which may be due to combined effect of the therapy. Relief provided in *Vibandha* may be due to purgative action of *Eranda Bhristha Haritaki* as well as *Yapana Basti*. Relief in *Angamarda* and *Gurugatrata* may be due to combined effect of *Abhyanga*, *Swedana* and *Basti* and due to breakdown of *Avarana* process of *Kapha* on *Vyana* by the therapy.

CONCLUSION

The therapy provided significant results in the signs & symptoms of PD. The developed ayurvedic treatment protocol has definite role in the management of PD and it also helps to improve the quality of life of the patients over the modern medication.

Financial support and sponsorship

IPGT and RA, Gujarat Ayurved University, Jamnagar.

Conflicts of interest

There are no conflicts of interest.

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