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An Open Clinical Trial to Evaluate the Efficacy of Nyagrodhadi Asthapana Basti in the Management of Prameha Upadrava with Special Reference to Diabetic Neuropathy

Dr. Shilpa C. Shetty[1], Dr. S.K. Hiremath[2], Dr. Doddabasayya Kendadamath[3]

[1]PG Scholar, [2,3]Professor & HOD,
[1,3]Department of Panchakarma, Taranath Government Ayurvedic Medical College and Hospital, Bellary, Karnataka, India
[2]Department of Agada Tantra, Shri. D.G.M Ayurvedic Medical College and Hospital Gadag, Bellary, Karnataka, India

ABSTRACT

Background

Diabetic Neuropathy (DN) is one of the most common troublesome micro vascular complication of diabetes mellitus. It is clinically present in 50% of all diabetic patients. The prevalence of neuropathy is related to age, duration of diabetes and the quality of metabolic control. Vascular complications, both micro and macro vascular predominate the feature of Indian diabetic patients due to delayed diagnosis and late presentation of the syndrome. Therefore many complications like neuropathy are present at the time of diagnosis.

Prameha being one of the Maharoga, due to chronicity attains Upadrava Avastha (DPN). DPN is a Vata Pradhana Tridoshaja Vyadhi. Lakshanas of DPN are attributed to Avaranajanya Dhatukshayaja Samprapti of Madhumeha.

Objectives

To evaluate the efficacy of Nyagrodhadi Asthapana Basti in the management of Prameha Upadrava with special reference to Diabetic Neuropathy.

Methodology

- **Study Design:** An observational clinical study with pre, mid and post test design.
- **Intervention:** 30 patients of DPN were randomly selected based on the signs and symptoms of DPN. Patients were assigned into a single group and subjected to Nyagrodhadi Asthapana Basti for 8days (Yogabasti pattern).
- Data was collected before intervention i.e. 0th day, after Basti Karma i.e. on 9th day and after Parihara Kala i.e. 25th day.
- Results were statistically analysed before, during and after intervention by using descriptive and inferential statistics, 't' test-paired/dependent t test, Wilcoxon Matched Pairs test.

Results

- Statistical results on parameters showed highly significant result on symptoms of Daha (burning sensation), Chumchumayana (tingling sensation), Shoola (Pricking pain) and Dourbalya (weakness) on 9th day (i.e. after Bastikarma) and on 25th day (i.e. after Pariharakala) with 'p' value of 0.0001 and insignificant result on symptom of Supti (numbness) with 'p' value 1.000.
- Statistical result on parameters showed highly significant result in reduction of FBS, PPBS, FUS and PPUS with 'p' value 0.0001.
- The result obtained in the value of Toranto clinical neuropathy scoring system showed

KEYWORDS: *Bastikarma, Prameha Upadrava, Nyagrodhadi Gana, Diabetic Neuropathy*

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statistically highly significant result with 'p' value 0.0001.

Conclusion

- The Nyagrodhadi Asthapana Basti is found to be effective and safe in the management of Diabetic peripheral neuropathy

INTRODUCTION

Globally an estimated 463 million adults are living with diabetes mellitus, this will rise to 629 million by 2045. In India about 8.9% of total population have diabetes[1]. Symptoms of diabetic neuropathy include tingling sensation, numbness (which may become permanent), burning sensation (specially in the evening) and pain[2].

Prameha is one among Ashta Mahagada and Santarpanajanya Vyadhi[3]. Prameha is a disease condition characterized by repeated (Prakarsha), excessive (Prabhuta) and turbid (Aavila) urination in terms of frequency, quantity and clarity[4]. The science of Ayurveda has addressed the Diabetic Neuropathy symptoms like Suptata and Daha especially in Kara & Paada, under the context of Prameha Poorvaroopa[5]. Also Daha, Paridhoopana and Shoola are mentioned in Prameha Upadrava[6].

Basti Karma is said to be Chikitsardha of all treatments, Pradhana Chikitsa for Vata Shamana. It not only cures VatajaVikara but also Pittaja, Kaphaja, Raktaja, Sansargaja or Sannipataja condition of Doshas[7]. It acts as Apatarpana/ Santarpana, Samshamana, Samshodhana, Samgrahana of Doshas according to the drugs used in it. Asthapana Basti stabilizes the Vaya/Ayu, stabilizes the normal function of Dosha, Dhatu, and stabilizes Deha i.e. strength of the body.

Acharya Sushruta says that Nyagrodhadi Gana Asthapana Basti is to be administered in Prameha condition where burning sensation is present[8]. This condition correlates with Diabetic Neuropathy. Nyagrodhadi gana is explained by Acharya Sushruta and Vagbhata, acts as Pittahara, Dahahara, Sangrahi, Medhogna[9,10].

Considering the gravity of the problem existing in the society, for the proper remedial measure, a study has been undertaken to **"Evaluate the efficacy of Nyagrodhadi Asthapana Basti in the management of Prameha Upadrava with special reference to Diabetic Neuropathy".**

Inclusion Criteria:

- Patients with clinical positive history of type2 Diabetic mellitus (controlled & uncontrolled) having the symptoms of Diabetic sensorimotor polyneuropathy.
- Diagnosed case of Diabetic Neuropathy.
- Patients of Age group - 40 to 70 years, either sex were selected for the study.
- Those who are fit for Bastikarma

Exclusion criteria:

1. Type 1 diabetic mellitus.
2. Multisystem involved Diabetic patients with other complications were excluded.
3. Autonomic and focal neuropathic patients were excluded.
4. Diabetic neuropathy patient suffering from trauma, infectious wound, gangrene and non healing ulcers of foot were excluded.

Diagnostic criteria:

History of diabetes with any of the following signs and symptoms

- Pain & Burning sensation-Toes, Feet, Legs, Fingers, Hands, Forearms.
- Tingling sensation- Toes, Feet, Legs, Fingers, Hands, Forearms.
- Weakness - Toes, Feet, Legs, , Fingers, Hands, Forearms.
- Sensory loss-Toes, Feet, Legs, Fingers, Hands, Forearms.
- Physical examination- Examination of deep tendon reflexes, Sensitivity for light touch, deep touch, temperature, pin prick sensation, two point discrimination, vibration, proprioception.

Subjective criteria:

- Shoola (Pricking pain)
- Daha (Burning sensation)
- Suptata (Numbness)
- Dourbalya (Weakness)
- Chumchumayana (Tingling sensation)
- **Objective critera**:
- Toranto clinical neuropathy scoring system

OBSERVATION AND RESULTS

The data was collected and scoring was given to each of the symptoms using gradation index. The parameters were assessed before, during and after intervention. Results were analysed statistically using student paired 't' test and Wilcoxon Matched pairs test, descriptive and inferential statistics were applied. The results were analysed individually and overall assessment was done on the basis of previously mentioned criteria.

Table no. 1: Showing the Comparison of before treatment, during treatment and after treatment times with mean FBS scores by dependent t test.

Time points	Mean	SD	Mean Diff.	SD Diff.	% of change	t-value	P-value
Before treatment	156.37	43.07	16.42	40.60	10.50	2.2149	0.0348*
During treatment	139.95	46.48					
Before treatment	156.37	43.07	34.14	42.51	21.83	4.3980	0.0001*
After treatment	122.23	39.34					
During treatment	139.95	46.48	17.72	28.09	12.66	3.4540	0.0017*
After treatment	122.23	39.34					

*p<0.05

Table no. 2: Showing the Comparison of before treatment, during treatment and after treatment times with mean PPBS scores by dependent t test

Time points	Mean	SD	Mean Diff.	SD Diff.	% of change	t-value	P-value
Before treatment	250.82	69.21	37.22	58.16	14.84	3.5050	0.0015*
During treatment	213.61	72.29					
Before treatment	250.82	69.21	63.42	76.55	25.28	4.5373	0.0001*
After treatment	187.41	70.62					
During treatment	213.61	72.29	26.20	46.79	12.27	3.0669	0.0047*
After treatment	187.41	70.62					

*p<0.05

Table no. 3: Showing the Comparison of before treatment, during treatment and after treatment times with mean FUS scores by dependent t test

Time points	Mean	SD	Mean Diff.	SD Diff.	% of change	t-value	P-value
Before treatment	0.43	0.57	0.15	0.53	34.62	1.5570	0.1303
During treatment	0.28	0.50					
Before treatment	0.43	0.57	0.38	0.49	88.46	4.3227	0.0002*
After treatment	0.05	0.15					
During treatment	0.28	0.50	0.23	0.47	82.35	2.7276	0.0107*
After treatment	0.05	0.15					

*p<0.05

Table no. 4: Showing the Comparison of before treatment, during treatment and after treatment times with mean PPUS scores by dependent t test

Time points	Mean	SD	Mean Diff.	SD Diff.	% of change	t-value	P-value
Before treatment	1.27	0.93	0.53	0.82	42.11	3.5654	0.0013*
During treatment	0.73	0.78					
Before treatment	1.27	0.93	0.88	0.92	69.74	5.2809	0.0001*
After treatment	0.38	0.58					
During treatment	0.73	0.78	0.35	0.49	47.73	3.8812	0.0006*
After treatment	0.38	0.58					

*p<0.05

Table no. 5: Showing the Comparison of before treatment, during treatment and after treatment time points with status of Burning Sensation by Wilcoxon matched pairs test.

Burning Sensation	Before treatment	%	During treatment	%	After treatment	%
Nil	2	6.67	14	46.67	26	86.67
Mild	0	0.00	10	33.33	3	10.00
Moderate	3	10.00	5	16.67	0	0.00
Severe	25	83.33	1	3.33	1	3.33
Before vs during	Wilcoxon Matched pairs test, Z=4.5407, p=0.0001*					
Before vs After	Wilcoxon Matched pairs test, Z=4.5402, p=0.0001*					
During vs After	Wilcoxon Matched pairs test, Z=3.4077, p=0.0001*					

*p<0.05

Table no. 6: Showing the Comparison of before treatment, during treatment and after treatment time points with status of Pain by Wilcoxon matched pairs test

Pain	Before treatment	%	During treatment	%	After treatment	%
Nil	11	36.67	17	56.67	27	90.00
Mild	0	0.00	8	26.67	3	10.00
Moderate	4	13.33	5	16.67	0	0.00
Severe	15	50.00	0	0.00	0	0.00
Before vs during	Wilcoxon Matched pairs test, Z=3.8230, p=0.0001*					
Before vs After	Wilcoxon Matched pairs test, Z=3.8230, p=0.0001*					
During vs After	Wilcoxon Matched pairs test, Z=3.1798, p=0.0001*					

*p<0.05

Table no. 7: Showing the Comparison of before treatment, during treatment and after treatment time points with status of Weakness by Wilcoxon matched pairs test.

Weakness	Before treatment	%	During treatment	%	After treatment	%
Nil	1	3.33	9	30.00	24	80.00
Mild	0	0.00	16	53.33	2	6.67
Moderate	20	66.67	3	10.00	3	10.00
Severe	9	30.00	2	6.67	1	3.33
Before vs during	Wilcoxon Matched pairs test, Z=4.5407, p=0.0001*					
Before vs After	Wilcoxon Matched pairs test, Z=4.6226, p=0.0001*					
During vs After	Wilcoxon Matched pairs test, Z=3.6214, p=0.0003*					

*p<0.05

Table no. 8: Showing the Comparison of before treatment, during treatment and after treatment time points with status of Numbness by Wilcoxon matched pairs test

Numbness	Before treatment	%	During treatment	%	After treatment	%
Nil	23	76.67	23	76.67	23	76.67
Mild	0	0.00	0	0.00	0	0.00
Moderate	2	6.67	4	13.33	4	13.33
Severe	5	16.67	3	10.00	3	10.00
Before vs during	Wilcoxon Matched pairs test, Z=0.0000, p=1.0000					
Before vs After	Wilcoxon Matched pairs test, Z=0.0000, p=1.0000					
During vs After	Wilcoxon Matched pairs test, Z=0.0000, p=1.0000					

Table no. 9: Showing the Comparison of before treatment, during treatment and after treatment time points with status of Tingling sensation by Wilcoxon matched pairs test

Tingling sensation	Before treatment	%	During treatment	%	After treatment	%
Nil	4	13.33	14	46.67	25	83.33
Mild	0	0.00	9	30.00	4	13.33
Moderate	6	20.00	6	20.00	0	0.00
Severe	20	66.67	1	3.33	1	3.33
Before vs during	Wilcoxon Matched pairs test, Z=4.3724, p=0.0001*					
Before vs After	Wilcoxon Matched pairs test, Z=4.3722, p=0.0001*					
During vs After	Wilcoxon Matched pairs test, Z=3.2958, p=0.0010*					

*p<0.05

Table no. 10: Showing the Comparison of before treatment, during treatment and after treatment times with mean Toranto clinical neuropathy scoring system scores by dependent t test

Time points	Mean	SD	Mean Diff.	SD Diff.	% of change	t-value	P-value
Before treatment	7.00	1.41	2.80	1.21	40.00	12.6240	0.0001*
During treatment	4.20	2.09					
Before treatment	7.00	1.41	3.43	1.14	49.05	16.5666	0.0001*
After treatment	3.57	2.11					
During treatment	4.20	2.09	0.63	1.10	15.08	3.1591	0.0037*
After treatment	3.57	2.11					

*p<0.05

DISCUSSION

Daha (Burning sensation)

In the present study, out of 30 patients, 28 patients had main complaint of Daha. After intervention, 24 patients had complete relief on Daha, 3 patients got marked relief from Daha and in 1 patient there is no change. The result on symptom of Daha showed statistically highly significant result with 'P' value 0.0001.

Daha (Burning sensation) is the common and early presenting sensory symptom of Diabetic peripheral neuropathy, also clinical feature depend on type of nerve fiber involved. In the present study majority of patient had Daha as a main symptom confirmed the earlier observation. Here Daha is due to Pitta & raktavrita Vata conditon.

Chumchumayana (Tingling sensation)

In the present study, 26 patients had Chumchumayana. After intervention, 24 patients had complete relief, 4 patients had marked relief and 1 patient had no relief. The result obtained on the symptom of Chumchumayana showed statistically highly significant result with 'P' value 0.0001.

Chumchumayana (Tingling sensation) is the common and early presenting sensory symptom of Diabetic peripheral neuropathy. In the present study, majority of patient had Tingling sensation as a main symptom confirmed the earlier observation. Here Chumchumayana is due to Pitta & Raktavrita Vata.

Highly significant result on Daha and Chumchumayana were observed in present study may be because of therapeutic procedure Basti which helps to remove Avarana. Nyagrodhadi Ghrita used in Basti have Vatapittahara property and Nyagrodhadi Gana have Raktapittahara action hence acted upon above symptoms.

Shoola (Pricking pain)

In the present study, out of 30 patients, 19 patients had main complaint of Shoola. After intervention, 16 patients had complete relief on Shoola and 3 patients got marked relief from Shoola. The result on symptom of Shoola showed statistically highly significant result with 'P' value 0.0001.

Shoola (pricking pain) is the common and early presenting sensory symptom of Diabetic peripheral neuropathy, also clinical feature depend on type of nerve fiber involved. In the present study majority of patient had Shoola (pricking pain) as a main symptom confirmed the earlier observation. Here Shoola (pricking pain) is due to Raktavrita and Majjavrita Vata conditon. Result on Shoola may be due to Avrana hara action of Basti, also Nyagrodhadi gana had Rakta Shodhana action. Hence, useful in the above symptom.

Dourbalya (Weakness)

In the present study, 29 patients had symptom of Dourbalya (weakness). After intervention, 23 patients had complete relief, 2 patients had marked relief and 1 patient not got relief. The resultobtained in the symptom of Dourbalya (weakness) showed statistically highly significant result with 'P' value 0.0001.

Dourbalya (weakness) is due to Ojokshaya and this is arrested by Mootrsangrahaniya action of Dravyas.

Suptata (numbness)

In the present study, out of 30 patients, 7 patients had Suptata. After intervention, 4patient had mild relief and 3 patients had no relief.

The result obtained in the symptom of Suptata (numbness) showed statistically insignificant result with 'P' value 1.0000.

Suptata is due to Kaphavrita Vata. Out of 30 patients, only 7 patients were presented with the symptom of Suptata, hence no inferences can be drawn from the result obtained.

Blood for FBS

In the present study, it was observed that, before intervention mean value of FBS was 156.37 mg/dl which reduced to 122.23 mg/dl after the intervention. Result obtained in the mean value from before intervention to after intervention showed statistically significant result with the P value 0.0001.

Blood for PPBS

It was observed that, mean value of PPBS, before intervention was 250.82 mg/dl which was reduced to 187.41 mg/dl after the intervention. Result obtained in the mean value from before intervention to after intervention showed statistically highly significant result with the P value 0.0001.

Urine for FUS

It was observed that, mean value of FUS, before intervention was 0.43% which was reduced to 0.05% after the intervention. Result obtained in the mean value from before intervention to after intervention showed statistically highly significant result with the P value 0.0002.

Urine for PPUS

It was observed that, mean value of PPUS, before intervention was 1.27% which was reduced to 0.38% after the intervention. Result obtained in the mean value from before intervention to after intervention showed statistically highly significant result with the P value 0.0001.

Toranto clinical neuropathy scoring system

It was observed that, the Mean value of Toranto clinical neuropathy scoring system, before treatment was 7 which reduced to 3.57 after the treatment. The result obtained in the value of Toranto clinical neuropathy scoring system showed statistically highly significant result with 'P' value 0.0001.

In Summing up, it can be said that the present study showed the significant remission in symptoms of Diabetic peripheral neuropathy corroborated with definite reduction in blood sugar level and urine sugar level. Therefore it is imperative that Nyagrodhadi Asthapana Basti is beneficial in successful treatment of the disease.

Probable mode of action of Basti

Basti treatment is well established in vascular and neuronal disorder and often recommended in complicated and chronic disorders.

In DPN, Vata pradhana Tridosha vitiation takes place in the beginning and Samprapti is due to Avaranajanya Dhatu Kshaya.. Basti is best to correct Vata Dosha by removing the Avarana of Vata Dosha. Nyagrodhadi Asthapana Basti is specially adviced for Prameha associated with Daha, the drugs of Nyagrodhadi Asthapana Basti are Kapha Medohara and Rakta Pittahara in nature there by it cleanses the channels (Srotoshodhana) removes the Medas Avarana and regulates the movements of Vata.

Daha and Chumchumayana is due to Pitta and Raktavrita Vata, Basti helps to remove Avarana. Nyagrodhadi Ghrita used in Basti have Vatapittahara property and Nyagrodhadi Gana also have Rakta, Pittahara action hence it will act on these symptoms. Dourbalya is due to Ojokshaya and this will be arrested by Mootrsangrahaniya action of Dravyas. Shoola is due to Raktavrita and Majjavrita Vata and it will subside by Rakta Shodhana Karma of this Basti. Kapha Medahara action of Nyagrodhadi Gana Dravyas will act on Supata.

Probable mode of action of drugs

- In the Samprapti of the Avaranajanya Madhumeha the Kapha and Pitta are the main Doshas whereas the most predominant Dushyas are Medha and Kleda. So in its management Drugs have to be selected which are Meda and Kledahara as well as have the Rasayana effect. Nyagrodhadi Asthapana Basti as mentioned in Sushruta Samhita is been administered.
- Nyagrodhadi Gana contains 25 drugs and having properties like Daha Medoghna, Rakta Pittahara.As Madhumeha Upadravas are due to Avarana of Vata by Kapha, Pitta and other Dhatus, this treatment is useful in the disease.
- Most of the drugs are having Kashaya Rasa and Ruksha Guna these Gunas does the Soshana of Bahushleshma and Medas which are the main entity of Samprapti of Prameha.
- In the Nyagrodhadi Gana drugs like Nygrodha, Plaksha, Madhuka, Madhooka, Amra, Priyala, Vetasa, Kadamba and Kapitana are having Dahahara, Pittashamana and Rakta Shodhana properties which helps to relieve Daha and Chumchumayana symptoms which are due to Pitta and Raktavrita vata.
- Madhuka, Madhooka, Kapitana, Shallaki, Palasha , Bhallataka are having Rasayana and Bruhmana properties which will be helpful in the symptom of Dourbalya.
- Suptata is due to Raktavrita Vata and Medhavrita Vata, drugs like Ashwtha, Plaksha, Amra, Badara and Tinduka does Raktashodhana and Nyagrodhadi Gana is Medoghna hence it will act on this symptom.
- Kakubha , Amra, Jambu, Katphala, Tinduka, Madhuka, Palasha and Nandivriksha have been proven to have hypoglycemic effect through clinical trials, so it will act on FBS, PPBS, FUS and PPUS values.
- Amrasthi, Shalmali Twak, Yashtimadhu and Arjuna had analgesic, neuroprotective and immune stimulant properties, established by various research works.
- Jambu, Amra, Plaksha, Vata, Kapitana, Udumbara, Bhallataka and Ashwatha are said to have Mootrasangrahaniya and Sthambana effect, which helps in reducing the Dhatukshaya through Prabhoota mootrata and it corrects Dhatu Kshaya related Vata Prakopa.

Considering these qualities, which are necessary for the management of Doshas and Dhatus involved in DPN, it is selected in the clinical trial.

CONCLUSION

- Diabetic peripheral neuropathy is a complex multifactorial disorder with varied clinical features.
- It cannot be directly correlated to any predefined condition in Ayurveda.
- Based on Nidana, Dosha Dushya Sammurchana and further progression in the Samprapti of Prameha, it can be considered as one of the Upadrava Avastha of Prameha. Nature of this Avastha of Prameha resulting from Avaranajanya Dhatukshayaja Samprapti of Madhumeha.

- Clinical presentation based on type of Avarana and also Laxanas of Dhatukshaya.
- The study was an observational, which was conducted on 30 patients. Among them, maximum numbers of patients were males and incidence of neuropathy was noticed more in age group above 45 years. Main etiological factor for development of Diabetic peripheral neuropathy is Chronic Diabetes mellitus and Uncontrolled Diabetes mellitus.
- Statistical results on parameters showed highly significant result on symptoms of Burning sensation, Tingling sensation, Pricking pain and Weakness on 9th day (i.e. after Basti Karma) and on 25th day (i.e. after Parihara Kala) with P value of 0.0001 and insignificant result on symptom of Numbness with p value 1.000.
- Statistical result on parameters showed highly significant result in reduction of FBS, PPBS, FUS and PPUS values.
- The Nyagrodhadi Asthapana Basti is found to be effective and safe in the management of Diabetic peripheral neuropathy.

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