

A CLINICAL OBSERVATIONAL STUDY IN THE MANAGEMENT OF DIABETIC PERIPHERAL NEUROPATHY

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Abstract

Diabetic Peripheral Neuropathy (DPN) is one of the most troublesome micro vascular complications of Diabetes Mellitus and which is the major cause for lower limb amputation. To manage DPN, Takradhara and Pushyanuga churna were planned in order to have an effective and safe result. Objective of the study is to evaluate the combined effect of Takradhara and Pushyanuga Churna (internally) in DPN. It is an observational clinical study with pre, mid and posttest design, where 40 patients of DPN were randomly selected and subjected to Takradhara procedure for 1st 10 days. Pushyanuga churna was administered with a dose of 6 g bd before food with warm water for 30 days (including the period of dhara). Result obtained with respect to the parameter daha (burning pain), cumcumayana (tingling sensation) had showed statistically highly significant result with p value 0.000, suptata (numbness) showed significant result with p value 0.014, dourbalya (weakness in extremities) showed insignificant result with p value 0.864. Hence, the combination of Takradhara and Pushyanuga churna are found to be effective in management of DPN.

Keywords: Diabetic Peripheral Neuropathy; Takradhara; Pushyanuga churna; Diabetes mellitus.

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INTRODUCTION

Diabetic Peripheral neuropathy is a descriptive term meaning a demonstrable disorder either clinically evident or subclinical that occurs in the setting of Diabetes mellitus (DM) without other cause of neuropathy. It is one of the most troublesome microvascular complication of DM, one in 6 Diabetics has neuropathy^{[1][2]} is that approximately 50 percent of patients with Diabetics will eventually develop neuropathy and which is the major cause for lower limb amputation.^[3] The prevalence of neuropathy is related to age, duration of Diabetes Mellitus and the quality of metabolic control. The Diabetic Control & Complication Trial study proved that a Glycosylated Haemoglobin (HbA1c) reduction from 9 to 7% for a mean follow up of 6.5 years was able both to reduce the onset of Diabetic Peripheral Neuropathy (from 9.6% to 2.8%) and to slow its progression.^{[4][5]} However, Euglycaemia is only able to halt the progression, rather than reverse it, once the nerve damage has been established. Simple measures like good glycaemic control (which reduces incidence and slows the progression of disease), neuro-adjuvants, following strict diet, visual inspection of feet and foot care can save the feet at risk. Currently available treatments are highly symptomatic, often ineffective and limited by side effects.^[6] This leads to a search for alternative method of which is safer, simpler and economical. Madhumeha is one among the four varieties of vataja prameha which has similarity with the disease Diabetes Mellitus. Diabetic Peripheral Neuropathy is one of the Upadrava (complication) of Diabetes Mellitus. The upadrava will have the samprapti (pathology) of its own. When main disease is managed well, complication will disappear.^[7] According to the Charaka samhita, it is mentioned in the context of madhumeha, due to strong bondage between morbid doshas and dushyas, madhumeha attains asadhya (incurable) stage, which in turn causes any upadrava.^[8] The various nidanas (etiologies), dosha dushya

sammurchana and further progression in samprapti are similar to that of Diabetic Peripheral Neuropathy. Daha (burning sensation), suptata (numbness), harsha (tingling sensation), shosha (wasting), dourbalya (weakness), anga sada (lethargy) are the symptoms attributed as the upadrava of Madhumeha are almost similar to the description of Diabetic Peripheral Neuropathy. DPN is a vatapradhana tridoshaja vyadhi and also it is a dhatukshayja (due to diminished dhatus) stage of madhumeha. To manage this condition Takradhara is a type of the Shirodhara procedure, in this medicated Takra (butter milk) is used, which acts by normalising aggravated doshas, also which acts as rasayana (rejuninator). Pushyanuga churna which has Tridosha shamaka action, helps in reducing the symptoms of DPN such as daha, cumcumayana etc. Hence, the present study was intended to assess the combined effect of Takra dhara and Pushyanuga churna (internally) in the management of DPN.

MATERIAL AND METHODS

Materials

The present study was an observational clinical study. The materials selected for the study includes,

- Takra and Amalaki kwatha for therapeutic procedure Takra dhara.
- Pushyanuga churna for internal administration.

Amalaki kwatha Churna

Fresh samples of Amalaki kwatha churna was taken from GAMC Hospital stores, Mysore (prepared and supplied by Government Central Pharmacy, Bangalore)

Pushyanuga churna

Fresh samples of Pushyanuga churna was taken from GAMC Hospital stores, Mysore

(prepared and supplied by Government Central Pharmacy, Bangalore)

Method of Preparation of Amalaki Kwatha

120 g (3 pala) of kwatha churna of amalaki (coarse powder of *Embilica officinalis*) was boiled in 5 litres (10 kudava) of water till it reduced to 1 litre (2 kudava). Then it was filtered and collected in a stainless steel vessel. This 1 litre (2 kudava) of kwatha was used along with the Takra (butter milk).^[9]

Method of Preparation of Takra

1500 ml (2 Prastha) of milk diluted with 6000 ml (8 Prastha) of water, boiled and reduced to original quantity of milk i.e. 1500 ml (2 prastha). It was allowed to cool on its own. After cooling, little quantity of curd was added and kept overnight to get fermented. Next day morning fermented curd was churned well, upper cream part is removed. At this stage, takra was ready to use. This Takra was added to amalaki Kwatha (decoction).^[10]

Methods

Inclusion criteria

- Patients with either sex of age group between 30 to 70 years were included.
- Insulin Dependent Diabetes Mellitus (IDDM) & Non Insulin Dependent Diabetes Mellitus (NIDDM) with peripheral neuropathy, both fresh & treated patients were included.

Exclusion criteria

Patients of DPN

- With other metabolic and endocrine diseases were excluded.
- With autonomic, proximal and focal neuropathic states were excluded.
- Suffering from infectious diseases was excluded.

- With wound/ulcers were excluded.
- With other complications of DM such as Diabetic Nephropathy, Diabetic Ketoacidosis and Diabetic Coma were excluded

Diagnostic criteria:

History of Diabetes Mellitus with any of the following symptoms of DPN

- Daha (Burning pain in extremities)
- Cumcumayana (Tingling sensation in extremities)
- Suptata (Numbness in extremities)
- Dourbalya (Weakness in extremities)

Assessment criteria (Subjective)

1. Daha (Burning sensation) in extremities.
2. Cumcumayana (Tingling sensation) in extremities.
3. Dourbalya (weakness) in extremities.
4. Suptata (Sensory loss) in extremities

Gradation Index for subjective criteria is shown in Table 1.

Physical assessment

Physical assessment consists of foot inspection, vibration perception using 128Hz tuning fork and muscle stretch reflex at ankle. Assessment was done on 1st day, 10th day and on 30th day.

Investigations

Investigations conducted in the study were,

- Fasting Blood Sugar (FBS)
- Post Prandial Blood Sugar (PPBS)
- Urine for Albumin, Sugar and Microscopy

Other required investigations were carried out wherever necessary to rule out other systemic diseases.

Study Design

This is an observational clinical study with pre, mid and posttest design. Random sampling method was employed. Patients diagnosed to have Diabetic Peripheral Neuropathy were selected incidentally from the OPD, IPD of Government Ayurvedic Hospital, Mysore. Study was carried out as per ethical clearance guidelines with institutional ethical clearance number 244113.

Intervention

All 40 patients were subjected to Takra Dhara procedure for first 10 days of intervention for duration of 45 minutes. All 40 patients were administered with Pushyanuga Churna internally, 6 g BD, before food with warm water (as adjuvant), during whole period of intervention, including the period of dhara. Duration of intervention was 30 days.

Procedure of Takradhara

Poorva Karma (pre-operative procedure)

All patients were subjected to dhara procedure in the morning hours. Patients were made to lie down on the dhara table in supine position. The eyes were covered with cotton pad and lightly bandaged to prevent the drugs entering the eyes during the procedure. Takra was taken in a steel vessel and made Luke warm.

Pradhana Karma (operative)

The takra was poured in dhara patra (vessel used for the procedure) and then it was allowed to flow on the forehead of the patients, in medium pace (i.e. neither very fast nor very slow rate) from a height of 4 inches. When the takra started pouring, then the vessel was moved in oscillating fashion in the stream of the flow. The takra was collected in separate vessel, reheated and used for dhara. The procedure was repeated for 45 minutes counting it as one sitting.

Pashchat Karma (post-operative)

After completion of procedure, eye bandage was removed and patients were allowed to take rest for few seconds. Takra adhered on the forehead and part of head was wiped off with a clean napkin. The Rasna choorna (powder of *Alpinia galanga*) was rubbed over the anterior fontanel. Then patients were asked to take rest for about 10 minutes. The patients were asked to take Luke warm water bath after one hour.

Overall assessment

The following criteria were framed to assess the overall effect of the intervention on the patients of Diabetic Peripheral Neuropathy:

1. Complete relief: Complete absence of symptoms of DPN was taken as complete improvement.
2. Marked improvement: More than 75% and less than 100% improvements in the symptoms was considered as marked improvement.
3. Moderate improvement: Improvement between 50% to 75% in symptoms was taken as moderate improvement.
4. Mild improvement: Improvement between 25% to 50% in symptoms was taken mild improvement.
5. Insignificant improvement: No change or less than 25% improvement in symptoms was taken as no improvement.

Statistical analysis

Results were analysed statistically using Contingency coefficient test, Chi square test and Descriptive statistics using SPSS (Statistical presentation of system software) for windows.

Table 1: Showing Gradation Index

Sl. No.	Assessment tools
	Daha (Burning sensation in extremities)
1	Da0- No daha Da1- Mild/ occasional Da2- Moderate /continuous Da3- Severe /disturbed sleep
	Cumcumayana (Tingling sensation in extremities)
2	C0- No pain C1- Mild/ occasional C2- Moderate /continuous C3- Severe /disturbed sleep
	Dourbalya (Weakness in extremities)
3	D0- Absent D1- Mild/present occasional D2- Moderate / present when working D3- Severe present continuously on rest
	Suptata (Numbness in extremities)
4	S0- Absent S1- Mild/occasional S2- Moderate/continuous when walking S3- Severe / whole day

RESULTS

In the present study, result obtained with respect to the parameters daha (burning sensation) and cumcumayana (tingling sensation) which showed statistically highly significant result with p value 0.000 (Table 2 and Table 3), parameter suptata (numbness) which showed statistically significant result with p value 0.04 (Table 5) and parameter dourbalya (weakness) which showed statistically insignificant result with p value 0.864. (Table 4) Overall effect of therapy showed, 5 (12.5%) patients had complete relief, 32 (80%) patients had marked improvement and 3 (7.5%) patients had moderate improvement. (Table 6)

DISCUSSION

Discussion on observations

In the present study, maximum prevalence of DPN was seen in the age group between 45 to 65 years. Age prediction in neuropathy is not possible as duration and control of DM is greater predictor than chronological age.

Number of male patients were higher i.e. 35 (87.5%) than female patients. Male patients were found more because in general, a chance of development of Diabetic Peripheral Neuropathy is more in men than in women.^[11] Maximum 36 (90%) patients were treated before. Treated cases were found more because of chronic nature of disease. Another probable reason may be DPN is a pain predominant disease, as patient wander from one centre to other seeking early results. Maximum 30 (75%) patients had disturbed sleep, because neuropathic pain which worsens at night.^[12] Maximum 28 (70%) patients had chronicity of DM from 4 years onwards. The prevalence of neuropathy in Diabetes Mellitus is very high among those who had Diabetes Mellitus for at least 10 years same observed in this study. Among 40 patients, 29 (72.5%) Patient had habit of tobacco smoking. Smoking speeds up neuropathy in Diabetic persons. Nicotine present in cigarette hastens up nerve damage in Diabetes mellitus.^[13] Tobacco smoking causes atherosclerosis and results in reduction of microcirculation. This may be the reason to develop neuropathy in these patients.

Table 2: Showing the results of clinical trial on symptom of Daha (Burning sensation)

Duration	Daha (Burning sensation)				Total
	Nil	Mild	Moderate	Severe	
Before R _x (0 day)	3 7.5%	0 0%	30 75%	7 17.5%	40 100.0%
During R _x (10 th day)	34 85%	6 15%	0 0%	0 0%	40 100.0%
After R _x (on 30 th day)	34 85%	6 15%	0 0%	0 0%	40 100.0%

Symmetric Measures			
		Value	Approximate Significance
Nominal by Nominal	Contingency Coefficient	0.695	0.000
N of Valid Cases		90	

Table 3: Showing the results of clinical trial on symptom of Cumcumayana

Duration	Cumcumayana(Tingling sensation)				Total
	Nil	Mild	Moderate	Severe	
Before(0 day)	3 7.5%	0 .0%	35 87.5%	2 5%	30 100%
During(10 th day)	15 37.5%	17 42.5%	6 15%	2 5%	30 100%
After(30 th day)	15 37.5%	17 42.5%	6 15%	2 5%	30 100%

Symmetric Measures			
		Value	Approximate Significance
Nominal by Nominal	Contingency Coefficient	0.600	0.000
N of Valid Cases		90	

Table 4: Showing the results of clinical trial on symptom of Dourbalya (weakness in extremities)

Duration	Dourbalya(Weakness in extremities)		Total
	Nil	Moderate	
Before(0 day)	37 92.5%	3 7.5%	30 100%
During(10 th day)	38 95%	2 5%	30 100%
After(30 th day)	38 92.5%	2 5%	30 100%

Symmetric Measures			
		Value	Approximate Significance
Nominal by Nominal	Contingency Coefficient	0.119	0.864
N of Valid Cases		90	

Table 5: Showing the results of clinical trial on symptom of Suptata

Duration	Suptata				Total
	Nil	Mild	Moderate	Severe	
Before	18 0.45%	0 0%	19 47.5%	3 7.5%	30 100%
During	20 50%	3 7.5%	10 25%	7 17.5%	30 100%
After	20 50%	3 7.5%	10 25%	7 17.5%	30 100%
Symmetric Measures					
Nominal by Nominal		Contingency Coefficient		Value	Approximate Significance
		N of Valid Cases		0.418	0.014
				90	

Table 6: Showing Overall effect of therapy on result

Result	Frequency	Percentage (%)
Complete	5	12.5
Marked	32	80.0
Moderate	3	7.5
Total	40	100
		FINAL
Chi-Square		29.600
Df		2
Asymptotic Significance		0.000

In present study, a sizable sample i.e. 24 (60%) patients reported with stress. Stress is one of the precipitating factors for increasing blood sugar level by secreting excessive cortisol. Increasing blood sugar is a key factor for developing neuropathy.^[14] Hence, it is said that stress is also one of the precipitating factor in development of DPN.

In this study, maximum 36 (90%) patients were Hindus, 24 (60%) patients were graduates, 29 (72.5%) patients belong to upper middle class, 23 (74%) patients were from urban area, 30 (75%) patients were on mixed diet, 25 (62.5%) patients were of Vata-pitta prakruti. Following observations does not have any research significance.

Discussion on Results

In the present study, among 40 patients, 37 patients had main complaint of daha.

After intervention, 34 (85%) patients had complete relief on daha, 6 (15%) patients got marked relief which showed statistically highly significant result with ‘P’ value 0.000. Daha (Burning sensation in extremities) 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 patients had daha as a main symptom confirmed the earlier observation. Among 40 patients, 37 patients had cumcumayana. After intervention, 15 (37.5%) patients had complete relief, 6 (15%) patients had moderate relief, 17 (42.5) patients had mild relief and 2 (5%) patient had no relief, which showed statistically highly significant result with ‘P’ value 0.000. Cumcumayana (Tingling sensation) is the common and early presenting sensory symptom of Diabetic Peripheral Neuropathy. In the present study, majority of patients had cumcumayana as a main

symptom confirmed the earlier observation. Among 40 patients, 22 patients had suptata. After intervention, 20 (50%) patients had complete relief, 3 (7.5%) marked relief, 10 (25%) patients had moderate relief and 7 (17.5%) patients had no relief. Significant result on daha, cumcumayana, suptata were observed on present study may be because of therapeutic procedure Takradhara which helps to pacify vata dosha as DPN is Vata predominant tridoshaja disease. Dhara also has stimulative effect and it improves peripheral circulation. Pushyanuga churna also have Tridosha shamaka action hence acted upon above symptoms.

In the present study, only 3 patients had symptom of dourbalya. After intervention, 1 patient had marked relief and 2 patients had mild relief. The result obtained in the symptom of dourbalya showed statistically non-significant result with 'P' value 0.864. Out of 40 patients, only 3 patients were presented with the symptom of dourbalya, hence no inferences can be drawn from the result obtained.

In the present study, it was observed that, before intervention mean value of FBS was 123.33 mg/dl which reduced to 103.86 mg/dl after the intervention. Result obtained in the mean value from before intervention to after intervention (F=19.466) showed statistically significant result with the P value 0.002. It was also observed that, mean value of PPBS, before intervention was 188.56 mg/dl which was reduced to 148.30 mg/dl after the intervention. Result obtained in the mean value from before intervention to after intervention (F=40.266) showed statistically significant result with the P value 0.001. Even though, no medications were selected particularly for the management of Diabetes mellitus in the intervention, Takradhara which is selected for the study, has pramehagna action, probably it might have influenced in normalising the blood sugar levels. Pushyanuga churna, is selected for addressing

neuropathic symptoms. Contents of which possesses pramehagna action might have influenced in reducing Blood sugar level. Ingredients which have pramehagna action are Yasthimadhu (*Glycerrhiza glabra*), Bilva (*Eagle marmelose*), Jambvasti (seeds of *Eugelina jambolina*), Amrasti (seeds of mango), Rakta chandana (red sandal wood), Arjuna (*Terminalia arjuna*), Pata (*Cissempeles pariera*), Mustaka (*Cyprus rotendus*), Amalaki (*Embllica officinalis*). Many research works were conducted in above said drugs established to have antidiabetic action.^{[15][16][17][18]}

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 madhumeha, it can be considered as one of the upadrava stage of madhumeha. Nature of this stage resulting from madhumehajanya dhatukshayaja pathology. Clinical presentation based on symptoms of dhaukshayaja stage of madhumeha. The study was an observational, which was conducted on 40 patients. Statistical results on parameters showed highly significant result on symptoms of daha, cumcumayana at the end of intervention with P value of 0.000 and significant result on symptom of suptata with p value 0.014, except for symptom of Dourbalya which showed statistically insignificant result with P value of 0.864. The combination of Takradhara and Pushyanuga churna are found to be effective in management of Diabetic Peripheral neuropathy.

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