

Clinical study to evaluate the efficacy of Madhutailika Basti in the management of Madhumehajanya Nadiprathan Shotha w.r.t. Diabetic Neuropathy

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Aim and Objectives: To evaluate clinical efficacy of Madhutailika Basti in the management of Madhumehajanya Nadipratan Shotha w.r.t. Diabetes Neuropathy. **Methodology:** A total of 30 subjects were selected from the OPD and IPD of Dr. D.Y. Patil College of Ayurveda, Research Institute and Hospital. The patients were assessed according to case report form for the duration of 30 days. In present study the reassessment of Madhutailika Basti has been done to understand its efficacy in Diabetic Neuropathy. Madhutailika Basti, contains Madhu, Erandamool Kwatha, Til Taila, Shatapushpa Kalka, Saindhava Lavana. **Conclusion:** The improvement was calculated by subjective parameters like Prabhutavil Mutrata (polyurea), Kshudha Vruddhi (polyphasia), Pippasa Vruddhi (polydipsia), Dourbalya (general weakness), Paridaha (burning sensation), Kandū (itching), Bhrama (vertigo), Anidra (insomnia), Nakta Mutra Pravrutti (urination during night), Hast Pada Chimchimaya (tingling) to score clinical outcome is indicated in the Management of neuropathic pain associated with diabetic neuropathy. Madhutailika Basti presents window of opportunity in the clinical management of Diabetic Neuropathy.

Keywords: Diabetic Neuropathy, Madhutailika Basti, Madhumehajanya Nadipratan Shotha

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Introduction

Diabetic peripheral neuropathy is a nerve damaging disorder associated with diabetes mellitus. Diabetic microvascular injuries involving small blood vessels that supplies to nerves i.e., *Vasa nervorum* are responsible for diabetic peripheral neuropathy.

In *Ayurveda*, *Madhumeha Vyadhi* has similarity with Diabetes Mellitus. *Madhumeha* is one of the four varieties of *Vataja Prameha*. It is *Asadhya* (incurable) stage, *Madhumeha* gives rise to many *Upadrava* (complication) viz. *Daha* (burning sensation), *Suptata* (numbness), *Harsha* (tingling sensation), *Shosha* (wasting), *Dourbalya* (weakness), and *Angasada*. These *Upadrava* (complication) of *Madhumeha*, which are nearly similar to the symptoms of diabetic peripheral neuropathy.

It is a common condition, often unreported and inadequately treated resulting in a great deal of morbidity.

The functions of peripheral nerves are damaged in diabetic peripheral neuropathy. In *Ayurveda*, *Vata Dosha* especially *Vyanavayu* performs the functions of peripheral nerves. The functions of normal *Vata Dosha* are *Utsahashakti* (enthusiasm), *Shwasa Prashwasa Kriya* (respiration), *Chesta* (motor and reflex activities) etc; hence it acts as receptor, as well as a stimulator.

The function of a peripheral nerve is to transmit signals from the spinal cord to the rest of the body or to transmit sensory information from the rest of the body to the spinal cord. Nerve impulse can be correlate with functions of normal *Vata Dosha* as it is self-originated, propagated, it reaches anywhere. Hence, the disease Diabetic peripheral neuropathy is considered as an abnormal function of *Vata Dosha*.

Prevalence of diabetic peripheral neuropathy in India is about 26.1%. In region of Maharashtra, it was found to be 30.3% in 2015 study. As estimated, it is 2.8% affecting 171 million people worldwide, in year 2000. With current trends, the prevalence worldwide is estimated to reach 4.4%, affecting 366 million people by the year 2030.

Hypothesis

- H_0 - *Madhutilika Basti* has no significant effect on *Madhumehajanya Nadipratan Shotha*.t Diabetic Neuropathy

- H_1 - *Madhutilika Basti* has significant effect on *Madhumehajanya Nadipratan Shotha*.t Diabetic Neuropathy

Need of Study

Diabetic neuropathy is relatively earlier and commonest poorly controlled complication occurring in almost every 3rd diabetic in same form or the other. Painful diabetic peripheral neuropathy is treated with tricyclic antidepressants, anticonvulsants, opioids, and topical capsaicin, of which duloxetine and pregabalin have been approved by the US FDA. These regimens are effective but most of them are expensive and having side effect. *Madhutilika Basti* is believed to have a noteworthy role in the management of such impaired metabolic condition by importing equilibrium state of *Doshas*, nourishes the *Dhatu* and maintains the blood sugar level. This research study is being conducted to find out cost effective treatment of Diabetes Neuropathy and improve the quality of life. The number of people suffering from diabetic neuropathy is rising tremendously and at an alarming rate on the global scale which is having a strong negative impact on the entire society at large and hence it is the prime need of the hour to find a reliable solution in order to combat the problem and hence the current study was undertaken.

Aim

To evaluate clinical efficacy of *Madhutilika Basti* in the management of *Madhumehajanya Nadipratan Shotha* w.r.t Diabetic Neuropathy

Objectives

01. To study the pathogenesis of *Madhumehajanya Nadipratan Shotha*.t. Diabetic Neuropathy
02. To develop a cost-effective treatment in the management of *Madhumehajanya Nadipratan Shotha*.t. Diabetic Neuropathy
03. To improve quality of life & prevent further complications.

Materials and Methods

Materials

Madhutilika Basti (*Uttarakhanda* in *Sharangadhara Samhita*, *Niruharana Basti* (06.29/30/31)

Ingredients

- *Madhu* (Honey) – 4 Pala – (16 Tola) - 160 ml
- *Erandamool Kwatha* (*Ricinus communis*) - 8 Pala (32 tola) = 320 ml
- *Til Tail* (*Sesamum indicum*) - 4 Pala (16 Tola) - 160 ml
- *Satapushpa Kalka* (*Anethum sowa*) - 3 Karsha = 30 gm
- *Saindhava* - 1 Karsha = 10 gms

SOP of preparation of Madhutailika Basti

Initially 100ml of *Madhu* and 5gm of *Saindhava Lavana* are taken in the equipment. Preparation is continued until *Lavana* is completely dissolved. Then 100ml of *Tila Taila* is added and again mixed for specific time period. Here oil layer should become minute globules, mixture should become homogeneous. It is followed by adding of 10gm of *Shatapushpa Kalka*. Mixing is done so that *Kalka* particles remain uniformly distributed and do not settle down at the base of the vessel. At last 320 ml of *Erandamula Kwatha* is added, mixing is continued until it properly mixes with oil globules. Homogeneity of final mixture is assessed with certain features under the heading *Suyojithaniruhalakshana*. Finally quantity of 530 ml *Basti* formulation is measured.

Methods

Research Place: Dept of Kayachikitsa, OPD/IPD, DY Patil School of Ayurveda, Nerul, Navi Mumbai

Table 1: Type of Study Single Arm Clinical Study

Sample size	30 patients
Medicine	Madhutailika Basti
Dose	530 ml
Duration	8 days
Kala	Prataha (Abhakata)
Type of Basti	Niruhavata
Parihara Kala	16 days

Sample

Total numbers of 30 subjects were selected from the OPD and IPD of Dr. D.Y. Patil College of Ayurveda, Research Institute and Hospital.

The patients were assessed according to case report form.

Method of Data Collection

A Performa was be prepared with details of history, physical examination, pathological investigations. The presenting symptoms were observed 0th day, 10th day, 20th day, 30th day.

Study Design

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Screening of the subjects was done

↓

Subjects were selected who were fulfilling the inclusive criteria

↓

Informed consent was taken from each subject

↓

Clinical study was conducted on 30 subjects

↓

CRF was filled

↓

Madhutailika Basti was given for 8 Days

↓

Follow up after every 10 days

↓

Study was conducted for 1 month

↓

Assessment was done according to the data collected

↓

According to the statistical analysis, Observation and result were drawn

↓

Discussion was done after completion of study

↓

Assessment was done according to the data collected

↓

Conclusion was drawn

Inclusion Criteria

- Age group 18-70 yrs

- Patients with clinical positive of type 2 diabetes mellitus having positive symptoms of Diabetic Neuropathy
- Patients on OHA

Exclusion Criteria

- Patients having insulin-dependent DM
- Patients having Diabetic complications other than neuropathy
- Radiculopathies
- Coronary artery disease, peripheral artery disease etc
- Tuberculosis, AIDS, and malignancies.
- Pregnant women

Duration of Treatment

- The duration of study was for 1 month.
- A Performa was prepared with details of history, physical examination, pathological investigations.
- The presenting symptoms were observed 0th day, 10th day, 20th day, 30th

Investigations

- CBC, ESR, BSL - Fasting & PP, Lipid Profile, Sr.Creatinine, Urine R/M, ECG
- Neuropathy analyser (Biothesiometer) which is specifically designed electronic machine to record the perceptions of vibration, heat and cold sensations exactly with the help of computer.
- We had used this instrument to record these sensations before and after the treatment at Diabecare Diabetes & Thyroid Clinic, Nerul, Navi Mumbai.
- Vibration perception study - It is used as a measure of large nerve fibre function in Studies of patient with diabetes and in other disorder.

Assessment Criteria

Table 2: Scoring of symptoms

Gradation	Scoring of Symptoms
Numbness	
No numbness	00
Numbness only in feet	01
Numbness on whole lower limbs	02
Numbness on other parts of the body also	03
Tingling sensation	
No tingling sensation	00
Tingling sensation only on feet	01

Tingling sensation on whole lower limbs	02
Tingling sensation on other parts of the body together with lower limbs	03
Burning sensation	
No burning sensation	00
Burning sensation only in foot soles	01
Burning sensation in whole lower limbs	02
Burning sensation in all over the body	03
Pain	
No pain	00
Pain Only in feet	01
Pain in legs	02
Pain in legs with difficulty in walking	03

Other Parameters

Table 3: Neuropathy Disability Score

Parameter	Grade 0	Grade 1	Grade 2	Total sum for both limbs
Ankle Reflex	Normal reflex	Present on reinforcement	Absent	4
Vibration	Present	Reduced/Absent	-	2
Pin Prick	Present	Absent	-	2
Temperature	Present	Absent	-	2

Maximum abnormal score is 10,

- Score of 3-5: symptoms of Mild Neuropathy,
- Score of 6-8: symptoms of Moderate Neuropathy,

Score of 9 or 10: symptoms of Severe Neuropathy

Observations and Results

Table 4: Wilcoxon Test

SN	Variables	BT	AT	p value	Result	Relief %
1.	Suptata	95	55	< 0.0001	ES	47.10%
2.	Hastpada Chimcimayan	85	60	< 0.0023	ES	29.41%
3.	Daha	94	56	< 0.0001	ES	40.42%
4.	Pain	88	58	< 0.0001	ES	34.09%
5.	NDS	239	137	< 0.0001	ES	42.68%

ES - Extremely Significant

The *Madhutailika Basti* provided highly significant relief in all the symptoms.

- p value of *Suptata* is <0.0001, hence result is extremely significant.
- p value of *Hastpada Chimcimayan* is <0.0023, hence result is extremely significant.
- p value of *Daha* is <0.0001, hence result is extremely significant.
- p value of *Pain* is <0.0001, hence result is extremely significant.

- p value of NDS is <0.0001, hence result is extremely significant.

Table 5: Paired 't' Test

SN	Variables	BT	AT	T value	P value	Result	% Relief
1.	HB	13.19	13.22	1	0.1628	NS	-0.22%
2.	ESR	13.086	13.733	0.3725	0.3561	NS	-4.94%
3.	Cholesterol	196.63	192.5	0.914	0.1841	NS	2.10%
4.	Bilirubin	0.82	0.8067	3.34	<=0.0012	ES	ES
5.	BSL Fasting	128.05	118.09	2.565	0.0079	ES	ES
6.	BSL PP	200.22	176.77	3.189	0.0017	ES	ES
7.	SR Cretinine	0.8029	0.7968	2.108	0.0217	ES	ES
8.	SR Uric Acid	6.054	6.107	2.257	0.0159	ES	ES

NS - Non-Significant, ES - Extremely Significant

- P value of **HB** is 1628 hence result is **non-significant**.
- P value of **ESR** is 3561 hence result is **non-significant**.
- P value of **Cholesterol** is 1841 hence result is **non-significant**.
- P value of **Bilirubin** is <=0.0012 hence result is
- P value of **BSL Fasting** is 0079 hence result is **extremelysignificant**.
- P value of **BSL PP** is 0017 hence result is **extremelysignificant**.
- P value of **SR Cretinine** is 0217 hence result is **extremelysignificant**.
- P value of **SR Uric Acid** is 0159 hence result is **extremelysignificant**.

Vibration Perception Test (VPT)

Table 6: Right Foot

SN	Variables	BT	AT	T value	P value	Result	Relief %
1.	Toe	16.791	13.894	7.126	<0.0001	ES	17.25%
2.	1st Mth	16.263	13.701	6.871	<0.0001	ES	15.75%
3.	3rd Mth	15.765	12.909	6.072	<0.0001	ES	18.12%
4.	5th Mth	14.425	11.89	5.808	<0.0001	ES	17.57%
5.	Instep	14.674	12.351	5.425	<0.0001	ES	15.83%
6.	Heel	14.787	12.712	4.543	<0.0001	ES	14.03%

ES - Extremely Significant

Table 7: Left Foot

SN	Variables	BT	AT	T value	P value	Result	Relief %
1.	Toe	15.447	12.518	6.38	<0.0001	ES	18.96%
2.	1st Mth	15.394	12.91	5.196	<0.0001	ES	16.14%
3.	3rd Mth	14.736	12.477	4.469	0.0001	ES	15.33%
4.	5th Mth	14.008	12.48	3.967	0.0004	ES	10.91%
5.	Instep	13.731	11.758	3.741	0.0008	ES	14.37%
6.	Heel	14.383	12.094	5.194	<0.0001	ES	15.91%

ES - Extremely Significant

Table 8: Age wise Distribution of 30 patients.

Age in yrs.	No. of patients	Percentage
40-50	4	13.33 %
51-60	12	40.00%
61-70	10	33.33%
70 & Above	4	13.33%

Age: In this, number of patients i.e., 13.33% belonged to age group of 40-50yrs., followed by 40% patients to 51-60 yrs. age group, 33.33% patients belonged to age group of 61-70 yrs. Followed by 13.33% patients to age group 70 yrs& above.

Table 9: Gender wise distribution of 30 patients

Sex	No. of patients	Percentage
Male	11	36.67%
Female	19	63.33%

Gender: It is evident from table that maximum no. of patients i.e., 63.33% was female and 36.67% were male.

Table 10: Religion wise Distribution of 30 Patients

Religion	No. of patients	Percentage
Hindu	26	86.67%
Muslim	4	13.33%

Religion: In this series of 30 patient maximum number of patients i.e. 86.67% patients were Hindu, whereas 13.33% patients were from Muslim community.

Table 11: Occupation wise Distribution of 30 Patients.

Occupation	No. of patients	Percentage
Service	6	20.00%
Housewife	14	46.67%
Retired	7	23.33%
Business	3	10.00%

Occupation: Maximum number of patients i.e. 20% patients were doing service, followed by 46.67 % were housewives 23.33% patients were Retired, and 10 % were in business.

Table 12: Marital status of 30 Patients.

Marital Status	No. of patients
Married	35
Unmarried	0

Marital status: The maximum i.e. 100% of the patients were married, followed by 0% patients were unmarried.

Table 13: Diet Habit of 30 Patients

Diet	No. of patients	Percentage
Vegetarian	6	20.00%
Mixed	24	80.00%

Diet Habit: Patients (20%) of this series were vegetarian and 80% were having the habit of mixed diet of vegetarian and non-vegetarian.

Table 15: Prakriti wise Distribution of 30 patients

Prakriti	No. of patients	Percentage
Vata-Pitta	4	13.33%
Kapha-Vata	18	60.00%
Kapha-Pitta	8	26.67%

Prakriti: All the patients of this series were having *Dvandaja Prakriti* with 26.67 % patients of *Kapha-Pitta* and 60 % of *Vata-Kapha Prakriti*. Remaining 13.33% patients were of *Vata-Pitta Prakriti*.

Table 16: Agni wise Distribution of 30 patients.

Agni	No. of Patients	Percentage
Sama	0	0.00%
Vishama	7	23.33%
Tikshna	3	10.00%
Manda	20	66.67%

Agni: 66.67 % patients were of *Mandagni*, 23.33 % were of *Vishamaagni*, 10 % patients were of *Tikshnaagni*, and none patients were of *Samaagni*.

Table 17: Koshta wise Distribution of 30 patients

Koshta	No. of Patients	Percentage
Krura	7	23.33%
Mridu	2	6.67%
Madhyam	21	70.00%

Koshta: Maximum number of patients of this series were of *Madhyamakoshta* (70 %), followed by *Krura* (23.33%) and *Mridu* (6.67%) *Koshta*.

Table 18: Socioeconomic wise distribution of 30 patients

Class	No. of Patients	Percentage
Upper Class	10	33.33%
Middle Class	17	56.67%
Lower Class	3	10.00%

Socioeconomic: Maximum number of patients of this series were from Middle class (56.67 %), followed by Upper Class (33.33%) and Lower Class (10%).

Discussion

Madhutailika Basti maintains the equilibrium of the body tissue with *Hridya* and prevents exhaustion or *Dhatupaka* to prevent loss of *Ojas*, and nourishes all *Dhatu* tissue including *Mansa- Majja* and *Shukra* and enhances more strength to the *Dhatu* at the cellular levels and increase the proper cellular.

It produces the following changes:

- Cure the vitiated or aggravated *Dosha* (elimination of circulatory waste products)
- Increases digestive capacity (altered metabolism - *Agni Sanrakshan*)
- Purification of *Koshtha* and remove the constipation (*Koshthashudi*)
- Strengthen the host defence mechanism without increasing circulatory levels of sugar, fats and metabolites.
- Enhances the function of all *Agni Sthula* and *Sukshmaagni* (*Aamapachana*)
- Production of better *Dhatu* and *Upadhatu* (immunomodulatory action - *Dhatusanrakshana*)
- Enhances strength of body (adaptogenic activity)
- Proper functioning of nervous tissues (improvement of micro circulation by modulation of macrophage function - *Strotoshodhana*)
- Increases the resistance of body (*Dhatuvarhdhana* - maintain tissue regeneration).

From the above discussion it is clear *Madhutailika Basti* is one among *Yapna Basti*. It is *Nirapada* and *Nishparihara / Ishatparihara*, having both *Langhana* as well as *Brihmana Karma*, this is *Nishparihara* and *Nirapada Basti* can be practiced even in *Bala*, *Vrudha*, *Stree*, *Sukumaras* without any complications. It is *Pushkala Phala Pradhana* and *Sarvakaladeyamana Basti* like *Matra Basti*. "Yasmat *Madhu Cha Tailam Cha Pradhanyenadeeyate*." This unique *Basti* contains *Madhu* and *Taila* as main ingredient, hence this *Basti* is named as *Madhutailika Basti*. *Madhu* is *Yogavahi*, and basically it does *Karshana* by *Rukshadiguna*. Similarly *Tilataila* also causes *Lekhana* by its *Teekshnosnadiguna* after reaching each and every *Srotas* by its *Sukshmaguna*. *Basti*

Alleviates the morbid Vata from the root along with other *Dosha* and in addition to that, it nourishes the body tissues.

Conclusion

Ayurveda suggested use of *Shodhana Chikitsa* for the management of metabolic disorder such as Diabetes. *Shodhana Chikitsa* pacifies vitiated *Doshas* and break pathogenesis of disease. *Basti Karma* normalizes *Vata, Kapha, Meda, Kleda* and *Sneha* for the management of *Avaranjanya Madhumeha*. *Basti* controls *Vyan* and *Apan Vayu* which play significant role in the pathogenesis of *Madhumeha*. *Basti* reduces *Shirahshoola, Anidra, Bhrama* and *Santapa* which may precipitate Diabetes. The proposed autoimmune theory of modern science may be correlated to the *Oja Dushtivastha* seen in long lasting *Prameha* and its *Upadravas* especially Diabetic Neuropathy. Although there was good symptomatic relief in Diabetic Neuropathy at the end of the trial revealed in these patients.

The patients showed excellent improvement in almost all the symptoms. The more bothering symptoms of Diabetic Neuropathy were pain, burning sensation, tingling sensation, numbness and hyperaesthesia. All these symptoms appeared to have improved in 30 days. The present study is carried out to evaluate the effect of *Madhutailika Basti* based on the properties like *Medho Kaphahara* and *Vatahara, Deepana, Pachana, and Srotoshodhaka*. *Madhutailika Basti* is believed to have a noteworthy role in the management of such impaired metabolic condition by importing equilibrium state of *Doshas*, nourishes the *Dhatu* and maintains the blood sugar level. This research study is being conducted to find out cost effective treatment of Diabetes Neuropathy & improve the quality of life.

Thus, procedure acts only on functional deformity and not on the structural deformity because this disease is *Asadhya*. No untoward effect of the drug was noticed after administration for a period of 8 days.

Result obtained with respect to the parameter burning sensation, tingling sensation, numbness, weakness & Neuropathy Disability Score had shown statistically improvement. *Madhutailika Basti* present window of opportunity in the clinical management of Diabetic Neuropathy. There were symptomatic

Relief in symptoms of DN in 4 weeks of treatment. There were no adverse effects were noted in present study. This type of clinical study should be conducted on large sample size to get further findings. Healthy dietetics and healthy lifestyle with the use of Ayurvedic drugs with singularly or in combination with modern drugs, depending upon the need, contributed significantly to achieve.

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