Original Research Paper

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Ayurveda

" RANDOMIZED CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFICACY OF MEHA-MUDGARA RASA IN THE MANAGEMENT OF MADHUMEHJANYA NADIPRATHAN SHOTHA W.R.T. DIABETIC NEUROPATHY"

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ABSTRACT

AIM & OBJECTIVES: - To evaluate clinical Efficacy of Meha-Mudgara Rasa in the management of Madhumehajanya Nadipratan Shotha w.r.t Diabetes Neuropathy

METHODOLOGY:- The 100 subjects were enrolled randomly in two groups, Group A (Meha Mudagara Rasa) & Group B (Pregabalin 75 mg) for the duration of 1 month. Meha-Mudgara Rasa contains Rasanjana, Bida Lavana, Devdar , Bilvaphala, Gokshurbeeja, Dadim, Bhunimba, Pippalimula, Trikatu, Triphala, Trivrita, Lohabhasma, Shudha Guggulu & Go-Ghrita. Pregabalin is described chemically as (S) -3-(aminomethyl)-5-methylnexanoic acid, indicated in the Management of neuropathic pain associated with diabetic peripheral neuropathy.

CONCLUSION: - Both the drugs are effective on subjective parameters with wilcoxon test. On comparing the effect on subjective parameters with Mann-Whitney the statistical difference is seen MMR VS Pregabalin. With effect on objective parameters in Group B, with paired t test ,there is statistical difference is seen in VPT RT &LT Foot .On comparing the effect on objective parameters with unpaired t test no statistical difference is seen MMR VS Pregabalin. Both the drugs found to be safe s no adverse effects were observed.

KEYWORDS : Diabetic Neuropathy, Meha-Mudgara Rasa, Pregabalin

INTRODUCTION

Diabetic peripheral Neuropathy is a nerve damaging disorder associated with diabetes mellitus. Diabetic micro vascular injuries involving small blood vessels that supplies to nerves i.e. vasa nervorum are responsible for diabetic peripheral Neuropathy. Diabetic peripheral neuropathy is a common condition, often unreported and inadequately treated resulting in a great deal of morbidity. Prevalence of diabetic peripheral neuropathy in India is about 26.1%. Peripheral diabetic neuropathy is pathologically characterized by peripheral demyelination, decrease in the nerve conduction and degeneration of myelinated and demyelinated sensory nerve fibres. It is presented with the symptoms such as tingling or burning sensation and numbness, sharp pains or cramps, insensitivity to pain, motor incoordination, loss of sense of vibration, change in temperature etc. If it is not treated, it may lead to loss of reflexes and deformities that may progress to gangrene**.** 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), Angasada. These Upadrava (complication) of Madhumeha, which are nearly similar to the symptoms of diabetic peripheral neuropathy.**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

HO- Meha Mudagara Rasa has no significant effect on Madhumehjanya Nadipratan Shotha w.r.t Diabetic Neuropathy

H1- Meha Mudgara Rasa has significant effect on Madhumehjaya Nadipratan Shotha w.r.t Diabetic Neuropathy

AIM AND OBJECTIVES

Aims:-

To evaluate clinical Efficacy of Meha Mudgara Rasa in the management of Madhumehajanya Nadipratan Shotha w.r.t Diabetic Neuropathy.

OBJECTIVES:-

- To study the pathogenesis of Madhumehjanya Nadipratan Shotha w.r.t Diabetic Neuropathy .
- To develop a cost effective treatment in the management of Madhumehajanya Nadipratan Shotha w.r.t Diabetic Neuropathy .
- To improve quality of life & prevent further complications.

MATERIALS AND METHODS

Materials:

Methods Table No:-1

Research Place	Dept of Kayachikitsa, OPD /IPD, DY Patil School of Ayurveda, Nerul, Navi Mumbai	
Type of Study	Randomized Control Clinical Trial	
Medicine	**Group A**- Meha Mudagara Rasa	**Group B-Tab. PREGALIN** (Pragabalin 75 mg)
Sample size	50 patients	50 patients
Dose	500 mg BD	1 Tab.OD
Duration	1 month	1month
Anupana	Koshna Jala	Koshna Jala

Inclusion Criteria:-

- The patients for this study were selected randomly irrespective of their age, sex, religion, etc.
- Patients with clinical positive history of type 2 diabetes mellitus having the symptoms of diabetic neuropathy (peripheral) were selected for the present study
- The pamtients were diagnosed Clinically with the help of following signs and symptoms of Madhumehajanya Nadiprathan Shotha.

Exclusion Criteria:

- The cases with complications like diabetic gangrene, carbuncles, diabetic coma, retinopathy, IDDM were excluded from present clinical trials.
- Any major diseases like Koch's, IHD, AIDS etc associated with diabetes mellitus.
- Thyroid dysfunction, Patients on Corticosteroid Therapy

Method Of Data Collection:

- CRF was prepared with details of history, physical examination, pathological investigations.
- The general condition of the patient, severity of symptoms before starting of the treatment were recorded properly.
- The parameter of signs & symptoms & investigations were analyzed statistically by applying Students't' test and 'Wilcoxon' test. & Mann-whitney Test.

Investigations

- CBC ESR, BSL- FASTING & PP, LIPID PROFILE , Sr.Creatinine, URINE R/M , ECG
- **Neuropathy analyzer (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 use 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:
Scoring of symptoms
Table No:-2

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:
Neuropathy Disability Score –
Table No:-3

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

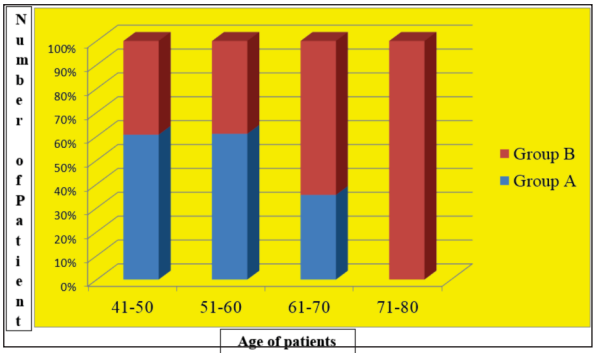
- Maximum abnormal score is 10,
- Score of 3-5: symptoms of mild Neuropathy,
- Score of 6-8: symptoms of moderate Neuropathy,
- Score of 9 or 10: symptoms of severe Neuropathy

OBSERVATIONS & RESULTS

The data obtained by this clinical study were subjected to resolutions on varied parameters to know the etiopathogenesis and progression of the disease. In the present study, In Group A 58 patients & in Group B 62 patients suffering from diabetic sensory poly-neuropathy fulfilling the inclusion criteria were randomly selected. Out of these in Group A, 8 patients were drop-out & In Group B, 12 patients were drop–out. Following pages contain the descriptive statistical analysis of the patients studied along with the observation.

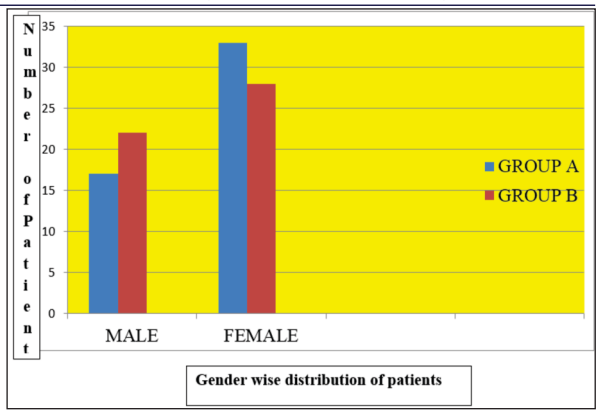
1) Age wise distribution in Group A & Group B (N-50) Table No:-4

Age	Group A	Percentage %	Group B	Percentage %
41-50	17	34%	11	22%
51-60	22	44%	14	28%
61-70	11	22%	20	40%
71-80	0	0%	5	10%



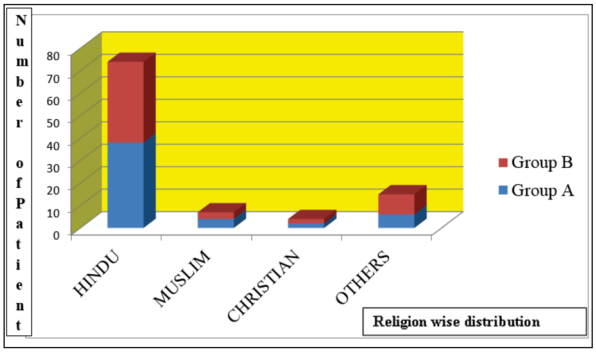
2) Gender wise distribution in Group A & Group B Table No:-5

Gender	Group A	Percentage %	Group B	Percentage %
Male	17	34%	22	44%
Female	33	66%	28	56%



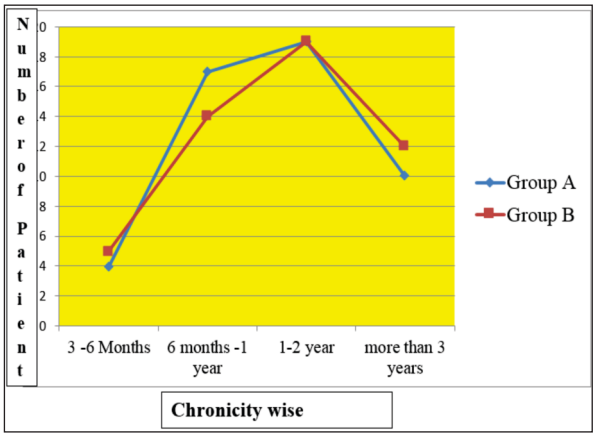
3) Religion wise distribution in Group A & Group B Table No:-6

Religion	Group A	Percentage %	Group B	Percentage %
Hindu	38	76%	36	72%
Muslim	4	8%	3	6%
Christian	2	4%	2	4%
Others	6	12%	9	18%



4) Chronicity wise distribution in Group A & Group B Table No:-7

Chronicity	Group A	Percentage %	Group B	Percentag %
3 -6 Months	4	8%	5	10%
6 months -1 year	17	34%	14	28%
1-2 year	19	38%	19	38%
more than 3 years	10	20%	12	24%



Clinical discussion in

- **Age:-** In Group A more patients with age group 51-60 enrolled (44%) whereas in Group B more patients with age group 61-70 enrolled (40%)
- **Sex:-** In both the groups female patients were enrolled more . Group A-66% & Group B -56%
- **Religion:-** In Both the groups Hindu patients were enrolled more .Group A-76% & Group B-72%
- **Occupation:-** In both the groups housewife category of patients were more. Group A-42% & Group B-40%.
- **Prakruti:-** In Group A Vata-Pittaja (24%) & In Group B Kapha-Vataja (34%) patients were more .
- **Chronicity:-** In both the groups patients with chronicity between 1-2 years were more .Group A-38% & Group B-38%

DISCUSSION ON RESULTS:

Effect of MMR on Subjective Parameters

Numbness :-There is Pre –Statistic value by Wilcoxon test is 1275 & Post-Statistic value is 946 . p value < 0.05. Thus we accept the alternative hypothesis that effect of MMR is seen on numbness in Pre and Post data.

Tingling Sensation:- There is Pre –Statistic value by Wilcoxon test is 1276 & Post-Statistic value is 946 . p value < 0.05. Thus we accept the alternative hypothesis that effect of MMR is seen on tingling sensation in Pre and Post data.

Burning Sensation: - There is Pre –Statistic value by Wilcoxon test is 1275 & Post-Statistic value is 861 . p value < 0.05. Thus we accept the alternative hypothesis that effect of MMR is seen on Burning sensation in Pre and Post data.

Pain:- There is Pre –Statistic value by Wilcoxon test is 1275 & Post-Statistic value is 1081 . p value < 0.05. We accept the alternative hypothesis that effect of MMR is seen on pain in Pre and Post data.

NDS (Neuropathy disability score):- There is Pre –Statistic value by Wilcoxon test is 1275 & Post-Statistic value is 1275. p value < 0.05. We accept the alternative hypothesis that effect of MMR is seen on NDS in Pre and Post data.

Effect of Pregabalin on Subjective Parameters

Numbness: - There is Pre –Statistic value by Wilcoxon test is 1275 & Post-Statistic value is 903. p value < 0.05. Thus we accept the alternative hypothesis that effect of Pregabalin is seen on numbness in Pre and Post data.

Tingling Sensation:- There is Pre –Statistic value by Wilcoxon test is 1275 & Post-Statistic value is 1270. p value < 0.05. We accept the alternative hypothesis that effect of Pregabalin is seen on Tingling in Pre and Post data.

Burning Sensation: - There is Pre –Statistic value by Wilcoxon test is 1275 & Post-Statistic value is 990 p value < 0.05. We accept the alternative hypothesis that effect of Pregabalin is seen on Burning Sensation in Pre and Post data.

Pain:- There is Pre –Statistic value by Wilcoxon test is 1275 & Post-Statistic value is 903. p value < 0.05. We accept the alternative hypothesis that effect of Pregabalin is seen on Pain in Pre and Post data.

NDS (Neuropathy disability score):- There is Pre –Statistic value by Wilcoxon test is 1275 & Post-Statistic value is 1275. p value < 0.05. We accept the alternative hypothesis that effect of Pregabalin is seen on NDS in Pre and Post data.

Comparative effect of MMR & Pregabalin on subjective parameters.

Numbness:- There is Pre –Statistic p value by Mann-Whitney test is 0.0438 & post- Statistic p value is 0.0413. p < 0.05. We accept the alternative hypothesis, there is a difference between MMR and Pregabalin .

Tingling Sensation:- There is Pre –Statistic p value by Mann-Whitney test is 0.0349 & post- Statistic p value is 0. p < 0.05. We accept the alternative hypothesis, there is a difference between MMR and Pregabalin.

Burning Sensation:- There is Pre- Statistic p value by Mann-Whitney test is 0.0441 & post- Statistic p value is 0.0343. p < 0.05. We accept the alternative hypothesis, there is a difference between MMR and Pregablin.

Pain:- There is Pre –Statistic p value by Mann-Whitney test is 0.0386 & post- Statistic p value is 0.05. p < 0.05. We accept the alternative hypothesis, there is a difference between MMR and Pregabalin.

NDS (Neuropathy disability score):- There is Pre –Statistic p value by Mann-Whitney test is 0.0540 & post- Statistic p value is 0.0396. p < 0.05. We accept the alternative hypothesis; there is a difference between MMR and Pregabalin. , there is a difference between PRE and POST results of VPT-LT Foot.

Comparative effect of MMR & Pregabalin on Objective Parameters.

HB

Pre- By Un-paired t test, it is found that T-Value = -0.93 P-Value = 0.352 DF = 93, p value > 0.05. We accept the Null hypothesis that there is no difference between the 2 groups of Pre-test of HB.

Post - By Un-paired t test, it is found that: T-Value = -0.91 P-Value = 0.363 DF = 96. p value > 0.05. We accept the Null hypothesis that there is no difference between the 2 groups of Post-test of HB.

ESR

Pre- By Un-paired t test, it is found that T-Value = 0.07 P-Value = 0.944 DF = 97. p value > 0.05. We accept the Null hypothesis that there is no difference between the 2 groups of Pre-test of ESR.

Post - By Un-paired t test, it is found that: T-Value = 0.57 P-Value = 0.573 DF = 58 . p value > 0.05. We accept the Null hypothesis that there is no difference between the 2 groups of post –test of ESR.

BSL-Fasting

Pre- By Un-paired t test, it is found that T-Value = 0.05 P-Value = 0.963 DF = 97. p value > 0.05. We accept the Null hypothesis that there is no difference between the 2 groups of BSL-Fasting.

Post - By Un-paired t test, it is found that: T-Value = 0.20 P-Value = 0.842 DF = 96. p value > 0.05. We accept the Null hypothesis that there is no difference between the 2 groups of BSL-Fasting.

BSL-Post prandial

Pre- By Un-paired t test, it is found that T-Value = -0.20 P-Value = 0.839 DF = 97. p value > 0.05. We accept the Null hypothesis that there is no difference between the 2 groups of BSL-postprandial.

Post - By Un-paired t test, it is found that: T-Value = -0.47 P-Value = 0.642 DF = 91. p value > 0.05. We accept the Null hypothesis that there is no difference between the 2 groups of BSL-postprandial.

Lipid- Cholesterol

Pre- By Un-paired t test, it is found that T-Value = -1.45 P-Value = 0.151 DF = 95. p value > 0.05. We accept the Null hypothesis that there is no difference between the 2 groups of Lipid Cholesterol.

Post - By Un-paired t test, it is found that: T-Value = -1.42 P-Value = 0.160 DF = 84. p value > 0.05. We accept the Null hypothesis that there is no difference between the 2 groups of Lipid Cholesterol.

Lipid –Triglycerides

Pre- By Un-paired t test, it is found that T-Value = 0.23 P-Value = 0.819. p value > 0.05. We accept the Null hypothesis that there is no difference between the 2 groups of Lipid triglycerides.

Post - By Un-paired t test, it is found that T-Value = 0.58 P-Value = 0.566 DF = 84. p value > 0.05. We accept the Null hypothesis that there is no difference between the 2 groups of Lipid triglycerides.

Serum Creatinine

Pre- By Un-paired t test, it is found that T-Value = 0.54 P-Value = 0.589 DF = 96. p value > 0.05. We accept the Null hypothesis that there is no difference between the 2 groups of Serum Creatinine

Post - By Un-paired t test, it is found that T-Value = -0.59 P-Value = 0.554 DF = 96. p value > 0.05. We accept the Null hypothesis that there is no difference between the 2 groups of Serum Creatinine

VPT RT.Foot

Pre- By Un-paired t test, it is found that T-Value = 2.79 P-Value = 0.006 DF = 93. p value < 0.05. We accept the Alternative hypothesis that there is difference between the 2 groups of VPT RT.Foot.

Post - By Un-paired t test, it is found that T-Value = 3.62 P-Value = 0.000 DF = 97. p value < 0.05. We accept the Alternative hypothesis that there is difference between the 2 groups of VPT RT.Foot.

VPT LT.Foot

Pre- By Un-paired t test, it is found that T-Value = -0.91 P-Value = 0.363 DF = 96. p value > 0.05. We accept the Null hypothesis that there is no difference between the 2 groups of VPT LT.Foot.

Post - By Un-paired t test, it is found that T-Value = 0.19 P-Value = 0.847 DF = 94. p value > 0.05. We accept the Null hypothesis that there is no difference between the 2 groups of VPT LT.Foot.

DISCUSSION

MMV is dominant in *Tikta* (bitter) MMV k*ashaya* (astringent) *rasa* and *Ruksha* (*dry*) *guna* among which *Tikta*(bitter) *rasa* is said to be "*kleda upashoshana*" while *Kashaya* (astringent) *rasa*t o be "*sharira kledasya upayokta*." The word *Ruksha* itself indicates dryness, which in turn means lack or decrease of *Kleda*. Thus, all the three dominant properties show a *Kleda*-reducing effect. *Bahu drava Shleshma* is the *dosha vishesha* and *Kleda* is one of the *dushya vishesha* in *Samprapti* of *Prameha*; thus, the dominating three properties directly affect both the *dosha* and the *dushya vishesha* and hence effectively counteract the *Samprapti*.

K*arapadatala Daha* and *Karapadatala,Suptata* (burning sensation and numbness in the palm and foot) are both common neurological complications of diabetes described in the *Ayurvedic* literature as *Purvarupa* of *Prameha*. *Karapadatala Daha* (burning sensation in palm and foot) is due to *Pitta* by provocation of *Ushna* quality or may be due to loss of *Udaka*, which might have been pacified by *Sheeta* quality of MMV. *Karapadatala suptata* (numbness in palm and foot) is due to *Vata* – decrease in *Chala guna* of *Vyana vayu* that might have been compensated by *Sara guna* of MMV.

Stress blocks the body from releasing insulin in people with type 2 diabetes; therefore, cutting stress is very essential for effective control of the blood sugar level. The ingredients present in the formulation MMV have different properties that may be helpful in minimizing the stress response or cutting stress. As *Haritaki and Bibhitaki*[are antistress agents and *Shunthi* is an antidepressant, they might have been cutting the stress directly. *Rasayana* effect of *Lauha bhasma Haritaki*, *Amalaki* and *Pippali*, antioxidant properties of *Amalaki*, *Shunthi*, *Maricha* and *Dadima* and immunomodulatory properties of *Amalaki* and *Devadaru* might have helped in minimizing the stress response, and in the manner controlling the disease.

High blood sugar is the main characteristic and diagnostic feature of diabetes. The MMV decreased this elevated blood glucose level, which may be by its ingredients

CONCLUSION

- Mostly people with chronicity of 1-2 year were more in the current study.
- Both the drugs are effective on subjective parameters with wilcoxon test.
- On comparing the effect on subjective parameters with Mann-Whitney the statistical difference is seen MMR VS Pregabalin.
- With effect on objective parameters in Group A, with paired t test there is statistical difference in MMR is seen in HB, BSL-PP,VPT-RT &LT Foot .
- With effect on objective parameters in Group B, with paired t test ,there is statistical difference is seen in VPT RT &LT Foot .
- On comparing the effect on objective parameters with unpaired t test no statistical difference is seen MMR VS Pregabalin.
- Both the drugs found to be safe s no adverse effects were observed.

Scope Of Study

Considering the time bound duration of the study, small sample size and infrastructural constrains for drug preparation, clinical and biochemical evaluation; drawing a concrete and precise conclusion would be premature and the beyond scope of the study. Keeping in view of these, the author very humbly suggest extending this research work to impart ultimate validity to present hypothesis and establish it as a principle.

Acknowledgement

This particular study was conducted with the help of Department of Kayachikitsa,D.Y.Patil School of Ayurveda, Nerul,Navi-Mumbai.

Ethical Clearance

This clinical study is ethically cleared by Institutional ethical committee. The drugs used in the study were authentified by Allarsin Ltd ,Mumbai.

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