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A Comparative Clinical Study to Evaluate the Combined Efficacy of Takradhara Followed by Somavalkala Kashaya Siddha Kala Basti and Takradhara Followed by Kantaka Panchamoola Kashaya Siddha Kala Basti in Management of Prameha Upadrava W.S.R to Diabetic Peripheral Neuropathy

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ABSTRACT

Diabetic peripheral neuropathy 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.

Prameha is one of the maharoga, due to chronicity attains upadrava avastha. DPN is vata pradhana Tridoshaja vyadhi. Lakshanas of DPN are attributed to Avaranajanya Dhatukshayaja samprapti of madhumeha.here in this study 40 patient were taken, made into 2 groups and treated with panchatiktha takrdhara followed by group A treated with somavalkala kashaya niruha basti, group B with kantakantaka panchamoola niruha basti in kala basti format.both group have got stasticaly significant results.

KEYWORDS: *Prameha, DPN, Somavalaka kashaya niruha basti, Kantakapanchamoola niruha basti*

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INTRODUCTION

In present era due to stressful and sedentary lifestyle man is becoming prey to various diseases, one among them is diabetes mellitus. Though this condition can be controlled, because Of hyperglycemia it can give rise to various complications like diabetic neuropathy, nephropathy, retinopathy and so on which can bring enormous burden on family, society and health care providers involved in management of diabetes due to its morbidity and mortality.

Diabetic neuropathy is a group of nerve disorders, among the four types of diabetic neuropathy, the peripheral neuropathy refers to the functional impairment of many peripheral nerves simultaneously and symmetrically. It is characterized by numbness, tingling sensation, burning sensation and pain in feet, hands[1].

Regarding the incidence it is observed that one in 6 diabetic patients has neuropathy that is approximately 50% of patients with diabetes will eventually develop

neuropathy and which is major cause for lower limb amputation[2].

The prevalence of neuropathy increases with the duration of diabetes mellitus. According to study in India, 19.1% of type 2 diabetic patients had peripheral neuropathy. According to an estimate, two-thirds of the diabetic patients have clinical or subclinical neuropathy[3].

In contemporary science the mainstays of therapy are anticonvulsant agents, tricyclic antidepressants, opiates. Each of these classes of medication has drug interaction and side effects that may be more pround in the elderly.

Madhumeha is one among the four varieties of vataja prameha[4]. which has similarity with the disease diabetes mellitus and diabetic neuropathy can be considerd as prameha upadrava. In this condition due to various nidanas, margavarana takes place either by pitta or kapha to normal gati of vata dosha leading to vata viatiation[5], The lakshanas such as kara pada daha, kara pada supthatha, kara pada chimachimayana are mentioned under context of prameha[6]. Daha, dourbalya, shula are mentioned in upadrava of prameha[7], [8] which are similar to diabetic neuropathy.

Diabetic Peripheral Neuropathy is vatapradhana tridoshaja avasta, since avarana of vata due to kapha and pitta[9] involved in the disease takradhara is preferred. Takradhara drava by virtue of its procedural effect it is pitta, vatahara and by medicinal effect of panchathiktha kashaya acts as kaphapittahara and pramehagna[10].

Samshodhana is indicated in prameha[11]. Among shodhana, Basti karma which is pradhanachikithsa for vata[12] dosha along with kaphahara and pittahara effect is adopted to manage in this diseases. Acharya charaka explains that somavalkala kashaya siddha kala basti relieves vimshati meha and acts as kaphapittahara[13] and acharya sushruta mentions kantaka panchamoola kashaya siddha kala basti effective in prameha, rakthapitta[14]and also possess kaphavatahara property. In the present study comparison of both bastis are taken.

Aims and objectives:-

To evaluate the Combined efficiency of takradhara followed by somavalkala kashaya siddha kala basti and takradhara followed by kantaka panchamoola kashaya siddha kala basti in the management of prameha upadrava w.r.t to Diabetic peripheral neuropathy.

Methodology

Study design:-A comparative clinical study.

Intervention:-40 patients were selected randomly and made into 2 groups, each group consists of 20 members,

Group A is given with Panchatikthaka kashaya siddha shiro takradhara followed by somavalkala kashaya siddha kala basti

Group B is given with Panchatikthaka kashaya siddha shiro takradhara followed by kantaka panchamoola kashaya siddha kala basti

Data collected before treatment, after treatment, after follow up

Unpaired 't' test will be done & analysed accordingly, Descriptive and inferential statistics will be applied accordingly.

Treatment protocol:-

Panchatiktha Takradhara, Deepana, pachana with pippali churna 2-3 grms, kostashodhana with Trivruth churna 50-60GM's with Triphala kashaya 80-100ml, Group A-Somavalakala kashaya siddha niruha basti, Group B-Kantaka panchamoola siddha kashya niruha basti.

Method of collection of data:

Patients fulfilling the inclusive criteria irrespective of sex, religion, socioeconomic status and occupation were enrolled for the study. A special case proforma containing all the necessary details pertaining to the study was prepared.

Study design:

A comapartive clinical study with pre test and post test design.

Sample size:

Minimum of 40 patients fulfilling the diagnostic & inclusion criteria were selected randomly.

Diagnostic criteria:

Lakshanas of prameha upadrava

Signs and symptoms of diabetic neuropathy

Histroy of hyperglycemia

Michigan neuropathy screening instrument-questionnaire part>/=7 positive.

FBS

PPBS

HbA1c

Inclusion criteria:

Subjects of Diabetic Mellitis with signs and symptoms of Diabetic peripheral neuropathy

Subjects of 30-70 years age group

Subjects of both sex.

Subjects who are eligible for basti and takradhara.

Exclusion criteria:

Subjects suffering from Type 1 DM, Gestational DM.

Known case of other endocraine disorder, Malignancy, Liver disorders, Cardiac, Renal pathology

Subjects with other systemic illness which interfere the course of treatment.

Subjects suffering from foot ulcer/ amputation.

Pregnant and lactating women.

Intervention and follow up period:

Minimum of 40 patients fulfilling the diagnostic & inclusion criteria were selected randomly and Takradhara followed by basthi was administered.

Groups:- 2

1. Group A:- Takradhara Followed By Somavalkala Kashaya Siddha Basti
2. Group B:- Takradhara Followed By Kantaka panchamoola kashaya siddha basti

Assessment parameter:

Assessment was done in 3 schedules before and after the intervention & after followup based on the grading criteria.

Before treatment : on 0th day

After treatment : 20th day

After treatment follow up : After 32th day

Subjective parameter:

Patients with following symptoms:-

Kara pada daha

Kara pada suptata

Kara pada chimchimayana

Dourbalya

Kara pada vedana

No	Symptoms	Grade 0	Grade 1	Grade 2	Grade 3
1	Kara pada daha	No symptoms	Occassional	Continues for a day	Distrubed sleep
2	Kara pada chimchimayana	No symptoms	Occassional	Continues for a day	Distrubed sleep
3	Kara pada vedana	No symptoms	Occassional	Continues for a day	Distrubed sleep
4	Kara pada supthatha	No symptoms	Occassional	Continues for a day	Whole day
5	Dourbalya	No symptoms	Occassional	Continues for a day	Present continues on rest

Objective criteria:-

	Right	Left
Symptoms scores	**Present-1 Absent-0**	**Present-1 Absent-0**
Pain		
Numbness		
Tingling sensation		
Weakness		
Ataxia		
Upper limb symptoms		
sub total score	/6	/6

Sensory test scores	**Abnormal-1 Normal-0**	**Abnormal-1 Normal-0**
Pinprick		
Temperature		
Light touch		
Vibration		
Position		
Subtotal	/5	/5

Reflex scores	**Absent-2 Reduced-1 Normal-0**	**Absent-2 Reduced-1 Normal-0**
Knee reflexes		
Ankle reflexes		

Scoring:-

No neuropathy- 0-5 points

Mild neuropathy- 6-8 points

Morderate neuropathy- 9-11 points

Severe neuropathy- 12+ points

Observations:-

Distribution of subjects according to age group:-

Group A-In this study, maximum number 10(50%) of patients belonged to the age group of 50-59 yrs, followed by 5 patients(25%)belonged to age group of 40-49 yrs and 2 members each were belonged to the age group of 60-69 and 30-39 yrs.

Group B-In this study, maximum number 12(60%)of patients belonged to the age group of 40- 49 yrs, followed by 7 patients (35%0belonged to agr group of 50-59 yrs, 2 patients belonged to age group of 30-39 yrs and 1 patient belonged to age group of 60-69 yrs.

Distribution of subjects according to Gender:-
Group A-In this study, maximum number of patients 55% were male in comparison with females.

Group B-In this study, maximum number of patients 75% were males in comparison with females.

Distribution of subjects according to symptoms:-
Group A-In this study, 20 patients (100%) having Chumchumayana, 19 patients (95%) having Daha, 14 patients (70%) having Supthatha, 6 patients (30%) having Dourbalya, 4 patients (20%) having Vedana.

Group B-In this study, 17 patients(85%) having Daha, 15 patients (75%) having Chumchumayana, 11 patients (55%) having Dourbalya, 8 Patients (40%)having Supthatha, 5 patients(20%) having Vedana.

Assessment of total effect on treatment:-
Effect of treatment on Daha:-Daha(burning sensation in extremities):-
In between the groups:-the mean effect of daha after treatment was 1.15 in both groups, After follow up mean was 0.15 in the both groups, t value is0.0000 and p value is = 1.0000 hence there is no significant difference between the both the groups.Daha is due to pitta predominance, the drug somvalkala have tiktha rasa and sheeta verya so having pittahara action hence it acted against this symptom in group A and kantaka panchamoola have gokshura which is madura rasa, madhura vipaka, usna verrya so having tridoshahara property, shatavari which is madura, tiktha rasa, sheeta verya so havingVatapittahara proprty, so these acted against this symptom in group B. on present study may be because of Therapeutic procedure Takradhara which helped to remove avarana. Dhara has stimulative effect and it improves peripheral circulation. Both group has vatahara effect which acted on this symptom.

Cucumayana (Tingling sensation in extremities):-
In between the groups:-the mean effect of cumcumayana after treatment was 1.05, after follow up mean was 0.25 in group A, the mean effect of cumcumayana after treatment was 1.00, after follow up mean was 0.25 in group B, t value after treatment is =0.2945, t value after follow up is=0.0000, p value obtained is 0.7699 before treatment, p value obtained is=1.000 after follow up, hence there is no significant difference between the groups.

Cumcumayana (Tingling sensation) is the common and early presenting sensory symptom of Diabetic Peripheral Neuropathy. In the present study, majority of patient had cumcumayana as a main symptom confirmed the earlier observation. Here Cumcumayana is due to Pittavrita Vata.

Significant result on daha and cumcumayana were observed on present study may be because of Therapeutic procedure Takradhara which helps to remove avarana. Dhara has stimulative effect and it improves peripheral circulation. Both group has vatahara effect which acted on this symptom. Basthi had curative effect as shakasucharantivata i.e effect in those conditions where vata is aggravated in shakhe hence, procedure basti acted on this symptom.

Dourbalya:-
In between the groups:-
According to statistical analysis mean effect of dourbalya AT, AF was 0.55, 0.20 respectively in group A

The mean effect of dourbalya of AT, AF was 0.55, 0.15 respectively in group B.

t value, p value after treatment was 0.0000, = 1.0000 respectively, after follow up was 0.4065, =0.6867 respectively. hence there is no significant difference in results between the groups

Dourbalya is vata pradhanaja lakshana, hence somvalkala which is having tiktha, kashaya rasa, sheeta veerya as niruha, anuvasana basthi acts on this lakshana in group A and kantaka panchamoola gana has shatavari which is having madhura rasa, madhura vipaka, guru guna hence Vatapittahara acted on this symptom in the group B.hence both the groups have no significant difference.

Takradhara due to its vatapitta hara nature, it acted on reducing dourbalya.Basti has pustikara karma due to this it enhanced bala of the patient and acted on the symptom dourbalya.Supthatha:-

In between the groups:-According to statistical analysis mean effect of supthatha AT, AF was 0.65, 0.60 respectively in group A

The mean effect of supthatha of AT, AF was 1.20, 0.40 respectively in group B.

t value, p value after treatment was 2.2989, = 0.0271 respectively which is statisticaly significant result, after follow up was 1.9942, =0.0533 respectively which is nothing significant result..

Supthatha is due to kaphavrita vata, result on supthatha may be due to avaranahara action of takradhara, also takra used in dhara procedure had kapha shamaka action.hence, useful in above

symptom. Basthi has avaranahara karma and also has action on shakhagata symptoms hence acted on supthatha

Vedana:-

In between the groups:-According to statistical analysis mean effect of vedana AT, AF was 0.55, 0.15 respectively in group A

The mean effect of vedana of AT, AF was 0.90, 0.35 respectively in group B.

t value, p value after treatment was 1.4978, = 0.1424 respectively, after follow up was 1.2924, =0.2040 respectively. hence there is no significant difference between the groups.

Vedana is vataprdhanaja lakshana, Takradhara has action on peripheral nerves and also has relaxing effect hence acted against on this symptom.the somavalkala has tiktha rasa, laghu guna, sheeta verya, katu vipaka hence has tridoshahara karma in group A, kantaka panchamoola has gokshura, shatavari hence has tridoshahara karma in group B has acted in the group B. Basti procedure is mainly vatahara in nature hence basti acted on reduction in vedana in patients

FBS:-

In between groups:-

According to statistical analysis mean effect of FBS of AT, AF was 162.25, 151.45 respectively in group A

The mean effect of FBS of AT, AF was 158.75, 150.10 respectively in group B.

t value, p value after treatment was 2.2965, = 0.7685 respectively, after follow up was 0.1275, =0.8992 respectively.hence no significant difference between the groups in results.

Blood for PPBS

Group A:-

In between the groups:-

According to statistical analysis mean effect of PPBS of AT, AF was 248.10, 218.40 respectively in group A

The mean effect of PPBS of AT, AF was 213.00, 204.80 respectively in group B.

t value, p value after treatment was 1.5604, = 0.1270 respectively, after follow up was 0.8560, =3974 respectively.hence there is no significant resluts between thw groups.

Urine for FUS:

In between groups:-

According to statistical analysis mean effect of FUS of AT, AF was 0.35, 0.00 respectively in group A

The mean effect of FUS of AT, AF was 1.20, 0.30 respectively in group B.

t value, p value after treatment was 4.4685, <0.0001 respectively, after follow up was 2.3486, =0.0241 respectively.

After treatment there is highly significant result between the groups, after follow up there is no significant result between the groups.

Urine for PPUS:-

Group A:-

ntervention showed statistically highly significant result with the P value< 0.0001.

In between the groups:-

According to statistical analysis mean effect of PPUS of AT, AF was 0.25, 0.00 respectively in group A

The mean effect of PPUS of AT, AF was 1.05, 0.15 respectively in group B.

t value, p value after treatment was 5.2872, <0.0001 respectively, after follow up was 1.8311, =0.0749 respectively.

After treatment it is observed that there is highly significant, after follow up there is no significant difference between the groups.

The drugs like somavlkala have phenol, tanin which is responsible for anti diabetic action hence reduced FBS, PPBS, FUS, PPUS in group A, The drugs like gokshura, shatavari, saireyaka has saponin, alkoloids flavonoids which irresponsible for anti diabetic action hence reduced FBS, PPBS, FUS, PPUS in group B.

Takradhāra with Panchatikthaka kashaya which has pramehgna action reduced cortisol levels in blood hence FBS, PPBS, FUS, PPUS levels decreased.

Toranto clinical neuropathy scoring system:-

In between the groups:-

According to statistical analysis mean effect of TCNS of AT, AF was 6.30, 5.35 respectively in group A

The mean effect of TCNS of AT, AF was 8.00, 5.60 respectively in group B.

t value, p value after treatment was 4.1359 = 0.0002 respectively, after follow up was 1.1079, =0.2749 respectively.

After treatment there is statically significant difference is observed between the groups, after follow up there is no statistically significant difference is observed between the groups.

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.

Vas scale:-

In between groups:-

According to statistical analysis mean effect of VAS Scale AT, AF was 1.65, 0.50 respectively in group A

The mean effect of VAS Scale of AT, AF was 2.60, 0.75 respectively in group B.

t value, p value after treatment was 2.2238, = 0.0322 respectively, after follow up was 0.8788, =0.3850 respectively.

After treatment there is statically significant diffrence is observed between the both groups. After follow up there is no significant difference between the groups.

Monofilament test:-

In between the groups:-

According to statistical analysis mean effect of Monofilament test of AT, AF was 8.40, 9.95 respectively in group A

The mean effect of Monofilament test of AT, AF was 8.20, 9.95 respectively in group B.

t value, p value after treatment was 0.5407, = 0.5919 respectively, after follow up was 2.5225, =0.0160 respectively.

After treatment there is nothing significant difference between the groups, after follow up there is statically significant difference oberved between the groups.

The drugs like Gokshura, shatavri, karamarda have steroidal saponin, flvonol glycosides, steroidal glycosides which are responsible for neuroprotective action which is causes regeneration of nerve fibers hence helped in reliving the nueropathic symptoms

Result:-

Group A:- The mean effect of group A before treatment, after treatment was 553.75, 817.75 respectivly.t value, p value are 10.2537, <0.0001, which is highly significant.

Group B:- The mean effect of group B before treatment, after treatment was 450.40, 769.95 respectively.t value, p value are 32.58885, <0.0001 which is highly significant.

Discussion on overall results:-Both the groups A and B got the highly significant result. the percentage of change is -48% in group A and -71 % in group B. here negative sign indicates increase in score in monofilament test when compared to before treatment, after treatment and after follow up which shows the improvement in results. hence group A has Mild relief from disease and group B has Moderate relief.

Both the groups A and B got highly significant results but when the results of Group A nad B rae compared to each other the group B is more effective than group A.

This is may be because of the combined effect of drugs in the kantaka panchamoola gana which has tridoshahara karma, pramehagna property, and also give rasayana effect to the patient. but in group A has only somavalkala drug which is tridoshahara, pramehagna karma but does not have rasayana effect, hence this may be reason that group B got highly significant result when compared to group A.

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.Overall assessment has shown that both the groups A and B got the highly significant result. the percentage of change is -48% in group A and -71 % in group B.here negative sign indicates increase in score in monofilament test when compared to before treatment, after treatment and after follow up which shows the improvement in results.

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