EFFECT OF SUNDIBALADWAYA KWATHA WITH DHANYAMLA DHARA IN PATIENTS OF DIABETIC PERIPHERAL NEUROPATHY

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ABSTRACT

Diabetic peripheral neuropathy (DPN), according to American Diabetes Association, defined as the presence of symptoms and/or signs of peripheral nerve dysfunction in people with diabetes after exclusion of other potential causes. Globally 537 million are living with diabetes, i.e. 1 in 10. This is predicted to rise to 643 million by 2030 and 783 million by 2045.Several studies suggest approximately 50 % of patients with diabetes in the course of time will end up in diabetic neuropathy. Among diabetic neuropathy sub classification, diabetic peripheral neuropathy is the most common one. Due to chronic hyperglycemia, micro vascular derangement's, oxidative stress etc. leads to nerve ischemia and impaired nerve repair, which accounts for diabetic peripheral neuropathy. DPN has its key feature of progression in symptoms over time like neuropathic pain, paraesthesia, burning sensation, numbness, etc. There is no definite clinically analogous disease similar to DPN in Ayurveda classics, but can be understood as complication arising due to a chronic vyadhi, which is prameha, upadrava of chronic prameha manifesting as avarana janya or dhathukshaya janya vathavyadhi, SundiBaladwaya kwatha with ksheerabala 7 avarthi anupana is a combination said in Chikitsa Manjari, vathavyadhi prakarana. It has srothosodhaka, rakthaprasadaka, nadeebalya and rasayana properties, which are apt for treating degenerative conditions. The intervention dhanyamladhara which is sparsaseethala helps in pacifying daha along with vatha kapha samana action. There was significant reduction of score in TCNS scale and improvement in VPT assessed through Neuropathy analyser. Thus the study was concluded to be effective in reducing the signs and symptoms of DPN.

**KEYWORDS:** Diabetic Peripheral Neuropathy, Ayurvedic Treatment Protocol.Prameha upadrava.

INTRODUCTION

According to the American Diabetic Association, DPN is defined as the presence of symptoms and/or signs of peripheral nerve damage in people with diabetes after exclusion of other potential causes. This leads to Peripheral nerve degeneration.[1]

The salient feature of DPN is progressive functional loss of neurons.[2] Diabetic peripheral neuropathy is found to be one of the common stumbling block in the chronic diabetic population, where people experience degeneration of their motor, sensory, and autonomic nerves as a result of metabolic and vascular diseases and presents as neuropathic pain, paresthesias, numbness, and even causes severe complications like limb amputations.

Diabetic neuropathy affects about 50%- 60% of people with persistent diabetes mellitus. Of which, the prevalence of Peripheral Diabetic Neuropathy ranges from 16 to 87% and associated neuropathic pain in about 26%. While considering diabetic and non diabetic population, the chance of probability of limp amputation is 10-20% high in the former one.[1]

Pathogenesis
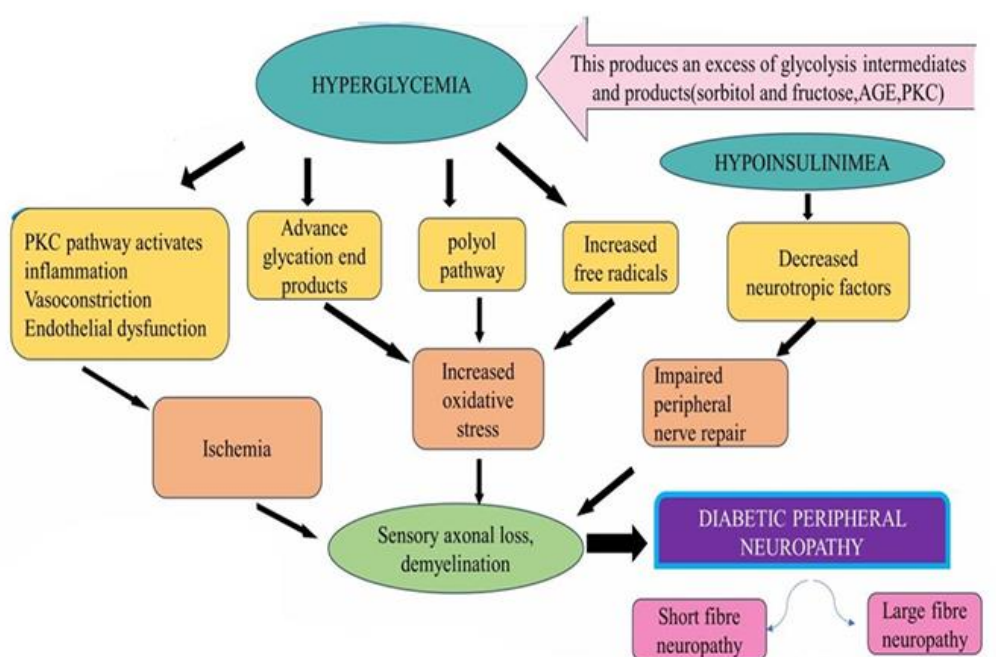
An explicit clinical condition resembling diabetic neuropathy is not referenced in Ayurveda, But conceptual analysis from the context of prameha upadrava as well as chronic madhumeha janya dhathukshaya or avarana eventually leading to vathavyadhi presentation.

Motor symptoms of Diabetic Peripheral Neuropathy

Symptoms	Lakshana	Reference
Wasting	Sosha Mamsopachaya Angasosha	Prameha upadrava[3] Pramehaupadrava Vatananatmaja vikara
Weakness	Dourbalya Sthamba Angasada Supthi Sadanam Tantra Chesta sanga	Prameha upadrava Prameha upadrava Kaphavruthaprana[4] Pittavrutha prana[5] Pittavrutha vyana Kaphavrutha vyana
Involuntary movements	kampa	Prameha upadrava

Sensory symptoms of Diabetic Peripheral Neuropathy

Symptoms	lakshana	References
Numbness	Supthi Karasupthi Padasupdii Angasupthi Swapam	Prameha poorvaroopa[6] Vatananatmaja vikara Kapha karma Twakgatha vatha Vyana avrutha prana[7] Medhakaphaavarana Sonithavrutha vatha Sarvagatha vatham Vyana pradusti vikaras
Burning Sensation	Daham Vidhaha Plosha Paridaha Paridhoopanam Daha Santapam	Prameha poorvaroopam Prameha upadravam Pitta nanatmajavikara Nanatmaja vikara of pitta Kapha kshaya Raktha medogata pitta Pittajaprameha upadrava Pittavrutha vata Sonithavrutha vata Pittavrutha prana Pittavrutha udana Pittavrutha samana
Heaviness of limbs	guruthwam	Kahavrtha vata Kaphavrtha vyana
Feeling of pins and needles	Soochibiriva nistoda	Sonithavrutha vata
Tingling sensation	Chumuchumayana Harsha Pippelika	Pittavrutha samana Sonithavrutha vata Twak gata vata

	Sancharanamiva	Kaphavrtha udana Mamsavrutha vatam
Hyperalgesia	Sparsa dvesha	Majja avrutha vata
Abnormal pain perception	Toda Soola Bheda,	Vyana vrutha prana Prameha upadrava Vata nanatmaja vikara

Acharya Susruta states that the weakness of rasayani prevents the dosha from ascending to the upper body, resulting in upadravas manifesting in the lower body, particularly as pidakas.[8] Dalhana mentions that the rasayanis as dhamanis.[9]

In the case of neuropathy, symptoms predominantly show in the lower limbs, particularly distally. In prolonged situations, the upper limb may also be affected. The impaired kapha, pitta, medas, rakta, and mamsa obstruct vata. The chalatwa will be reduced due to blockage. This results in either chestahani or vimargagamana of vata. The srotas will exhibit poornata, and the dhatus will be in vridha or sama avastha. It can result in the impairment of motor or sensory functions due to vata dosha, manifesting as negative symptoms in neuropathy such as paresthesia, muscle weakness, and atrophy. It also induces aberrant sensory functioning, namely unpleasant symptoms such as hyperesthesia and burning feelings. The anubandha of different doshas or dushyas manifests various symptoms. In kaphanubandha, characteristics such as supti, gauravam, and saithyam are observed, whereas in pitta anubandha, symptoms like daha and toda are evident. Various clinical symptoms arise depending on the affected dhatus.[10]

In neuropathy, the involvement of tridoshas with ten dusyas results in the simultaneous occurrence of multiple avaranas., in chronicity leading to dhathukshaya and further presents as vathavyadhi.

SundiBaladwaya kwatha with ksheerabala 7 avarthi anupana is a combination said in Chikitsa Manjari, vathavyadhi prakarana. It has srothosodhaka, rakthaprasadaka, nadeebalya and rasayana properties, which are apt for treating degenerative conditions.[11]

Dhanyamla which is vatha kaphahara and sparsa seethala is administered in dhara form[12] which helps in reducing symptoms of both short fibre and large fibre neuropathy.

MATERIALS AND METHODS

The patients with confirmed diagnosis of diabetic peripheral neuropathy having stable general condition will be recruited for the study from OPD of Thiruvananthapuram Government Ayurveda Hospital. The kashaya extract of sundibaladwayakwatham will be obtained from GMP certified company.

Primary Purpose Method of collection of data -the participants will be diagnosed clinically and with neuropathy analyser and screened with exclusion criteria after signing detailed informed consent.

DESIGN OF THE STUDY

- Study Type - interventional
- Estimated enrolment – 30 patients
- Sampling method - probability sampling
- Allocation- randomised sampling
- Endpoint Classification- efficacy study
- Intervention Model -single group assessment
- Masking -open label

METHOD OF COLLECTION OF DATA

Method of collection of data -the participants will be diagnosed clinically and with neuropathy analyser and screened with exclusion criteria after signing detailed informed consent.

INTERVENTION

- One sachet (3g) aqueous extract of sundibaladwaya kwatham morning and evening each, mixed with 60 ml lukewarm water and 20 drops of Ksheerabala tailam (7) avarthi 30 minutes before food (1st -90th day)
- Dhara is done with Dhanyamla for 30 minutes (1st- 14th day). Dhara is done in dharapathi. Warrm dhanyamla is gently poured to participant's body from a height of 15-20cm. Dhara is poured in anuloma gathi only, while changing participant's body, in seven positions like sitting, supine, left lateral, supine ,right lateral, supine and sitting afterwards body is wiped off and allowed to rest for 30 minutes and then a warm water bath is advised.

DATA ANALYSIS OF PRIMARY OUTCOME MEASUREMENTS

Outcome Variable

1) Reduction of score (TCNS scale)

2) Improvement in qualitative variables of Neuropathy Analyser (score).

PLAN OF ANALYSIS

The collected data will be subjected to statistical analysis using "Wilcoxon Signed Rank Test".

ASSESSEMENT TOOL

1) Toronto clinical neuropathy score (TCNS)

2) VPT Neuropathy analyser

ASSESSMENT

TCNS

0-5 – no neuropathy

6-8 -mild neuropathy

9-11- moderate neuropathy

>/= 12 -severe neuropathy

VPT neuropathy analyser

Vibration perception

Cold perception

Hot perception

Monofilament study

Each assessed and analysed through in built programming of analyser as

Normal

Mild

Moderate

Severe

OBSERVATION
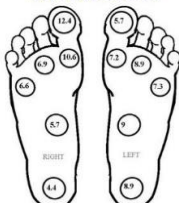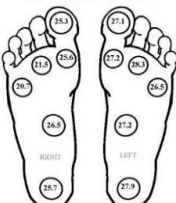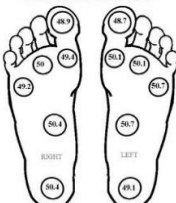
Effect on Toronto Clinical Neuropathy Score
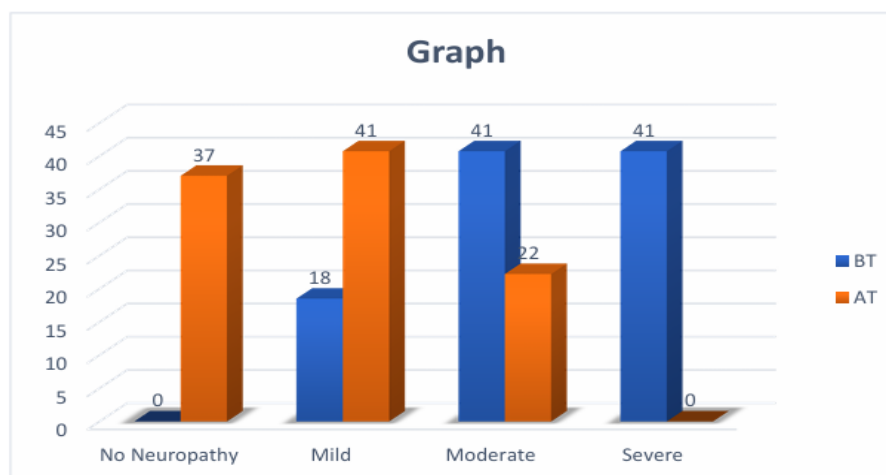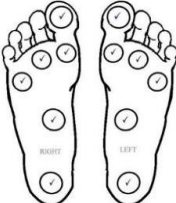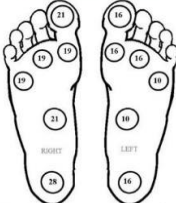
Before starting treatment, there were, respectively, 0%, 18%, 41%, and 41% of the participants in stages of no neuropathy, mild, moderate and severe. However, after treatment, the percentage proportion in these stages was changed to 37%, 41%, 22%, and 0%, respectively.

This intervention demonstrated strong efficacy in improving sensory perception and reducing neuropathy severity among participants. The data suggests that the intervention could be an effective strategy for treating sensory impairments related to neuropathy. The Wilcoxon Signed Rank Test consistently yielded P-values below 0.01, indicating statistically significant improvements.

Effect on VPT Neuropathy Analyser

Effect of intervention on		% of normal participants before treatment	% of normal participants after treatment	P value obtained
vibration	Right	19%	44%	Less than 0.001
	Left	15%	52%	Less than 0.001
Cold perception	Right	44%	96%	0.001
	Left	44%	96%	0.004
Hot perception	Right	0%	70%	Less than 0.001
	Left	0%	70%	Less than 0.001

EFFECT ON VPT ANALYSER

DISCUSSION

Madhumeha is a type of prameha, which over time and with dhatukshaya, shifts towards a Vata-dominant thridosha dushti state as it becomes more chronic. Diabetic Peripheral Neuropathy (DPN) involving thridosha dushti, can be associated with this Vata- predominant Madhumeha, with Kapha or Pitha dushti. The condition getting worsened in the upadrava Avastha of prameha leading to complex Vata vaigunya, such as uttarothara dhathu poshana impairement, margavarana, rakta dushti, indriya pradosha, and ojakshaya. The samprapthi mainly includes the dhathukshaya or avarana of vatha by other doshas and dhathus presenting as vathavyadhi. For samprapthi vighatana, samana or sodhana can be done with interventions which is vatha, kapha and pitta samana at the same time also srothosodhaka should be used.

Being an anushanga vyadhi, which means it involves a persistent cycle of dosha and dhatu disturbances along with ojakshaya.

The symptoms of numbness and paraesthesia, i.e. long fibre neuropathy Vatha-Kapha predominant can be conceptually correlated and for symptoms like burning sensation,

hot/cold imperceptions, i.e. short fibre neuropathy Pitha predominant dushti can be accounted.

The obtained data suggests that "Dhanyamla dhara" and aquous extract of "Sundibaladwaya kwatha" with Ksheerabala 7 avarthi is effective in reducing symptoms of Diabetic Peripheral Neuropathy.

Terminal manifestation of DPN mainly include degeneration of myelin sheath and axon. The myelin sheath is formed by lipid constituents, so an evident loss of lipid structure is there as the disease progress. The symptoms of DPN parasthesia, pain and tingling sensation(LFN) indicating involvement of vatha kapha dosha and burning sensation(SFN) is because of vitiation of vatha pitha. Hence drugs pacifying thridosha dushti is useful in diabetic neuropathy. Sundibaladwaya Kwatha With Ksheerabala Anupana, mentioned in Chikitsa Manjari, vathavyadhi chiktsa, mainly for supthivatha condition acts on vatha kapha dusthti. Ksheerabala tailam said in Chikitsa Manjari vathavyadhi chikitsa indicated for Aseethi vatha roga(80 vatha nanathmajaroga).

Dhanyamla dhara, which on the other hand is sparsaseethala (AH), dahajwarahara (charaka), jeevanam, dahanasanam(Sushrutha), more beneficial in reducing daha.

Parisheka or dravasweda is indicated in vatha-pitha samsrishta vikaras. The potency of drug administered through parisheka, traverses into the body getting processed by the effect of bhrajakagni in the skin through thiryak gatha dhamani, with the help of bhrajaka pitha. Thus this intervention may help in samana of prakupitha Vatha along with pacification of vitiated Pitha and Kapha and reduce symptoms of both short and large fibre neuropathy.

Both sundibaladwaya kwatha and dhanyamla dhara were done as different individual studies before, with significant results. Sundibaladwaya kwatham study was found to be more beneficial in large fibre neuropathy, where as dhanyamladhara was found to be significant in short fibre neuropathy, so when these were combined together ,in this study results were promising in symptomatic relief for both large fibre and short fibre neuropathy.

While analysing objectively, both large and short fibre neuropathic symptoms has relieved but more effective relief was for large fibre neuropathy. This observation might be because Dhanyamla dhara was only given for initial 14 days, whereas internal administration of sundibaladwayakwatham with ksheerabala anupana was for 90 days.

CONCLUSION

Chronic prameha or madhumeha leading to malasanchaya in rasa, rakthavahasrothas leading to dhathukashaya or avarana vathavyadhi manifesting as nadisosha.(0) The intervention dhanyamladhara and sundibaladwayakatha is found to be effective in reducing signs and symptoms of diabetic neuropathy as evident from the subjective score. Even though short fibre and large fibre neuropathy shows improvement but large fibre neuropathy has significantly remarkable improvements as 56.67 % of the study population was participants with large fibre neuropathy, and data showed significant improvement in all of them. The subjective symptoms like parasthesia, Burning Sensation, Numbness, Aching pain, worsening of symptoms at night, and pin prick sensation, loss of hot and cold perception, were found to have statistically significant improvement.

The data indicates that the treatment is effective in significantly reducing the severity of large fibre neuropathy, short fibre neuropathy and mixed fibre neuropathy, particularly in eliminating severe cases and reducing the overall severity of symptoms.

The majority of patients experienced a shift from severe or moderate neuropathy to mild neuropathy with a small proportion achieving complete symptomatic resolution improving the overall neuropathy status in a proportion of patients. The persistence of mild and moderate neuropathy in other patients indicates that while the treatment provided significant benefits, there may be room for enhancement to achieve more comprehensive improvements across all levels of neuropathy severity. The data clearly shows that the treatment had a positive and substantial effect on mixed fibre neuropathy too.

REFERENCES

1. Pop-Busui R, Boulton AJM, Feldman EL et al. Diabetic neuropathy: a position statement by the American Diabetes Association. Diabetes Care, 2017; 40: 136–54. [Google Scholar]
2. Ang L, Mizokami-Stout K, Eid SA et al. The conundrum of diabetic neuropathies—past, present, and future. J. Diabetes Complications, 2022; 36: 108334. [Google Scholar]

3. A.H.Ni 10/24 A.H. Su 2/17 Srikantha Murthy KR. Vagbhata's Astanga Hrdayam. Vol. 2. Varanasi: Choukhamba Krishnadas Academy; 2012. nidanasthanam, Chapter 10 Sloka 24.

4. Dalhana, Srikantha Murthy KR. Illustrated Susrutha Samhitha. Vol. 1. Varanasi: Chaukhambha Orientalia, 2012; nidana sthana, chapter 1, sloka no 35.

5. Dalhana, Srikantha Murthy KR. Illustrated Susrutha Samhitha. Vol. 1. Varanasi: Chaukhambha Orientalia, 2012; nidana sthana, chapter 1, sloka no 34.

6. C.S. Ni 4/47Sharma RK, Das B. Caraka Samhitha: Text with English translation and critical exposition based on Cakrapani Datta's Ayurveda Dipika. Varanasi: Choukhamba Sanskrit Series Office, 2011; nidana Sthana chap 4 Sloka 47.

7. 41) Agnivesa. Charaka Samhita. Chakrapani Datta's Ayurveda Deepika (Sanskrit), 1st ed. Varanasi: Chaukhambha Sanskrit Series Office, 2006; Chikitsa sthana chap-28 sloka 204.

8. Srikantha Murthy KR. Illustrated Susrutha Samhitha. Vol. 3. Varanasi: Chaukhambha Orientalia, 2012. Chikitsa Sthana, Chapter 2, Sloka 8.

9. S.S. Ni 1/20 Dalhana, Srikantha Murthy KR. Illustrated Susrutha Samhitha. Vol. 1. Varanasi: Chaukhambha Orientalia, 2012; nidana sthana, chapter 1, sloka no 20.

10. Srikantha Murthy KR. Vagbhata's Astanga Hrdayam. Vol. 2. Varanasi: Choukhamba Krishnadas Academy, 2012. Suthrasthanam, Chapter 11, Sloka 37.

11. Nambudri DS. Chikitsamanjari, Edition 12, Vidyarambam publishers, Alapuzha, 2015, chapter 45.

12. Dr. Shreevathsa, Arhanth Kumar A. Dharakalpam. Varanasi: Chaukhambha Orientalia; chapter 22 [2007].