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Randomised controlled clinical study to evaluate the efficacy of *Rajinidvandvadi Kwatha* and *Nisha Amalaki Kwatha* in *Prameha Upadrava* vis-a-vis Diabetic Peripheral Neuropathy

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ABSTRACT

In *Ayurveda*, although there is no direct correlation for Diabetic Peripheral Neuropathy but the most basic symptoms mentioned under *Purvaroopa* and *Upadrava* of *Prameha* such as *Karapada Daha, Karapadasuptata, Toda* (*Shoola*), *Harsha / Chuchumaya* (tingling sensation), *Shosha* (wasting), *Dourbalya* (weakness), and *Angasaad* (malaise) all these resemble the condition of DPN. Pathology behind it is can be studied under *Madhumeha Upadrava* caused by *Avarana Janya Vata Prakopa*. And *Upadravas* are those which develop after the onset of main disease and are dependent on *Pradhaana Vyadhi*. It will have the same *Nidaana, Dosha*, and *Dushyas* as that of the main Disease, though they have *Samprapti* of its own. When main Disease is managed well, complications will disappear. With this intention, *Rajanidvandvadi Kwatha* one of the classical *Ayurvedic* formulations mentioned under *Prameha* whose all the ingredients are herbal in origin and are known to have *Pitta* and *Vatahara* effects but its efficacy has not been documented. Also, *Rajani* (*Nisha*) is considered to be *Agraoushadha* (Drug of choice) in *Prameha* hence an effort has been made to evaluate the efficacy of *Rajanidvandvadi Kwatha* in *Prameha Upadrava.*

Key words: *Prameha Upadrava, Diabetic Peripheral Neuropathy, Rajanidvandvadi Kwatha, Nishamalaki Kwatha.*

INTRODUCTION

Diabetic Peripheral Neuropathy (DPN) can cause significant health concerns and decreases the quality of life. If left untreated it may even lead to debilitating consequences like loss of motor activity, foot ulcers, progress to gangrene and amputation. Prevalence[1] of DPN in south India is about 26.1%. Now it is the duty of Vaidya, to try to understand the cause of this disease well enough to design rational therapy to manage it. In *Ayurveda*, although there is no direct correlation for DPN but the most basic symptoms mentioned under *Purvaroopa* and *Upadrava* of *Prameha* such as *Karapada Daha*, *Karapadasuptata*, *Toda* (*Shoola*), *Harsha/ Chuchumaya* (tingling sensation), *Shosha* (wasting), *Dourbalya* (weakness), and *Angasaad* (malaise) all these resemble the condition of DPN. Pathology behind it is can be studied under *Madhumeha Upadrava* caused by *Avarana Janya Vata Prakopa*. And *Upadravas* are those which develop after the onset of main disease and are dependent on *Pradhaana Vyadhi*. It will have the same *Nidaana, Dosha*, and *Dushyas* as that of the main Disease, though they have *Samprapti* of its own. When main Disease is managed well, complications will disappear.

With this intention, *Rajanidvandvadi Kwatha*[2] one of the classical *Ayurvedic* formulations mentioned under

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Prameha whose all the ingredients are herbal in origin and are known to have *Pitta* and *Vatahara* effects but its efficacy has not been documented. Also, *Rajani* (*Nisha*) is considered to be *Agraoushadha* (Drug of choice) in *Prameha* hence an effort has been made to evaluate the efficacy of *Rajanidvandvadi Kwatha* in *Prameha Upadrava.*

OBJECTIVES

1. The present study is intended to understand the aetiopathogenesis of *Prameha Upadrava* vis-à-vis Diabetic Peripheral Neuropathy
2. To evaluate the efficacy of *Rajanidvandvadi Kwatha* in the treatment of *Prameha Upadrava* vis-à-vis Diabetic Peripheral Neuropathy
3. To evaluate the efficacy of *Nishamalaki Kwatha* in the treatment of *Prameha Upadrava* vis-à-vis Diabetic Peripheral Neuropathy
4. To compare and ascertain the efficacy of *Rajanidvandvadi Kwatha* with *Nishamalaki Kwatha* in the treatment of *Prameha Upadrava* vis-à-vis Diabetic Peripheral Neuropathy.

MATERIALS AND METHODS

Study Design: An Open labeled, randomized, comparative, interventional clinical study

Source

Clinical source: Minimum of 40 candidates were selected based on inclusion and exclusion criteria from the OPD and IPD of PG studies in Kayachikitsa of MIAMS, Manipal & medical camps and other referrals

Drug: *Rajadvandvadi Kwatha Choorna containing Vidanga, Haridra Daruharidra, Khadira, Usheera, Puga* in equal quantity & *Nishamalaki Kwatha Choorna* was prepared in Rasashala of Muniyal Institute of Medical Science and Hospital, Manipal after collecting the authenticated drugs.

Method of collection of data:

A special case proforma was prepared incorporating all the clinical manifestations and assessment criteria including laboratory investigation with minimum 40 patients suffering from *Prameha Upadrava* was selected as per inclusion and exclusion criteria including detailed history and physical examination.

Diagnostic criteria

History of diabetes with any of the following signs and symptoms

1. *Karapada Daha*
2. *Karapada Suptata*
3. *Toda*
4. *Chumchumayana*
5. *Dourbalya*

Inclusion criteria

1. Patient presenting with *Pratyamta Lakshana of Prameha Upadrava* (DPN) as *Karapada Suptata, Karapada Daha, Dourbalya, Chumchumayana, Toda* with Fasting Blood Sugar greater than 120 mg/dl and postprandial serum glucose level of greater than 180mg/dl.
2. Diagnosed case of Diabetic Peripheral Neuropathy
3. Patients of either sex will be selected.
4. Age group- 30 to 70 years.

Exclusion criteria

1. Type 1 Diabetes Mellitus patients
2. Gestational diabetes
3. Diabetes Mellitus produced due to other illnesses like Acromegaly, Cushing's syndrome, pancreatic disorders etc.
4. Autonomic and focal neuropathic patients will be excluded

Investigations

Blood: FBS, PPBS,

Glycosylated haemoglobin (HbA1c) (before treatment)

Urine: FUS {if required}

Assessment criteria

1. *Daha*
2. *Chumachumayana*

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3. *Toda (Shoola)*
4. *Dourbalya*
5. *Suptata*

Objective criteria[4-6]

1. Toranto clinical neuropathy screening system
2. Young et al criteria diabetic neuropathy symptom score

Intervention

Group A (Study group)

Rajanidvandvadi Kwatha Choorna with lukewarm water will be given 30mins before food twice a day (Morning and Night) for 30 days.

Group B (Control group)

Nisha Amalaki Kwatha Choorna with Lukewarm water will be given 30minutes before food twice a day (Morning and Night) for 30 days

OBSERVATIONS

Among the 40 patients taken for the study 40% of the patients were 50-60 years. 80% patients were males and 20% were females. 90% of the patients belonged to Hindu Religion. 90% of patients were married. Majority of the patient belonged to upper middle class i.e. 90%. 95% of the patients had the dietary habit of taking mixed diet. 60% of the patients had the habit of taking coffee or tea regularly. 60% of the patients had sedentary life style. Majority of Patients belonged to *Vatapitta Prakruti* i.e. 60%; 90% patients exhibited Madhyama Sara, 95 % recorded *Madhyama Samhanana*, 90% patients had *Madhyama Pramana*, 95% patients having *Madhyama Satva* and *Satmya*, 75% of the patients had *Avara Vyayama Shakti*. 75% had *Madhyama Koshtha*.

RESULTS

Effect on *Daha*: there was 49% relief in Group A which is slightly more when compared in Group B (43%). Hence, the result on the effect of treatment on *Karapadadaha* in Group A was better than Group B ($p<0.05$).

Effect on *Chumchumayana*: there was 46% relief in Group B which is slightly more when compared in Group A (42%) ($p<0.05$). Hence, the result on the effect of treatment on *Chumchumayana* in Group B was better than Group A.

Effect on *Toda*: There was 46% relief in Group A which is slightly more when compared in Group B (43%). Hence, the result on the effect of treatment on *Toda* in Group A was better than Group B ($p<0.05$).

Effect on *Dourbalya*: There was 32% relief in Group B which is slightly more when compared in Group A (27%). Hence, the result on the effect of treatment on *Dourbalya* in Group B was better than Group A.

Effect on *Suptata*: There was 55% relief in Group B which is slightly more when compared in Group A (52%). Hence, the result on the effect of treatment on *Suptata* in Group B was better than Group A.

Toranto Score: there was 49% relief in Group A which is slightly more when compared in Group B (35%). Hence, the result on the assessment of treatment through Toranto in Group A was better than Group B.

NDS+ NSS Score: there was 48% relief in Group A which is slightly more when compared in Group B (42%). Hence, the result on the assessment of treatment through NDS+NSS in Group A was better than Group B.

FBS: there was 8% relief in Group B which is slightly more when compared in Group A (4%). Hence, the result on the assessment of treatment through FBS in Group B was better than Group A.

PPBS: there was 12% relief in Group B which is slightly more when compared in Group A (4%).

Table 1: Effect of *Rajanidvandvadi Kwatha* and *Amalaki Kwatha* on the symptoms of *Prameha Upadrava*

Daha	Mean		BT-AT	% Relief		SD	SEM	Median	Z	P
	BT	AT								
Group A	1.85	0.95	0.9	49	BT	0.587	0.131	1.25	-4.24	<0.001
					AT	0.686	0.153	0.25		

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Group B	1.85	1.05	0.8	43	BT	0.813	0.182	2	-3.77	<0.001
					AT	0.759	0.17	1		

Chumchumayana	Mean		BT-AT	% Relief		SD	SEM	Median	Z	P
	BT	AT								
Group A	1.8	1.05	0.75	42	BT	0.696	0.156	2	-3.87	<0.001
					AT	0.999	0.223	1		
Group B	1.95	1.05	0.9	46	BT	0.51	0.114	2	-4.24	<0.001
					AT	0.605	0.135	1		

Toda	Mean		BT-AT	% Relief		SD	SEM	Median	Z	P
	BT	AT								
Group A	1.85	1	0.85	46	BT	0.671	0.15	2	-4.12	<0.001
					AT	0.795	0.178	1		
Group B	1.85	1.05	0.8	43	BT	0.745	0.167	2	-4.000	<0.001
					AT	0.759	0.17	1		

Dourbalya	Mean		BT-AT	% Relief		SD	SEM	Median	Z	P
	BT	AT								
Group A	1.3	0.95	0.35	27	BT	1.081	0.242	1	-2.65	0.016
					AT	0.999	0.223	1		
Group B	1.4	0.95	0.45	32	BT	0.995	0.222	2	-3.000	0.004
					AT	0.887	0.198	1		

Suptata	Mean		BT-AT	% Relief		SD	SEM	Median	Z	P
	BT	AT								
Group A	1.65	0.8	0.85	52	BT	0.587	0.131	2	-4.12	<0.001
					AT	0.616	0.138	1		
Group B	1.65	0.75	0.9	55	BT	0.745	0.167	2	-4.243	<0.001
					AT	0.639	0.143	1		

Table 2: Effects of *Rajanidvandvadi Kwatha* and *Amalaki Kwatha* on objective criteria

NDS+NSS	Mean		BT-AT	% Relief		SD	SEM	Median	Z	P
	BT	AT								
Group A	11.000	5.750	5.25	48	BT	1.257	0.281	11	-3.42	<0.001
					AT	4.038	0.903	5		
Group B	11.300	6.500	4.8	42	BT	1.031	0.231	11	-3.733	<0.001
					AT	3.411	0.763	7		

FBS	Mean		BT-AT	% Relief		SD	SEM	Median	Z	P
	BT	AT								
Group A	181.200	173.150	8.05	4	BT	44.169	9.877	174.5	-1.64	<0.105
					AT	26.617	5.952	177.5		
Group B	176.800	162.700	14.1	8	BT	41.110	9.193	177.000	-3.175	<0.001
					AT	31.490	7.042	161.000		

PPBS	Mean		BT-AT	% Relief		SD	SEM	Median	Z	P
	BT	AT								
Grou	269.900	259.100	10.8	4	BT	64.366	14.393	261.5	-1.72	0.09

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p A					AT	53.926	12.058	260.00		
Group B	276.950	244.100	32.85	12	BT	68.428	15.301	293.000	-3.400	<0.001
					AT	66.538	14.878	249.000		

Toranto	Mean		BT-AT	% Relief		SD	SEM	Median	Z	P
	BT	AT								
Group A	10.25	5.25	5	49	BT	2.268	0.507	11	-3.833	<0.001
					AT	4.166	0.932	5		
Group B	9.8	6.4	3.4	35	BT	1.824	0.408	10	-3.946	<0.001
					AT	2.683	0.600	7		

DISCUSSION

For the genesis of *Prameha Upadrava* (DPN), the vitiated *Vayu* carries away *Pitta* from its normal site i.e., *Mahasrotas* leading to *Vimargagamana* of *Vyana Vayu* and *Pitta* which after spreading to the whole body gets *Sthana Samsraya* in *Twacha* and produces various features according to *Anubandha*. If we see the literature of counter part of modern medicine, that gives a similar picture of Diabetic Peripheral Neuropathy. It is supposed that small nutrient vessels (vasa nervosum) which provide nutrition to nerves, become occluded (i.e**.,** S*rotorodha* occurs, one of the chief causes of *Vata-Prakopa*). This leads to deficiency in nutrition of nerves (i.e., deficiency in *Tarpana* of *Snayu-Snayugata, Tarpaka Kapha Kshaya*). In a diabetic patient, the usual pathway of glucose metabolism (i.e., via Glucose -6-PO4) becomes depressed and sorbitol pathway becomes predominant. The enzyme sorbitol dehydrogenase acquires more rapid action and as a result, sorbitol and fructose are formed in excess and become accumulated in tissues which causes damage to nerve tissue and produces axon degeneration which leads to neuropathy. Here axon degeneration and demyelination of nerve sheath may be attributed to *Vata Prakopa* and *Kapha Kshaya*. The rapid rate of activity of enzyme sorbitol dehydrogenase may be attributed to *Pitta Vriddhi*. Normalcy of *Vayu* is needed for proper healing, growth, and proper maintenance of tissue. Thus, involvement of *Tridoshas* is apparent in DPN. *Rajanidvandvadhi Kwatha* is having *Tikta, Kashaya Rasa Rasa* and *Ruksha Guna* among which *Tikta* (bitter) *Rasa* is said to be "*Kleda Upashoshana*" *Meda Shoshana* and *Kapha Harana* while *Kashaya* (astringent) *Rasa* to be "*Sharira Kledasya Upayokta*." helps in *Sthireekarana* of *Dhatus* and also does *Kleda, Meda,Vasa, Majja, Lasika, Sweda, Mutra, Pitta, Shleshma, Upashoshana.* They are having opposite qualities to that of *Kapha* and *Medas* which is the main entity of the pathogenesis of *Prameha* so these together is helpful in *Sthulapramehi* & effectively counteract the *Samprapti*. Most of the ingredients in the formulations are having the properties like *Rakthaprasadana*, *Kushtahara* & *Vranaropana* etc. along with *Dahaprashamana*, *Sheeta Veerya* which are helpful for *Kara Pada Daha* and *Kara Pada Supthi.* Here, Peripheral Neuropathies and vasculopathies which are quite in accordance with the late complications of Diabetes Mellitus & for the skin lesions in modern science which are produced in the disease *Prameha* can be treated. Also, *Tikta Rasa* removes *Sroto Rodha,* does *Sroto Vivarana* & the action of *Lekhana* might be seen and thereby helps in alleviating *Kapha Prakopa.* It can be understood in terms of an elevated glycated end product at the cellular level which activates polyol pathway or sorbitol/aldose reductase pathway that decreases the level of glutathione and nitric oxide which is an important vasodilator in turn increase in reactive O2 radicals. This sorbitol cannot cross cell membrane, accumulates & causes osmotic stress on cells by drawing water into cells causing inflammation. Correlating it to Diabetic neuropathy which is a *Vatapradhana Tridoshaja Vyadhi* having *Anubandha* with *Pitta* and *Kapha*. Where, *Kapha*, *Pitta* that are mainly responsible factor for *Avarana* of *Vata*, in

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Madhumeha Samprapti. Vidanga has *Nadibalya* effect and thus useful when there is neuropathy.

Conclusion

Rajanidvandvadi Kwatha showed significant improvement in the objective criteria's like Toranto score, NDS+NSS Score after 30 days of treatment in the patients. While *Nishamalaki Kwatha* had significant improvement in FBS, PPBS. From this study it is evident that *Rajanidvandvadi Kwatha* has got an added effect in all the subjective parameters like *Daha*, *Toda* whereas in *Chumchumyana, Dourbalya* & *Suptata Nishamalaki Kwatha* showed better results.

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