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CLINICAL TRIAL OF AN INDGENOUS COMPOUND DRUG NISHAAMALKI IN THE MANAGEMENT OF MADHUMEHA VIS-À-VIS DIABETES MELLITUS

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***ABSTRACT**: A Clinical trial of Indigenous compound drug 'Nishamalaki' was carried out in the CRI (Ayurveda) Hospital, Jaipur on the patient of Madhumeha. For this study, patients were randomly divided into two groups of 25 individuals each and they were termed as group A and B. The individuals of group a were administered Nishamalaki in a dose of one gram twice daily along with diet control, the patients were followed every fort nightly. A significant improvement in the symptoms along with lowering of blood glucose level was observed in the individuals of group B, while the individuals of group A responded initially but could not sustain the same.*

INTRODUCTION:

Madhumeha, often correlated with Diabetes Mellitus stands as a global problem. Diabetes Mellitus is the most common of the serious metabolic diseases. When a patient presents sign and symptoms attributable to an osmotic diuresis and is found to have hyperglycemia, essentially all the physicians agree that Diabetes is present. It was well known to the ancient Indian Physicians who described not only the sweet taste of urine as one of the major symptoms but also the relationship of the disease with obesity and consequences of bio-chemical abnormalities in the body creating dislipidaemia in the glucose metabolism.

An elaborate description of its clinical features and effective management are seen in classical texts. A number of herbal preparations and plant extracts have been used with varying degree of success in the management of **NIDDM**. In the present study on herbal preparation viz. Nishamalaki was taken under trial and its effects on clinical features, blood and urine sugar levels was assessed.

MATERIAL AND METHODS:

1. **Selection of cases:-** Clinical trail of the drug was carried out in the CRI(Ay.). hospital at Jaipur.

   Patients belonging to the near by areas of Jaipur were selected to ensure regular follow up.

- Patients were randomly divided in two groups. Group A and B the groups contained 25 patients having at least two follow up. All the patients were between age group of 30 to 70 yrs. Having diagnosed as **NIDDM.**
- Patients of group – A were administered a placebo (Barley Powder) in a dose of one gram thrice daily for six weeks

along with diet control and they were followed every Fortnightly.

- Patients of group B were …. Every fortnightly.
- Patients diagnosed as **IDDM** and individuals having systematic complications were considered unfit for the studies.

H. Parameters for Assessment:

- Clinical parameters: Certain classical sign and symptoms based on the protocol cleared by the respective ethical committee of **CCRAS** were taken up for study e.g. Prabhutamutrata (polyuria), avilamutrata (Turbid urine), Kshudhadhikya (Poly phagia) Trisha (Polydypsia) and Sthaulya (obesity). Symptoms were graded as 'O' (Nil), '4' (Mild), '7' (Moderate and '10' as severe
- Sthaulya was assessed on the basis of ponderal index. (cm.kg.)

Pathological parameters :-

- Value of fasting blood sugar and **PPBS.** (Before and after treatment)
- Urine sugar (Before and after treatment)

Treatment Response:-

Response of the treatment was observed on the basis of improvement in clinical features Blood and Urine sugar levels after one month of therapy.

RESULTS AND OBSERVATION

TABLE NO.1. INCIDENCE OF AGE & SEX

S.No.	Age group (Yrs.)	Group	Male	Female
1.	31-40	A	5(20%)	1(4%)
		B	3(12%)	
2.	41-50	A	8(32%)	3(12%)
		B	9(36%)	2(8%)
3.	51-60	A	3(12%)	4(16%)
		B	5(20%)	2(8%)
4.	61-70	A	-	1(4%)
		B	1(4%)	3(12%)

*n= 25 Table shows that most of the patient in both the groups were in the age group of 41-50yrs.

Table No.2-Incidence of dosa prakriti.

S.No	Prakriti	Group -A	Group –B
1.	V	1(4%)	1(4%)
2.	P	3(12%)	2(8%)
3.	K	1(4%)	2(8%)
4.	V-P	6(24%)	5(20%)
5.	V-K	6(24%)	7(28%)
6.	P-K	6(24%)	7(28%)

7.	S	2(8%)	1(4%)

*n= The table shows that Dvandaja Prakriti was predominant in both groups.

Table No.3
INCIDENCE OF MANASPRAKRITI

S.No.	M. Prakriti (on basis of Predominence)	Group - A	Group - B
1.	Sattva	9(36%)	10(40%)
2.	Raja	15(60%)	14(56%)
3.	Tama	1(4%)	1(4%)

n = 25 Most of the patient have Rajo guna pradhana, Manas Prakriti

Table No-4-Incidence of severity of symptoms (BT)

S.No.	Symptoms	Group A				Group B			
		Nil	Mild	Mod.	Severe	Nil	Mild	Mod.	Severe
1.	PradhutaMutra	0 (0.0%)	4 (16.0%)	18 (72%)	3 (12.0%)	2 (8.0%)	5 (20%)	14 (56.0%)	4 (16.0%)
2.	Avil Mutrata	16 (64%)	6 (24%)	2 (8%)	1 (4%)	18 (72%)	5 (20%)	2 (8%)	O (0%)
3.	Kshudhadhikya	0 (0%)	7 (28%)	15 (60%)	3 (12%)	6 (24%)	5 (20%)	12 (48%)	2 (8%)
4.	Trisha	1 (4%)	8 (32%)	11 (44%)	5 (20%)	3 (12%)	9 (36%)	11 (44%)	2 (8%)

*n=25; BT-Before Treatment

Table No-5-Incidence of severity of symptoms (AT)

S.No.	Symptoms	Group A				Group B			
		Nil	Mild	Mod.	Severe	Nil	Mild	Mod.	Severe
1.	PradhutaMutra	1 (4%)	12 (48%)	8 (32%)	4 (16%)	2 (8%)	16 (64%)	7 (28%)	0 (0%)
2.	Avil Mutrata	17 (68%)	8 (32%)	0 (0%)	0 (0%)	20 (80%)	4 (16%)	1 (4%)	0 (0%)
3.	Kshudhadhikya	1 (4%)	17 (68%)	7 (28%)	0 (0%)	7 (28%)	14 (56%)	3 (12%)	1 (4%)
4.	Trisha	1 (4%)	5 (60%)	9 (36%)	0 (0%)	6 (24%)	13 (52%)	6 (24%)	0 (0%)

*n=25; AT-After Treatment

Table No. 6. – Mean symptom score (BT & AT)

S.No.	Symptoms	Group A			Group - B		
		BT	AT(1)	AT(2)	BT	AT(1)	AT(2)
1.	PradhutaMutra	6.88	6.40	5.80	6.32	5.36	4.52
2.	Avil Mutrata	1.92	1.80	1.28	1.36	1.24	0.92
3.	Kshudhadhikya	6.52	5.32	4.68	4.96	4.12	3.48
4.	Trisha	6.36	5.40	4.92	5.32	4.68	3.76

N=25; BT-Before Treatment; After Treatment

Table No -7 Showing significance of the treatment on symptoms (Group B)

S.No.	Symptoms	X difference	SD(+)	SE(+)	t	P
1.	PradhutaMutra	1.80	2.28	0.46	3.913	<.001***
2.	Avil Mutrata	0.44	2.68	0.54	0.814	<.4
3.	Kshudhadhikya	1.48	2.95	0.59	2.508	<.02*
4.	Trisha	1.56	2.59	0.52	3.000	<.01**

N= 25;*** Highly significant, ** Significant, *Less significant

Table No -8 Showing significance of the treatment on symptoms (Group A)

S.No.	Symptoms	X difference	SD(+)	SE(+)	t	P
1.	PradhutaMutra	1.80	1.87	0.47	2.297	<.05*
2.	Avil Mutrata	0.64	2.40	0.48	1.333	<.2
3.	Kshudhadhikya	1.04	1.76	0.56	1.857	>.1
4.	Trisha	1.14	2.16	0.54	2.111	<.05

N= 25;*less significant

Table No. 9: Treatment response on sthaulya (Based on ponderal Index)

S.No	Group	Before treatment	After treatment
1.	A (25)	4.558	4.498
2.	B(25)	4.983	4.856

The table shows mean ponderal Index (CM/kg.) of both the groups.

Table no.10; Treatment response on Urine Sugar level (Before & After Treatment)

S.No	Group		Nil (0)	Mild (+)	Moderate (+ +)	Severe (+ + +)
1.	A (25)	BT	6 (24%)	7 (28%)	10 (40%)	2 (8%)
		AT	8 (32%)	9 (36%)	7 (28%)	1 (4%)
2.	B (25)	BT	7 (28%)	6 (24%)	9 (36%)	3 (12%)
		AT	10 (40%)	8 (32%)	5 (20%)	2 (8%)

Table – 11; Treatment response on Blood sugar level

S.No	Group	FBS				PPBS			
		X diff.	SE	t	p	X diff.	SE	t	p
1.	Group A (n=25)	13.83	12.3	1.124	>.2	20.28	19.98	1.015	>.3
2.	Group B (n=25)	13.96	8.08	1.178	<.1*	18.64	13.53	1.378	<.1*

* less significant

Table – 12 ; Influence of Prakriti on Blood sugar (Group – B)

S.No	Prakriti	FBS				PPBS			
		X diff.	SE	T	P	X diff.	SE	T	P
1.	Vataja (n=1)	2.0	-	-	-	4.0	-	-	-
2.	Pittaja (n=1)	18.5	69.25	.267	NS	19.0	83.0	0.229	NS
3.	Kaphaja (n=2)	24.0	2.0	12.0	<.001**	17	7.5	2.267	<.1*
4.	V-P (n=5)	8.4	20.84	0.40	>.7	15	36.18	0.414	<.7
5.	V-K (n=7)	24.28	11.52	2.10	<.1*	22	19.16	1.148	>.3
6.	P-K (n=7)	12.29	10.43	1.17	>.2	14.29	12.47	1.145	>.3
7.	Sama (n=1)	14	-	-	-	-	-	-	-

*less significant ** highly significant

Table – 13 ; Influence of Prakriti on Blood sugar (Group – A)

S.No	Prakriti	FBS			PPBS				
		X diff.	SE	T	P	X diff.	SE	T	P
1.	Vataja (n=1)	30.0	-	-	-	50.0	-	-	-
2.	Pittaja (n=3)	10.0	47.25	.212	NS	12.0	35.3	0.338	NS
3.	Kaphaja (n=1)	30.0	-	-	-	19.0	-	-	-
4.	V-P (n=6)	1.0	14.67	0.068	NS	7.5	23	0.326	NS
5.	V-K (n=6)	11.0	9.08	1.211	>.3	13.66	5.72	2.388	<0.05
6.	P-K (n=6)	21.0	15.51	1.354	>.3	32.83	21.64	1.517	>.2
7.	Sama (n=2)	32.5	11.75	2.765	>.2	39.0	25.5	1.529	>.2

DISCUSSION:

- The indigenous compound drug Nishamalaki selected for clinical trial is a combination of Haridra (Curcuma longa) and amalaki (Emblica officinalis), also advocated by Vagbhata as a drug of choice for the treatment of prameha. Shamaka properties. Haridra is well known as a blood purifier while the Amalaki has a potent Rasayana effect.

- Group B, in general showed better response to the treatment considering symatology and decrease in the level of blood and urine sugar. This indicates the efficacy of drug as hypoglycemic agent.

- Patients with NIDDM have two physiologic defects, abnormal insulin secretion and resistance to insulin action in target tissues.

- Insulin resistance may be due to any one of three general causes; an abnormal insulin molecule, an excessive amount of circulting anti bodies and target tissue defects.

- It may be possible that this medicine may have some role against circulating antagonists and on the target tissue defects. Both the medicines included in the compound have Tridosa shamaka AND Rasayana property. They are acting at the level of Rasa, Agni and Srotas, thus they may exert a positive response on the whole system

- Response of the treatment was found better among the individuals having Kaphja content in their body constitution, favours the better prognosis of Kapahaja prameha as described in the classics.

- No untoward effect was observed during the period of therapy.

CONCLUSION:-

The drug Nishamalaki seems to be a simple, safe and cost effective remedy for the treatment of Diabetes mellitus. It may not be so useful in the individuals having fasting blood sugar levels above 200 mg%. In such condition oral hypoglycemic agent may be added. Having high safety profile this drug may also be used as adjuvant along with the modern oral hypoglycemic agents.

REFERENCES

1. Charak : Charak samhita, Choukhamba publications Varanasi.
2. Davidson: Text book of medicine, ELBS publications
3. G.C.Nanda et al: Nishamalaki in Madhumeha (NIDDM): A clinical study. Journal of Research in Ayurveda and siddha pp-34-40, vol. XIX, No-1-2.
4. Harrison : Principles of internal medicine, 11th Ed. Mc Graw Hill Book Company.
5. Madhavakara: Madhava Nidanam, Choukhamba publications, Varanasi

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