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EFFECT OF AN INDIGENOUS FORMULATION IN HYPERLIPIDEMIC PATIENTS OF DIABETES MELLITUS TYPE II

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ABSTRACT

Purpose: Patients with type II diabetes mellitus have several lipid abnormalities, including elevated plasma triglycerides (due to increased VLDL and lipoprotein remnants), elevated levels of dense LDL, and decreased plasma levels of HDL-C. Diabetic dyslipidaemia in India is one of the main causes for Coronary Artery Disease (CAD) mortality. As per critical judgment of some authors of recent era, *Prameha* is compared and correlated with Diabetes mellitus and *Meda* is compared with body fat. *Meda* is considered as the first *Dushya* to get vitiated in the pathological process of *PramehaRoga* as aggravated *Kapha* vitiates it selectively due to their identical characteristics. **Method:** In this clinical study, 20 clinically diagnosed patients were administered Indigenous Formulation 2 capsule twice a day in empty stomach for 60 day with Luke warm water. **Result:** The results were statistically **highly significant** in *Panduvarnamootrata*, *Kara PadaDaha*, Sr. Cholesterol, Sr. Triglycerides & FBS .While statistically **significant** result found in the symptoms of *Pipasadhikya*, *AavilMootrata*, *KshudaAdhikya*, *SwedaAdhikya*, *Kricchvyavayata* & Sr. LDL. **Conclusion:** From the observation & result it can be concluded thatIndigenous Formulation can be used effectively in the management of Hyperlipidemic state in Diabetes Mellitus Type II.

Keywords: Diabetes Mellitus Type II, Hyperlipidemia, Indigenous Formulation.

INTRODUCTION

The international rise and incidence of diabetes is staggering. The WHO predicts that the global prevalence of Diabetes will increase to 300 million by 2025 with India set to have 57 million diabetics by 2025[1]. Macrovascular disease is the most common cause of morbidity and mortality in T2DM[2]. Two third of Type 2 diabetic patients die of macro vascular disease. Among them three fourth are from Coronary Artery Disease[3]. There are several associations between dyslipidemia and the increased risk of cardiovascular disease in patients with type 2 diabetes mellitus. Dyslipidemia is the major risk factors for macrovascular complications leading to cardiovascular disease (CVD) in type 2 diabetes mellitus (T2DM)[4]. Macrovascular disease is defined as illnesses affecting the larger arteries supplying the heart, brain, and the legs, thereby causing ischemic heart disease, cerebrovascular disease, and peripheral vascular disease[5]. In patients with diabetes, alteration in distribution of lipid increased risk of atherosclerosis.

The multifactorial involvement of *Meda* (fat), *Kapha*, *Vata*, and *Agni* (digestive metabolic activity) is a common pathophysiologic phe-

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nomenon of both *Prameha* and obesity.The role of *DushtaMeda* (fat/adipose tissue) is of great importance in the pathogenesis of *Prameha*. Its role is not only as *Dushya* (disturbed functioning of the *Dhatus*), but something more than that. In *Ayurveda*, *Ama* refers to the toxic intermediary products of digestion and metabolism that result from improperly digested food. The relationship between *Prameha* and *Ama* is well documented. If the *Agni* (digestive metabolic activity) is not proper, accumulation of *Ama* occurs, which ultimately leads to *Prameha*and*Medodushti*.

The measures used for *Sthaulya* (obesity) can be utilized for the management of *Prameha*, such as *Apatarpana* (Balanced diet with restricted calories). Measures that minimize the morbid *Kapha* and (fat) will improve the health of the patient. The foods recommended for *prameha* in the classical *Ayurvedic* texts should be included in the patient's diet. Balanced nutrition, appropriate physical exercise, and administration of herbal supplements will help to manage *Prameha, Medadhatudushti*.

MATERIALS & METHODS

A) Aims & objectives:

The present clinical trial has been undertaken with the following three objectives:

1 Conceptual and clinical studies on Hyperlipidemia in Diabetes mellitus type-II &*Medodushti* in*Madhumeha*.

2 To evaluate the efficacy of Indigenous Formulation in Hyperlipidemic patients of Diabetes Mellitus type II.

B) Selection of cases:

The study was conducted on 20 clinically diagnosed & confirmed patients of Hyperlipidemia and Diabetes mellitus type II on the basis of subjective & objective parameters. Patients were randomly selected from OPD & IPD of Aarogyashala, P.G. Department of Kayachikitsa NIA, Jaipur. A regular record of assessment of all patients was maintained according to Proforma prepared for the purpose.

(A) Inclusion Criteria: Patients with following conditions were excluded from clinical trial:

(a) Diagnosed and confirmed cases of Hyperlipidemia and Diabetes Mellitus Type II (based on NCEP-Adult treatment panel III guideline; TC>200 mg/dl, TG>150 mg/dl, LDL-C>130 mg/dl, HDL<60 mg/dl. (Fasting blood sugar>126 mg/dl Post prandial blood sugar> 200 mg/dl).

(b) Patients between the age group of 20-60 years of either sex.

(c) Patients willing to sign the consent form.

(B)Exclusion Criteria: Patients with following conditions were excluded from clinical trial:

(a) Patients having Type - DM I [IDDM]

(b) Patient of type II DM who are on Insulin therapy.

(c) Malignancy or any other serious illness.

(d) Diabetes Insipidus.

(e) Drug induced DM.

(f) Fasting Blood Sugar >200mg/dl.

(g) Uncontrolled Hypertension (Diastolic blood pressure >110 mm of Hg)

Administration of Drug:

20 patients were administered Trial Drug Indigenous Formulation in dose of 2 tab. twice in a day (2gm/day) with lukewarm water for 60 days.

Table No. 1 Contain of Trial Drug

S. No.	Constituents	Botanical Name/ Latin name	Part Used	Ratio
1	***Daruharidra***	*Berberisaristata*	Root	1
2	***Mulethi***	*Glycyrrhizaglabra*	Root	1
3	***Chitraka***	*Plumbagozeylanica*	Root	1
4	***Dhatri***	*Emblicaofficinalis*	Fruit	1
5	***Haritaki***	*Curcuma longa*	Fruit	1
6	***Bibhitaki***	*Terminalia belerica*	Fruit	1

-Indigenous Formulation

Study Design:-

The study held on:

a. Single Centre
b. Open Label
c. Randomized

ROUTINE EXAMINATION, ASSESSMENT AND FOLLOW UP STUDY:-

The full details of history & physical examination of patient were recorded, before starting treatment Proforma was developed. Further clinical & physiological assessment were done at every follow-up on 30 days' interval & after the completion of trial.

CRITERIA FOR ASSESSMENT:

The effect of trial drug were assessed in terms of Subjective & Objective Laboratory parameters**:**

(A) Subjective assessment: All the patients registered for clinical trial asked for any changes in their clinical manifestations.

(I) Symptom of*Medodhusti*

1. *KshudraShwasa* (Breathlessness on exertion)
2. *Kshudhadhikya* (excessive hunger)
3. *Swedadhikya (excessive sweating)*
4. *Dourbalya* (weakness)
5. *Kricchavyavayata*(difficulty in sexual intercourse)
6. *Krathana* (snoring)
7. *Sharir Gaurav* (Heaviness in body)

(II) Symptom of *Madhumeha*

1 *Avilmutrata* (Turbid urine)
2 *Prabhootmootrata*
3 *Pipasadhikya* (excessive thirst)
4 *Tandra* (Drowsiness)
5 *Hastpaadtaldaah* (Burning sensation in palm and soles)
6 *Saad* (Lethargy)
7 *PanduvarnaMutra*(Yellowish white urine)

B) Objective Parameters:

For Objective parameters following examinations done (Laboratory and Anthropometric):

Laboratory Parameters:

Hematological

- Hemoglobin (gm %)
- Total leucocyte count (TLC) in /mm^3
- Erythrocyte sedimentation rate (ESR) in mm/hour.

Bio-chemical

- Serum Total cholesterol
- Serum Triglycerides
- Serum Low Density Lipoprotein (LDL)
- Serum Very Low Density Lipoprotein (VLDL)
- Serum High Density Lipoprotein (HDL)
- C-Reactive protein (CRP)
- Fasting Blood sugar (F.B.S.)
- Post prandial (P.P.B.S)
- Blood Urea
- Serum Creatinine

❖ **Urine Routine Examination**

- **Body Mass Index (BMI)**
- **Body weight**
- **Waist- Height Ratio**

For assessment of improvement in Clinical Manifestations following Symptom Rating Scale were used:

Symptoms	***Score***
Absent	0
Mild	1
Moderate	2
Severe	3

OBSERVATIONS & RESULTS:

Maximum number of the patients were from urban area i.e. 85%.Most of the patients having 77% middle class socio-economic status. Many patients were having positive family history of obesity i.e. 10, familial history of DM i.e. 8. Most of patient given occupation history that resemble to table work i.e. 48%, House worker on second number i.e.30.95%.Observation of addiction in the present study revealed that majority of the patients were addicted to some or other things. Maximum number of patients i.e. 15 out of 20 were addicted to Tea/Coffee followed by 12 Alcohol Tobacco chewing, 4 patient addicted to smoking. Data reveal that majority of patient (out of 20 patient) taking *Snigdha I.e.15, Guru i.e. 13, Sheet i.e. 10*dominant*Guna Ahar.* Present study reveals that most of the patients 55% were having *Vishmagni*, 24% patients were having *Tikshnagni*. Majority of patient were i.e. 53% having *AvaraVyayama Shakti*, followed by 42% had *Madhyama*. Most of the patient i.e.55% were having *Vata-kaphajaSharirikaPrakriti*, 52% of patients were having *RajasikaManasikaPrakriti*, 64% patients were having *Sarva rasa Satmya* and 80% patients were having *MadhyamaSatva.*

II. The results of the therapeutic trial:

Table No. 2 :Table showing Effect of therapeutic trial on clinical symptomatology in 20 patients of DM-II with Hyperlipidemia (Wilcoxon matched pairs signed ranked test):

Variable		**Group**	**Mean**	**Mean Diff.**		**% Relief**	**S.D.**	**S.E.**	**P Value**	**Significance**
				BT	**AT**					
Prabhoot-Mutrata	Freq. of Urine	**A**	1.47	1.37	0.10	7.14%	0.56	0.13	> 0.05	**NS**
	Quantity of urine	**A**	1.52	1.21	0.31	20.7%	0.67	0.15	> 0.05	**NS**
Pipasadhikya		**A**	1.42	1.10	0.31	22.22%	0.47	0.11	< 0.05	**S**
Saad		**A**	1.78	1.52	0.26	14.8%	0.65	0.15	>0.05	**NS**
Avilmootrata		**A**	1.47	1.00	0.47	27.11%	0.67	0.15	< 0.05	**S**
Tandra		**A**	1.42	1.10	0.31	22.3%	0.58	0.11	> 0.05	**NS**
Panduvarnmootrata		**A**	1.52	0.68	0.84	55.2%	0.76	0.17	< 0.001	**HS**
Sharir Gaurav		**A**	1.21	1.00	0.21	17.4%	0.63	0.14	> 0.05	**NS**
Karpaddaha		**A**	1.78	1.05	0.73	41.2%	0.45	0.10	<0.0001	**HS**
Kshudadhikya		**A**	0.84	0.52	0.31	37.5%	0.47	0.10	< 0.05	**S**
Kshudrashwas		**A**	1.15	0.9	0.25	21.8%	0.44	0.99	> 0.05	**NS**
Swedhadhikya		**A**	1.75	1.45	0.30	17.2%	0.47	0.10	< 0.05	**S**
Dorbalya		**A**	1.73	1.47	0.26	15.2%	0.56	0.12	> 0.05	**NS**

Krichvyavyaata	**A**	1.15	0.78	0.36	31.8%	0.49	0.11	< 0.05	**S**
Krithanta	**A**	0.63	0.42	0.21	32.24%	0.41	0.97	> 0.05	**NS**

Table No. 3: Table showing Effect of therapeutic trial on lab parameters in 20 patients of DM-II with Hyperlipidemia based on objective parameters (Paired't' Test):

Variable	Group	Mean		Mean Diff.	%Relief	SD±	SE±	T	P	S
		BT	AT							
Heamo-globin	**A**	12.268	12.4	-.1263	1.10%	0.6419	0.1473	0.857	> 0.05	**NS**
TLC	**A**	0.7016	7.237	-.2211	31.50%	0.425	0.0975	2.267	< 0.05	**S**
ESR	**A**	27.789	26.368	1.4211	5.12%	2.1681	0.4975	2.256	> 0.05	**NS**
Total cho-lesterol	**A**	222.79	210	12.711	5.70%	7.125	1.632	7.792	<0.0001	**HS**
Tri-glyceride	**A**	184.51	173.32	11.168	6.10%	7.002	1.606	6.94	<0.0001	**HS**
HDL	**A**	50.579	52.74	-2.158	4.20%	5.08	1.165	1.852	> 0.05	**NS**
LDL	**A**	128.12	121.1	6.842	5.31%	11.12	2.549	2.684	< 0.05	**S**
VLDL	**A**	37	35.21	1.789	4.80%	4.78	1.1	1.632	> 0.05	**NS**
Blood Urea	**A**	32	31.78	0.2105	0.60%	2.8	0.6428	0.377	> 0.05	**S**
Sr. creati-nine	**A**	0.8737	0.8421	0.2135	3.60%	0.88	0.021	1.555	> 0.05	**NS**
FBS	**A**	159	157.5	1.63	1.10%	3.933	0.903	1.81	< 0.05	**S**
PPBS	**A**	221.3	213.7	0.763	3.50%	7.55	1.732	4.4	<0.001	**HS**
CRP	**A**	1.474	1.453	0.021	1.50%	0.0855	0.0196	1.073	> 0.05	**NS**
Urine sug-ar	**A**	1.158	0.9947	0.1632	1.41%	0.306	0.0701	2.32	< 0.05	**S**
Urine Pro-tine	**A**	0.3421	0.306	0.3063	11.40%	0.2432	0.0557	0.660	> 0.05	**NS**
Sp. Gravi-ty	**A**	1.023	1.02	0.0031	3.00%	0.0119	0.0027	1.136	> 0.05	**NS**
Body weight.	**A**	67.005	67089	2.158	3.20%	1.358	0.3177	6.79	<0.0001	**HS**
BMI	**A**	27.001	26.723	0.778	2.80%	0.4524	0.1038	7.5	<0.0001	**HS**
WHR	**A**	0.9589	0.9311	0.0279	2.90%	0.0274	0.0062	4.43	< 0.001	**HS**

DISCUSSION

Probable Modes of Action ofIndigenous Formulation*:*

Most of drug have perfect properties in **Indigenous Formulation** to cure Diabetic Dyslipidemia According to Ayurveda concepts.

- ***Amalaki***is potent *Rasayanaushadha* five *Rasa* (except *Lavan*) with its *Rasayana-guna, Tikta rasa Amalaki* possess anti-diabetic effects *Acharya vagbhatta* also mention it in *Agreya for Prameha*.***Haritaki:*** *Acharya Charka* mentioned in*Sutrasthan* Chapter 1 *Haritaki*-have same properties as *Amlaki*fewer lack then it. *Haritaki have also Laghu, RukshaGuna, UshnaVeerya and Tridoshshaak property, these are very useful for Mad-*

*humehiRogi.**Bhibhitaki**: Have Kashaya Rasa, UshnaVeerya, LaghuRukshaGuna and TridoshShamak*properties. According to *Rasa, Veerya&Guna* it is very useful to desolve*VaikritKapha and DushtMedodhatu*so these virtues help in reduce diabetic Dyslipidemia.***Daruharidra:*** it have *Tikta, Kashaya rasa, Laghu, RukshaGuna, UshanaVeerya, and KatuVipak.DaruharidraPittasaraka, Yakridutte-jaka, Deepana, Rakta-Shodhaka, Trishna-Nigraha, Kaphaghna, Shothhara, Vrana-shodhana Karma.**Chitrak***Have *Katu Rasa and KatuVipak.* ***Katu****Vipak*genrate*pachak-agni* desiccants the food removes obstruction and dilates the passages and allays *KaphaDoshas*. ***Mulethi:*** have*Vata-pittashamak* property, *Madhur Rasa* and-*MadhurVipak.* It has*Vata-Kaphahara*property. *Madhura Rasa* being habituated since birth produces greater strength in *Srotasa*, *Dhatus* (tissues) and improves the strength of *Oja* due to their *Ojovardhaka*, *Rasayana* properties which play an important role in pathogenesis of *Madhumeha.*

CONCLUSION

1. Observations of current study reveals that Diabetic Hyperlipidaemia has peak incident at 4th and 5th decade of life, affecting more Sedentary life spending, *GurvadiA-har-Vihar* taking personand patient who had genetically predominant familial history of obesity and Diabetes.
2. It can be concluded that the proposed indigenous medicines In current research exhibit significant hypoglycaemic activity and can be used safely in patients of *Madhumeha*(Diabetes Mellitus) with success in combination with each other.
3. The trial indigenous drug was ffective in reducing Fasting Blood Sugar, Post Prandial Blood Sugar.
4. From this data finally we can conclude that Indigenous formulation was effective on *Panduvarnmootrata, karpaddaha, Pi-pasadhikya, Avilmutrata, Swedadhikya*.

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