International Journal of Institutional Pharmacy and Life Sciences 2(3): May-June 2012

# INTERNATIONAL JOURNAL OF INSTITUTIONAL PHARMACY AND LIFE SCIENCES

**Pharmaceutical Sciences** 

Research Article.....!!!

Received: 29-05-2012; Revised; Accepted: 01-06-2012

# CLINICAL EVALUATION OF MEHANT - AN AYURVEDIC POLYHERBAL FORMULATION IN PREDIABETES

Upasani Sughosh V.\*1, Dr. Nandedkar Ravindra Y.2, Dr. Patil Satish H.3, Shah Virag S.1

- 1. Department of Clinical Pharmacy, R. C. Patel Institute of Pharmaceutical Education and Research, Shirpur, 425 405, Dhule, Maharashtra, India.
- 2. Director and Research Scientist, Anuyash Diabetic Clinic and Research Center, Jalgaon-425001, and Anuyash Ayurvedic Diabetic Clinic, Pune, 411 045, Maharashtra, India.
- 3. Medical Officer, Anuyash Diabetic Clinic and Research Center, Jalgaon, 425001, Maharashtra, India.

#### **Keywords:**

Prediabetes, Mehant, Ayurvedic Polyherbal Formulation, Antidiabetic, Fasting Glucose Level

# **For Correspondence:**

# Upasani Sughosh V.

Department of Clinical Pharmacy, R. C. Patel Institute of Pharmaceutical Education and Research, Shirpur, 425 405, Dhule, Maharashtra, India **E-mail:** 

upasanisughosh@gmail.com

#### **ABSTRACT**

Diabetes is chronic metabolic disorder which is group of different complications. Currently India is leading the world in number of diabetes, furthermore it having second ranking in number of Prediabetes. Management of prediabetes can be done with the help of combination therapies only. There are various features which are involved directly or indirectly as etiological factors for prediabetes which is starting point of T2DM such as Heredity, Age, Obesity, Sex, Diet, Physical Inactivity, Hypertension, Socio-economic Status, sedentary Lifestyle and various stresses etc. For prevalence and treatment there are many ways such as drugs (modern medications), Alternative systems like Ayurvedic, Diet, Lifestyle intervention and recently Spice therapies are seen useful and effective. Various researches conducted in the last few decades on plants, mentioned in ancient Indian Ayurvedic literature or used traditionally for T2DM which is known as Pramehas in Ayurveda, have shown antidiabetic property. In present study evaluation of Ayurvedic Polyherbal formulation for Prameha (Prediabetes), having its constituents as Andrographis panicullata, Enicostemma littorale, Gymnema sylvestre, Murraya koenigii, Trigonella foenum graecum, which are well known and studied antidiabetic medicinal plants was done. A significant reduction was noted after three months administration of Mehant in FBSL and PPBSL also individually and collectively. Prediabetes can be cured but not T2DM.

#### BACKGROUND

At this epoch the world is anguished from many health dilemmas. Most of them are geographical, ecological, depending on a variety of human races or ethnic backgrounds. But T2DM is such a disease or disorder which creates a big issue in front of health professionals worldwide who are engaged to defeat it since long time. T2DM is a most vital international health problem. According to International Diabetes Federation (IDF) Diabetes Atlas, the global T2DM prevalence in the age group 20–79 years is estimated to be 6.6% for the year 2010 which translates into 285 million people suffering from T2DM (1). Currently India is leading the world in number of diabetes, furthermore it having second ranking in number of prediabetes (2).

# INTRODUCTION

The prediabetes is known by various terminologies such as Impaired Fasting Glucose (IFG) and/or Impaired Glucose Tolerance (IGT) or Borderline diabetes etc. Various healthcare systems describe the prediabetes in various expressions array but the diagnostic criterion is somewhat in a similar, but not all due to lack of a 'Gold Standard' for comparison (3).

# **Definition**

According to Indian Council of Medical Research (ICMR), which sets the national guideline to ensure the uniformity in the management of diabetes throughout the country so they develop it with the help of WHO, the term prediabetes is used for the condition in which fasting blood glucose level is  $\geq 110$  and < 126 mg/dl (4) which seems to be same as that of the World Health Organizations criterion,  $\geq 110$  and < 125 mg/dl.

# **Sign and Symptoms**

Prediabetes typically has no signs or symptoms. The American Diabetes Association (ADA), Indian Health Services (IHS) and Australian Diabetes Society (ADS) indirectly indicates that prediabetes only be can detected when incidental screening for diabetes takes place (5). Patients should monitor for signs and symptoms of T2DM. These include the following:

- Constant hunger
- Unexplained weight loss or weight gain

- Flu-like symptoms, including weakness and fatigue
- Blurred vision or visionary problems
- Slow healing of cuts or bruises
- Tingling or loss of feeling in hands or feet
- Recurring gum or skin infections
- Recurring vaginal or bladder infections

# **Risk Factors / Causes**

Following are associated with insulin resistance and are risk factors for the development of T2DM.

- Age  $\geq$  30 years (4)
- Family history of diabetes (4)
- Sedentary lifestyle (4)
- Metabolic syndrome (5)
- Cardiovascular disease (6)
- Hypertension (4) or family history of cardiovascular diseases (4,5)
- Overweight or obese (4)
- Women who have had gestational diabetes, had high birth weight babies (greater than 9 lbs.), and/or has Polycystic Ovarian Syndrome (PCOS) (4)
- Middle age women who has Large bra cup size at age 20 (7),

# **Pathophysiology**

Prediabetes is primary stage of non insulin dependent diabetes or T2DM so the Etio-Patho-Physiology similar to that of T2DM.

# **Clinical Diagnosis**

Prediabetes is often an incidental finding in people who are undergoing biochemical testing for diabetes or at the time or routine pre-testing for any surgery. There is no alike specific criterion for detecting for prediabetes from any healthcare organizations apart from fasting glucose and plasma glucose level after 2-h post glucose load. Clinical diagnosis can be done with considering three basic factors as Medical History (as discussed in causes), Physical inactivity, Biochemical tests.

• BMI (2,6,8)

- Waist-Hip Ratio (2,6)
- Fasting BSL (2,6,8)
- OGTT (2,6,8)
- Blood Pressure (2,6,8,10)
- Lipid Profile (6,8)
- Physical Activity (2,6,10)

# Prevention

Clinical trials have shown that people at high risk for developing diabetes can be given treatments that delay or prevent onset of diabetes. The goals of prevention are to delay the onset of T2DM diabetes, preserving the function of the beta cells, and preventing or delaying the microvascular and cardiovascular complications. The first therapy should always be an intensive lifestyle modification program because weight loss and physical activity are much more effective than any medication at reducing diabetes risk. The ADA recommends that the Metformin is only drug that should be considered for use in prevention of diabetes. Other drugs that have delayed diabetes have side effects or haven't long lasting benefit (6). The exact mechanism through which Metformin reduces hepatic glucose production remains unclear; Metformin facilitates glucose transport by increasing tyrosine kinase activity in insulin receptors and enhancing glucose transporter trafficking to the cell membrane (10).

# **Ayurvedic Aspect**

Ayurveda and other Indian literature advocate the use of medicinal plants in treatment of various human diseases. India has about 45,000 plant species and among them, several thousands have been claimed to possess medicinal properties. Various researches conducted in the last few decades on plants, mentioned in ancient literature or used traditionally for T2DM, have shown antidiabetic property (11). In India *Ayurveda* (*Sanskrit* Word for meaning of "knowledge of life or living") and other Indian literature mentions the uses of various plants. Primary Ayurvedic treatment includes diet, exercise (*Yoga*), meditation (*Dhyan-Dharana*), herbs, massage, *Surya Namaskar*, exposure to sunlight (Sun Bath), controlled breathing (*Pranayam*) and detoxification treatments. The Indian word for T2DM is "*Madhumeha*", from Sanskrit literature - Ayurveda, the word

Madhumeha is a combination of two different words "Madhu" meaning "sweet or sweetness" as like honey and "Meha" meaning "excessive urination". All the renowned classic texts of Ayurveda like Charaka Samhita (1000 B.C.), Sushruta Samhita (600 B.C.) and subsequent works refer to this disease under the term Madhumeha or Ikshumeha (literally meaning sugar in the urine). Ayurveda express the initial of T2DM as "Prameha". According to various Samhita there are 20-22 types of Pramehas which are classified into three major groups can be seen. The classification of Pramehas is according to their "Prakruti" or nature. The terminologies differ from Samhita to Samhita such as Charaka Samhita, Sushruta Samhita, Ashtaanga Hridaya and Maadhav Nidaan depending upon urine's colour, odor, viscosity, taste, appearance, its contents and other such properties. Plants have always been an exemplary source of drugs and many of the currently available drugs have been derived directly or indirectly from them. Mehant an Ayurvedic Polyherbal formulation having its constituents as Andrographis panicullata (12), Enicostemma littorale (11), Gymnema sylvestre (11,14), Murraya koenigii (13,14), Trigonella foenum graecum (11,14,15), Clinical significance of Mehant on fasting blood glucose level and post prandial blood glucose level has been evaluated in this trial study.

# MATERIALS AND METHODS

Study has been carried out to compare blood glucose level in pre-diabetic patients at Anuyash Diabetic Clinic and Research Center, Jalgaon as well as Anuyash Ayurvedic Diabetic Clinic, Pune, Maharashtra. Total twelve patients of either sex in the age range of 24 -70 years with newly detected Impaired Fasting Blood Glucose Level were included in this study. The study period was for three months and the patients were followed up every month. Dietary advice was similar to all patients, with physical exercise. The initial and end point reading of FBSL and PPBSL was taken for study. All the essential formalities are completed for this study.

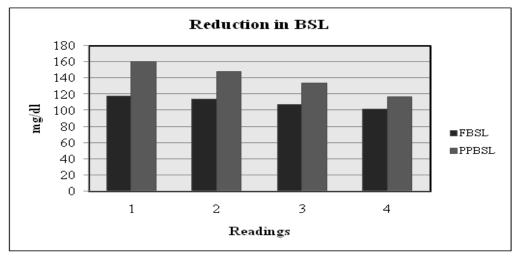
#### RESULT

There was notable significant reduction takes place in both FBSL and PPBSL levels (Table No.1, Fig. No.1). The reduction is significant as compared to pre-treatment initial reading and post treatment final follow-up readings.

Table No. 1: Statisti	cally reduction	n in the FBSL	and PPBSL	$(Mean \pm SD)$
				( ,

Test	Initial	1 <sup>st</sup> follow up	2 <sup>nd</sup> follow up	End Point		
FBSL	$117.6667 \pm 10.74$	$113.6667 \pm 8.99$	$106.6667 \pm 9.09$	$101.5 \pm 8.80$		
PPBSL	$160.3333 \pm 26.36$	$147.75 \pm 24.05$	$133.9167 \pm 25.73$	$116.4167 \pm 40.87$		
<i>P</i> <0.0001, statistically significant as compared to initial reading						

Fig No. 1: Reduction in the FBSL and PPBSL



# DISCUSSION

A significant reduction was noted after three months administration of Mehant in FBSL individually and collectively. The decrease in PPBSL was more marked in collectively as compare to FBSL. The Mehant shows significant effect on the prediabetes conditioned patients, as it contains the beneficial composition of well known antidiabetic plant extract, which are already reported for their activity. Our study shows positive effect of Ayurvedic polyherbal formulation, further study is ongoing for other relative biochemical parameters and more number of patients for effective conclusions.

#### CONCLUSION

In this evaluation of clinical significance of Ayurvedic polyherbal formulation it is observed that, it has a significant effect on the prediabetes. Is doesn't showed any kind of side effects.

#### ACKNOWLEDGMENT

The authors are thankful to Asst. Prof. Pravin V. Ingle, R. C. Patel Institute of Pharmaceutical Education & Research, Shirpur-425405, Dhule, Maharashtra, India, for providing guidance in research work. I extend my thanks to specially Ms. Manali Mulay and to my supportive friends, colleagues whose help improves my work and ability for it.

#### REFERENCES

- 1. Misra. A Review of the Epidemiology of Diabetes in Rural India. Diabetes Res. and Clin. Pract, 2011; 303-311.
- 2. Mohan V. Incidence of Diabetes and Pre-Diabetes in a Selected Urban South Indian Population. (Cups 19), JAPI, 56; 152-157.
- 3. Giess. Implications of Alternative Definitions of Prediabetes for Prevalence in U.S. Adults. Diabetes Care, Vol 34, 2011; 387-391.
- 4. ICMR. ICMR Guidelines for Management of Type 2 Diabetes. 2005.
- 5. Aroda V. Approach to the Patient with Prediabetes. J. Clin. Endocrinol Metab., 1993, Vol (9), 2008; 3259-3265.
- 6. USDHHS. Insulin Resistance and Pre-Diabetes. NIH Publication No. 09–4893, 2008.
- 7. Ray. Breast Size and Risk of Type 2 Diabetes. CMAJ, Vol 178(3), 2008; 289-295.
- 8. Aroda V. Approach to the Patient with Prediabetes. J. Clin. Endocrinol Metab., 1993, Vol (9), 2008; 3259-3265.
- 9. Alan G. Diagnosis, Management of Prediabetes in Continuum of Hyperglycemia, Prediabetes Consensus Statement. Endocr. Pract, Vol 14(7), 2008; 933-946.
- 10. Tripathi K. Essential of Medical Pharmacology, Jaypee Brothers Medical Publishers (P) Ltd., New Delhi, 6<sup>th</sup> edtn, 2008; 269.
- 11. Bhoyar P. Herbal Antidiabetics: A Review.Int.J.Res.Pharm.Sci., Vol 2(1), 2011; 30-37.
- 12. Ravikumar. Antidiabetic and Antioxidant Efficacy of Andrographis Paniculata in Alloxanized Albino Rats. Int. J. of Pharm. & Tech., Vol 2(4), 2010; 1016-1027.
- 13. Vinuthan. Effect of Extracts of Murraya Koenigii Leaves on the Levels of Blood Glucose and Plasma Insulin in Alloxan-Induced Diabetic Rats. Indian J. Physiol. Pharmacol., Vol 48(3), 2004; 348–352.
- 14. Grover.Medicinal Plants with Anti-Diabetic Potential.J. of Ethnopharmacology 1981, 2002; 81-100.
- 15. Md. Ismail. Role of Spices in Diabetes Mellitus. RJPBCS, Vol 1(3), 2010; 30-34.