

THERAPEUTIC EFFECT OF TUKHM-E-HAYAT (WITHANIA COAGULANS) IN THE MANAGEMENT OF PRE-DIABETICS (IMPAIRED FASTING GLUCOSE & IMPAIRED GLUCOSE TOLERANCE)

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Objectives: Prediabetes is the precursor stage before diabetes mellitus in which all the symptoms of diabetes mellitus are not present, but blood sugar is abnormally high. Prediabetes is not a clinical entity in its own right but rather an increased risk for diabetes and cardiovascular disease. It is a metabolic diathesis. According to the latest survey of W.H.O the burden of prediabetics is more than diabetics which will soon be converted into indolent diabetes. Thus there is a need to find out the way to lessen this prediabetic burden. The purpose of this study was to determine the effect of Tukhm-e-Hayat for treating Prediabetes & to collect data to warrant further clinical trials.

Methods : A case series was conducted with ten (20) patients of IFG & IGT, clinically diagnosed after excluding the possible causes by proper laboratory work-up & confirmed by blood sugar fasting levels and glucose tolerance test, Subsequently patients were treated with Tukhm-e-Hayat .

Results : In Patients of both types of Pre-Diabetes (IFG, IGT) , there was significant improvement in blood sugar levels within an average of 4 months treatment.

Discussion : The literature review related to Tukhm-e-Hayat used for the treatment in this study, showed that this drug possess anti-inflammatory, analgesic, laxative, antimicrobial & acetylcholine like actions, suggesting possible mechanism of action in Prediabetes.

Conclusion: The preliminary findings indicate that Tukhm-e-Hayat is effective in Prediabetes.

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KEYWORDS: : Prediabetes, Impaired fasting glucose (IFG), Impaired glucose tolerance (IGT), Tukhm-e-Hayat .

Introduction:

Prediabetic is a new nomenclature created in 2002 by ADA(American Diabetes Association and Department of Health and Human services. The definition of prediabetes has been revised over time. Prediabetes was deliberated to bring attention to the consequences of the disease and its related complication. It includes either impaired fasting glucose and impaired glucose tolerance or combinations of these two (Eldin, et al., 2008).

Prediabetes is a practical and convenient term referring to impaired fasting glucose, impaired glucose tolerance or a glycated haemoglobin (HbA1c) of 6.0% to 6.4% each of which places individual at high risk of developing diabetes and its complications (Goldenberg, et al., 2013). It is estimated that worldwide 6.7% of adult population which is approx. equal to 318 million persons have prediabetes. It is estimated that by 2040 the number of persons with prediabetes will reach 482 million which means about 7.8% of the adult population will get affected with this problem(Anjana, et al., 2011)

The prevalence of prediabetes is increasing worldwide and it is anticipated that more than 470 million people will have prediabetes in 2030 (Deepa et al., 2015).

There are different factors which are responsible for the development of prediabetes like environmental factors plays central role in the etiology of Type 2 diabetes but certain studies also advocate about the role of these common factors in the development of prediabetes(Faerch, et al., 2009), Physical inactivity is greatly associated with development of insulin resistance which affects glucose metabolism and leads to impaired glucose control (Balkau, et al., 2008). It is observed tht there is significant alliance of diet with two hour plasma glucose supports the association of diet with etiology of prediabetes (Faerch, et al., 2009). Smoking affects lipid metabolism and there is relation between smoking and hepatic lipase activity which is related to hepatic insulin resistance observed in subjects of IFG. Genetic components are important determinants for prediabetes.

Prediabetes remains undiagnosed for even several years as the disease mostly develop without any symptoms and signs, but sometime symptoms develop in prediabetic stage. These are same as symptoms of Type II diabetes(Eldin, et al., 2008).

Impaired Fasting Glucose is defined as fasting plasma glucose of 6.1-6.9 mmol/L (100-125mg/dl).

Impaired Glucose Tolerance is defined as 2 hour plasma glucose of 7.8-11.0 mmol/L(140-200)/dl.(W.H.O 2010)

According to ADA, has same cut off value for IGT but has lower cut off value for IFG i.e., 100-125mg/dl and has additional hemoglobin A1c based criteria(HbA1c) based criteria of a level of 5.7% -6.4% for the diagnosis of prediabetes.

Based on the interventions management of prediabetes is broadly classified into two major groups which include Lifestyle modifications and Pharmacological interventions.

UNANI PERSPECTIVE:

As far as prediabetes is concerned, Unani scholars were not much aware about the entity like IFG and IGT which comes under prediabetes. However they had understanding of diabetes as per available classical Unani literature. Diabetes is termed as *Ziyabetus*, have several synonyms like *Diabetush*, *Dibatush*, *Debatish*, *Dawarah*, *Dulabia*, *Zalqul Kulya*, *Zalqul Majari* and so on. (Ibn Sina, 1933A).

Zakariya Razi in *Kitab-ul-Havi-Fit-Tibb* says that the patient of diabetes complains of polydypsia, whereas the consumed water is passed out as such. He further mentioned about other symptoms associated with this disease like polyuria. Polydypsia even nocturia and incontinence of urine.

According to Unani concepts there are 3 types of *Quwa*, which play major function in the absorption, digestion and excretion of water absorbed by kidneys from the liver. These are *Quwwat-e Jaziba*, *Quwwat-e Masika* and *Quwwat-e-Dafia*.

In diabetes mellitus, derangement of temperament (*Suea- Mizaj kulliya haar*) leads to disturbance in the renal function. Absorptive faculty of the kidney absorbs water from blood and liver but due to weakness of retentive faculty of kidneys the renal tubules are unable to retain water from the urinary filtrate. As result of expulsive faculty of kidneys is increased and causes increase in excretion of water (polyuria). To meet the water requirement of kidneys the liver absorbs water from the stomach and intestine causing dryness of these organs so the patient feels thirsty and tends to take water frequently (Polydypsia) (Razi, 2002; Majoosi 2010 A, B).

Ziyabetus is broadly classified into two groups *Ziyabetus Har* and *Ziyabetus Barid*. On the basis of presence of sugar in the urine *Hakeem Ajmal Khan* also classified the diabetes into two types *Ziyabetus shakri* and *Ziyabetus sada/ Ghair shakri*.

Ziyabetus is explained in detail by Unani physicians like *Majoosi*, *Razi*, *Ibn Sina* and *Samarkandi*. Greeks and Arabs especially *Razi* and *Majoosi* proposed the sole cause of diabetes is hot impaired temperament of kidneys and due to excessive heat absorptive faculty of kidneys become enhanced due to which fluid is diffused more towards kidneys, in addition to it the retentive power of kidney is weakened and are unable to hold urine which is excreted out in large quantity and a cycle of thirst and micturition is established (Majoosi 2010 A, B, Kirmani 1926).

Razi proposed that it is due to hot impaired temperament of kidneys and it also may be due to liver dysfunction, coldness of whole body, insomnia and cold water (Razi 1961)

Ibn Sina defined causes of diabetes as weakness of kidneys, dilatation of vessels of kidney and coldness of whole body or coldness of liver and kidneys (Ibn Sina 1933 A,B)

Jurjani categorized the causes of diabetes into 4 groups weakness of kidney, dilatations of vessels of urinary tract, Hot derangement in the temperament of kidneys cold derangement in the temperament of kidneys.

Unani scholar had good understanding regarding the clinical features of diabetes.

Methods :

Informed consent was taken from patients in compliance with the declaration of Helsinki

Intervention:

In this case series patients were advised to take *Tukhm-e-Hayat* in the form of Concoction (*Kheesanda*) (10 in Number) & two times daily in morning and evening for a period of 4 months.

Case Presentation:

Case 1: A 52 year old female presented in Moalejat OPD of AKTCH, A.M.U with chief complaints of dysuria. she was diagnosed for IFG on Blood sugar levels. Subsequently she was advised to take the test formulation for a period of 4 months, she was significantly relieved of her symptoms after four months of treatment.

Case II : A 51 year male presented in Moalejat OPD of AKTCH, A.M.U with complaints of recurrent urination. He also had polydypsia from several years. He was advised to undergo the blood sugar profile which revealed IFG and IGT. Subsequently he was advised to take the test formulation. Patient was effectively relieved of the symptoms within 4 months of treatment.

Case III :

A 40 year old female presented in Moalejat OPD, AKTCH, A.M.U with complaints of itching of the whole body from 2 months not relieved by any treatment. She was advised to undergo blood sugar profile revealing IGF. Subsequently, with 4 months of treatment with test formulation she was relieved of her itching.

Case IV:

A 36 year old male presented in Moalejat OPD of AKTCH, A.M.U, with chief complaints of polyuria. Patient was advised to undergo sugar profile revealing IGT. Subsequently patient got relieved by test formulation after 4 months.

Case V :

A 58 year female presented Moalejat OPD of AKTCH, A.M.U with complaints of fatigue, generalized bodyache and needle prick sensation in extremities. Patient was diagnosed for IGF revealed by blood sugar levels. She was subsequently advised to take the test formulation. Patient was effectively relieved of the symptoms within 4 months of treatment except that of peripheral needle prick sensation.

Outcome Measures:

Patients were evaluated for improvement in their symptoms & blood sugar levels which were recorded every month.

Results:

These patients were significantly relieved of their symptoms on an average of 4 months of treatment as shown in Table 1.

Table 1: Effect of test formulation on Blood sugar levels:

| S.N | 0 day | 30th | 60th | 90th | 120th |
|-----|-------|------|------|------|-------|
| 1 | 112 | 105 | 105 | 100 | 98 |
| 2 | 120 | 110 | 108 | 100 | 100 |
| 3 | 114 | 104 | 108 | 102 | 101 |
| 4 | 105 | 100 | 103 | 103 | 99 |
| 5 | 124 | 121 | 118 | 116 | 100 |
| 6 | 111 | 109 | 108 | 104 | 100 |
| 7 | 108 | 100 | 100 | 98 | 95 |
| 8 | 125 | 120 | 118 | 110 | 100 |
| 9 | 119 | 113 | 111 | 105 | 99 |
| 10 | 113 | 109 | 105 | 105 | 98 |
| 11 | 108 | 100 | 98 | 101 | 95 |
| 12 | 121 | 112 | 106 | 105 | 100 |
| 13 | 108 | 100 | 98 | 95 | 96 |
| 14 | 112 | 102 | 100 | 101 | 100 |
| 15 | 117 | 107 | 106 | 100 | 100 |
| 16 | 122 | 102 | 101 | 101 | 100 |
| 17 | 123 | 118 | 116 | 114 | 104 |
| 18 | 109 | 100 | 104 | 100 | 99 |
| 19 | 113 | 110 | 111 | 107 | 100 |
| 20 | 118 | 114 | 109 | 106 | 98 |

Discussion :

Prediabetes although having no symptoms or very few symptoms but has significant role in development of diabetes and cardiovascular diseases, so this disease was designed to find out the effect of this drug in prevention of diabetes. In the present study almost all patients showed a good response during & after study as depicted by their sugar levels in table 1.

In our patients of Prediabetes, we prescribed the test formulation for 4 months to evaluate its effect in IFG and IGT. The ideal aim of any therapy is to relieve patients of their symptoms, with minimal adverse effects. Be cost effective & at the same time prevent relapses which was achieved by this drug.

This drug have been used since the time immemorial for its properties. it has been used extensively for gastrointestinal disorders like dyspepsia, flatulent colic, inflammation of piles, cleaning of teeth because of specific properties that help to combat these disorders.

Tukhm-e-Hayat possesses properties like *Hypoglycemic*, (Hemlatha.S, et al.,2004) *Hypolipidaemic*, (Kalam, A.1996) *Anti inflammatory*, *Blood purifier*, because of which it is effective in prediabetes. Research indicates that *Tukhm-e-Hayat* contains a high proportion of alkaloids, Withanoloids, Aminoacids and essential oils.

Conclusion:

This case series provides a novel direction in which the test formulation can be used in the treatment of Prediabetes. Therefore further studies may be performed to warrant the effectiveness & mechanism of action of this drug in IFG and IGT of prediabetes.

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