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A MONITORING OF GLYCEMIC CONTROL IN MEDICATION-NEEDED DIABETES MELLITUS PATIENTS USING COENZYME Q10

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ABSTRACT

Nearly 33 million people in India have diabetes as of today. Prediabetic diseases, including impaired glucose tolerance and impaired fasting glucose, are also on the rise, suggesting that the incidence of diabetes may continue to climb. Between August 2019 and February 2020, this study was carried out (6 months). All of the individuals ranged in age from 18 to 65. At the beginning of the trial, the 12th week, and the 24th week, the fasting blood glucose, blood HbA1c level, lipid profile (LDL, Triglycerides, HDL, and TC), blood coenzyme Q10 level, and BMI of 40 patients were analyzed. Each visit also included a remark on adverse incidents. The study's results demonstrated that the Metformin with Coenzyme Q10 group had lower fasting blood glucose and HbAlc levels after treatment. In conclusion, type 2 diabetes mellitus patients accepted coenzyme Q10 and metformin well. Biguanide and coenzyme Q10 therapy ensures successful long-term glycemic control and can offer additional advantages not just in Diabetes but also as an antioxidant in other illnesses when more sophisticated treatments for diabetes become available.

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1. INTRODUCTION

Diabetes mellitus (DM) is a long-term, progressive metabolic condition that causes hyperglycemia primarily as a result of an absolute (Type 1 DM) or relative (Type 2 DM) insulin hormone shortage [1]. One of the most prevalent non-communicable illnesses in the world is type 2 diabetes [2]. The underlying etiology of the disease is little known despite its high and rising incidence worldwide. Environmental and genetic variables are both significant. An oral glucose tolerance test can detect impaired glucose tolerance between standard glucose tolerance and overt diabetes. Subjects with poor glucose tolerance are more likely to develop type 2 diabetes, making them a crucial target population for diabetes prevention strategies [3].

Non-insulin-dependent diabetes mellitus (NIDDM) is a second unique subclass of diabetes that includes non-ketosis-prone and non-insulin-dependent kinds of diabetes that are not due to other illnesses or disorders [4]. Obese NIDDM and non-obese NIDDM are the two categories this subclass has been split into. Diabetes can lead to enduring complications, including retinopathy, which can lead to loss of vision; nephropathy, which can result in kidney failure; peripheral neuropathy, which heightens the likelihood of foot ulcers, amputations, and Charcot's joints; and autonomic neuropathy, which causes symptoms in the gastrointestinal, genitourinary, and cardiovascular systems, as well as sexual dysfunction [5]. Diabetes patients are more likely to have atherosclerotic cardiovascular, peripheral arterial, and cerebral diseases. People with diabetes frequently have hypertension and impaired lipoprotein metabolism [6].

There are numerous readily available assays for the diagnosis and screening of DM. According to the guidelines set by the American Diabetic Association (ADA) in 1997 or the criteria established by the World Health Organization (WHO) National Diabetic Group in 2006, a single high glucose reading accompanied by symptoms such as increased urination, excessive thirst, increased appetite, and weight loss, or consistently elevated values on two separate occasions, either in fasting plasma glucose (PPG) at 7.0 mmol/L (126 mg/dL) or in an oral glucose tolerance test (OGTT) two hours after consuming a glucose solution, According to the World Health Organization (WHO), the 1997 ADA criteria for diagnosing diabetes mellitus (DM) prioritize the fasting plasma glucose (FPG) test over the oral glucose tolerance test (OGTT). Fructosamine and glycated hemoglobin (HbAIc) remain reliable for tracking long-term blood glucose levels [7].

In July 2009, the International Expert Committee (IEC) proposed including the HbAlc value of 6.5 percent as an additional diagnostic criterion for diabetes mellitus (DM). The group presented the elimination of the term "pre-diabetes" and suggested that those with a HbAlc level between 6.0 percent and 6.5 percent be identified as being at a heightened risk of developing DM. The International Electrotechnical Commission (IEC) has proposed a specific threshold for diagnosing diabetes mellitus (DM) that emphasizes specificity. This approach aims to strike a balance between the negative consequences of mistakenly diagnosing individuals as having diabetes, including social stigma and financial burden, and the relatively minor clinical implications of delaying the diagnosis in patients with an HbAlc level below 6.5 percent [8-10].

2. METHODS

Randomized, parallel assignment, open-label study conducted with 40 samples. Group 1 received COENZYME Q10 100mg bid along with METFORMIN (20 patients) and group 2 received METFORMIN prescribed dose according to blood glucose level (20 patients). The glucose oxidase method IS used to measure the fasting blood glucose in patients. It is relatively inexpensive and specific. A venous blood sample is taken (5ml) in the fasting state (overnight 12 hours). HbA1c is measured using an enzymatic assay. The current enzymatic approach for measuring HbA1c utilizes an enzyme that selectively breaks down the N-terminal valine. A 5ml sample of venous blood is collected. CoQ10 is quantified using the high-performance liquid chromatography (HPLC)-t" dilution method, following the extraction of the compound from plasma. Venous blood samples are collected, and plasma is extracted. A 5 ml venous blood sample was obtained after a 12-hour overnight fast to estimate the levels of Total cholesterol (mg/dl), triglycerides (mg/dl), HDL cholesterol (mg/dl), and LDL cholesterol (mg/dl) using an enzymatic technique. The height and the weight are measured using the standardized method in metric units. BMI is calculated using the standard formula.

3. RESULTS

The screening process comprised a complete clinical examination, a full medical and pharmacological history review, and a series of laboratory tests, including those for the fasting lipid profile, HbA1c, and blood coenzyme Q10. After 65 patients were screened, 25 were disqualified based on the selection criteria. Forty individuals of both sexes, who met the eligibility requirements and were between 18 and 65, were enrolled in the research. A computer-generated randomization chart was used to allocate the research participants randomly to either of the two groups, Group A or Group B, each of which had 20 patients (Table 1).

Table 1: Group Allocation and Dosage Regimen

Group A	Coenzyme Q10 100mg bid along with Metformin (prescribed according to blood glucose level) daily for six months
Group B	Tab. Metformin (according to blood glucose level) daily for six months

3.1. ADVERSE EFFECTS MONITORING

Participants were educated to maintain dairy on any adverse effects during medication, and additional observed effects were noted and tabulated. All patients were reviewed at the end of the 11th, 12th, and 24th week. At each visit, Fasting Blood Sugar, HbA 1c level, blood coenzyme Q10 level, and fasting lipid profile were done and noted; adverse event monitoring was also done throughout the study period. The 40 participants who took part in the study for six months were prescribed drugs, their blood investigations were done, and study data was documented. They were followed up for four weeks after the study duration was completed.

3.2. BIOCHEMICAL INVESTIGATIONS

Fasting blood glucose, HbAlc level, Blood Coenzyme Q10 level, Fasting Plasma lipid profile – LDL, Triglycerides, HDL, and TC were done, respectively.

3.3. SECONDARY MEASURE

The secondary efficacy outcome measures include the percentage change in Total Cholesterol, Triglycerides, LDL, and HDL from the initial values till the end of the 24 weeks. [Duration: From the beginning to the end of 24 weeks]and the percentage change in BMI from the initial measurement until the conclusion of 24 weeks. [Duration: From the beginning to the end of 24 weeks.]

3.4. SECONDARY SAFETY OUTCOME MEASURES

Safety was assessed based on adverse events that were voluntarily reported and changes in laboratory data following the research. Additionally, the relevance within and between groups was evaluated using ANOV A. The values obtained before and after treatment were compared using a one-sample Student's t-test. P values less than 0.05 were regarded as significant. HDL level in metformin and coenzyme Q10 group at baseline 41.75±5.94 did not change much at the end of the treatment period (6 months), 41.30±5.43. In the metformin group, a baseline level of 42.05±7.98 has been minimally reduced to 40.95±6.53 at six months, which is insignificant according to pValue. Also, both groups did not have significant outcomes in Total Cholesterol. In the Metformin and Coenzyme Ql0 group, there was a mild reduction at three months of the treatment period 169.88, compared to baseline data 170.68 but at the end of 6months 171.73, there were no significant changes in the values.

The Value of blood coenzyme Q10 at baseline in the metformin and coenzyme Q10 group is 1.02±0.24. At 3month a minimal increase in the level to 1.16±0.23, which is significant statistically. At 6month the level further increased to 1.31±0.22, which 1s highly substantial according to pValue. In the metformin group, a baseline level of blood coenzyme Q10 is 1.03±0.21. At 3month it mildly reduced 0.99±0. 20, which is not significant. At the end of the treatment period, the level was 1.02±0.19, which is also not substantial according to pValue (Table 2).

Table 2: Incidence of Adverse Effects

S.No	Adverse effect	coenzyme Q10 Group (2)	MetforminGroup (2)
1	Nausea	-	-
2	Vomiting	-	-
3	Loss of appetite	-	-
4	Head ache	1(5%)	-
5	Abdominal Pain	-	1(5%)
6	Flatulence	1(5%)	-
7	Diarrhoea	-	2(10%)
8	Cough	-	-
	Total	2	3

While a definitive cure for the condition does not yet exist, therapy possibilities encompass modifying one's lifestyle, addressing obesity, administering oral hypoglycemic medications, employing insulin sensitizers such as metformin, and other approaches. A biguanide, known for its ability to reduce insulin resistance, remains the recommended initial drug, particularly for patients who are obese. Metformin enhances the sensitivity of both insulin in the liver and insulin in the muscles. Metformin prevents hepatic gluconeogenesis from happening. Through both direct and indirect actions, it also improves muscle insulin sensitivity. At the cellular level, higher insulin receptor tyrosine kinase activity, increased GLUT4 transporter number and training, and better glycogen synthesis all contribute to improved insulin action in muscle. The operation of beta cells is unaffected directly.

Fasting and postprandial insulin levels regularly fall in metformin-treated diabetic individuals, suggesting the pancreas' natural compensatory response to increased insulin sensitivity.

4. CONCLUSION

Metformin is the sole oral antidiabetic medication that has demonstrated efficacy in reducing macro-vascular problems when taken as a standalone treatment. Most people who get metformin have weight loss or do not experience weight gain.

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COMPETING INTEREST

The authors declare no conflict of interest.

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