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ASSESSMENT OF THE EFFICACY AND SAFETY OF SNEC 30 (CURCUMA LONGA) CAPSULES IN THE TREATMENT OF TYPE 2 DIABETES: AN OPEN LABEL, PROSPECTIVE, COMPARATIVE, RANDOMIZED STUDY

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ABSTRACT

Background: Diabetes mellitus (DM) is a chronic metabolic disorder wherein a person has excessive concentrations of blood sugar. Several studies have demonstrated inconsistent effects of curcumin on glycemic outcomes and lipid parameters in patients with prediabetes and type 2 diabetes mellitus (T2DM). This study aimed to assess the effect of curcumin on glycemic control in T2DM subjects. **Methodology:** A total number of 80 patients of either sex between the age group 18 to 65 years (both inclusive) having type 2 diabetes were recruited in the study. At Day 0 subjects were randomized for ongoing conventional treatment or SNEC 30 Capsule co-administered with the conventional treatment. Study specific tests like Hba1c, Post Prandial glucose and other biochemistry and hematology tests were performed at the screening and at the end of study duration (3 Months). **Results:** Out of 80 patients with Type 2 diabetes that were randomized for the study, 59 patients were male and 21 were female. Among 80 subjects, 69 subjects completed the study and 11 subjects dropped-out (05 from SNEC 30 group and 06 subjects from conventional group). When SNEC 30 group (35 patients) (Arm A) was compared with group that received conventional treatment (Arm B=34 patients), it was observed that post-treatment decrease in values of Hb1Ac and blood glucose levels recorded,

was significantly higher (p<0.0001) in the SNEC 30 arm. **Conclusion:** The study concluded that SNEC 30 capsule along with the standard treatment are more effective as compared to alone standard treatment in type 2 diabetes patients.

KEYWORDS: Type 2 diabetes, SNEC 30, Curcuma Longa, HbA1c.

INTRODUCTION

Diabetes is a metabolic disease presenting with elevated blood glucose level. This disease accounted for not only 1.5 million deaths in 2012, but also an extra 2.2 million deaths for its attribution to cardiovascular disease and other diseases. Accordingly, diabetes has become a worldwide burden especially in less developed countries.[1] The global prevalence of diabetes is predicted to be13.5% of the total world population in 2040.[2]

The symptom of high blood sugar in turn produces polyuria, polydipsia, and polyphagia. Three main types of diabetes are type 1, type 2, and gestational diabetes. Type 1 result from the body's failure to produce insulin, whereas in type 2 diabetes (T2DM) the body fails to use insulin properly. On the other hand, gestational diabetes develops during pregnancy to pregnant women who were not afflicted with the condition before and in most instances disappears after giving birth.[1] Amongst the three type of diabetes, T2 DM is the most common form of DM characterized by hyperglycemia, insulin resistance, and relative insulin deficiency. Type 2 DM results from interaction between genetic, environmental and behavioral risk factors.[3] In order to manage with the worldwide issues of diabetes, effective prevention and management are entirely required.

T2DM is a preventable disorder.[1] Prevention should also be initiated in people with prediabetes or impaired glucose tolerance that are prone to T2DM. People living with type 2 DM are more vulnerable to various forms of both short- and long-term complications, which often lead to their premature death. Extensive research over the past several years has indicated that pro-inflammatory cytokines and oxidative stress play a role in the pathogenesis of T2DM.[4]

Lifestyle modification and pharmacologic intervention are suggested.[5] However, a single oral antidiabetic drug may be insufficient in controlling blood glucose at all times and additional insulin seems to be a bit costly and patient compliance may make it a not so preferred option. This may lead to another problem as the economic burden of diabetes

treatment has affected many countries around the world.[6] Hence, the more affordable alternative therapy for diabetes, either as additional supplement or as prevention is necessary. Herbal medicine is an interesting approach for diabetes treatment. Some evidence has conclusively demonstrated the efficacy of medicinal plants in prediabetes and type 2 diabetes mellitus.[7,8]

Curcumin is an active ingredient contained in the rhizome of Curcuma longa plant or turmeric. This natural substance has purported anti-inflammatory, anti-depressant, and anti-diabetic effects.[9] Animal study revealed that curcumin and its analogues resembled the action of antidiabetic drug namely thiazolidinedione group through activation of peroxisome proliferator-activated receptor-Î³ (PPAR-Î³).[10] Thus, curcumin may correct the responsible targets relating to glucose and lipid control in the body[5] which play an important part in diabetes management.[5] Curcumin's effects on glycemic outcomes and lipid parameters have been translated in humans through several randomized controlled trials enrolling subjects with pre- diabetes[6,7] and T2DM.[8–11] The inconsistency among the results of those studies has raised a question regarding the role of curcumin in diabetes management. Therefore, we performed this study to evaluate SNEC 30 Capsule utility in type 2 diabetes where there is a reasonable probability of curcuminoids being useful or curative and also to assess the side effects and acceptability of the regimens.

Methodology

The study protocol was approved by KGMC Institute Ethics Committee Ref Code 86th ECMII-A/P 25 and written informed consent was obtained from all the participants. The Clinical trial was registered in CTRI.This study was an open label, comparative and randomized. A total number of 80 Patients of either sex between the age group 18 to 65 years (both inclusive) having type 2 diabetes were recruited in the study.

The inclusion criteria of the study were either the subject or his legally accepted representative who was willing to give informed consent, patients aged between 18 to 65 years, having history of type 2 diabetes, being administered oral hypoglycemic agents and the HbA1c of the patients ranged between 7.0-9.5 %.Patients suffering from Type 1 diabetes mellitus, severe hyperglycemia (FBS >234 mg% or PPBS > 360 mg%), having fasting serum cholesterol >260mg% and serum Triglycerides>300 mg%, HbA1c more than 9.5 %, patients with psychiatric disorder and hematological disorders, BMI >35 kg/m^2, history of smoking, patients having known hypersensitivity to the study drugs and any severe infection were

excluded from study. At Day 0 subjects were randomized for ongoing conventional treatment or SNEC 30 Capsule co-administered with the conventional treatment. The study subjects were divided in two groups; one group received conventional treatment (prescribed by the Physician) and the other received 2 capsules of SNEC 30 twice daily with 240 ml water for 12 weeks along with the conventional treatment.

Study specific tests like Hba1c, Post Prandial glucose and other biochemistry and hematology tests were performed at the screening and at the end of study duration (3 Months).

Statistical analysis

All results are presented as mean ± S.D and compared using the non-parametric Mann's Whitney test for two groups. The data was analyzed using SPSS 20 software. Data variations before and after administration of turmeric were analysed by non-parametric paired t test. Data variations between the groups was analyzed by independent t test. A P value of 0.05 was considered as statistically significant.

RESULTS

Results were represented in tables (1-2) and figures (1-2). Total 80 subjects were enrolled for the study, 69 completed the study (Group I: 35 Subjects & Group II 34 Subjects) & 11 dropped out the study.

Table 1: Gender distribution of the Study subjects.

Treatment	SNEC 30 (%) Group I	Conventional (%) Group II
Males	31(77.5)	28 (70%)
Females	9 (22.5)	12 (30%)

Table 2: Effect of SNEC 30 and conventional treatment on HbA1c and blood sugar level (fasting and post prandial) biochemical parameters of diabetic subject.

Variable	Time	Arm A (SNEC 30) N=35	Arm B (Conventional) N=34	p-value* (Arm A Vs Arm B)
HbA1c (%)	Pre- treatment	9.25 ± 2.12	8.47 ± 1.23	NS
	Post-treatment	6.11 ± 1.73	6.44 ± 1.72	NS
	Difference	-3.14 ± 1.58	-2.02 ± 1.67	<0.01
	%Difference	-33.48 ±15.13	-23.38 ±18.33	<0.05
	p-value ** (Pre- and post-treatment)	<0.0001	<0.0001	
Fasting Blood Sugar (mg/dL)	Pre-treatment	176.09 ± 64.18	160.37 ± 49.53	NS
	Post-treatment	127.22 ± 45.64	132.85 ± 49.94	NS
	Difference	-48.87 ± 44.60	-27.53 ± 39.02	<0.05

	% Difference	-25.6 ± 16.08	-16.10 ± 20.05	<0.05
	p-value ** (Pre- and post-treatment)	<0.0001	<0.0001	
PP (mg/dL)	Pre- treatment	255.80 ± 103.10	207.94 ± 77.16	<0.05
	Post-treatment	181.03 ±68.98	182.29 ± 88.38	NS
	Difference	-74.78 ± 67.05	-25.65 ± 84.25	<0.01
	% Difference	-24.68 ± 21.78	-8.03 ± 45.20	NS
	p-value ** (Pre- and post-treatment)	<0.0001	NS	

**Student's unpaired t-test was performed to compare the values between the two study arms and ** Student's paired t-test was performed compare the values before and after the treatment. P-values <0.05 was considered significant. (NS= not significant).*

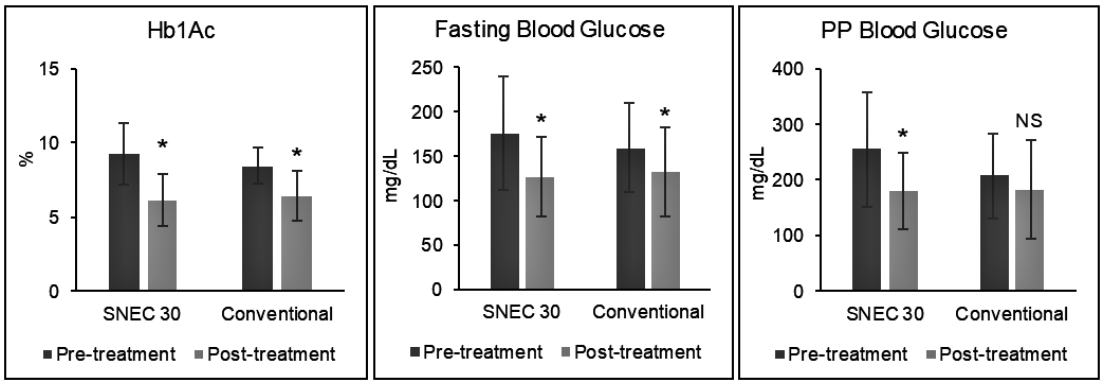

Figure 1: Pre-treatment and post treatment values for Hb1Ac, Fasting blood glucose and Postprandial Glucose in subjects from both study arms. Student's paired t-test was performed compare the values before and after the treatment. (*) P-values <0.05 was considered significant. (NS= not significant)

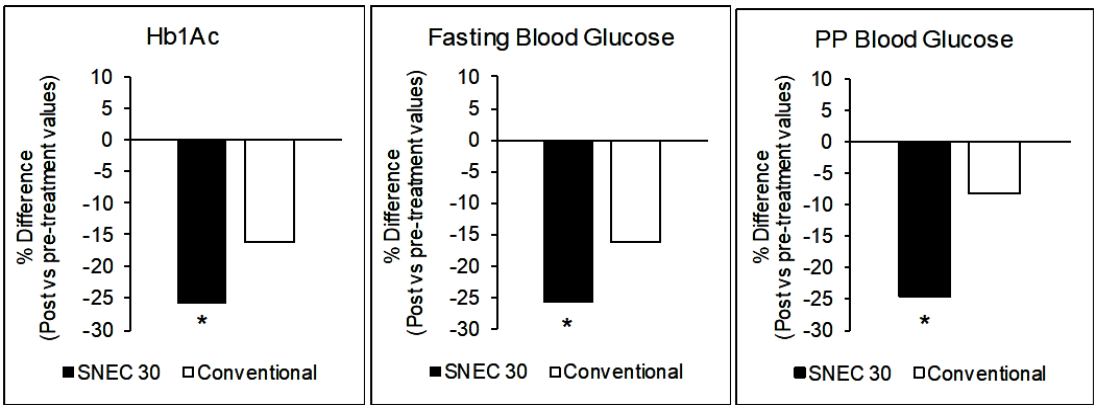

Figure 2: Efficacy of the treatment as measured by the percentage difference calculated between the Pre-treatment and post treatment values for Hb1Ac, Fasting blood glucose and Postprandial Glucose in subjects from both study arms. Student's unpaired t-test was performed to compare the values between the two study arms. (*) P-values <0.05 was considered significant. (NS= not significant)

Table 2 and figure 1 shows the mean difference between both the groups using Independent t-test or student unpaired t-test. From the table, pre and post difference among the laboratory parameters like HbA1c, Fasting blood sugar and Post prandial using paired-t test was also found out. On comparing the mean difference of laboratory parameters between the groups (SNEC 30mg and Conventional), it was found to be statistically insignificant except the post prandial. The pre and post difference, was found to be statistically significant (P-value <0.05) among the entire laboratory investigations except post prandial in conventional method**.**

DISCUSSION

In developing countries, 80% of individuals depend primarily on traditional medicine to meet their healthcare needs. Although various treatment regimens are available, the importance and beneficial effects of dietary phytochemicals is being explored. Turmeric rhizome (C. longa) is commonly used in Indian households for treating common cold, sore throat, fever, biliary disorders, anorexia, wounds and sinusitis. The average content of curcumin in turmeric powder is 2-8 % and thus on an average, 500 mg of turmeric contains 22 mg of curcumin.[12] Turmeric has been shown to have beneficial effects in several diseases including diabetes mellitus. Therefore, turmeric has been shown to exhibit antioxidant, antidiabetic and anti-inflammatory properties and hence may be used as a good adjuvant.[13] In the current study, conducted to determine whether or not SNEC 30 capsules have any effect on certain biochemical markers in patients of type 2 diabetes, the results showed statistically significant improvement in Hba1c and overall assessment of disease condition as assessed in the patient after 3 month's treatment.

To understand the efficacy of the treatment, biochemical levels for fasting, pp blood sugar and HbA1c analysed before and after the treatment were analysed in the study. The differences in the pre and post treatment values were calculated and the percentage difference was calculated for normalizing the values.

Our study demonstrated a significant decrease in fasting and post prandial plasma glucose levels in both treatment arms. The decrease in glucose levels in Arm A (turmeric supplementation) may be due to better drug compliance and health education of patients on recruitment of subjects. Comparatively there was a greater reduction in diabetic patients supplemented with turmeric powder. A previous study reported that curcumin increases glycogen storage in liver and suppresses activities of gluconeogenic enzymes thereby reducing blood glucose in db/db mice.[14] This could be a plausible explanation in humans as

well. Another study conducted by Maithli K. et al 2015 reported that Turmeric supplementation in metformin treated type 2 diabetic patient significantly decreased fasting glucose (95 ± 11.4 mg/dl, P \ 0.001) and HbA1c levels (7.4 ± 0.9 %, P \ 0.05).

Subjects who were administered with SNEC 30 showed decreased glycosylated hemoglobin levels when compared with subjects treated with conventional treatment. Glycosylated hemoglobin reflects average blood glucose fluctuations over a period of 60-90 days and thus is an index of long term glucose homeostasis. Hyperglycemia leads to increased production of free radicals due to glucose auto-oxidation, which in turn enhances the glycosylation of proteins. Some previous studies have shown that the antioxidant property of curcumin may reduce the glycosylation of hemoglobin in the presence of high glucose concentration.[13–15]

SNEC 30 capsule was well tolerated during the conduct of the study. There was no adverse event reported during the trial in type 2 diabetes patients as per the investigator's assessment.

CONCLUSION

Based on the results of the current Study it can be concluded that SNEC 30 capsule along with the standard treatment are more effective as compared to alone standard treatment in type 2 diabetes patients.

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