

# Effect of Lycopene Rich Foods and Pure Lycopene Capsule Supplementation on Fasting and Post Prandial Blood Glucose Levels of Diabetic Subjects

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**Abstract:** We aimed to verify the beneficial effects of processed tomato ketchup prepared in the laboratory on hypolipidemic subjects with hyperlipidemia condition. Using purposive sampling technique, 90 diabetic subjects between 35 - 55 years of age group, BMI levels falls between 18.5 - 34.9 (kg/m<sup>2</sup>) were selected for the study and the total sample is divided under two experimental groups with 30 subjects under each group, supplemented with pure lycopene gel capsule and tomato powder respectively, and the remaining 30 subjects placed under control group without any intervention and the study was carried out for a period of 3 months. The parameters like physico-chemical analysis shows that the samples were superior safe during storage and nutrient analysis shows that the tomato powder was nutritionally rich and lycopene content was very high. The effects of tomato products on fasting and post prandial blood sugar levels showed that they were found to be decreased significantly at 1% level and 5% level after supplementation.

**Keywords:** tomato powder, tomato products, lycopene capsules, fasting blood sugar level, post prandial blood sugar level, diabetic subjects, supplementation studies

## 1. Introduction

Tomato is a globally famous food and contains several phytonutrients including lycopene,  $\beta$ -carotene, anthocyanin, and flavonoids (Lee HS, et al.2013). The increased temperature used to produce tomato juice, ketchup, tomato paste and canned tomato enhances the bioactive composition. Lycopene is a naturally occurring chemical that gives fruits and vegetables a red color is due to the pigments called carotenoids (Schweiggert RM, et al.2014). Lycopene is found in watermelons, pink grapefruits, apricots, and pink guavas. It is found in particularly high amounts in tomatoes and tomato products (Seifi M, et al.2013). In North America, 85% of dietary lycopene comes from tomato products such as tomato juice or paste. One cup (240 ml) of tomato juice provides about 23 mg of lycopene. Processing raw tomatoes using heat (in the making of tomato juice, tomato paste or ketchup, for example) actually change the lycopene in the raw product into a form that is easier for the body to use (Friedman M; 2013).

## 2. Methodology

Tomatoes are important agricultural crop world - wide. Their pigments important pigment like carotenoids like lycopene has much therapeutical use in many ways. They have been associated with health benefits such as lowering the risk of some chronic diseases.

Experimental design; Quasi - experimental research design was thought to be appropriate for the study. In this study, research area selected was Chittoor district region, A. P to take up lycopene supplementation on Type II diabetes subjects at the private diabetic Clinic, Chittoor. For sample selection, Purposive sampling technique was followed for the study.

The total Sample size was 90 diabetic subjects, out of which 30 subjects were placed in the control group without any

intervention and 30 subjects were in experimental Group - I where lycopene in the form of pure tomato capsule has been supplemented and 30 subjects for experimental group - II, where lycopene in the form of tomato powder has been supplemented.

### Criteria for sample selection

The study sample is selected keeping the following pre - determined criteria,

#### Inclusion criteria:

- Age between 25 - 60 years
- Patients who were willing
- Patients who are on Oral diabetic medication (In Lycopene supplementation in diabetes)

#### Exclusion criteria:

- Patients who were not interested in intervention studies
- Patients with multiple complications
- Patients who are undergoing surgeries

### Selection of tools and technique

A questionnaire was prepared by the investigator to collect the relevant data from the subjects It includes general information, anthropometric parameters, medical history, dietary parameters and biochemical parameters

- a) General information, anthropometric data, medical data, and dietary history are collected.
- b) Food analysis (Tomato powder)
  - Lycopene quantification (Ranganna S, 2001)
  - Nutrient analysis (Protein, Fat, Carbohydrates, Energy and Ash) (Suzanne Nielsen, 2010)
  - Shelf life (Moisture, Rancidity, pH test (Suzanne Nielsen, 2010)
  - Microbial count analysis (Laird D. T. et al, (2012)
  - Sensory evaluation studies (Harry, (2010)
  - Laboratory investigations were done to subjects

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- c) Fasting blood sugar (FBS), and Postprandial blood sugar (PPBS) changes in Diabetes Mellitus (DM) subjects pre and post level of supplementation POD METHOD (Trinder, 1969)

### Food product development and standardization

#### Development of tomato powder

Select the dark red tomatoes >1000 g > rinse the tomatoes well > slice the tomatoes thinly > place the tomato slices on a baking sheet and keep in dehydrator > adjust the dehydrator to an optimum temperature > continue to dry the tomato slices till they dry and flip the slices till they become brittle > cool the slices > make tomato powder by placing it in grinder > store it in sachets and place them in air tight container.

#### Tomato's pure lycopene capsules

For the capsule supplementation 20 mg pure lycopene capsules from tomato source was obtained by piping Rock.com, which was chosen because it's made with natural tomato.

#### Supplement Facts

Serving size: 1 Soft gel

Serving per Container: 120

Each capsule contains Lycopene: 20 mg

Other Ingredients present in the capsule: Gelatine, Safflower Oil, Vegetable Glycerine, Yellow Beeswax.

**Directions given by Piping Rock company;** For adults, take one (1) quick release soft gel one to two times daily, preferably with meals. Piping Rock Lycopene 20 mg supplies a precisely - calibrated serving of red - hot antioxidant nutrition Known for giving tomatoes their bright red color, lycopene is a carotenoid plant pigment with high antioxidant activity. Commonly used to neutralize age - accelerating free radicals, lycopene also optimizes prostate health, colon health, heart health, immune function and healthy aging. We are proud to offer you superior - quality lycopene nutrition in our highly absorbable, quick release liquid capsules. Piping Rock Lycopene 20 mg is an affordable, convenient supplement for reinforcing your antioxidant defences and supporting your overall well - being.

#### Sensory evaluation (Organoleptic test) of food supplement

By using the hedonic scale sensory evaluation of laboratory prepared product 'tomato powder' was conducted on the subjects who are willing to participate to study the sensory acceptance of developed food product.

This scale was quickly adopted for measuring the acceptability of foods and beverages, This equal - interval property helps to justify the practice of analyzing the responses by assigning successive integer values (1, 2, 3, ... up to 9) to the scale points and testing differences in average acceptability using parametric statistics. The reliability, validity and discriminating ability of the scale were proven in food acceptance tests with soldiers in the field (Harry, (2010).

#### Lycopene capsule intervention

In normal individuals as an antioxidant, lycopene has been taken by mouth in doses of 6.5, 15, and 30 milligrams daily for eight weeks. Where as to treat heart disease, lycopene has been taken by mouth in the form of tomato products, capsules, and in doses of 40 - 80 milligram doses daily for 1 - 12 weeks (Xinli Li and Jiahong Xu; (2013). As per the lab analysis Lycopene content estimated in tomato powder was 112.75 mg/100g. In this Comparative intervention study 40 mg of lycopene as taken as standard dose for diabetic's supplementation. Dose assignment and patient selection were done with the help of relevant consultant diabetologist.

#### Experimental design

##### Experimental group - I

20 mg of pure lycopene soft gel capsule has been supplemented to 30 patients twice in a day, i. e., 2 capsules per day with meals for 45 days

##### Experimental group - II

18 g of tomato powder sachets (Consist 20 mg of lycopene) has been supplemented to 30 patients twice in a day, i.e., 2 sachets per day with meals and advise them to take in the form of juice or soup or pasta sauce for 45 days.

**Control group** 30 patients were recruited for control group in the study. They were neither supplemented tomato powder sachets nor lycopene capsules. They were asked to follow their own household diets.

#### Data analysis

##### Data pool up

The collected data was pooled up according to the objectives of the study.

##### Statistical analysis

The collected data were subjected to statistical analysis using tools.

- Cross tabulation
- Percentage of parameters
- Means and standard deviation Anova for clinical signs and blood profile
- Comparison of means using t - test other statistical tools for blood profile
- Graphical representation of for blood profile

### 3. Results and Discussion

The results of general information collected on diabetic subjects selected for the study are presented below;

#### General information

##### Age

**Table 1:** Percentage distribution of sample according to age

Age (Years)	Group			Total (n=90)
	Control (n=30)	Experiment - I (n=30)	Experiment - II (n=30)	
26 - 35	0 (0)	1 (3)	3 (10)	4 (5)
36 - 45	9 (30)	6 (20)	14 (46)	29 (32)
46 - 55	18 (60)	11 (37)	11 (37)	40 (44)
Above 55	3 (10)	12 (40)	2 (7)	17 (19)

Figure in () indicates percentage.

The percentage distribution of the sample according to age presented in Table 1 shown that in control group a majority of 60 percent of patients were in between 46 to 55 years and next higher 30 percent were between 36 - 45 years; whereas in experimental group - I 40 percent of patients were above 55 years and next higher 37 percent of patients 46 - 55 years, whereas in experimental group - II 46 percent of patients were between 36 - 45 years and next higher 37 percent of patients above 46 - 55 years. This table revealed that diabetes mellitus highly prevalent in the age middle adulthood due to the unhealthy lifestyle, faulty food habits and sedentary activities.

**Gender:**

**Table 2:** Percentage distribution of sample according to gender

Gender	Group			Total (n=90)
	Control (n=30)	Experiment - I (n=30)	Experiment - II (n=30)	
Male	22 (73)	17 (57)	28 (93)	67 (74)
Female	8 (27)	13 (43)	2 (7)	23 (26)

Figure in () indicates percentage.

The percentage distribution of the sample according to gender presented in Table 2 shown that in control group a majority of 73 percent of patients were males and 27 percent of patients were female; whereas in experimental group - I majority 57 percent of patients were males and 43 percentile patients were female; Whereas in experimental group - II higher 93 percent of patients were male and 7 percent were female. This table revealed that diabetes mellitus highly prevalent in the males due to lifestyles, stress and faulty dietary habits.

**Place:**

**Table 3:** Percentage distribution of sample according to place

Place	Group			Total (n=90)
	Control (n=30)	Experiment - I (n=30)	Experiment - II (n=30)	
Chittoor	6 (20)	9 (30)	5 (17)	20 (22)
Chittoor District	24 (80)	21 (70)	25 (83)	70 (78)

Figure in () indicates percentage.

The percentage distribution of the sample according to place presented in Table 3 shown that in control group a majority of 80 percent of patients were from the Chittoor district region and next higher 20 percent of patients were from Chittoor regional; whereas in experimental group - I majority 70 percent of patients were from the Chittoor district region and 30 percentile patients were from Chittoor region; whereas in experimental group - II higher 83 percent of patients were from the Chittoor district region and 17 percent were from Chittoor region. This table revealed that diabetes highly prevalent in the Chittoor district.

**Education:**

**Table 4:** Percentage distribution of sample according to education

Education	Group			Total (n=90)
	Control (n=30)	Experiment - I (n=30)	Experiment - II (n=30)	
Illiterate	11 (37)	6 (20)	9 (30)	26 (29)
Primary	9 (30)	7 (23)	5 (17)	21 (23)
High School	6 (20)	9 (30)	11 (36)	26 (29)
Pre - University	4 (13)	5 (17)	5 (17)	13 (15)
College	0 (0)	3 (10)	0 (0)	4 (4)

Figure in () indicates percentage.

The percentage distribution of the sample according to educational status presented in Table 4 shown that in control group a majority of 37 percent of patients were illiterate and next higher 30 percent of patients were studied high school; whereas in experimental group - I majority 30 percent of patients were high school and 23 percentile patients were studied in primary school; whereas in experimental group - II higher 36 percent of patients were studied high school and next higher 30 percent were illiterate. This table result revealed that the majority of the patients between illiteracy to primary school may cause low of health education that may cause of unhealthy lifestyle to early onset and uncontrolled diabetes.

**Occupation:**

**Table 5:** Percentage distribution of sample according to occupation

Occupation	Group			Total (n=90)
	Control (n=30)	Experiment - I (n=30)	Experiment - II (n=30)	
Employee	12 (40)	23 (77)	25 (83)	60 (67)
Unemployee	18 (60)	7 (23)	5 (17)	30 (33)

Figure in () indicates percentage

The percentage distribution of the sample according to occupation presented in Table 5 shown that in control group a majority of 60 percent of patients were unemployed and 40 percent of patients were employed; whereas in experimental group - I majority 77 percent of patients were employees and 23 percentile patients were unemployed; Whereas in experimental group - II higher 83 percent of patients were employed and next highest 17 percent were unemployed. This table result revealed that the majority of the patients were in some occupation with sedentary physical activity and changes in life style lead to diabetes.

**Income Level:**

**Table 6:** Percentage distribution of sample according to income levels

Income level	Group			Total (n=90)
	Control (n=30)	Experiment - I (n=30)	Experiment - II (n=30)	
Low	11 (37)	19 (63)	15 (50)	45 (50)
Middle	19 (63)	6 (20)	10 (33)	35 (39)
High	0 (0)	5 (17)	5 (17)	10 (11)

Figure in () indicates percentage.

The percentage distribution of the sample according to income level presented in Table 6 shown that in control group each 63 percent of patients were laid in middle income group; whereas in experimental group - I majority 63 percent of patients were low income group and next higher 20 percentile patients were middle income group; Whereas in experimental group - II higher 50 percent of patients were low income group and next higher 33 percent were middle income group. This table result revealed that the low income status may cause early onset of the diabetes due to the lack of early medical concern and medical education.

**Type of family:**

**Table 7:** Percentage distribution of sample according to type of family

Type of family	Group			Total (n=90)
	Control (n=30)	Experiment - I (n=30)	Experiment - II (n=30)	
Nuclear	28 (93)	18 (60)	21 (70)	67 (74)
Combined	2 (7)	12 (40)	9 (30)	23 (26)
Extended	0 (0)	0 (0)	0 (0)	0 (0)

Figure in () indicates percentage.

The percentage distribution of the sample according to family type presented in Table 7 shown that in control group each higher 93 percent of patients were from nuclear families and 7 percentile of patients were from combined families; Whereas in experimental group - I majority 60 percent of patients were from nuclear families and 40 percentile of patients were from combined families; whereas in experimental group - II higher 70 percent of patients were from nuclear families and 30 percentile of patients were from combined families.

**Physical Activity pattern:**

**Table 8:** Percentage distribution of sample according to physical activity pattern

Physical activity pattern	Group			Total (n=90)
	Control (n=30)	Experiment - I (n=30)	Experiment - II (n=30)	
Sedentary	30 (100)	30 (100)	30 (100)	90 (100)
Moderate	0 (0)	0 (0)	0 (0)	0 (0)
Heavy	0 (0)	0 (0)	0 (0)	0 (0)

Figure in () indicates percentage

The percentage distribution of the sample according to income level presented in Table 8 shown that in control group and experiment group - I and II cent percent of patients, this table results revealed that the sedentary physical activity may cause early onset of the diabetes.

**Medical History:**

**Table 9:** Percentage distribution of sample according to medical history

Medical History	Group			Total (n=90)
	Control (n=30)	Experiment- I (n=30)	Experiment- II (n=30)	
Diabetes Mellitus	30 (100)	30 (100)	30 (100)	90 (100)
Hypertension	1 (3.3)	2 (6.7)	4 (13.3)	7 (7.8)

Heart disease	2 (6.7)	4 (13.3)	2 (6.7)	8 (8.9)
Kidney Diseases	0 (0)	0 (0)	0 (0)	0 (0)
Urinary Disease	0 (0)	0 (0)	1 (3.3)	1 (1.1)
Hypothyroidism	4 (13.3)	4 (13.3)	3 (10)	11 (12.2)
Malignancy	0 (0)	0 (0)	0 (0)	0 (0)
Gastro intestinal Disorder	0 (0)	0 (0)	0 (0)	0 (0)
Others	3 (10)	4 (13.3)	1 (3.3)	1 (1.1)

Figure in () indicates percentage.

The percentage distribution of the sample according to medical history presented in Table 9 shown along with diabetes in the control group patients 3.3 percent, 6.7 percent in experimental group - I and 13.3 percent in experimental group - II were hypertensive. In the control group were 6.7 percent, 13.3 percent in experimental group - I and 6.7 percent in experimental group - II was suffered with heart disease. In the control group, 13.3 percent, 13.3 percent in experimental group - I and 10 percent in experimental group - II were suffered with hypothyroidism. And a minor percent of patients had urinary disease and other health diseases. This data revealed that patients were suffering with the more than one number of the complications due to unhealthy life style and low health educations.

**Nutritional Deficiency:**

**Table 10:** Percentage distribution of sample according to presence of nutritional deficiency

Nutritional deficiency	Group			Total (n=90)
	Control (n=30)	Experiment - I (n=30)	Experiment - II (n=30)	
Anemia	3 (10)	4 (13.3)	3 (10)	10 (11.1)
Osteoporosis	0 (0)	0 (0)	0 (0)	0 (0)
Osteomalacia	0 (0)	0 (0)	0 (0)	0 (0)
Vitamin - A deficiency (cataract)	0 (0)	0 (0)	0 (0)	0 (0)
Others	0 (0)	0 (0)	0 (0)	0 (0)

Figure in () indicates percentage.

The percentage distribution of the sample according to nutrition deficiency compliance, presented in Table 10 shown that in control group 10 percent of patients were suffered with anemic, 13.3 percent of patients in experimental group - I and 10 percent of patients, in overall total patients 11.1 percent of patients were anemic. None of the other nutritional deficiencies were seen in these diabetic patients. This data revealed that a small sector population was suffering from the nutritional deficiency due to the metabolic abnormalities occur in the diabetes.

**Ill status:**

**Table 11:** Percentage distribution of sample according to current ill status

Ill status	Group			Total (n=90)
	Control (n=30)	Experiment - I (n=30)	Experiment - II (n=30)	
Loss of appetite	1 (3.3)	0 (0)	0 (0)	1 (1.1)
Fever	1 (3.3)	0 (0)	0 (0)	1 (1.1)
Nausea	2 (6.7)	2 (6.7)	0 (0)	4 (4.4)
Others	1 (3.3)	1 (3.3)	0 (0)	2 (2.2)

Figure in () indicates percentage.

The percentage distribution of the sample according to current ill status presented in Table 11 shown that in control group majority 3.3 percent of patients were suffered with various ill signs loss of appetite and fever, 6.7 percent of patients' nausea and only 3.3 percent of patients other ill conditions; whereas in experimental group - I 6.7 percent of patients were suffering with nausea and only 3.3 percent of patients other ill condition, none of the patients in experimental group - II was suffered with any ill conditions and overall total subject only 1.1 percent of patients suffered with loss of appetite and fever and 4.4 percent of patients' nausea, 2.2 percent of patients were suffering with other ill conditions. This data revealed that diabetes will decrease the immunity may cause frequent illness.

**Dietary Habits:**

**Table 12:** Percentage distribution of sample according to dietary habits

Dietary Habits	Group			Total (n=90)
	Control (n=30)	Experiment - I (n=30)	Experiment - II (n=30)	
Vegetarian	0 (0)	0 (0)	0 (0)	0 (0)
Non vegetarian	30 (100)	30 (100)	30 (100)	90 (100)
Ovo vegetarian	0 (0)	0 (0)	0 (0)	0 (0)

Figure in () indicates percentage.

The percentage distribution of the sample according to dietary habits presented in Table 12 shown that in the control group majority 100 percent of patients were non - vegetarian This data revealed that sent percent of the patients were taking non - vegetarian that may be correlated with their ill complication because most of the non - vegetarian foods are consist high fat and it may alter the blood sugar levels.

**Family history:**

Family history of disease may promote the early onset of disease into the next generation. It leads to early progression of disease. Patients had a strong family history of diabetes, hypertension, kidney disease and other disease may further generate early onset diseases.

**Table 13:** Percentage distribution of sample according to family history

Family history	Group			Total (n=90)
	Control (n=30)	Experiment - I (n=30)	Experiment - II (n=30)	
Diabetes	6 (20)	5 (16.7)	3 (10)	14 (15.6)
Hypertension	0 (0)	0 (0)	0 (0)	0 (0)
Heart disease	0 (0)	0 (0)	0 (0)	0 (0)
Kidney disease	0 (0)	0 (0)	0 (0)	0 (0)
Others	0 (0)	0 (0)	0 (0)	0 (0)

Figure in () indicates percentage

The percentage distribution of the sample according to family history presented in Table 13 shown that diabetes as family history, 20 percent of patients in the control group, 16.7 percent of patients experimental group - I, 10 percent of patients experimental group - II and in total 15.6 percent of patients had a family history of diabetes. This data revealed that family medical compliance may alter the genetic system of the body which may cause early onset of diabetes.

**Vices:**

Alcohol consumption and smoking harms nearly every organ of the body. It progresses the atherosclerosis.

**Table 14:** Percentage distribution of sample according to Vices

Vices	Group			Total (n=90)
	Control (n=30)	Experiment - I (n=30)	Experiment - II (n=30)	
Smoking	6 (20)	7 (23.3)	7 (23.3)	20 (22.2)
Alcohol	3 (10)	5 (16.7)	1 (3.3)	9 (10)
Chewing habits	5 (16.7)	3 (10)	5 (16.7)	13 (14.4)

Figure in () indicates percentage.

The percentage distribution of the sample according to vices presented in Table 14 result shown in the control group, 20 percent of patients had a history of smoking habits, 10 percent of patients had a history of alcohol consumption and 16.7 percent of patients had a history of pawn chewing; in experimental group - I 23.3percent of patients had a history of smoking habits, 16.7 percent of patients had a history of alcohol consumption and 10 percent of patients had a history of pawn chewing; 23.3 percent of patients had a history of smoking habits, 3.3 percent of patients had a history of alcohol consumption and 16.7 percent of patients had a history of pawn chewing. And in total patients 22.2 percent of patients had a history of smoking habits, 10 percent of patients had a history of alcohol consumption and 14.4 percent of patients had a history of pawn chewing This data revealed that at least sections of patients were ad a past history of consumption of cigarette, alcohol and pawn, which increase the alteration in blood sugar levels may cause serious early onset of diabetic complication.

**Anthropometric data**

**Height:**

**Table 15:** Percentage distribution of sample according to height

Height	Group			Total (n=90)
	Control (n=30)	Experiment - I (n=30)	Experiment - II (n=30)	
Below 150	1 (3.3)	0 (0)	2 (6.7)	3 (3.3)
150 - 160	11 (36.7)	8 (26.7)	8 (26.7)	27 (30)
160 - 170	13 (43.3)	13 (43.3)	13 (43.3)	39 (43.3)
170 - 180	5 (16.7)	9 (30)	7 (23.3)	21 (23.3)

Figure in () indicates percentage.

The percentage distribution of the sample according to height presented in Table 15 result shown in the control group majority 43.3 percent of patients were between 160 - 170 centimetres of height and next higher 36.7 percent of patients were between 150 - 160 centimeters of height; whereas in experimental group - I higher 43.3 percent of patients were between the 160 - 170 centimeters of height and next higher 30 percent of patients were between 170 - 180 centimeters of height; whereas in experimental group - II higher 43.3 percent of patients were between the 160 - 170 centimeters of height and next higher 26.7 percent of patients were between 150 - 160 centimeters of height. This data revealed that the majority of the diabetic patients were in the 160 - 170 centimeters of height.

**Weight:**

**Table 16:** Percentage distribution of sample according to weight

Weight	Group			Total (n=90)
	Control (n=30)	Experiment - I (n=30)	Experiment - II (n=30)	
Below 50	0 (0)	1 (3.3)	0 (0)	1 (1.1)
50 - 60	5 (16.7)	3 (10)	3 (10)	11 (12.2)
60 - 70	8 (26.7)	6 (20)	10 (33.3)	24 (26.7)
70 - 80	12 (40)	11 (36.7)	9 (30)	32 (35.6)
Above 80	5 (16.7)	9 (30)	8 (26.7)	22 (24.4)

Figure in () indicates percentage.

The percentage distribution of the sample according to height presented in Table 16 result shown in the control group majority 40 percent of patients were between 70 - 80 kilograms of weight, next higher 26.7 percent of patients were between 60 - 70 kilograms of weight and each 16.7 percent of patients were in between 50 - 60 kilograms and above 80 kilograms of weight; whereas in experimental group - I higher 36.7 percent of patients were between the 70 - 80 kilograms of weight and next higher 30 percent of patients were above 80 kilograms of weight; whereas in experimental group - II higher 33.3 percent of patients were between the 60 - 70 kilograms of weight and next higher 30 percent of patients were between 70 - 80 kilograms of weight; in total patients majority 35.6 percent of patients were in between 70 - 80 kilograms and next higher 26.7 percent of patients were between 60 - 70 kilograms. This data revealed that higher body weight may affect their body composition and uncontrolled the blood sugar levels also. So, that weight is parameter need to be controlled and monitored to prevent the progression of diabetes condition.

**Body Mass Index:**

**Table 17:** Percentage distribution of sample according to Body Mass Index

BMI levels (kg/m <sup>2</sup> )	Group			Total (n=90)
	Control (n=30)	Experiment - I (n=30)	Experiment - II (n=30)	
<18.4 (Underweight)	0 (0)	2 (6.7)	0 (0)	2 (2.2)
18.5 - 24.9 (Normal)	7 (23.3)	5 (16.7)	8 (26.7)	20 (22.2)
25 - 29.9 (Overweight)	18 (60)	19 (63.3)	17 (56.7)	54 (60)
30 - 34.9 (Obesity Grade - I)	5 (16.7)	4 (13.3)	5 (16.7)	14 (15.6)

Figure in () indicates percentage.

The percentage distribution of the sample according to height presented in Table 17 result shown in the control group majority 60 percent of patients were overweight their BMI was in between 25 - 29.9 kg/m<sup>2</sup> and next higher 23.3 percent of patients were normal nutritional status their BMI in between 18.5 - 24.9 kg/m<sup>2</sup> and only 16.7 percent of patients were in grade - I obesity and their BMI was in between 30 - 34.9kg/m<sup>2</sup>; whereas in experimental group - I majority 63.3 percent of patients were overweight their BMI was in between 25 - 29.9 kg/m<sup>2</sup> and next higher 16.7 percent of patients were normal weight and their BMI was in

between 18.5 - 24.9 kg/m<sup>3</sup>; whereas in experimental group - II majority 56.7 percent of patients were in overweight nutritional status and their BMI was in between 25 - 29.9 kg/m<sup>2</sup> and next higher 26.7 percent of patients were in normal weight and their BMI was in between 18.5 - 24.9 kg/m<sup>3</sup>; This data reveal that higher body mass index, which increases the more deposition of adipose fat in blood, which may alter the body composition may cause of metabolic complications like diabetes.

**Standardization and Supplementation:**

**(a) Standardization and supplementation Food product standardization:**

**Table 18:** Laboratory analysis of lycopene, protein, fat, carbohydrates, energy and ash levels in supplemented products

Nutrients	Tomato powder
Lycopene (mg/100 g)	112.75
Protein (g/100g)	7.9
Fat (g/100 g)	1.9
Carbohydrates (g/100g)	72.7
Energy (kcal/100g)	339
Ash (g/100g)	9.7

The Table 18 shown that 100 g of developed tomato powder contained 112.75 mg of lycopene, 7.9 g of proteins, 1.9 g of fat, 72.7 g of carbohydrates, 339 kcal of energy and 9.7 g of ash.

**Shelf life analysis supplemented product**

Dilution plate technique the dilution plate count is the most frequently used technique for determining the number of viable microbial in samples and in addition may be used a method. The technique is based upon the assumption that when a known weight of the sample is agitated in the suitable liquid, the microorganisms before detached from the sample and each of the detached cells gives rise to discrete colony when plate on a nutrient medium in a Petri dish. These colonies are counted and the number of cells in the original sample estimated since the number of cells even in a small sample is large. The suspension of cells must be diluted so that a small number of well separated colonies develop on each petri dish. The method procedure was enclosed (Annexure -)

**Table 19:** Microbiological analysis of supplemented products

Sample	Tomato powder	
	24 hours' incubation (Cfu/g)	48 hours' incubation (Cfu/g)
Fresh sample	5	6
15 days old	9	10
30 days old	32	34

The Table 19 shown that microbiological analysis of fresh supplement products for 24 hours' incubation was 5 Cfu/g, on the 15 th day 9 Cfu/g and on 30 th day 32 Cfu/g; whereas after 48 hours' incubation of fresh supplemented product 6 Cfu/g, on the 15 th day 10 Cfu/g and on the 30 th day 36 Cfu/g.

The limit range for microbial growth on food sample is 20 - 25 colonies. If the number of colonies is more than that, the food sample is not consumable. If 15 days old food sample the microbial growth was seen, but it was less than 20 colonies which implies that it is consumed. At 30 days old samples, the food sample shown dense growth of colonies which indicates, it is deteriorated keeping the shelf life in view the investigator supplemented the freshly prepared the samples once in every 15 days.

**Table 20:** Analysis of Moisture, pH and Rancidity of the supplemented products

Samples	Moisture content (%)	pH	Rancidity
Fresh sample	7.8	5.1	0.39
15 days old	9.1	6.4	0.57
30 days old	10.9	7.7	0.72

The Table 20 shown that the supplemented product, i.e., Tomato powder moisture content on 1<sup>st</sup> day was 7.8 g, 91 g on 5<sup>th</sup> day and 10.9 g on 30<sup>th</sup> day.; whereas pH of tomato powder on 1<sup>st</sup> was 5.1, 6.4 on 15<sup>th</sup> day and 7.7 on 30<sup>th</sup> day; whereas rancidity on 1<sup>st</sup> day 0.39, 0.57 on 15<sup>th</sup> day and 0.72 on 30<sup>th</sup> day.

**(b) Sensory evaluation of tomato powder**

**Table 21:** Percentage distribution patients, according to sensory evaluation of supplemented lycopene food (Tomato powder)

Hedonic Scale	Appearance (n=30)	Smell (n=30)	Taste (n=30)	Texture (n=30)	Color (n=30)	Overall acceptance (n=30)
Like very much - 9	2 (6.7)	-	-	10 (33.3)	2 (6.7)	1 (3.3)
Like much - 8	9 (30)	13 (43.3)	12 (40)	14 (46.7)	19 (63.3)	14 (46.7)
Like moderately - 7	19 (63.3)	11 (36.7)	11 (36.7)	6 (20)	9 (30)	15 (50)
Slightly like - 6	-	6 (20)	7 (23.3)	-	-	-
Neither like nor dislike - 5	-	-	-	-	-	-
Slightly dislike - 4	-	-	-	-	-	-
Dislike moderately - 3	-	-	-	-	-	-
Dislike much - 2	-	-	-	-	-	-
Dislike very much - 1	-	-	-	-	-	-

Figure in () indicates percentage.

The percentage distribution of sensory evaluation of supplemented lycopene food presented in Table 21 shown that in hedonic scale check the different attributes such as appearance, smell, taste, texture, color, and overall acceptance. For Appearance attribute - 63.3 percent of patients said like moderately to the food supplement, 30 percent like much; Of Smell - 43.3 percent of patients said like much and 36.7 percent like much and 20 percent of patients said like slightly; For Taste – 40 percent of patients said like much and 36.7 percent like moderately and 23.3 percent of patients said like slightly; For Texture - 46.7 percent of patients like much and 33.3 percent like very much; For Color - 63.3 percent of the subjects said like

much, 30 percent like very much; For Overall acceptance - 50 percent of patients said like moderately and 46.7 percent like much the food supplement.

This revealed that formulated food supplement got a high score on a hedonic sensory evaluation scale, most of the score laid in 7 like moderately. This may help increase the acceptance of food supplement in diabetic patients.

**Biochemical parameters**

The results of tomato products supplementation studies and statistical analysis carried out are presented here below from table 22 to 26.

**Table 22** Comparison of paired t - test Fasting Blood sugar level changes before, intermittently, and after the intervention in the control group, experimental group - I and II

Type of Group	Fasting Blood sugar	N	Mean	Std. Deviation	t - test	p value
Control group	Pre - Test	30	152.33	28.659	1.729 NS	0.094
	Post - Test	30	156.8	24.938		
Experimental –I group	Pre - Test	30	173.400	47.693	1.261 NS	0.217
	Post - Test	30	164.530	36.678		
Experimental –II group	Pre - Test	30	184.830	44.393	2.342*	0.026
	Post - Test	30	164.200	37.037		

\*\*=Indicates significant at 1% level

\* =Indicates significant at 5% level

NS=Indicates not significant

The comparison paired - t - test of Fasting blood sugar levels pre and post of the study in three groups presented in Table 22 shown that in control group mean and SD values raised from 152.33±28.659mg/dl to 156.8±24.938mg/dl, with the mean difference of 4.47 mg/dl, t - value was 1.729 NS and p - value was 0.094. This revealed that Fasting blood sugar level lowers was statistically not significant; whereas in

experimental group - I after intervention mean and SD values decreased from 173.400±47.693mg/dl to 164.530±36.678mg/dl, with the mean difference of 8.87 mg/dl, t - value was 1.261 N Sand p - value was 0.217. This revealed that reduction was statistically not significant; whereas in experimental group - II after intervention mean and SD values decreased from 184.830±44.393mg/dl to

164.200±37.037mg/dl, with the mean difference of 20.63 mg/dl, t - value was 2.342\*and p - value was 0.026. This revealed that reduction was statistically significant at the 5% level;

This data revealed that fasting blood sugar in control group was raised may cause of faulty dietary habits and the absence of medical foods in their diet, whereas in experimental group-I and II slight reduction was shown that lycopene had an effect in mild hypoglycaemia

**Table 23:** Comparison of paired t - test Postprandial blood sugar level changes before, intermittently, and after the intervention in the control group, experimental group - I and II

Type of Group	Postprandial blood sugar	N	Mean	Std. Deviation	t - test	p value
Control group	Pre - Test	30	201.500	58.491	2.932**	0.007
	Post - Test	30	219.170	53.086		
Experimental -I group	Pre - Test	30	197.170	64.008	1.874	0.071
	Post - Test	30	184.430	57.838		
Experimental -II group	Pre - Test	30	204.170	53.043	3.726**	0.001
	Post - Test	30	178.500	51.085		

\*\*=Indicates significant at 1% level

\* =Indicates significant at 5% level

NS=Indicates not significant

The comparison paired - t - test of Postprandial blood sugar levels in pre and post of the study in three groups presented in Table 23 shown that in control group mean and SD values raised from 201.500±58.491mg/dl to 219.170±53.086mg/dl, with the mean difference of 17.67 mg/dl, t - value was 2.932\*\*and p - value was 0.007. This revealed that the race was statistically significant at the 1% level; whereas in experimental group - I after intervention mean and SD values decreased from 197.170±64.0084mg/dl to 184.430±57.838mg/dl, with the mean difference of 12.74 mg/dl, t - value was 1.874 N Sand p - value was 0.004. This revealed that reduction was not statistically significant; whereas in experimental group - II after intervention mean and SD values decreased from 204.170±53.043mg/dl to 178.500±51.085mg/dl, with the mean difference of 25.67 mg/dl, t - value was 3.726\*\*and p - value was 0.001. This revealed that reduction was statistically significant at the 1% level;

This data revealed that fasting blood sugar in control group was raised may cause of faulty dietary habits and the absence of medical foods in their diet, whereas in experimental group-II slight reduction was shown that lycopene had an effect in mild hypoglycaemia

Similar results was found in Wang L, et al., (2006) resulted that dietary intake of lycopene or lycopene - containing foods had positive effect on the risk of type 2 DM; whereas Subhash K, et al., (2007) resulted that supplementation with tomatoes (cooked) to diabetic group for a period of 30 days, showed a significant improvement in antioxidant enzyme levels (p<0.001) and decreases blood glucose and lipid per oxidation rate (p<0.001), supplementation with tomato lycopene may serve as the best method of preventing the oxidative stress in diabetic patients.

**Table 24:** Comparison of different treatments on Pre - Fasting blood glucose levels (Diabetic)

		N	Mean	Std. Deviation
FBS PRE	Control	30	152.33	28.66
	Experiment I	30	184.83	44.39
	Experiment II	30	173.40	47.69
	Total	90	170.19	42.83

**Anova**

		Sum of Squares	Df	Mean Square	F	Sig.
FBS PRE	Between Groups	16307.756	2	8153.878	4.828	0.010*
	Within Groups	146934.033	87	1688.897		
	Total	163241.789	89			

Significant at 1% level

**Table 25:** Comparison of different treatments on Post - Final blood glucose levels

		N	Mean	Std. Deviation
POST FBS	Control	30	156.80	24.94
	Experiment I	30	164.20	37.04
	Experiment II	30	164.53	36.68
	Total	90	161.84	33.18

**Anova**

		Sum of Squares	Df	Mean Square	F	Sig.
POST FBS	Between Groups	1146.756	2	573.378	0.515	0.599
	Within Groups	96829.067	87	1112.978		
	Total	97975.822	89			

From the above table 24, 25 it was observed that after 45 days of supplementation, there is no significant change in mean fasting blood glucose levels within the groups.

**Table 26:** Comparison of different treatment on Pre and Post postprandial blood glucose levels

PPBS PRE	Control	30	201.50	58.49
	Experiment I	30	204.17	53.04
	Experiment II	30	197.17	64.01
	Total	90	200.94	58.09
POST PPBS	Control	30	219.17	53.09
	Experiment I	30	178.50	51.09
	Experiment II	30	184.43	57.84
	Total	90	194.03	56.43

**Anova**

		Sum of Squares	Df	Mean Square	F	Sig.
PPBS PRE	Between Groups	748.889	2	374.444	0.109	0.897
	Within Groups	299617.833	87	3443.883		
	Total	300366.722	89			
POST PPBS	Between Groups	28953.867	2	14476.933	4.951	0.009*
	Within Groups	254417.033	87	2924.334		
	Total	283370.9	89			

Significant at 5% level

From the above table 26 it was observed that after 45 days of supplementation, there is no significant change in mean Pre PPBS, and a significant change in mean post PPBS, between the groups.



#### 4. Conclusions

The available evidence and the present research data on the effects of tomato products and lycopene supplementation on diabetes mellitus supports the view that increasing the intake of these tomatoes and tomato products and pure lycopene nutraceuticals has positive effects on blood sugar levels with potent antioxidant properties, as a potential therapeutic approach to protect or reverse oxidative stress, and aid in controlling diabetes.

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