

## Effect of Probiotic Curd (Indian Dahi) Supplementation in Delaying the Progression of Pre- Diabetes to Diabetes Mellitus-A Pilot Study

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### Abstract

**Background:** Diabetes mellitus comprises a group of metabolic disorders such as hyperglycemia, dislipidemia, microvascular complications etc. The prevalence of type 1 and type 2 diabetes mellitus (DM) is rising dramatically. Diabetes is one of the most common non-communicable diseases leading to morbidity and mortality particularly in developing countries. The increased risk for developing multiple atherosclerotic risk factors among diabetic cases has been attributed to micro-vascular complications. Cardiovascular disease (CVD) is commonly associated with type 1 or type 2 DM cases. Also, CVD is the major cause of morbidity and mortality. Approximately, 80% deaths among the diabetic population were due to CVD, while 75% of the deaths among the hospitalized diabetic cases were also due to the complications of CVD.

**Aim:** To find out the association between the intake of probiotic curd and CVD risk factors among recently diagnosed prediabetic cases.

**Methods:** The study was a hospital based case-control study. The study cases were newly diagnosed with prediabetic condition, aged between 20-50yrs of both genders. Out of 75 cases screened, 25 cases were recruited as prediabetic cases based on their HbA1c values (DCCT-5.7 to 6.5%) and supplemented with probiotic curd while remaining 50 cases were not supplemented probiotic curd considered as control cases. The cases were drawn from the outpatient Department of Osmania General Hospital Hyderabad, India for the study purpose. To study the beneficial effects of probiotic curd on prediabetic cases, various biochemical parameters viz fasting blood glucose, HbA1c (glycated Hb) lipid profile, i.e., total cholesterol, triglycerides LDL (Low Density Lipoproteins), and HDL (High Density Lipoproteins) cholesterol were analyzed in both supplemented and control groups using commercially available kits.

**Results:** The results indicated significant changes as per the clinical parameters at different level in the values of fasting blood glucose, total cholesterol, HDL, LDL and triglycerides in the prediabetic cases supplemented with probiotic curd for a period of 30 days as compared to the control cases.

**Conclusions:** From this study, it was concluded that the supplementation of probiotic delays the progression of prediabetes mellitus to diabetes mellitus.

**Keywords:** Probiotic Curd, Pre Diabetes, Lipid Profile, Cardiovascular disease (CVD).

### Introduction

The term "Diabetes mellitus" describes a metabolic disorder of multiple aetiologies characterized by chronic hyperglycemia with disturbances in carbohydrate, fat and protein metabolism. The

metabolic changes coupled with the defects in insulin secretion and action/insulin resistance or both causes long-term micro vascular damage, dysfunction and failure of various organs particularly kidney [1].

According to the latest 2016 data of World Health Organization (WHO), an estimated number of 422 million adults are living with diabetes mellitus [2]. Prevalence of Diabetes is increasing rapidly every year and as per 2017, an estimated 415 million people had diabetes worldwide. The projected number is almost to be doubled by 2030 [3, 4]. As per the international diabetes foundation [2016] India was the diabetic capital [3] and currently more than 62 million Indians are affected with diabetes the average age for onset of diabetes among the general population is 42.5 years [5, 6]. Nearly 1 million Indians die due to diabetes every year [5]. The WHO estimates that diabetes resulted in 1.5 million deaths in 2012, making it the 8th leading cause of death [2].

Pre diabetes is the initial stage with impaired glucose tolerance/impaired fasting glucose or both. Pre-diabetes should not be viewed as a clinical entity in its own right but rather as an increased risk for diabetes and cardio vascular disease (CVD). Pre-diabetes is associated with age (above 45 years), obesity (especially abdominal and visceral obesity), dyslipidemia with high triglycerides and/or low HDL cholesterol, hypertension and sedentary life style. According to the National Institutes of Health (NIH), prediabetes is reversible. Treatment includes lifestyle modifications, such as diet, exercise and medication [6].

A national study to determine the prevalence of diabetes and pre-diabetes (impaired fasting glucose and/or impaired glucose tolerance) was conducted in India by ICMR Delhi. A total of 363 primary sampling units (188 urbans, 175 rural), in three states (Tamilnadu, Maharashtra and Jharkhand) and one union territory (Chandigarh) of India were sampled using a stratified multi-stage sampling design to survey individuals aged  $\geq 20$  years [7]. The prevalence rates of diabetes and prediabetes were assessed by measurement of fasting and 2 h post glucose load capillary blood glucose. Of the 16,607 individuals selected for the study, 14,277 (86%) participated, of whom 13,055 gave blood samples. The weighted prevalence of diabetes (both known and newly diagnosed) was 10.4% in Tamilnadu, 8.4% in Maharashtra, 5.3% in Jharkhand, and 13.6% in Chandigarh. The prevalence's of prediabetes (impaired fasting glucose and/or impaired glucose tolerance) in Tamilnadu, Maharashtra Jharkhand Chandigarh, were 8.3%, 12.8%, 8.1% and 14.6% respectively. Multiple logistic regression analysis showed that age, sex, family history of diabetes, urban residence, abdominal obesity, generalized obesity, hypertension and income status were significantly associated with diabetes. Significant risk factors for prediabetes were age, family history of diabetes, abdominal obesity, and hypertension and income status. As per the ICMR-India Diabetes study, in 2017, the overall prevalence of prediabetes in all 15 states was 10.3 (10 -10.6) [8]. The prevalence prediabetes varied from 6% while in Northeastern states the prevalence of prediabetes ranged from 14.7 to 15.9. Projections for the whole of India would be 62.4 million people with diabetes and 77.2 million people with prediabetes [8].

## Materials and Methods

### Institutes Scientific / Ethical Committee Approval:

The study was approved by the Scientific Advisory Committee and IEC of the ICMR-NIN. After the study period, control prediabetic cases were also supplemented with probiotic curd. Informed consent was also obtained from the prediabetic cases.

## Selection of the Study Cases and Bio-Chemical Parameters

As part of the study, about 75 prediabetic cases were screened randomly to check RBS ( $>125$ mg/dl) using accucheck kit in outpatient department of Osmania General Hospital, Hyderabad India. Cases with prediabetic condition were instructed to attend the clinic on fasting following day to check their FBS (110 - 125 mg/dl) value. Twenty-five cases were confirmed with prediabetes by Glycated haemoglobin test (6.0-6.5%) and were supplemented with probiotic supplementation for a period of one month. Both males and Females in the age group of 25 to 50 years were included.

The cases were further categorized into two groups. i.e. Group A and B.

- **Group A** cases (25) were supplemented with 100 gms / day of freshly prepared curds using toned milk (100 ml) supplied by Mother Dairy, fermented with known Probiotics i.e. *Lactobacillus bulgaricus* and *Streptococcus thermophilus* cultured overnight and Supplemented for a period of 30 days.
- **Group B** cases (50) served as control were not supplemented with probiotic curd. All the participants were instructed to be on their regular diet, exercise and medication (if any), apart from their routine duties. They were advised not to take any fermented foods or drinks during the study.

## Inclusion and Exclusion Criteria

**Inclusion Criteria:** Both males and Females in the age group of 25 to 50 years were included. FBS value was 110-125 mg/dl and HBA1C values 6.0-6.5% were taken into consideration include the case in the study.

**Exclusion Criteria:** Pregnant women and lactating women and cases having hypertension and metabolic syndrome were excluded.

## Results and Discussion

The results of biochemical parameters of prediabetic supplemented and control groups are shown in the table 1.

A total of about 300 suspected cases for diabetes mellitus were screened and based on based on Glycated Hb levels 75 cases were categorised as prediabetic cases. The cut of point was taken according to World Health Organization (WHO) standard i.e  $<5.9$  is normal, 6.0-6.4 is prediabetes and above 6.5 is confirmed as diabetes [9]. Out of 75 prediabetic cases were selected, 25 cases were supplemented with 100gm probiotic curd containing *Lactobacillus bulgaricus* ( $1 \times 10^7$  CFU/gm) and *Streptococcus thermophilus* ( $1 \times 10^6$  CFU/gm) for a period of 30 days. The control groups of 50 cases were not supplemented with any probiotic curd. All the study cases were instructed to follow the regular diet.

Among the 25 supplemented prediabetic cases, the initial (0 day) FBS (mg/dl) value was about  $114.1 \pm 15.24$  which was reduced to  $109 \pm 18.51$  after 30 days, where as in the non supplemented group (50 control cases), the values were increased from  $118.33 \pm 7.99$  to  $149.33 \pm 38.99$  from 0 day to 30th day. The results of both supplemented and non supplemented group were clinically significant.

The Glycated haemoglobin (HbA1c %) of supplemented group showed significant difference before and after supplementation with  $6.42 \pm 1.04$  at '0' day and  $5.23 \pm 0.52$  at 30th day ( $p < 0.01$ ) as against no difference among the control cases.

There was a significant ( $p < 0.01$ ) difference observed in total cholesterol (mg/dl) values in the supplemented group. The total cholesterol values reduced from  $192.31 \pm 33.31$  to  $170.94 \pm 35.81$  before and after supplementation, while in non supplemented group the values of '0' day and '30' day remains the same i.e  $170.66 \pm 47.78$  and  $178.66 \pm 44.14$  respectively.

The Triglyceride (mg/dl) values of supplemented group were significantly reduced from  $139.21 \pm 27.99$  to  $111.69 \pm 47.06$ . However, the results showed no changes in non supplemented cases which were  $114.70 \pm 19.33$  to  $112.59 \pm 33.06$  at 0 and 30 day.

High Density Lipoprotein (HDL) protein is very important biochemical parameter in determining the CVD. In the supplemented group, HDL (mg/dl) values increased slightly from  $54.77 \pm 13.88$  to  $59.46 \pm 16.87$  providing protection against CVD. There was a slight reduction from  $54.50 \pm 12.27$  to  $49.05 \pm 14.51$  in non supplemented group at 0 day and 30th day respectively. Low Density Lipoprotein (LDL) (mg/dl) values were reduced in supplemented group from  $122.71 \pm 32.15$  to  $105.10 \pm 32.04$  before and after supplementation. However, there was a significant difference in sup-

plemented cases as compared to control values.

From the results of this study, it is clear for the beneficial effects of probiotic curd in the maintainance of blood glucose and cholesterol in the Prediabetic cases. Probiotic also improves gut immunity by interacting with prebiotics such as dietary fibre and release short chain fatty acids in gut which maintains the proper microbiota in the gut milieus. Therefore, the developed probiotic curd can be recommended as a food supplement along with the regular diet with life style modifications for prediabetes cases to delay in progression to diabetic cases who are more prone to risks of cardio vascular diseases etc [10]. However, probiotic curd developed with various combinations of live beneficial gut friendly bacteria provide better health benefits and therefore, long term studies with large number of cases need to be evaluated to unravel more beneficial effects probiotic curd at the community level.

### Conclusion

Our results indicate that there were significant clinically at different levels in the values of FBS and HDL. However, other biochemical parameters including HbA1c, total cholesterol, triglycerides were statistically significant at different levels between the prediabetic cases supplemented with probiotic curd for a period of 30 days and control cases. Therefore, from this study it is concluded that supplementation of probiotic curd delays the progression of pre diabetes to Diabetes mellitus

**Table 1: Effect of Probiotic Supplementation on Below Parameters in Pre Diabetic and Control Cases**

Sl.No	Parameter	Group	0 day	30 day	P value
1	FBS (mg/dl) < 110 – Normal 110-125 – Pre diabetes > 125 - Diabetes	Group A (N=25)	$114.10 \pm 15.24$	$109 \pm 18.51$	0.229
		Group B (N=50)	$118.33 \pm 7.99$	$149.33 \pm 38.99$	0.108
2	HbA1c (DCCT %) < 6.0 - Normal 6.0- 6.5 – pre diabetic > 6.5 – Diabetes	Group A (N=25)	$6.42 \pm 1.04$	$5.23 \pm 0.52$	0.015
		Group B (N=50)	$6.35 \pm 0.88$	$5.45 \pm 0.56$	0.09
3	Total cholesterol < 200mg/dl – Normal	Group A (N=25)	$192.31 \pm 33.31$	$170.94 \pm 35.81$	0.009
		Group B (N=50)	$170.66 \pm 47.78$	$178.66 \pm 44.14$	0.379
4	Triglycerides 30-135mg/dl – Normal	Group A (N=25)	$139.21 \pm 27.99$	$111.69 \pm 47.06$	0.03
		Group B (N=50)	$114.70 \pm 19.33$	$112.59 \pm 33.06$	0.79
5	HDL >35-40mg/dl - Normal	Group A (N=25)	$54.77 \pm 13.88$	$59.46 \pm 16.87$	0.497
		Group B (N=50)	$54.50 \pm 12.27$	$49.05 \pm 14.51$	0.443
6	LDL <130mg/dl – Normal	Group A (N=25)	$122.71 \pm 32.15$	$105.10 \pm 32.04$	0.03
		Group B (N=50)	$82.61 \pm 17.38$	$78.36 \pm 18.61$	0.43

Group A: pre diabetic cases; Group B: control cases

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