



Lifestyle Intervention and Prediabetes Remission: Evidence from an Occupational Health Centre in Mumbai

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Abstract

Introduction: Prediabetes, is a medical condition characterized by impaired fasting glucose (IFG) or impaired glucose tolerance (IGT) or Glycated Haemoglobin (HbA1C) value between 5.7 to 6.4 [1]. Around 136 million Indians and 589 million people worldwide suffer from this condition [1,2]. People diagnosed with Prediabetes in the course of time may suffer from various microvascular complications and have an increased risk of developing type 2 diabetes in future which is a major concern in health care worldwide [2,3]. Various studies have demonstrated that lifestyle intervention can prevent Type 2 Diabetes in pre-diabetes with risk reductions ranging from 30% to 60% compared with placebo [4,5].

Method: This retrospective study was conducted on corporate employees enrolled for 4 months under a program named lifestyle management program (LSMP) with prediabetes (HBA1C: 5.7 - 6.4). The study was done from 1st December 2023 till 31st May 2024 on employees diagnosed as prediabetes using HbA1c as a diagnostic tool. The study sample constituted thirty diagnosed prediabetic corporate employees of unknown duration, age group 35 - 45 years, male and female and HbA1c 5.7 - 6.4. The primary outcome was the change in HbA1c levels following the lifestyle intervention.

Result: Among 30 patients which were enrolled in study, Mean HBA1C was 6.08 at the initiation of study and mean HbA1C after study interval was 5.71 in which 60% patient shown reduction in HbA1C and 40% patient had successful prediabetes remission with Lifestyle intervention applied in the study population.

Conclusion: The findings support the integration of lifestyle changes for managing prediabetes for its reversibility and should remain the recommended approach to address this condition for corporate employees.

Keywords: Lifestyle Management Program (LSMP); Prediabetes; Impaired Fasting Glucose (IFG)

Introduction

According to the American Diabetes Association (ADA), Prediabetes is an intermediate state of hyperglycemia with glycemic parameters above normal but below the diabetes threshold. Prediabetes is considered a key risk factor for developing metabolic syndrome, as they often overlap with component of metabolic syndrome due to its association with insulin resistance and considered to be an at-risk state, with high chances of developing diabetes [1]. While, prediabetes is commonly an asymptomatic condition and considered a transitional stage of increased risk of developing diabetes in future but some observational studies suggests an association between prediabetes and complications of diabetes such early nephropathy, small fiber neuropathy, early retinopathy, and risk of macrovascular disease. International diabetes federation estimated prevalence around 589 million worldwide and projects an increase in prevalence of prediabetes to 730 million globally by 2045 [2].

Type 2 Diabetes Mellitus is a chronic metabolic disorder characterized by high blood sugar, insulin resistance and relative lack of insulin. The causes for type 2 diabetes include obesity, lack of exercise, sedentary lifestyle and genetics factors that causes Insulin Resistance characterized by sustained high blood sugar levels. According to the study it states rising in prevalence of diabetes since last 2 decades as 285 million people worldwide had diabetes in 2010 and in 2025, 537 million people are suffering from diabetes [2,3]. According to ADA, the top three countries in terms of the number of type 2 diabetes mellitus individuals with diabetes are China (20.8 million in 2000, 142.3 million in 2025), India (31.7 million 2000, 101 million in 2025) and United States of America (17.7 million in 2000, 42 million in 2025). India is termed the “Diabetes capital of the world” due to its higher prevalence of diabetes relative to its population and the rapid increase in cases in recent decades and this increase is a warning sign for Indian health care system to be vigilant for adequate diabetes mellitus management [3].

Diagnosis of prediabetes and diabetes mellitus

World Health Organization (WHO) has defined prediabetes as a state of intermediate hyperglycemia using two specific parameters, impaired fasting glucose (IFG) 110 to 125 mg/dl and impaired glucose tolerance (IGT) defined as 2 hour plasma glucose of 140 to 200 mg/dl after ingestion of 75 g of oral glucose load or a

combination of the two based on a 2 h oral glucose tolerance test (OGTT) [4].

The American Diabetes Association (ADA), on the other hand has the same cut –off value for IGT 140 – 200 mg/dl but has a lower cut –off value for IFG 100 – 125 mg/dl and has additional glycated hemoglobin (HbA1C) based criteria of a level of 5.7% to 6.4% for the definition of prediabetes [4]. The usefulness of diagnosis of diabetes or prediabetes on basis of IFG and IGT have been challenged due to inability of these blood glucose cut points to capture pathology related to diabetes and probability of developing diabetes in future [5,6]. The Glycated Hemoglobin also known as the Hemoglobin A1c test or HbA1C test is a simple blood test to diagnose prediabetes and diabetes and monitor progress. HbA1C test is used to evaluate an average blood sugar level over the past 90 days and represents a percentage. Hemoglobin is a protein only found in red blood cells. Since RBCs live about an average of 3 months, the HBA1C test will reflect an average of blood sugar. HbA1C has the advantage that fasting was not required and results are more stable. HbA1c is believed to represent an average blood sugar level and should ideally represent hyperglycemia more accurately except in some conditions e.g. hemoglobinopathies, severe iron deficiency anemia, kidney diseases where HBA1C may be an imprecise tool to measure average blood sugar [7,8].

| Diabetes test | Normal | Prediabetes | Diabetes |
|-------------------------------|--------|-------------|----------|
| Hemoglobin A1c % | <5.7 | 5.7 – 6.4 | >= 6.5 |
| Fasting blood glucose, mg/dl | <100 | 100 - 125 | >125 |
| Oral glucose tolerance, mg/dl | <140 | 140 - 199 | >199 |

Table 1: American Diabetic Association diagnostic criteria for normal glucose, prediabetes, and diabetes.

According to the American Diabetes Association (ADA), A1c levels over 6.5% are considered diagnostic of diabetes, values between 5.7% – 6.4% are diagnosed of prediabetes and test results less than 5.6% are normal [9].

Health risks associated with Prediabetes

- **Microvascular complications:** Several studies have shown an association of increased risk of chronic kidney disease

and early nephropathy in prediabetes population [10,11]. It is also found to be associated with neuropathic manifestations like both hyperesthesia and hypoesthesia, small fiber neuropathy, autonomic activity, reduced heart rate variability, increased prevalence of male erectile dysfunction and also the prevalence of retinopathy is increased in some prediabetes studies [13,14].

- **Macrovascular Disease:** Prediabetes has been associated with increased risk of developing macrovascular disease and are associated with an increased risk of heart disease due to their shared underlying mechanisms, like insulin resistance [15]. Many Cross sectional studies have shown an increased prevalence of coronary heart disease in individuals with prediabetes [16,17].

It can be stated that the rationale behind treatment of prediabetes includes prevention of development of diabetes and also prevention of complications of prediabetes itself described above. Majority of published literature and guidelines support that lifestyle interventions focusing on dietary modification and increased physical activity should be the foundation of therapy for prevention of prediabetes. There is increasing evidence to prove the efficacy of pharmacotherapy and supports its use in adults with prediabetes. Due to the favorable long term safety profile and observed positive outcomes with metformin, organization such as American Diabetic Association have recommended the use of metformin in certain high - risk individuals but the end point of pharmacotherapy is yet to be defined. Lifestyle interventions remain an essential part of the management of prediabetes while the use of pharmacotherapy should be an individual case-based approach [18,19].

The two largest diabetes prevention studies, the United States Diabetes Prevention Program (DPP), and the Finnish Diabetes Prevention study (DPS) have both shown beneficial effects of lifestyle interventions. In the DPP study, after a 3 year follow up, intensive lifestyle interventions lead to a 58% risk reduction. The intensive lifestyle involved changes in diet and physical activity aimed at producing weight. In the DPS, the benefits were found to be dependent on achievement of the number of predefined goals of the intervention by the participant. These goals consisted of weight reduction greater than 5 percent, total fat intake less than 30% of energy intake, saturated fat intake less than 10% of energy

intake, fiber intake greater than or equal to 15g per 1000kcal, and exercise greater than 4 hour weekly. While both these studies were among Caucasians, studies in Asian population have also shown similar benefits [20,21]. Metformin was noted to be less effective than lifestyle in the USDPP trial but in the Indian DPP (IDPP) trial it was noted to be as effective as lifestyle intervention. Metformin has been found to be more beneficial to individuals with higher Body mass index and higher Fasting Plasma Glucose [22]. Pharmaceutical treatment options other than metformin are associated with adverse effects that limit their use for prediabetes. Secondary intervention with metformin is advocated for high - risk individuals but criteria for such consideration benefit of early intervention, long term cost effectiveness of such interventions and the end point of therapy remain unclear [23].

Prediabetes reversal vs prediabetes remission

Prediabetes Reversal is defined as a state of normal glucose level for at least 1 year and imply a more complete or permanent return to health, potentially with a reduced risk of future diabetes through switching to well-balanced meals high in healthy, fiber-rich foods, along with incorporating more physical activity. Definition of Prediabetes remission on the contrary to prediabetes reversal is defined as a return to normal fasting blood glucose levels, normal glucose tolerance after an oral glucose tolerance test (OGTT), and a normal HbA1c level (<5.7%) without the use of glucose-lowering medication through lifestyle changes such as weight loss by dietary changes, increased physical activity, and stress management which all play a crucial role in achieving prediabetes remission. Remission is a temporary state, requiring ongoing lifestyle management to maintain, while reversal, though often used interchangeably, is sometimes seen as a more permanent return to normal [24].

Review of Literature

In 2002, Knowler, *et al.* hypothesized that lifestyle intervention in prediabetes would prevent or delay the development of diabetes. The study did random assignment of patients with prediabetes to receive a placebo or a lifestyle modification program with around 7% weight reduction goals. Lifestyle modification includes dietary modification and at least 150 minutes of physical activity per week. The average follow up was 2.8 years. The incidence of diabetes was 11.0 and 4.8 cases per one hundred Persons - years in the placebo and lifestyle groups, respectively. The lifestyle intervention reduced the incidence by 58% compared with placebo [25].

In 2011, Gong, *et al.* reported a study started in 1986 when 577 adults with impaired glucose tolerance from Da Qing, China, were randomly assigned by clinic to a control group or one of the three lifestyle intervention groups (diet, exercise, and diet plus exercise). In the 20 – year follow up of the Da Qing diabetes prevention study, those receiving a lifestyle. Intervention had a 51% lower incidence of diabetes. Group based lifestyle interventions over 6 years can prevent or delay diabetes for up to 14 years after the active intervention [26].

In 2013, Schellenberg, *et al.* meta analysis has compared effectiveness of lifestyle intervention to standard care on minimizing progression of prediabetes to diabetes or reducing all - cause mortality in diabetes. This meta-analysis study identified 9 randomized controlled trials with prediabetes patients who were at risk of diabetes and 7 out of 9 reported that lifestyle intervention decreased the risk of development of diabetes up to 10 years after lifestyle intervention [27].

An Indian study by Dutta, Deep., *et al.* have demonstrated increasing prevalence of prediabetes in India and lifestyle intervention and other oral hypoglycemic agents can be used for prediabetes reversal and development of diabetes. However with significant side effects of medicines and inability of these agents to change underlying pathophysiology but those medicines have to be used because implementing lifestyle intervention has been challenge in India because of poor long term compliance and limited population awareness which is also the main cause of numerous undiagnosed cases of prediabetes and diabetes in India [28].

Research study

Aim and objectives

To study the effects of underlying lifestyle modification in prediabetes reversibility and minimizing progression of prediabetes patients to type 2 diabetes mellitus on corporate employees with diagnosed prediabetes in Mumbai using HbA1c as the study parameter.

- Diet Intervention.
- Physical Activity - Moderate intensity exercise (jogging, walking, cycling) of 150 minutes/week.
- Enough Sleep (7 – 8 hours).

Materials and Methods

Approval from Institutional Ethics Committee was received and the study conducted on the employees of a corporate company in Mumbai.

Inclusion criteria

- Age - 35 - 45 years, male and female.
- Patients with HbA1c – 5.7 – 6.4%. (Less than 45 days)
- Patients who did monthly follow up visits and were adherent to the advice.

Exclusion criteria

- Patients on oral antidiabetic medications.
- Patients on steroids, beta blockers, statins, antipsychotics, thiazides, hematinic tablets.
- Patients with anemia or chronic kidney diseases
- Pregnant and Lactating females.

This is a Single Centre, Retrospective Observational Study.

In a predesigned format prepared at the commencement of this study, data was collected from electronic medical records which included age, gender, annual health check – up reports of complete blood count, lipid profile, renal function test, liver function test, thyroid profile, FBS, PPBS and HbA1c, Vitamin D3 and Vitamin B12, Ultrasound of whole abdomen, ECG, 2DEcho and past medical history.

The HbA1C test was done by sending a sample to a NABL Certified Laboratory. The laboratory test used blood drawn from a venous sample into a K2 EDTA (lavender top) tube.

Based on the inclusion, exclusion criteria, thirty diagnosed prediabetes corporate employees who underwent lifestyle modification program from 1st December 2023 till 31st May 2024 were included in this study.

The lifestyle modification program includes intensive lifestyle management of each clinic visit, monthly follow up with physician and dietician. The health check visits were provided suggestions and positive reinforcement for healthy behavior including goal setting, physical activity, dietary planning, enough sleep (7 – 8 hours).

The goals for the participants were engaged in:

- Physical Activity – Moderate intensity exercise of 150 minutes/week.
- Enough Sleep of 7 – 8 hours.

Dietary changes

Patients referred to registered dietician for diet intervention in prediabetes to follow a healthy eating plan. Focus on eating a balanced diet (according to the individual’s calculated basal metabolic rate) that is rich in fiber, vitamins, minerals. Carbohydrates - 50%, Proteins - 30% and Fats - 20%. Drink plenty of water 2 - 2.5 liters / day. Quit smoking and reduce alcohol intake.

| | | | |
|---------------|------|------|------|
| 26 | 6.4 | 5.9 | 0.5 |
| 27 | 6.2 | 5.8 | 0.4 |
| 28 | 6 | 5.7 | 0.3 |
| 29 | 6.1 | 5.6 | 0.5 |
| 30 | 6.4 | 5.9 | 0.5 |
| Average value | 6.08 | 5.71 | 0.37 |

Table 2: HbA1C study.

The time difference between initial HbA1C and final HbA1C is between 90 to 120 days.

Statistical report

Study Population

- n = 30 Prediabetic Patients

| S. NO. | Initial HbA1C | Final HbA1C | Change |
|--------|---------------|-------------|--------|
| 1 | 5.9 | 5.7 | 0.2 |
| 2 | 6.3 | 5.8 | 0.5 |
| 3 | 6 | 5.4 | 0.6 |
| 4 | 6.1 | 5.8 | 0.3 |
| 5 | 6.4 | 6.1 | 0.3 |
| 6 | 5.9 | 5.9 | 0 |
| 7 | 6.2 | 6 | 0.2 |
| 8 | 5.8 | 5.7 | 0.1 |
| 9 | 5.9 | 5.4 | 0.5 |
| 10 | 6.2 | 5.9 | 0.3 |
| 11 | 6.1 | 5.6 | 0.5 |
| 12 | 5.8 | 5.7 | 0.1 |
| 13 | 6.2 | 5.6 | 0.6 |
| 14 | 6.3 | 6.2 | 0.1 |
| 15 | 5.9 | 5.5 | 0.4 |
| 16 | 5.7 | 5.5 | 0.2 |
| 17 | 6 | 5.8 | 0.2 |
| 18 | 6.2 | 5.7 | 0.5 |
| 19 | 6.2 | 5.9 | 0.3 |
| 20 | 6.2 | 5.6 | 0.6 |
| 21 | 5.9 | 5.5 | 0.4 |
| 22 | 5.8 | 5.3 | 0.5 |
| 23 | 6.3 | 6.1 | 0.2 |
| 24 | 6.1 | 5.4 | 0.7 |
| 25 | 5.8 | 5.3 | 0.5 |

| | Initial | Final | Difference (Initial-Final) |
|------------|---------|-------|----------------------------|
| Mean HbA1C | 6.08 | 5.71 | 0.37 |
| SD | 0.20 | 0.24 | 0.18 |
| Minimum | 5.70 | 5.30 | 0.00 |
| Maximum | 6.40 | 6.20 | 0.70 |

Table 3: Comparison of Mean HbA1C at 2 timepoints.

Statistical test

Students paired t test.

Calculated t = 11.1, S, P < 0.001.

Conclusion: Reduction in Mean HbA1C between Initial and final HbA1c is found Significant.

| | Initial | Final |
|----------------------------|-------------|-----------|
| Prediabetic (5.7% to 6.4%) | 30 (100.0%) | 18(60.0%) |
| Normal HbA1C (<5.7%) | 0(0.0%) | 12(40.0%) |

Table 4: Distribution of HbA1C at 2 timepoints.

Data: Number (%)

Statistical test

McNemar’s test

S, P < 0.001

Conclusion: Significant reduction in HbA1C values.

Interpretation: Out of 30 prediabetic patients, 12 (40.0%) became Normal after treatment.

| | Initial | Final |
|-------------|---------|-------|
| Prediabetic | 100.0 | 60.0 |
| Normal | 0.0 | 40.0 |

Table 5: Data for Graph.

Implementation of the study

There are multiple approach for prediabetes remission which includes lifestyle modification or oral/injectable antidiabetic medications or both. This study assures that only proper guided lifestyle intervention can achieve prediabetes remission in corporate employees also.

Imitations of the study

- The study data presented to investigate the effectiveness of lifestyle intervention to normalize blood sugar level collected retrospectively hence recall biases can be present.
- The definition of Prediabetes reversal needs 1 year of disease free period so limited study interval does not allow us to term prediabetes reversal term.
- We had taken a small sample size and study duration and therefore to establish the positive correlation between HBA1C reduction with lifestyle modification needs a bigger sample size with longer study duration or a prospective study.

Conclusion

- Prediabetes is prevalent in corporate employees due to their sedentary lifestyle, long working hours, and unhealthy eating habits and lifestyle interventions can lead to remission of prediabetes.
- Lifestyle management programme (LSMP) launched by organization with the objective to help corporate employees to maintain healthy behaviors is right to develop an initiative-taking approach to prediabetes reversal.

- Strategies targeting lifestyle interventions aimed at the entire population at risk of prediabetes can make health care more sustainable and can prevent such preventable disease, and reduce all cause morbidity and mortality rates.

Disclosure Statement

The authors have no conflicts of interest to disclosure.

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