

'Daily 2-only meals and exercise' lifestyle modification for remission of type 2 diabetes mellitus: A therapeutic approach

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ABSTRACT

This case series has documented five patients diagnosed with type 2 diabetes (T2D), referred to the various Diabetes Reversal Centers of the 'World free of obesity and diabetes' campaign in Maharashtra, India. It demonstrates the therapeutic effects of lifestyle modification for remission of diabetes along with weight reduction and reversal of insulin resistance. This resulted in reduction of their glycated haemoglobin level, which signified the long-term effects of this lifestyle modification. Diabetes reversal by lifestyle modification is a healthier option and must be encouraged in all the patients in the pre-diabetes group (HbA1c- 5.7–6.4%) and those with newly diagnosed type 2 diabetes mellitus (HbA1c- >6.5%) without any complications, thus promoting good health seeking behaviour. There are pieces of evidence of complete diabetes reversal of the patients with HbA1c ranging from 8 to 15% by just lifestyle modification and also without any complications among the patients registered under the 'World free of obesity and diabetes' campaign. India is a low-middle-income country with prevalence of T2D on rise. It is thus necessary to provide the community with a cost-effective and sustainable solution for primary and secondary prevention of this lifestyle disease.

Keywords: HbA1c, life style modification, obesity, type 2 diabetes

Introduction

The prevalence of type 2 diabetes (T2D) in India is around 7.3%. The morbidity and mortality rates associated with it are fairly high.^[1] According to the World Health Organization, diabetes mellitus is a chronic, metabolic disease characterised by elevated levels of blood glucose, which leads to the damage of the vasculature, eyes, kidneys and nerves. It is also closely linked to the epidemic of obesity that requires long-term medical attention.^[2] Many of these complications arise from the

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combination of resistance to insulin action, inadequate insulin secretion, and an excessive or inappropriate glucagon secretion. A systematic review showed that the estimated country-level health care expenditure on diabetes mellitus in India after amending purchasing power difference was 31 billion US dollars in 2017, pushing India to the fourth place globally after USA, China, and Germany. Looking at the economic burden, in India, diabetes alone exhausts 5–25% share of an average Indian household earning.^[3] Given the rising cost of these anti-diabetic medicines and insulin, patients may potentially save significant money by disease remission. This lifestyle modification gives the patients liberty to live without any intensified restrictions and transforms their lifestyle into a healthy one.

The incidence of obesity is also on rise. It has become a major adjuvant of T2D because of change in lifestyle to a more

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sedentary one. Medications manage the symptoms of diabetes, but they cannot prevent the progression of the disease and have rarely led to complete remission and reversal of the disease.^[4] Lifestyle modification has the potential to fill this gap in diabetes care. However, although lifestyle modifications are universally acknowledged to be the first-line treatment of T2D, it is not the current first line of practice in India. This might be attributed to the lack of information, education, and communication at a community level. Family physicians have a large role in the same.

The cases included in this study exemplify that lifestyle modification can be practiced as a therapeutic alternative to anti-diabetic medications and insulin therapy in T2D patients with obesity. 'Daily 2-only meals and exercise' was a lifestyle modification proposed under the 'World free of obesity and diabetes' campaign.^[5,6]

Case Report

Our case series presented five patients. On the initial consultation with diabetologists, all patients had received advice for initiation of various pharmacological therapies for their T2D, including metformin, glimepiride, and voglibose. These patients enrolled into the World free of obesity and diabetes' campaign voluntarily for remission of their T2D by lifestyle modification. They were then directed to visit the nearest Diabetes Reversal Center (DRC) for further consultation. Patients were asked to visit the DRC monthly after the primary visit. Patient characteristics are summarised in Table 1.

Investigations

The following investigations were prescribed to the patients: 1. HbA1c- monthly

- 2. Pre- and post-meal blood sugar twice daily with a glucometer
- 3. Blood pressure
- 4. Weight monthly
- 5. Waist circumference monthly
- 6. Fasting insulin

Treatment

The patients were given the following 2-OMEX lifestyle modification as a therapeutic approach for their diabetes remission:

Dietary regimen

The patient has to have two meals only in a day, with each meal containing the order of the following foodstuffs:

First – Six to eight dry fruits (four almonds and four walnuts) for omega fatty acids and micro-nutrients (excluding sugar-containing dry fruits such as raisins, dates, and apricot)

Second – One bowl of salad for fibres and early satiety (excluding sugar-containing vegetables – beetroot, carrots)

Third – One bowl of sprouted beans/pulses or two boiled eggs for proteins and micro-nutrients

Fourth – Food items cooked at home for meal (cooked without sugar, jaggery, honey, or sugar substitutes).

The patient can only have fluids such as water, tea, or coffee without any added flavour or diluted buttermilk in between these two meals, with all these without sugar, jaggery, honey, or sugar substitutes. This way, the patient feels satiated all the time without any starving or cravings and can thus follow the diet plan meticulously.

Exercise routine

The patient has to walk for a minimum of 4.5 km in 45 min every day. This suffices the criteria of at least 150 minutes of moderate grade cardiovascular exercise per week as advised by the American Heart Association.^[7]

Patients were examined once a month, and investigations were recorded. At each visit, patients' daily blood sugar diaries were reviewed and weaning of diabetic pharmacotherapy was performed under medical supervision. Blood sugars were measured by patients four times daily during this period. The target daily blood sugars were <120 mg/dl (fasting) and <200 mg/dl during the initial weaning phase and <100 mg/dl (fasting) and <140 mg/dl thereafter.^[8] In addition, patients' weight, waist circumference, and blood pressures were measured and recorded at each visit, and the fasting insulin level was measured after 3 months.

Outcome and follow-up

There were five major outcome measures in this case series:

- 1. Time for discontinuation of anti-diabetic medications.
- 2. Fasting insulin (IU/ml)
- 3. Serum HbA1c levels (%)
- 4. Patient weight (kg)
- 5. Patient waist circumference (cm)

One of the outstanding outcomes from this case series was the complete discontinuation of medications in the

Table 1: Characteristics of the patients						
Patient No.	Age (In years)	Sex	Years lived with T2D	Co-morbidities/Complications	Type of pharmacotherapy	
1.	45	Male	1	Peripheral vascular occlusion	None	
2.	35	Male	4	None	Ayurvedic medications	
3.	54	Male	3	Peripheral vascular occlusion	None	
4.	51	Male	<1	Obesity	None	
5.	56	Male	<1	Hypertension	oral hypoglycaemic agents	

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	Table 2: Changes in the health parameters from the time of enrollment to the end of follow-up							up
Patient No.	Initial HbA1c (%)	Final HbA1c (%)	Initial Weight (kg)	Final Weight (kg)	Initial waist circumference (cm)	Final waist circumference (cm)	Initial Fasting insulin (IU/ml)	Final Fasting insulin (IU/ml)
1.	7.8	6.5	79	71	104	96	6.5	2.5
2.	12.9	6.7	79	69	98	88	8.9	5.7
3.	6.6	5.7	74	66	83	76	16.2	5.0
4.	7.0	6.3	73	61	99	86	10.4	7.5
5.	8.0	6.4	87	77	106	99	9.6	7.5

Table 3: Changes in medications from the time of	
enrollment to the end of follow-up	

Patient No.	Initial medications	Final Medications	No. of days to come off medications
1.	None	None	-
2.	Ayurvedic medications	None	7
3.	None	None	-
4.	None	None	-
5.	Metformin 500 mg TDS, Vildagliptin 50 mg BD	None	8

patients within a month of initiation of 2-OMEX lifestyle modification [Tables 2 and 3]. There was a reduction of HbA1c (glycosylated haemoglobin) levels for all patients during this course to non-diabetic levels within 3 months. No symptoms of hypoglycaemia were reported in any of the patients.

Discussion

Recent evidence suggests that remission and reversal of T2D are possible. Diabetes Prevention Program Outcomes Study (DPPOS)^[9] in the United States and the Finnish Diabetes Prevention Study (FDPS)^[10] have indicated that the benefits of lifestyle modification can last for periods from 10 to 23 years. Recently, the post-trial follow-up of the Indian SMS (short message service) study^[8] also showed that the effect of lifestyle modification persisted for an additional 3 years after cessation of the active phase of the trial. Lifestyle modification has proven to be a successful, safe, cost-effective, and preferred prevention strategy in diabetes reversal.^[11]

The 2-OMEX plan proposed in this study is based on the hypothesis that the meal frequency limitation will limit the insulin spikes and thus reduce the cause for insulin resistance and ultimately reduction in the resulting incidence of obesity. A study by Watve *et al.*^[11] verifies this concept suggesting that insulin is a driver but not the navigator for a steady-state glucose level. This institutes that the current line of clinical action, which is to maintain normoglycaemia by oral hypoglycaemic agents or external source insulin, for the management of T2D has limited success, largely because it is based only on the concept of glucose–insulin relationship.^[12] Thus, by reducing the frequency of food consumption in the 2-OMEX plan, the insulin secretion and consequently the insulin level are reduced, thereby reversing the effects of hyperinsulinemia.^[13] A study was performed by the authors of this study to verify this concept, which concluded that

there is no linear correlation with insulin levels and the quantity of food consumed. $^{\left[14\right] }$

Obesity is the strongest risk factor for T2DM (type 2 diabetes mellitus) and is associated with metabolic abnormalities resulting in insulin resistance. There exists an inverse linear relationship between body mass index and the age at diagnosis of T2DM.^[15,16] Calorie restriction and weight loss are important factors for remission of T2D, as recently demonstrated in an open-label Diabetes Remission Clinical Trial (DiRECT). This case series showed that there was approximately 8-12% weight loss and 12-14% waist circumference reduction by the 2-OMEX lifestyle. The DiRECT study showed diabetes remission and maintenance through caloric restriction (~840 calories/day) and weight loss in a non-insulin-dependent diabetic population.^[17] However, calorie counting dietary measures have low compliance. Therefore, we developed a chronology of low-calorie and essential nutrient-containing foodstuffs that would make the patient feel satiated before consuming the actual meal. This helped in reducing the calorie intake without the patient actually calculating each calorie consumed and could also have a normal meal that is cooked for the family at home. This makes it easier for the patient to adapt to this lifestyle physically as well as mentally.

A systematic review suggested that patients with T2D who have a baseline HbA1c of greater than 8% may achieve better glycaemic control when individual health education is given rather than the usual care.^[18] Adherence to 2-OMEX lifestyle needs to be stressed because these lifestyle measures and modifications can have a large impact on the degree of diabetic control that patients can achieve, as seen in this case series. It improved the quality of life of the patient as it aided in good health seeking behaviour as well as gave him hope to combat this lifestyle disease. Therefore, 2-OMEX, because of its minimally restrictive regimen, improves the adherence. This case series will aid in commemoration of a simple lifestyle intervention for the lifestyle disease, that is, diabetes, among the physicians and the patients.

Learning points

Patients who have developed T2DM because of their lifestyle must be given the first choice of medically supervised lifestyle modification for the remission of their condition and minimising the use of pharmacological interventions in patients with T2D.

There is a chance of diabetes reversal, and lifestyle modification is a practically feasible strategy for this. With proper health education and counselling, we found compliance to this lifestyle modification better than the adherence to lifelong medications.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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