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Research Article

Best of Science and Nature - Alternative Approaches to Preventing and Treating Type 2 Diabetes

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Abstract

The aim of this exploratory work was to determine alternate and complementary approaches to caring for prediabetics and diabetics, especially those that may not be getting sufficient benefit from current medications or unable to use current medication due to drug compatibility and side effect concerns. Using data from six special case studies, we will illustrate those serious metabolic disorders like diabetes can be arrested with natural bio actives that work holistically to address the various cellular mechanisms associated with onset of a disease. Undesired weight gains and Type 2 Diabetes Mellitus (T2DM) are primarily caused by consumption of high fat and carbohydrate, inactive lifestyle, chronic inflammation, oxidative stress, and genetic susceptibility. The development of T2DM is regulated by several interrelated mechanisms, and effective prevention or early treatment requires an approach that addresses multiple mechanisms associated with the onset of the disease as well as boosts the body's natural self-defense system, all at the same time. Clinical research findings from six special cases are presented. The ages of the subjects during the studies ranged from 23 to 78. Five were diabetics or prediabetic, and one was relatively healthy individual that wanted to maintain his health with natural alternative medication. All six subjects were treated with OptiCel Glucose Balance (OGB) alone or in combination with their prescription product for diabetes, Metformin. OGB is dietary supplement product designed with highly bioavailable and clinically proven effective combination of select natural polyphenol bioactive and Magnesium. The product is designed to prevent and treat the early onset of diabetes by interfering with glucose absorption and by mitigating negative effects of chronic oxidative stress and inflammation. After using OGB for at least 3 months, the relatively healthy subject's glucose level improved some and he lost 10 pounds of weight, essentially maintaining his overall healthy status, which was his goal for participating in the study. The other five subjects achieved clinically significant decrease in blood glucose levels within 4 to 6 weeks. The results indicate that OGB alone or together with Metformin works significantly faster in lowering glucose and to a healthy level without side effects when compared to clinical findings with current pharmaceutical treatment options, which take 3 months to 6 months to show clinically meaningful results. OGB's speed of action also suggests that it works more holistically to address the various cellular disease onset mechanism at the same time. The learnings also suggest that the select polyphenols and magnesium in OGB may safely and more effectively supplement and or potentially replace T2DM pharmaceutical medications.

Keywords: Diabetes; Glucose; HbA1c; OptiCel; Polyphenols

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Introduction

T2DM is the fastest growing, prevalent and debilitating chronic diseases [1] in the USA and around the world. The conditions that cause enhancement of intestinal glucose absorption, reduction of glucose and fat uptake by muscles and the heart, stimulation of lipid synthesis and storage in adipose tissue, increase in the number of adipocytes (fat cells), and suppression of thermogenesis are known to promote diabetes [1-7]. On the other hand, the metabolic conditions, including inhibition of glucose absorption, enhancement of glucose and fat uptake by muscle and heart tissues, suppression of fat, cholesterol and glucose biosynthesis by the liver, reduction of the number of adipocytes, and promotion of thermogenesis, have been shown to prevent and treat the development of diabetes [1-7].

The development of T2DM is a complex metabolic process and involves different tissues, multiple modes of action and various cellular mechanisms [5-7]. Sustained levels of hyperglycemia lead to activation of the chemical and biological mechanisms that induce diabetes and hamper multiple body's defense mechanisms that help prevent the disease. Thus, effective care would be one that holistically downregulate the inducers of disease and concurrently upregulate the promoters of health.

Here, we report on six subjects with Diabetic (T2DM) or prediabetic conditions. The subjects were treated with OGB, a potent, highly bioavailable, formulation of select natural bioactive polyphenols plus Magnesium. OGB ingredients are designed into a formula to work synergistically to achieve better out comes through a more holistic approach addressing both positive and negative factors on blood glucose balance and overall health. A daily dose of OGB contains highly bioavailable natural bioactive, theracurmin (60 mg), quercetin (30 mg), trans-resveratrol (100 mg), epigallocatechin (100 mg), and magnesium (200 mg). These bio actives were selected based on their clinically demonstrated bioavailability and efficacy [1,2,5-7,8-19] as well as their ability to work synergistically at the cellular level. Each one of the ingredients is Generally Recognized as Safe (GRAS) and the combination product is reasonably expected to be safe [8].

Case 1 - Subject: 59 year old cancer patient male, taking 2 Rx medications for the cancer. Not taking diabetes Rx med because of side effects and compatibility concerns with the Rx for cancer.

Results		TNF-a	IL-6	CRP	Glucose	HbA1c	Findings
	Start	1.2	3.4	2.22	176	7.8	After using OptiCel Glucose Balance for 6 weeks, clinically significant improvements on inflammation markers and diabetes health markers, without any side effects. Subject was recommended to continue with OptiCel.
	3 weeks	1.2	7.1	3.4	152	-	
	6 weeks	0.9	3.6	0.5	124	6.4	

Case 2 – Subject: 54 year old female, on two prescription medications (Metformin and Statin)

Results		CRP	Glucose	A1c	Weight	LDL/TC	Findings
	Start	6.0	128	6.2	-	120/220	Subject substituted her medications with OptiCel Glucose Balance for 6 weeks. Subject's lipid (LDL and Total Cholesterol TC) and glucose profiles improved significantly. Subject reported better mobility and no joint pain. Subject continuing OptiCel alone.
	3 weeks	-	-	-			
	6 weeks	1.6	90	5.8	-	75/180	

Case 3 – Subject: 26-year-old female, on maximum dose of Metformin (2 grams per day) for 15 months and still overweighed, and prediabetic.

Results			Glucose		Weight		Findings
	Start		135		195lbs		6 weeks after adding OptiCel to Metformin, subject achieved healthy glucose level and loss of 18 pounds. These are clinically significant results. Subject continuing to add OptiCel Glucose Balance
	6 weeks		80		177lbs		

Case 4 – Subject: 23 years old female, significantly overweighed and with a family history of diabetes.

Results			Glucose		Weight		Findings
	Start		124		140		After one month on OptiCel Glucose Balance, the subject showed clinically significant improvements on her glucose profile and weight management.
	4 weeks		80		129		

<u>Case 5 – Subject: 62 year old male,</u> relatively healthy but with a family history of diabetes, interested in maintaining his healthy glucose levels with alternative natural product.

Subj.			Glucose		HbA1c	Weight	Findings
M62	Start		110		6.1		Subject maintained his health status and with some improvements in his glucose level and weight. Subject also reported more energy, better sleep and mental focus while using OGB.
	4 weeks on OGB		95		6.0		
	8 weeks off OGB						
	8 weeks on OGB		95		6.0	- 10lbs	

Table 1: Blood work results after Treatment with Metformin and or OptiCel Glucose Balance.
(Fasting glucose = mmol/L, HbA1c = %)

Material and Methods (units for Glucose readings - mmol/L, HbA1c - %)

Six subjects were treated with OptiCel Glucose Balance over a period ranging from 4 weeks to 21 weeks. The subjects were asked to read and confirm understanding of informed consent form which provided details of the study, OGB product description, study procedures, potential side effects and eligibility criteria.

Fasting glucose levels were measured using OneTouch glucose meter or by LabCorp as part of their blood work. Hemoglobin HbA1c measurement was assessed by LabCorp Inc. Standard bioassays were also used to assess key inflammation markers on two subjects before and after treatment with OGB. All subjects were instructed to take two tablets of OGB daily and to maintain a diary of food intake and answer assessment of Quality of Life (QoL) questions at the beginning and at the end of the study. The clinical success aim was for fasting glucose of under 100, and post lunch, at or lower than 140. Results from the six case studies are presented in tables 1 and 2.

The first subject is a 59 year old male. After undergoing various treatments for thyroid cancer, he was taking two maintenance prescription medications. This subject's T2DM was out of control and was not able to take traditional diabetes prescription medications due to drug compatibility and side effect concerns.

The subject's Integrative Medicine Physician recommended to the patient to try OptiCel under the physician's supervision. The subject was put on OptiCel Glucose Balance after signing the informed consent. After 6 weeks on OGB, the subject showed remarkable improvements on glucose levels and on key systemic inflammation markers, (Table 1).

The second subject is 54 year old female with family history of T2DM and heart diseases, and also complained of joint aches and

Case 6 – Subject: 78 year old male, diabetic.				
Days of OptiCel (OGB) Use	**Fasting Glucose**	**Glucose 2 Hours Post Meal**	**HbA1c**	**Findings /Comments**
Study's Clinical Target	**Under 100 (80 – 99)**	**Under 140**	**Under 6.5**	
Study Part 1				
Day 0, Baseline	125	160	6.9	On 2 grams of Metformin a day
3-day use of OGB	95	135	NE	Metformin and OGB; fasting glucose balanced. No adverse events
10-dayuse of OGB	95	135	NE	Healthy glucose levels; no adverse events
Study Part 2				
After 2 months without OGB	130	175	6.9	Metformin only, subject was back to baseline, diabetic condition
30-day use of OGB	90	120	NE	Return to healthy glucose levels, further improvement in balance, and no adverse events
90-day use of OGB	85	120	6.4	Clinically significant improvement on HbA1c
150-day use of OGB	80	120	6.3	Maintaining healthy blood glucose levels. Now working with his physician to reduce or replace his daily doses of metformin.

Table 2: Fasting and Prandial Blood Glucose Levels after Treatment with Metformin and OGB.

NE: not evaluated

pains. The subject was on two prescription medications (Metformin and Statin) for over 10 years, and yet continuing to be prediabetic with elevated cholesterol and fasting glucose levels. The subject substituted OGB for her two prescription medications. After 6 weeks with OGB, her blood work was analyzed by her endocrinologist and showed clinically significant improvements, (Table 1).

The third is 26 year old female on maximum dose of Metformin (2 grams per day) and still overweighed and prediabetic. The subject's endocrinologist recommended OGB be added to her daily medication. The subject was also encouraged to walk for 20 minutes to 30 minutes, 3 to 4 times a week. After 6 weeks with OGB, the subject showed clinically significant improvements in glucose balance and on weight management, (table 1)

Fourth is a 23 year old female, unsuccessful at managing a healthy weight and with a family history of T2DM. She was very concerned seeing her family members struggling with T2DM. She established glucose baseline reading, purchased, and started taking OGB. After 4 weeks on OGB, she got glucose level assessment where she showed clinically significant improvements on her glucose and weight measures, (table1).

Fifth is a 62 year old male, with a family history of T2DM, relatively healthy and interested in maintaining his healthy glucose levels and HbA1c. Subject was put on OGB for a month by a physician, then off for two months and then on for two months. Five months after the start of the study, the subject maintained healthy glucose level markers including 95 fasting glucose, down from 110, and weight loss of 10 pounds, (table 1).

Sixth is a 78 year old male, with T2DM for more than 25 years. He started taking 500mg of Metformin daily, eventually reaching the maximum allowed dose of 2000 mg/day. The subject was generally in good health and exercises regularly (3-4 times per week). He usually ate balanced meals, and his diet was primarily vegetarian. Despite healthy lifestyle and treatment with maximum dose of Metformin (2000mg/day), his T2DM was uncontrolled for several years. His fasting glucose level in the morning and 2 hours after a meal (post-prandial) were elevated (Table 2). The subject's options became limited to the potential addition of another drug with increased likelihood of more side effects without any guarantee of better blood glucose control.

The subject was treated with OGB together with his normal Metformin intake. The study was divided into two parts. Part 1 was to evaluate the onset and speed of action of OGB which is designed to be more holistic in addressing the various mechanisms involved in the development of diabetes all at the same time, and Part 2 was designed to assess the benefits accruing from prolonged use of the product.

Part 1: The subject's baseline blood glucose levels were assessed, and he was also given QoL assessment questioner. He was then given a 10-day supply of OGB for part 1 of the study. His glucose levels were measured twice daily that is, fasting and post-prandial levels. The subject was also instructed to take two tablets of OGB daily and to maintain a diary of his food intake and assessment of QoL measures.

The blood glucose levels before and after OGB supplementation are shown in Table 2. After 3 days of taking OGB, both fasting and post-prandial glucose levels decreased by 30 mmol/L and 25 mmol/L,

respectively. These findings are clinically highly significant and are comparable to those observed in healthy individuals. Healthy blood glucose levels continued to be maintained over the 10-day duration of part 1 of the study.

Part 2: After concluding of Part 1 of the study, the subject was off OGB and only on Metformin for a 2-month period. At that time, his blood glucose increased to unhealthy levels again (Table 2). During Part 2, blood glucose levels were measured every other day. After commencing use of OGB again, measurements showed a steady decrease in blood glucose levels. Specifically, 30 days after restarting OGB, his blood glucose level was reduced to the normal level. In fact, the subject had the lowest healthy blood glucose level in his 25-year history of treatment with Metformin. The use of OGB continued for 5 months showing improved and sustained benefits from OGB. No adverse events were reported, and the subject also reported improved sleep pattern, mental focus, and more energy.

Results and Discussion

Currently, typical diabetes medications like Metformin are started at a lower dose (500mg) and increased to a maximum allowed dose (2000mg) over time if necessary. If blood glucose levels remain uncontrolled, patients may require additional medications. Metformin is absorbed through the upper small intestinal region. Once absorbed, it is delivered to the liver where it lowers hepatic glucose production, decreases intestinal absorption of glucose and improves insulin sensitivity, thus resulting in better glucose cellular uptake and utilization [19,20]. The resulting effect of Metformin in T2DM is to lower both fasting and post-prandial plasma glucose levels. Metformin helps in managing T2DM for a period of time by addressing 2 or 3 of the mechanisms associated with the onset of the disease. However, to properly manage and potentially prevent and or treat the disease early, a more holistic approach would be needed to address all known pathways and mechanisms that trigger disease on set and those that inhibit the disease development [21].

The results from these case studies indicate that OGB formula comprehensively addresses T2DM when taken with or without Metformin. The speed of improvement in the subject's health condition documented after 4 weeks of use of OGB was clinically remarkable and better than expected. Meaningful changes in glucose readings usually take 12weeks to 24 weeks. The speed of improvement observed with these subjects suggest that the OGB formula works by comprehensively addressing the multiple mechanisms associated with the onset of T2DM, which has not been possible with current prescription medications. Magnesium and the select highly bioavailable and potent polyphenols present in the OGB formulation are effective in ameliorating diabetes-associated complications - hyperglycemia, dyslipidemia, insulin resistance, a pro-inflammatory response, and lipid peroxidation in various experimental models of diabetes. Enhancing intracellular antioxidant capacity in addition to activating NAD-dependent deacetylase sirtuin-1 (SIRT1) and AMP-activated Protein Kinase (AMPK) are the prime mechanisms involved in the therapeutic effects of these agents [1-7,22-26].

Thus, these results show that OGB, which is formulated with a combination of selected polyphenols and magnesium, is effective in treating T2DM when taken with or without Metformin. These important health impacts demonstrated by OGB are mediated by modulating multiple mechanisms which target different tissues at the cellular level [1-7,18,19,22-26]. The key to getting clinically meaningful outcomes is to select a combination of highly bioavailable natural bioactives that produce an additive and or synergistic effects by addressing the various mechanisms involved in inhibiting disease development there by preventing or at least mitigatingT2DM.

In summary, select natural polyphenols and highly bioavailable magnesium prevent or treat diabetes by inhibiting glucose absorption and suppressing the Glucose Transporter 2 (GLUT2) [1-7,22-26], stimulating clearance of glucose from blood through enhancement of Glucose Transporter 4 (GLUT4), suppressing glucose biosynthesis in the liver and by promoting glucose oxidation via activation of "adenosine Monophosphate Activated Protein Kinase" (AMPK) and sirtuin 1 (SIRT1).

As a next step, the subjects are continuing to use OGB. Those that add OGB to their prescription products are working on their medication regimen with their physician to reduce and potentially replace prescription medications with OGB, overtime.

Conclusion

These varieties of case studies illustrate the principle of an integrative and holistic approach towards preventing or treating diabetes with a select combination of natural polyphenol bioactives and a mineral. Specifically, while more studies are needed, these results indicate that OptiCel Glucose Balance could be an excellent supplement to current T2DM medications and may potentially replace such medications overtime.

Conflict of Interest

All authors declare there is no conflict of interest in the publication of this article. Gabe Tzeghai, Satya Majeti and Haile Mehansho work at Summit Innovation Labs, LLC and maker of OGB.

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