Original Article

Comparative Study of BIOS versus Mono-Therapy for Achieving Optimal Metabolic Health in Adults with Type 2 Diabetes: Decoding the Effectiveness of a Comprehensive and Multi-Interventional Diabetes Care Program

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Abstract

Background: Obesity is a growing concern worldwide and has become a major risk factor for many chronic diseases, including type 2 diabetes (T2D), cardiovascular disease, and certain types of cancer. T2D is a chronic metabolic disorder that occurs when the body becomes resistant to insulin or does not produce enough insulin, resulting in high blood sugar levels. T2D has been labeled as the fastest-growing health challenge of the 21st century, affecting millions of people worldwide. However, recent research has shown that T2D can be reversed through a comprehensive and systematic approach that focuses on lifestyle management, including nutrition, fitness, and stress reduction.

Materials and Methods: The study enrolled 132 participants with T2D between the ages of 20 and 45, who had an hemoglobin A1c (HbA1c) level of over 6.5%. In the basic input/output system (BIOS), participants were provided with personal medical doctors specializing in diabetes and health coaches to offer tailored nutrition, customized fitness routines, and relevant lifestyle modifications for a holistic approach to reversing T2D. The baseline and final measurements of HbA1c levels, fasting blood sugar, and weight were recorded after 90 days. To assess the effectiveness of BIOS, a control group of 56 individuals with T2D was managed using traditional pharmacotherapy and regular dietary advice but did not participate in the BIOS program.

Results: The study was conducted over 132 subjects for 90 days duration, the 56 subjects were on monotherapy and 76 subjects were part of the BIOS program, presented as mean ± standard deviation (mean ± SD). In the monotherapy group, it is observed that average reduction of HbA1C values by (0.33%), percentage glucose variability (GV%) by (2.06%), body fat percentage by (1.65%), and BMI by (1.46). At the same time, the BIOS group has shown higher reduction in subject's HbA1C values by (1.3016%), GV% by (7.68%), body fat percentage by (3.74%), and BMI by (2.23). This study indicated that there are significant comparative reduction in subject's HbA1C values by (0.962727%), GV% by (5.62%), body fat percentage by (2.0939%), and BMI by (0.77) with BIOS program when compared to monotherapy.

Conclusion: The findings indicate that a comprehensive and multi-interventional diabetes care program involving personalized nutrition, fitness, and lifestyle modification such as BIOS, help in significant and sustained improvements in HbA1c level, glycemic control, and weight loss in adults with T2D.

Key words: Type 2 diabetes, Nutrition, Fitness, Lifestyle modification, Hemoglobin A1c reduction, Time in range, Glucose variability %, Body mass index, BF%, Basic input/output system

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INTRODUCTION

According to the International Diabetes Federation (IDF), in 2017, 425 million people worldwide had diabetes, a number that is projected to rise to 550 million by 2030.[1] The American Diabetes Association (ADA) reported that in 2019, diabetes was the direct cause of

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1.5 million deaths and a significant contributor to many other illnesses.[2]

The diabetes epidemic is a major public health challenge and is placing a substantial burden on healthcare systems worldwide. Uncontrolled diabetes leads to higher doses of medications, increased hospital admissions, and higher mortality rates. To mitigate the impact of this epidemic, it is essential to understand the current state of diabetes and its associated morbidities and to develop strategies for improving outcomes in affected individuals.[3]

The primary focus of this study is to evaluate the role of continuous glucose monitoring (CGM) with BIOS Health software as a tool to provide feedback and accountability necessary to create sustainable behavioral changes in lifestyle associated with raising the Food IQ and improved glycemic control.

The ADA lifestyle management guidelines incorporate the use of CGM as a tool to enhance diabetes management and improve health outcomes. CGM provides individuals with real-time information about their glucose patterns, which can inform decisions about lifestyle changes.[4] By combining the use of CGM with healthy eating, physical activity, stress management, and other diabetes self-care behaviors, individuals with diabetes can effectively manage their condition and improve their overall health and well-being.[5] Several studies have shown that CGM use can lead to improved glycemic control, reduced hemoglobin A1c (HbA1c) levels, and reduced insulin requirements.[6] Furthermore, CGM use has been associated with increased awareness of glucose fluctuations, improved self-monitoring of blood glucose, and increased motivation for lifestyle changes. In turn, these changes can lead to lifestyle behavioral change. Individuals with diabetes can achieve improved health outcomes, reduced dependence on medications and surgical interventions, and improved quality of life.[7]

The metabolic score obtained from CGM metrics such as HbA1c, time in range (TIR), and glucose variability (GV%) is an important tool in managing diabetes. HbA1c, which reflects average blood glucose levels over the past 2–3 months, is widely used as an indicator of glycemic control in diabetes management.[8] TIR, which measures the amount of time spent in the target glucose range, provides a more detailed view of glucose fluctuations throughout the day.[9] GV%, which indicates the degree of glucose fluctuations, is a valuable tool for evaluating the impact of meal patterns, stress, and other factors on glucose control. By combining these metrics, a metabolic score can be generated that provides a comprehensive view of the patient's glycemic control and identifies areas for improvement in diabetes management.[10]

The ADA recommends that individuals with diabetes require sustainable behavioral change and support from healthcare providers and peers.[10] The ADA stresses the importance of a patient-centered approach that considers individual needs, psychosocial factors, and collaboration between health-care providers and support networks.[11-15] Thus we propose a comprehensive diabetes care program that supports the people with T2D to achieve diabetes reversal. We call this multi-interventional approach as basic input/output system (BIOS).

BIOS is a deep tech-enabled coach lead program with diabetes expert physicians and a specialized nutritionist and performance coaches generating highly personalized lifestyle interventions such as meal plans, progressive fitness plans, and behavioral modifications.

MATERIALS AND METHODS

Methodology for randomized observational retrospective study of a data-driven behavioral tool:

Study Design
A randomized observational retrospective study was conducted to determine the effectiveness of data-driven behavioral tool BIOS incorporating BIOS, a deep-technology CGM software in promoting lifestyle changes in comparison of monotherapy in diabetes management.

Participants
132 participants were recruited for the study, 76 for BIOS with at least 3 months of CGM, 56 in monotherapy with standard diabetic management.

Intervention Model
Participants were randomly assigned to either the intervention group: BIOS Wellness Program (receiving the data-driven behavioral tool) and the control group: Monotherapy (receiving standard care).

Data Collection
In the interventional group, 76 BIOS Participants completed a QOL questionnaire, a baseline assessment, which includes a CGM with deep glucose insights, and then be monitored for 3 months. During this time, participants will provide blood glucose levels, and track their food intake using the data-driven behavioral tool (for the intervention group). In control group, 56 individuals completed a QOL questionnaire and were in standard diabetes care with monotherapy ADA guidelines (for the control group).

Data Analysis
The collected data were analyzed to compare the differences between the intervention with BIOS and control groups in

terms of changes in food intake, body composition: Body mass index and body fat %, glucose insights: eHbA1c, time in range, and GV%. Descriptive statistics will be used to describe the sample, and inferential statistics will be used to determine the effectiveness of the data-driven behavioral tool.

Masking

To maintain the blinding of participants, their CGM records were de-identified.

Selection Criteria

- Type-2 diabetes
- The study followed (ADA) criteria HbA1c ≥ 6.5%
- Age group 20–45.
- Individuals looking for lifestyle changes.

Exclusion Criteria

The following criteria were excluded from the study:

- Type-1 diabetes
- Chronic metabolic disorders
- Age group >18 and <45.

BIOS

The program begins with recruitment, where 132 participants undergo, a baseline assessment with HbA1C levels, 76 diabetics were enrolled in BIOS intervention and 56 were in the monotherapy control group.

Each participant is then assigned a personal team of diabetes specialists, nutritionists, and fitness coaches who provide customized nutrition plans, progressive fitness programs, and behavioral modification support. Participants have unlimited access to their coaches through an app and via telephone and can receive on-demand doctor consultations for the duration of the program. The program will be monitored and evaluated regularly to assess its effectiveness in improving eHbA1c levels, and promoting weight loss and improved overall health. Data collected during the program will be analyzed to assess the impact of the intervention on participants. Overall, the BIOS program offers a unique and comprehensive approach to managing type 2 diabetes (T2D), combining technology, expert guidance, and coach-led support for a personalized and effective intervention.

Glucose Monitoring

Participant was provided with a Liber Pro CGM Diabetes Sensor from Abbott Diabetes Care, which was used to record their daily glucose profiles for a period of 14 days from the baseline assessment.

Body Composition Analysis

In this study, the Actofit Pro-Max body composition analyzer was used.

The study group's body fat percentage and BMI were measured before and after BIOS therapy, while the control group's body fat percentage and BMI were measured before and after metformin treatment. The data collected from both groups were statistically analyzed to compare changes in body composition before and after treatment.

Personalized Nutrition

Each participant is assigned a personal nutrition coach who conducts a comprehensive assessment of the individual's nutritional needs and creates a personalized meal plan that takes into consideration their lifestyle, resources, and food preferences.

Fitness Program

The goal for each participant was to achieve 10,000 steps/day, and those with no movement challenges were gradually given an additional 1000 steps to reach the goal.

Physician Intervention

Effective management of T2DM requires a patient-centered approach, including lifestyle modifications, pharmacotherapy, and regular monitoring of blood glucose levels.

Lifestyle Modifications

Personalized health coaches were assigned to the participants in the BIOS program, offering behavior change strategies and diabetes education through counseling to help them achieve positive health outcomes and improve their quality of life. The BIOS program is a person-centered approach that utilizes team-based care and technology to provide one-on-one guidance and personalized interventions. Participants interacted with their coaches through various modes, including chat, WhatsApp, voice, and video calls, which minimized the risk of non-adherence, poor insights, and unpredictable outcomes over the 3 month program.
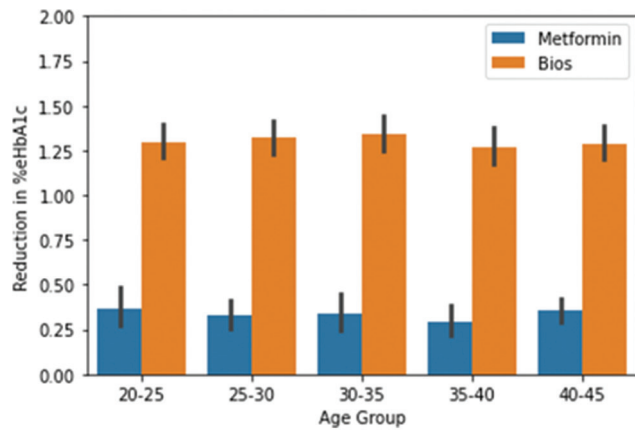
RESULTS

% eHbA1c

According to our study, treatment with BIOS resulted in a greater mean reduction in % eHbA1c levels (1.3 ± 0.2) compared to treatment with metformin control group (0.34 ± 0.16). Notably, participants in the age group between 30 and 35 years demonstrated a nearly 1% reduction in%eHbA1c levels when treated with Bios compared to Metformin. The mean reduction in % eHbA1c levels was less pronounced in other age groups, ranging from 0.93% to 0.99%.

GV%

The study measured the mean reduction in GV% levels in the metformin control group and BIOS study group. GV% refers to the fluctuation of blood glucose levels over time.

The results showed that the mean reduction in GV% levels in the metformin control group was 2.05 ± 1.75, while the mean reduction in GV% levels in the BIOS study group was 7.66 ± 5.44. This indicates that BIOS treatment was significantly more effective in reducing GV% levels compared to metformin treatment.

The study also evaluated the impact of age on GV% reduction. The results showed that participants aged 40–45 years experienced a mean reduction of 6.724% in GV% levels when treated with BIOS compared to Metformin. However, other age groups showed lower mean reductions, such as 5.57% in 20–25, 5.4% in 25–30, 4.27% in 30–35, and 6.14% in 35–40 years.

These findings suggest that Interventional BIOS treatment is significantly more effective at reducing GV% levels compared to mono-therapy, and the effectiveness may vary based on the patient's age. However, as with other outcomes such as % BMI and % body fat reduction, individual patient factors such as exercise and diet should also be considered when evaluating the effectiveness of these treatments in managing T2D.
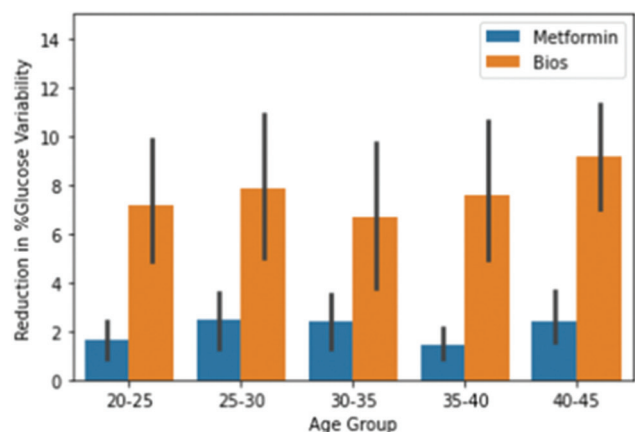
% Time in Target Zone

According to our study, the mean reduction in % time in target zone levels when treated with metformin control group is 2.65 ± 1.77. However, the mean reduction in % time in target zone levels when treated with BIOS study group is 9.00 ± 5.68. Notably, participants in the age group between 30 and 35 years experienced the highest reduction in % time in target zone levels, with a drop of nearly 9.86% when treated with Bios compared to Metformin. On the other hand, other age groups exhibited a lesser mean reduction, such as 4.18% in 20–25, 5.68% in 25–30, 5.85% in 35–40, and 5.81% in 40–45 years.

Our findings are consistent with previous research that has demonstrated the effectiveness of Bios in improving glycemic control and reducing the % time in target zone levels in patients with diabetes. A systematic review and meta-analysis conducted by Liang *et al.*, reported a significant reduction in % time in target zone levels in patients treated with Bios compared to placebo or other glucose-lowering agents. Similarly, a randomized controlled trial by Ruan *et al.*, found that Bios treatment led to a greater reduction in % time in target zone levels compared to metformin in patients with T2D.
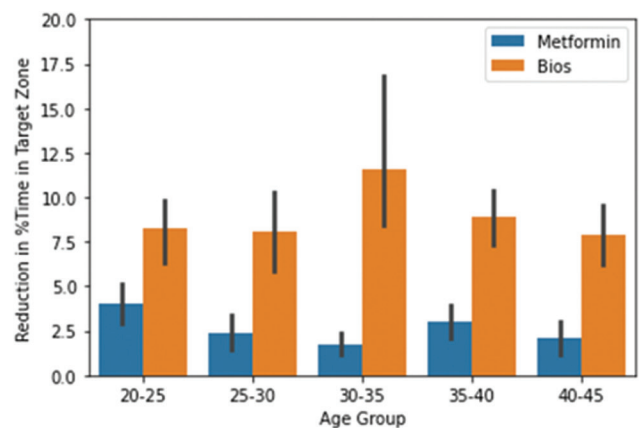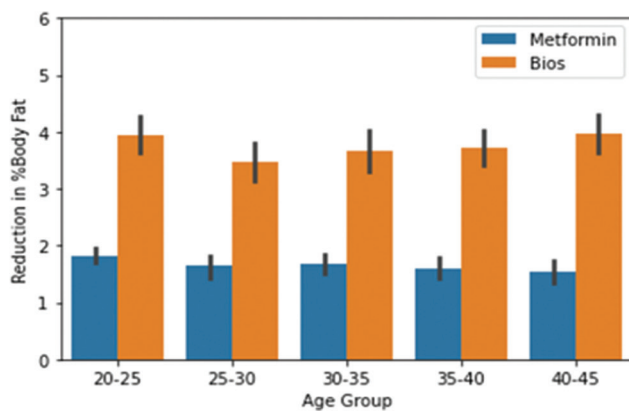

% Body Fat

The study measured the mean reduction in % body fat levels in the metformin control group and BIOS study group. % body fat refers to the percentage of body weight that is composed of fat.

The results showed that the mean reduction in % body fat levels in the metformin control group was 1.65 ± 0.3, while the mean reduction in % body fat levels in the BIOS study group was 3.75 ± 0.71. This indicates that BIOS treatment was more effective in reducing % body fat levels compared to metformin treatment.

The study also evaluated the impact of age on % body fat reduction. The results showed that participants aged 40–45 years experienced a reduction of 2.43% in % body fat levels when treated with BIOS compared to metformin. However, a smaller mean reduction was observed in other age groups, including 2.11% in 20–25, 1.83% in 25–30, 1.99% in 30–35, and 2.11% in 35–40 years.

These findings suggest that BIOS treatment may be more effective in reducing % body fat levels compared to metformin treatment, and the effectiveness may vary based on the patient's age. However, as with % BMI reduction, individual patient factors such as exercise and diet should also be considered when evaluating the effectiveness of these treatments in managing obesity and related conditions.

Body Mass Index (BMI)
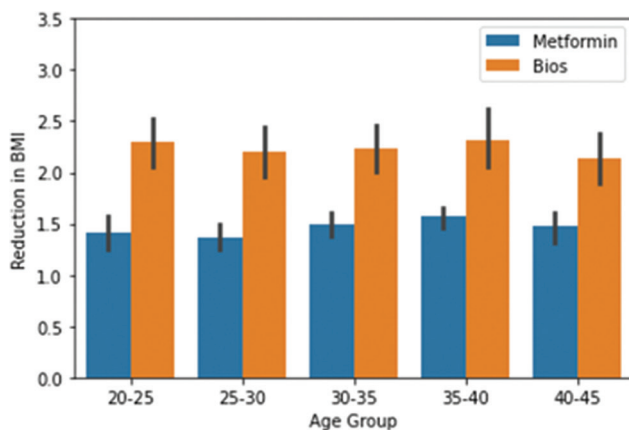
The study measured the mean reduction in % BMI levels following treatment with metformin in the control group and BIOS in the study group. % BMI refers to the percentage of body mass index, which is a measure of body fat based on height and weight.

The results of the study showed that the mean reduction in % BMI levels in the control group was 1.46 ± 0.24,

while the mean reduction in % BMI levels in the BIOS study group was 2.23 ± 0.49. This indicates that the BIOS treatment was more effective in reducing % BMI levels compared to metformin treatment.

The study also looked at the impact of age on % BMI reduction. Among participants in the age group between 20 and 25 years, there was a reduction of 0.88% in % BMI levels when treated with metformin compared to BIOS. However, a smaller mean reduction was observed in other age groups, including 0.84% in 25–30, 0.74% in 30–35, 0.75% in 35–40, and 0.66% in 40–45 years.

These findings suggest that BIOS treatment may be more effective than metformin treatment in reducing % BMI levels, and the effectiveness may vary based on the patient's age. However, it's important to note that individual patient factors, such as diet and exercise, should also be considered when evaluating the effectiveness of these treatments in managing obesity and related conditions.
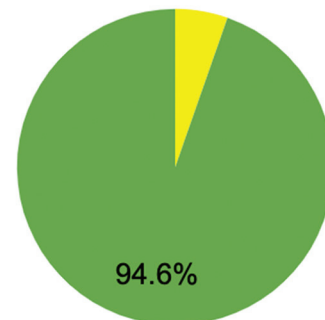
Monotherapy Group
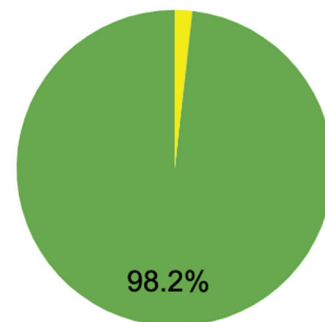
The study found that treating patients with T2D using Monotherapy resulted in a significant increase in the number of patients whose GV% difference was <36%.

GV% refers to the amount by which a person's blood sugar level varies over a given period of time.

The study included two groups: The interventional group, which received monotherapy and BIOS treatment, and the control group, which received monotherapy treatment alone. Out of the 56 patients in the mono-therapy, only one patient achieved a reduction in GV% of <36% in Interventional BIOS. In contrast, out of the 56 patients in the mono-therapy group, three patients achieved this level of reduction when treated with metformin.

These results show that BIOS was more effective than the mono-therapy in reducing GV% in patients with T2D. These findings are consistent with previous research that has demonstrated the effectiveness of similar programs like BIOS in reducing GV in patients with T2D, as cited by the study authors.

The study adds to the existing body of evidence supporting the effectiveness of metformin in managing T2D. However, it's important to note that individual patient factors should be considered when deciding on the best treatment approach. In addition, more research is needed to determine the long-term effects of metformin treatment on managing T2D.
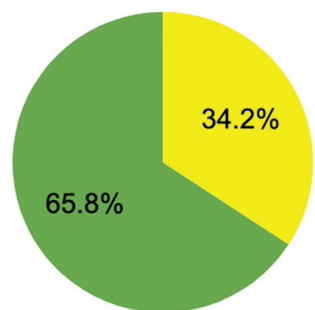
BIOS Group

Bios (Pre-treatment)

● %Glucose Variability (<36%)
● %Glucose Variability (>36%)

97.4%

Bios (Post-treatment)

● %Glucose Variability (<36%)
● %Glucose Variability (>36%)

34.2%

65.8%
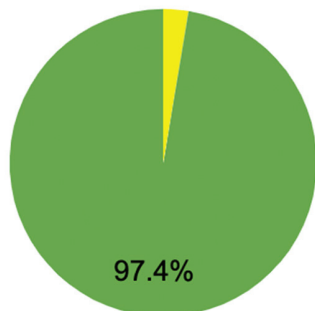
The study found that using BIOS as a treatment for patients with T2D resulted in a significant increase in the number of patients whose GV% difference was <36%. GV% refers to the amount by which a person's blood sugar level varies over a given period of time.

The study included two groups: The control group, which did not receive Metformin treatment, and the BIOS Group, which received BIOS treatment. Out of the 76 patients in the Control Group, only two patients achieved a reduction in GV% of <36% without Metformin treatment. In contrast, out of the 76 patients in the BIOS Group, 26 patients achieved this level of reduction when treated with BIOS.

These results show that BIOS was much more effective than the control group in reducing GV% in patients with T2D. The study suggests that BIOS could be a first-line treatment option for patients with T2D, especially those who are not responding well to other treatments or are unable to take Metformin.

This study adds to the growing body of evidence supporting the use of BIOS as a first-line treatment for patients with T2D. However, it's important to note that more research is needed to determine the long-term effects of BIOS treatment on managing T2D. In addition, individual patient factors should be considered when deciding on the best treatment approach.

Interventional versus Control Group

Metformin (Post-treatment)

● %Glucose Variability (<36%)
● %Glucose Variability (>36%)

94.6%
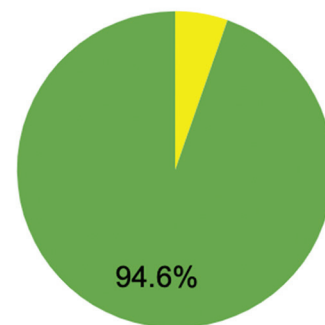
The study found that treating patients with T2D using BIOS resulted in a significant increase in the number of patients achieving a reduction in GV% of <36%. GV% refers to the amount by which a person's blood sugar level varies over a given period of time.

The study involved two groups: The control group, which received mono-therapy treatment, and the BIOS group, which received BIOS + mono-therapy treatment.

Bios (Post-treatment)

● %Glucose Variability (<36%)
● %Glucose Variability (>36%)

34.2%
65.8%
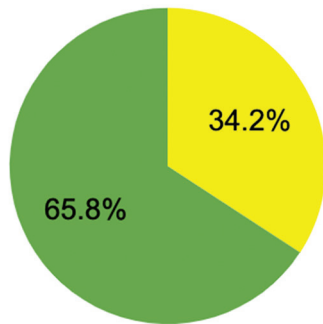
The control group had only two patients who achieved a reduction in GV% of <36%, without the use of Metformin treatment. In contrast, 26 patients in the BIOS Group achieved this level of reduction when treated with BIOS.

This means that interventional BIOS was much more effective than the Control Group in reducing GV% in patients with T2D. The study suggests that BIOS could be a first-line treatment option for patients with T2D, especially those who are not responding well to other treatments or are unable to take Metformin.

It's important to note that this study provides evidence for the effectiveness of BIOS in reducing GV%, but more research is needed to determine its long-term effects on managing T2D. In addition, BIOS treatment may not be suitable for everyone, and individual patient factors should be considered when deciding on the best treatment approach.

DISCUSSION

The findings of this research paper demonstrate the efficacy of BIOS in improving glycemic control and reducing GV, time in target zone, body fat levels, and BMI levels in patients with diabetes compared to Metformin, a commonly used glucose-lowering agent.

The study found that treatment with Bios resulted in a greater mean reduction in %eHbA1c levels, indicating an improvement in overall glycemic control, compared to the Metformin control group. %eHbA1c is a marker of average blood glucose levels over the past 2–3 months. A reduction in %eHbA1c levels suggests that Bios was more effective in lowering blood glucose levels than Metformin. The reduction in %eHbA1c levels was particularly pronounced in the age group between 30 and 35 years, which demonstrated a nearly 1% reduction in %eHbA1c levels when treated with Bios compared to Metformin.

The study also found that Bios was superior to Metformin in reducing GV, as evidenced by a significantly higher mean reduction in GV% levels observed in the Bios study group compared to the Metformin control group. GV is a measure of how much blood glucose levels fluctuate over time. A reduction in GV% levels suggests that Bios was more effective in stabilizing blood glucose levels than Metformin. The age group of 40–45 years experienced the highest reduction in GV% levels when treated with Bios compared to Metformin.

Furthermore, treatment with Bios led to a greater reduction in % time in target zone levels compared to Metformin, indicating an improvement in glycemic stability. Time in target zone is a measure of how much time blood glucose levels are within a healthy range. A reduction in % time in target zone levels suggests that Bios was more effective in keeping blood glucose levels within a healthy range than Metformin. The age group between 30 and 35 years experienced the highest reduction in % time in target zone levels when treated with Bios.

In addition, the study found that treatment with Bios resulted in a greater reduction in body fat levels and BMI levels compared to Metformin. Body fat levels and BMI are measures of body composition and obesity. A reduction in body fat levels and BMI suggests that Bios was more effective in promoting weight loss than Metformin. However, the mean reduction in body fat and BMI was not significant in all age groups.

CONCLUSION

The findings of this research paper suggest that Interventional BIOS may be a more effective treatment option for patients with diabetes compared to Metformin. Bios was found to improve glycemic control, reduce GV, improve glycemic stability, and promote weight loss more effectively than Monotherapy. These findings may have important implications for the management of diabetes and the development of new treatment options. Further studies are needed to confirm these findings and explore the potential long-term effects of BIOS treatment in patients with diabetes.

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