Role of Nanotechnology Structured Water to Achieve Controlled Blood Glucose Level in Type 2 Diabetic Patients: A Randomised Controlled Trial

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ABSTRACT

Introduction: Type 2 Diabetes Mellitus (DM) occurs due to insulin resistance or low insulin secretion or sometimes a combination of both. Nanotechnology structured water is a type of water that is produced using energy field modulators to change the biological, chemical and physical properties of water molecules and improve the bioavailability of this nano-water.

Aim: To find out the effect of drinking nanotechnology structured water (Magnalife®) on the blood glucose levels in patients with Type 2 diabetes mellitus.

Materials and Methods: This study was a randomised control trial involving Type 2 Diabetic patients (n=387) who were randomly divided into two groups. Group A (n=191) given nanotechnology structured water and Group B (n=196) with ordinary bottled water. Blood glucose level was measured as Glycated Haemoglobin (HbA1c) in the same laboratory for both groups. It was tested at baseline and at the end of the third

month after drinking the water, they were given in a daily dose of 20 mL/kg body weight divided over the day. Turkey test and independent t-test were used to compare the results.

Results: At the end of the study, only 352 patients were included (35 patients dropped out for different reasons). Interventional group (Group A) showed a significant difference between baseline HbA1c (8.1%±1.38) vs. HbA1c after 3 months (6.6%±0.85), (p<0.001). While there was no significant difference in pre-post HbA1c tests (7.9%±1.36) vs. (7.8%±1.16), (p=0.274) among the control group (Group B). The study revealed elevation in the percentage of patients with (HbA1c <7) in Group A from (25.1%) at baseline to (61.2%) after 3 months of intervention, while in Group B, the percentage of patients with (HbA1c <7) decreased from (27.2%) to (19.5%).

Conclusion: The use of nanotechnology structured water Magnalife® in Type 2 diabetic patients is innovative way to achieve better control of blood glucose level.

Keywords: Diabetes mellitus, Glycated hemoglobin HbA1c, Nanotechnology water

INTRODUCTION

Type 2 diabetes is a combination of disorders of metabolic processes leading to hyperglycemia and has a high risk of complications like microvascular and cardiovascular systems [1,2]. The principal physiological abnormalities are improper insulin secretion and insulin resistance [3,4]. Diabetes is the most important threat to human health as an epidemic disease. The total number of diabetic patients is estimated to increase from 171 million in 2000 to 366 million in 2030, its incidence is rapidly increasing, while by 2030, this incidence is evaluated to be doubled [5].
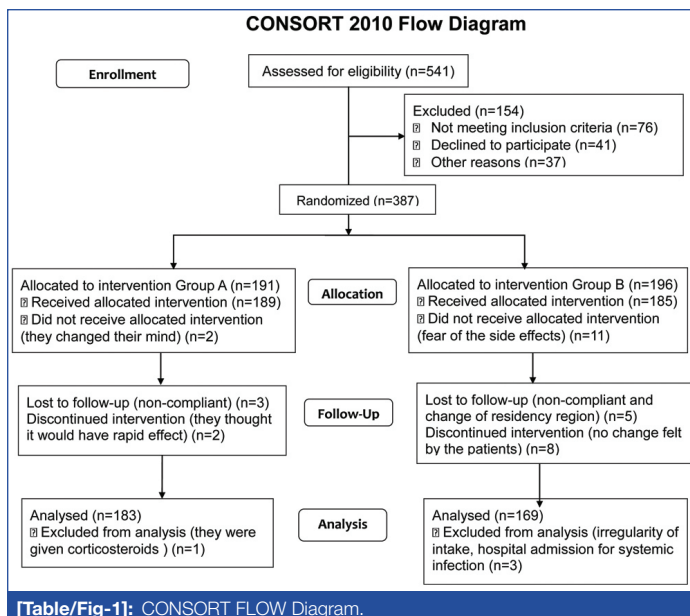
Structured water with nanotechnology can be produced by exposing water to energy field modulators for a certain period of time until nano molecules with specific energy and size are produced, and these molecules have different physical properties and biological properties and can act at the cellular level [6]. It has been known that structured water is effective in several chronic diseases including diabetes, but scientific experimental results are seldom reported. A study about the structured water reported that it increases glutamate decarboxylase activity [7]. Also, structured water was found to reduce dental plaque [8]. Another study had demonstrated that structured water was effective in treating urolithiasis [9]. Also, it has a preventive effect against recurrent stones in idiopathic hypercalciuria patients [6]. Additionally, it has a prophylactic effect against Urinary Tract Infections (UTI) in patients with recurrent cystitis [10]. In another study, drinking structured water for 6 weeks suppressed the lymphocyte DNA damages in animals with Diethylnitrosamine (DEN)- induced cancer [11].

The present study was conducted with an aim to assess the effects of drinking nanotechnology structured water Magnalife® by Type 2 diabetic patients on blood glucose levels and to compare the results with the ordinary bottled water.

MATERIALS AND METHODS

A randomised controlled trial with the registration number (NCT04082351) was conducted from July 2016 to February 2018 in which 387 patients with Type 2 Diabetes Mellitus from the Diabetes Care Centre in Sulaymaniyah, Kurdistan Region of Iraq were recruited. Clinicians in the Diabetes Centre referred their patients to participate in the research; they explained all the required information in detail to the patients and written informed consent from the patients was taken before conducting the study. All patients who agreed to contribute in the study were randomly divided into two groups A and B, depending on the CONSORT guideline of randomisation. A simple randomisation process was undertaken using computerised random numbering.

Every patient with Type 2 DM history for one year and above and using a single or multiple oral hypoglycemic medications were included. Regular investigations were done to exclude any metabolic complications of the disease. All patients were screened for other disease conditions, and medications that may affect the blood sugar such as malignancy, steroids, immunotherapy, chemotherapy, radiotherapy, chronic infections and drugs that antagonise or synergize the insulin effects and any patient with one of those conditions were excluded from the study. The inclusion and exclusion criteria, as well as details of patients' eligibility and the final number of patients, are shown in [Table/Fig-1].

[Table/Fig-1]: CONSORT FLOW Diagram.

Glycated haemoglobin HbA1c was tested for all the patients as a baseline measurement. In Group A, patients were given nanotechnology structured water Magnalife® and in Group B they were given ordinary bottled drinking water as a control. The bottles were not labelled to avoid any bias in the study. Then they were given instructions to drink the given water bottles in a daily dose of 20 mL for each kilogram of their body weight. The investigator asked the participants to follow their usual lifestyle in relation to food and drink intake as well as physical activities. They were instructed to take their medications as usual. All patients were asked to come to assess the HbA1c level at the end of the third month of their participation.

STATISTICAL ANALYSIS
The results were evaluated statistically by using the Statistical Package for the Social Sciences (SPSS) version 23.0. All the data were expressed as mean±SD and SE. Comparisons between groups were made by using the Turkey test. Independent t-test was used to compare the results. Changes were considered statistically significant when the p-value was ≤0.05.

RESULTS
Baseline demographic and clinical characteristics of the participants are shown in [Table/Fig-2]. Group A demonstrated a difference between baseline HbA1c (8.1%±1.38) vs. HbA1c after 3 months (6.6%±0.85) which was statistically significant (p<0.001). While Group B showed little change in pre-post HbA1c tests (7.9%±1.36) vs. (7.8%±1.16), and that was statistically non-significant (p=0.274) as illustrated in [Table/Fig-3].

Variables	Group A	Group B
No. of patients (n)	183	169
Age range (years)	24-76, mean=50.2	30-77, mean=49.3
Male:female ratio	103:80	83:86
Hypertension	85 (46.45%)	59 (34.91%)
Smoking status- current	20 (10.93%)	16 (9.47%)
Smoking status- past	42 (22.95%)	51 (30.18%)
Non-smoking status	121 (66.12%)	102 (60.35%)

[Table/Fig-2]: Showing baseline demographic, clinical characteristics, age and sex ratio of patients.

Groups	Baseline HbA1c	HbA1c after 3 months	p-value*
Group A	8.1%±1.38	6.6%±0.85	p<0.001
Group B	7.9%±1.36	7.8%±1.16	p=0.274

[Table/Fig-3]: Showing HbA1c results at baseline and after 3 months.
p-value was calculated by independent sample t-test

In Group A, the percentage of patients with HbA1c<7 increased from 25.1% at the beginning to 61.2% at the end of the study. In Group B, that percentage of patients with HbA1c<7 declined from 27.2% to 19.5% [Table/Fig-4].

Groups	% patients with (HbA1c<7) baseline	% patients with (HbA1c<7) after 3 months
Group A	46 (25.1%)	112 (61.2%)
Group B	46 (27.2%)	33 (19.5%)

[Table/Fig-4]: Showing percentage of patients with HbA1c <7 at beginning and after 3 months.

DISCUSSION
Since this is the first study conducted on nanotechnology structured water and including such large numbers of diabetic patients, the present authors have little data to compare the present results with. The results of drinking Nano-water resulted in decreased HbA1c after three months. These results agree with the results of Oda M et al. who showed that drinking structured water in rats led to enhanced sugar uptake [12]. The cause of reduction in blood sugar level can be explained by the idea that the structured water help to promote the translocation of sugar transport carrier GLUT4 to the cell membrane to increase sugar uptake, furthermore, there will be increased phosphorylation of insulin receptors through suppression of (a redox-sensitive protein) by suppressing tyrosine-protein phosphatase activity. Furthermore, it activates PI3 kinase and Akt [13,14]. Also, the blood sugar level is decreased because this water minimises sugar tolerance damage in Type 2 diabetes model mice [15,16]. Additionally, structured water can improve the symptoms of diabetes model mice [17-19]. The present results indicated that drinking nanotechnology structured water decreased the HbA1c to normal or near-normal levels compared to baseline values in most of the patients which is higher than what has been reported in another study which showed that 45% of the 411 Type 2 diabetic patients (mean age, 71.5 years) who took daily 2 liters of structured water, HbA1c and blood glucose levels were lower after drinking this water [20]. The blood glucose levels were even lower after long term drinking. Drinking this water for a more extended period leads to an elevation in the percentage of patients who improved [21,22]. The difference may be due to that the nanotechnology structured water is produced by a more advanced procedure that includes nanotechnology to produce nanomolecules and hence more effects on the patients. In a clinical study performed at the First Central Hospital in Jilin Changchun City in China that involved 65 patients with diabetes who took 2 litre of this water daily for 2 months, the results indicated that there was a significant reduction in blood glucose levels in 89% of patients, [16] which is similar to the present results. Furthermore, a double-blind randomised clinical trial for 29 Type 2 diabetic patients which was done at the Fukuoka Tokusyukai Hospital, Fukuoka City, Japan. Urinary 8-OHdG (an internal oxidation marker) levels of patients who drank 1 litre of this water daily for six months were significantly lower [23]. Besides, a double-blind clinical study which included 100 subjects performed at Hiroshima University from November 2008 to September 2009, with daily 2 liters of structured water, the results showed that this water has antimetabolic syndrome effects such as a significant decrease in starved blood sugar levels [24]. In that clinical trial, it was suggested that drinking 2 liters of natural mineral water per day was anti-metabolic syndrome health. While in the present study, drinking ordinary bottled water did not affect the levels of HbA1c even after three months, but still, all results are near or similar to the present results. Finally, even in animals, the consumption of structured water resulted in decreased blood sugar levels in diabetic rats [25]. Another study has shown that glycemic control was better after four months of magnetised water intake [26]. Other studies found that reduced water has a suppressive effect on Type 1 diabetes

mellitus [27,28]. Furthermore, another study found that drinking alkaline or magnetised water lowered blood glucose levels after different periods of intake [29]. Also, it was confirmed that drinking magnetised water for 60 days lowered blood glucose levels in goats compared to those with ordinary water [30].

LIMITATION

This study had limitations that a small number of patients were included and long term follow-up was not done. A relation with body mass index and type of physical activities was not established.

CONCLUSION

Nanotechnology structured water Magnalife® represents a reasonable way to control blood sugar levels in Type 2 diabetes mellitus, and it decreases blood sugar levels in a large number of patients. Since it reduces the blood sugar, then it may help to prevent the diabetes-associated complications.

Disclaimer: This study was presented as a poster in the American Diabetes Association Scientific Sessions 2018, Orlando, FL, US.

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