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Original Research Article

Evaluation of voglibose on body weight in rats

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ABSTRACT

Background: As of 2018, 2.1 billion people nearly 30% of the world's population are either obese or overweight. Worldwide obesity has nearly tripled since 1975. It is an emerging health problem with major adverse effects on health. It is a risk factor for many chronic diseases but is best known for its role in metabolic syndrome, which can lead to type 2 diabetes mellitus as well as cardiovascular diseases. Anti-obesity drugs are available but have many side effects. Voglibose, an antidiabetic drug, is an alpha glucosidase inhibitor which shows promising results in the reduction of body weight with minimal side effects.

Methods: Voglibose (7 mg/kg) was administered to rats fed with normal laboratory chows and high fat diet to see its effect on body weight, body mass index, abdominal and thoracic circumference, and lipid profile at the end of 12 weeks.

Results: Administration of voglibose significantly reduced food consumption, feed efficiency and increase in body weight induced by high fat diet in rats. Rats fed on normal diet also showed reductions in the same parameters, suggesting its weight lowering effect. Reductions in the anthropometric measurements, hypolipidemic effects and glucose lowering effects were also observed.

Conclusions: Voglibose prevented high fat diet-induced obesity and improvement in metabolic profile, which ultimately has systemic effects on body weight in rats. Further studies are needed to see its potential therapeutic use in obese patients with type 2 diabetes mellitus, and related complications.

Keywords: Body weight, High fat diet, Metabolic syndrome, Voglibose

INTRODUCTION

Obesity can result from increased energy intake, decreased energy expenditure, or a combination of the two.[1] Obesity is chronic excess of nutrient intake relative to the level of energy expenditure. Being overweight increases a person's risk of serious illnesses. Like cardiovascular disease (mainly heart disease and stroke), type 2 diabetes, musculoskeletal disorders (especially osteoarthritis) and certain types of cancer (endometrial, breast, etc).

According to a study, number of overweight and obese people globally increased from 857 million in 1980 to 2.1 billion in 2013. This is one-third of the world's population.[2] Obesity is a risk factor for many chronic diseases but is best known for its role in metabolic syndrome, which can lead to type 2 diabetes (T2D) as well as cardiovascular disease.

Diabetes mellitus is characterized by chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action or both. Diabetes mellitus is one of the leading causes of morbidity and mortality worldwide. In addition to the 415 million adults who are estimated to currently have diabetes, there are 318 million

adults with impaired glucose tolerance, which puts them at high risk of developing the disease in the future. This is projected to increase to 642 million by the year 2040. With an estimated 69.[1] million people living with diabetes in India, corresponding to 8.7% of India's adult population, India has the world's second largest diabetes population.[3]

Excess abdominal fat, assessed by measurement of waist circumference or waist-to-hip ratio, is independently associated with a higher risk for diabetes mellitus and cardiovascular disease.[1] A surrogate marker for body fat content is the body mass index (BMI), which is calculated as: BMI =Weight (kg)/Height (m2). In clinical terms, a BMI between 25 and 29.9 kg/m^2 is called overweight, and a BMI greater than 30 kg/m2 is called obese.

Psychological consequences of being overweight or obese can include lowered self esteem and anxiety, and more serious disorders such as depression and eating disorders such as binge eating, bulimia and anorexia. The reasons for why this is so aren't hard to fathom. Eating is pleasurable, and because this is true all manner of people (fat and thin both) enjoy eating. It comes as no surprise that eating leads to weight gain and thus the need to control the weight gain.

An intestinal enzyme, α-glucosidase, acts on carbohydrate digestion and glucose absorption.[4] The action of α-glucosidase inhibitors is to delay intestinal absorption of carbohydrates by inhibiting degradation, which results in altered postprandial glucose and insulin levels.[5] Acarbose, miglitol and voglibose (VO) are three major oral hypoglycemic drugs used to treat patients with T2DM by delaying the absorption of glucose, thereby managing the disease and related complications.[6] Recently, it was reported that the α -glucosidase inhibitors provide significant beneficial health outcomes in post hoc analyses of randomized placebo-controlled trials.[7]

The recent health crisis has spurred research in weight control, including studies in diet, exercise, surgery and antiobesity drugs. Drugs available to reduce weight are orlistat, metformin etc. Metformin is used to treat diabetes, but several studies show that it also helps non-diabetics to lose weight by reducing hunger. Many side effects may occur with the use of this medication like lactic acidosis, diarrhea, nausea, vomiting, and flatulence. Voglibose is an alpha-glucosidase inhibitor used for lowering post-prandial blood glucose levels in patients with diabetes mellitus. With reference to adverse drug events, voglibose is more tolerant and it has less drug side effects due to its relatively lower doses.

Very few studies have been conducted which showed its possible effect on body weight reduction in high fat diet induced obese rats but no study has been conducted to evaluate its role in maintenance of body weight.

Hence, the present study was done to evaluate the effect of voglibose in maintenance of the body weight and its role in prevention of weight gain in rats fed with high fat diet.

Aim of the study was to study the effect of voglibose on body weight in normal and high fat diet induced obese rats.

Objectives

Primary objectives

- To study the effect of voglibose on body weight in rats fed with normal diet
- To study the effect of voglibose in prevention of weight gain with high fat diet.

Secondary objectives

- To study effect of voglibose on lipid profile
- To study effect of voglibose on blood glucose levels

METHODS

The commencement of the study was done after the approval from Institutional Animal Ethics Committee (IAEC). The experiments were performed as per norms laid by Committee for the Purpose of Control and Supervision of Experimentation on Animals (CPCSEA).

Animal feed

Normal diet

Rats were fed with commercially available 'Nutrimix Std-1020' manufactured by Baramati Agro Ltd, acquired from Nutivet Life Sciences, Pune.

High fat diet/Cafeteria diet (CD)

The CD consisted of three diets

- Condensed Milk (8g) + Bread (8 g)
- Chocolate (3 g) + Biscuits (6 g) + Dried Coconut (6g)
- Cheese (8 g) Boiled Potato (10 g)

The three diets were presented to the individual rats on days one, two, and three, respectively, and then repeated for 12 weeks in the same succession. Food and water (ad libitum) were replenished once daily in the morning.

Rats were housed in standard big polypropylene with provision for drinking water and space for pellets. They were housed under standard condition of temperature (25±5°C) and relative humidity (55±10%) and 12/12 hour light/dark cycle.

Study drugs

Voglibose (Torrent Pharma, India) was used as test drug. Voglibose was given mixed in distilled water and administered orally on the basis of body weight for 12 weeks. Distilled water was given orally as control in equivalent volume.

Study design

Rats were divided into four groups. Each group was assigned eight rats on a random basis.

Table 1: Groups of rats.

Groups	Drug
N + DW	Normal Diet + Distilled Water (p.o.)
N + VO	Normal Diet + Voglibose (3.5 mg/kg twice daily p.o.)
HFD + DW	High Fat Diet + Distilled Water (p.o.)
HFD + VO	High Fat Diet + Voglibose (3.5 mg/kg twice daily p.o.)

Parameters

Body weight gain (g)

Individual body weight were recorded at the start of the study (Day 0) and weekly thereafter. Mean body weight gain was calculated for each group weekly throughout the study period.

Food consumption (g)

Food consumption of each animal per day was determined by measuring the difference of weight of chows 24 hours apart. This value was used to calculate mean food consumption for the respective group weekly throughout the study period.

Feed efficiency

$$(FE\ \%) = \frac{\text{Mean body weight gain}}{\text{Energy Intake}} \times 100$$

Anthropometrical parameters

Were measured by a non elastic tape at day 0, 6 weeks and end of the experiment.

- *Body length (cm)*: Measured from nostril to the base of the tail (pelvic-caudal junction)
- *Body mass index (g/cm^2) (BMI)* = body weight (g) length^2 (cm^2)
- *Abdominal circumference (AC) (cm)*: Measured immediately anterior to the forefoot.
- *Thoracic circumference (TC) (cm)*: Measured immediately behind the foreleg.

Blood biochemical analysis

Lipid profile

The levels were estimated manually on spectrophotometer by using lipid estimation kit (Transasia Biomedicals Ltd., Mumbai).

- Total cholesterol
- Triglyceride
- HDL
- LDL = Total cholesterol - HDL - (TG/5).
- LDL = Total cholesterol - TG - HDL
  Atherogenic Index is the next bullet point

Blood glucose levels

Fasting blood glucose and post prandial blood glucose were done at the beginning, at 6 weeks and at the end of the study.

Statistical analyses

Quantitative data presented with the help of Mean and Standard deviation. Comparison among the study groups was done with the help of Student's t - test. Qualitative data was presented with the help of frequency and percentage table. Results were graphically represented where deemed necessary. Appropriate statistical software, including but not restricted to MS Excel, SPSS ver. 20 was used for statistical analysis. Graphical representation was done in MS Excel 2010.

RESULTS

A total of 100 patients were studied during the period of 1 year. The patients were randomly divided into two groups.

Table 2: Comparison of mean body weight gain (g) between groups.

Body weight gain (g)	N + DW (Mean± SD)	N + VO (Mean± SD)	HFD + DW (Mean± SD)	HFD + VO (Mean± SD)
Week 0	11.2±0.5	11.4±0.5	21.3±0.5	21.6±0.5
Week 1	12.1±0.5	11.7±0.5	23.4±0.5	21.8±0.5
Week 2	13.3±0.6	12.1±0.6	24.6±0.6	22.1±0.5
Week 3	14.6±0.6	12.4±0.6	25.3±0.6	22.3±0.6
Week 4	15.3±0.7	12.7±0.7	26.2±0.7	22.5±0.6*
Week 5	16.2±0.7	12.9±0.7	27.5±0.7	22.7±0.7*
Week 6	17.4±0.8	13.2±0.8	29.1±0.8	22.9±0.7*
Week 7	18.2±0.8	13.6±0.8	30.6±0.9	23.2±0.7*
Week 8	18.6±0.8	13.9±0.8	31.4±0.9	23.4±0.8*
Week 9	19.1±0.9	14.3±0.9	32.3±0.9	23.6±0.8*
Week 10	19.4±0.9	14.8±0.9	33.8±1.0	23.9±0.9*
Week 11	19.7±0.9	15.1±0.9	34.1±1.0	24.3±0.9*
Week 12	19.9±0.9	15.4±0.9	34.8 ±1.0	24.8±0.9*

*shows significance (P< 0.05) when compared to HFD + DW group

Table 3: Comparison of Mean Food consumption (g) between groups.

Food consumption (g)	N + DW (Mean±SD)	N + VO (Mean±SD)	HFD + DW (Mean±SD)	HFD + VO (Mean±SD)
Week 0	15.09±0.21	15.10±0.20	15.31±0.22	15.09±0.20
Week 1	15.53±0.19	15.32±0.17	16.1 ±0.24	15.86±0.18
Week 2	15.97±0.17	15.64±0.18	16.98 ±0.27	16.64±0.19
Week 3	16.44±0.18	15.81±0.18	17.88±0.31	17.21±0.22
Week 4	16.89±0.19	16.26±0.19	18.82±0.37	17.50±0.23*
Week 5	17.37±0.22	16.45±0.20	19.82±0.44	18.06±0.23*
Week 6	17.86±0.28	17.16±0.21	20.87±0.51	18.92±0.24*
Week 7	18.37±0.34	17.82±0.23	21.99±0.62	19.25±0.24*
Week 8	18.89±0.42	18.14±0.33	23.16±0.71	20.12±0.25*
Week 9	19.32±0.41	18.66±0.36	24.4±0.81	20.83±0.26*
Week 10	19.72±0.42	19.02±0.39	25.89±0.82	21.62±0.27*
Week 11	20.14±0.39	19.79±0.43	27.16±0.87	22.55±0.27*
Week 12	21.04±0.32	20.55±0.40	27.78±0.74	24.8±0.9*

*shows significance (P<0.05) when compared to HFD + DW group

The mean food consumption increased all the groups during the 12 weeks period. The difference in mean food consumption between the N+DW and N+VO Group was statistically not significant. It was observed that the increase in mean food consumption was significantly lower in HFD+VO Group as compared to HFD+DW Group from Week 4.

Table 4: Comparison of Mean Feed efficiency (%) between groups.

Feed efficiency (%)	N + DW (Mean ± SD)	N + VO (Mean ± SD)	HFD + DW (Mean ± SD)	HFD + VO (Mean ± SD)
Week 0	2.35±0.08	2.38±0.07	3.34±0.12	3.36±0.12
Week 1	2.43±0.09	2.44±0.09	3.43±0.14	3.40±0.13
Week 2	2.45±0.09	2.49±0.10	3.52±0.14	3.48±0.15
Week 3	1.91±0.15	2.03±0.16	3.68±0.20	3.61±0.19
Week 4	1.93±0.16	1.99±0.16	3.54±0.16	3.13±0.07*
Week 5	1.82±0.15	1.85±0.16	4.01±0.38	3.66±0.19*
Week 6	1.84±0.16	1.87±0.16	3.61±0.17	3.04±0.05*
Week 7	1.86±0.16	1.90±0.17	3.73±0.19	3.12±0.06*
Week 8	1.88±0.17	1.93±0.18	3.79±0.25	3.18±0.08*
Week 9	1.91±0.18	1.97±0.18	3.85±0.22	3.23±0.21*
Week 10	1.32±0.21	1.35±0.22	3.91±0.05	3.26±0.22*
Week 11	1.75±0.48	1.80±0.49	3.43±0.55	2.94±0.02*
Week 12	1.86±0.67	1.92±0.69	3.76±0.76	3.15±0.18*

*shows significance (P<0.05) when compared to HFD+DW group

The difference in mean feed efficiency between N+DW Group and N+VO Group was statistically not significant. The mean feed efficiency was significantly higher in HFD+DW Group as compared to HFD+VO Group from Week 4.

Table 5: Comparison of anthropometrical parameters between groups.

Parameters		N + DW (Mean±SD)	N + VO (Mean±SD)	HFD + DW (Mean±SD)	HFD + VO (Mean±SD)
AC (cm)	Week 0	16.30±1.14	16.42±1.15	17.12±1.22	17.04±1.18
	Week 6	16.52±1.16	16.48±1.15	17.84±1.26	17.33±1.25*
	Week 12	16.71±1.19	16.54±1.16	18.23±1.30	17.62±1.28*
TC (cm)	Week 0	14.85±1.01	14.87±1.02	15.21±1.14	14.93±1.05
	Week 6	14.92±1.04	14.96±1.04	16.03±1.21	15.05±1.10*
	Week 12	15.01±1.09	15.04±1.10	16.98±1.62	15.18±1.13*
Body length (cm)	Week 0	20.34±1.75	20.72±1.81	20.94±1.86	20.66±1.78
	Week 6	20.42±1.77	20.77±1.83	21.63±1.89	20.84±1.85
	Week 12	20.44±1.80	20.81±1.84	22.12±1.89	20.91±1.85
BMI (g/cm^2)	Week 0	0.45±0.08	0.39±0.06	0.48±0.08	0.40±0.05
	Week 6	0.51±0.11	0.42±0.07	0.55±0.11	0.43±0.04*
	Week 12	0.68±0.15	0.44±0.08	0.72±0.14	0.44±0.04*

AC - Abdominal circumference; TC - Thoracic circumference

*shows significance (P<0.05) when compared to HFD+DW group

The mean body weight increased in all the groups during the 12 weeks period. The difference in mean body weight gain between the N+DW and N+VO group was statistically not significant. It was observed that the increase in mean body weight gain was significantly lower in HFD+VO Group as compared to HFD+DW Group from Week 4 ($p<0.05$).

During the 12-week period, there was increase in the values of anthropometrical parameters (Abdominal circumference (AC), Thoracic circumference (TC), Body Length and BMI values in all the groups. The difference in anthropometrical parameters between the N+DW and N+VO Group was statistically not significant. The difference in Body Length values between the HFD+DW and HFD+VO Group was statistically not significant while the difference in AC, TC and BMI values were statistically significant.

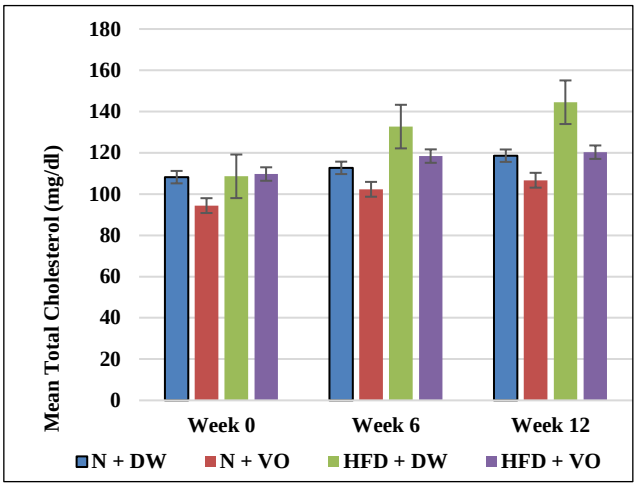

Figure 1: Comparison of mean total cholesterol (TC) values between groups.

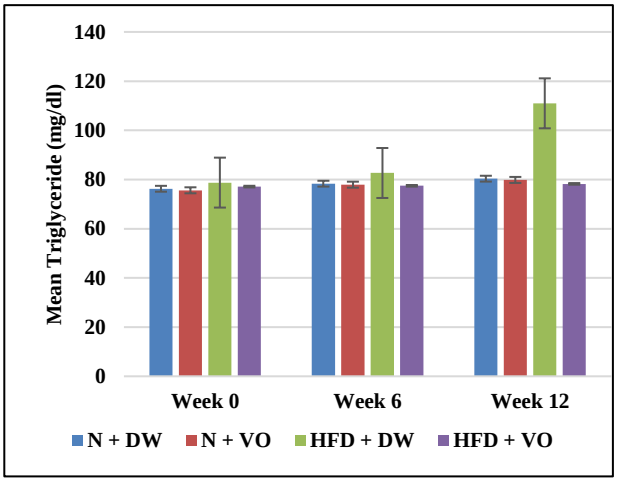

Figure 2: Comparison of mean triglyceride (TG) values between groups.

During the 12-week period, there was increase in Total Cholesterol (TC) values in all the groups. The difference in TC values between the N+DW and N+VO Group was statistically not significant. The difference in TC values between the HFD+DW and HFD+VO Group was statistically significant at Week 6 and Week 12.

During the 12-week period, there was increase in Triglyceride (TG) values in all the groups. The difference in TG values between the N+DW and N+VO Group was statistically not significant. The difference in TG values between HFD+DW and HFD+VO Group was statistically significant at Week 6 and Week 12.

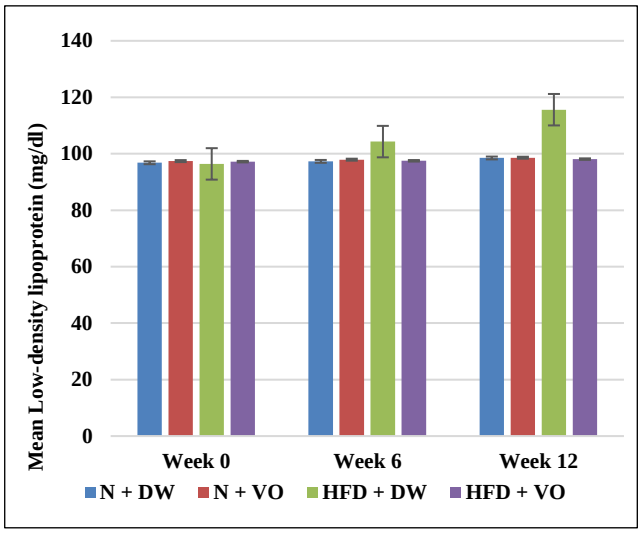

Figure 3: Comparison of mean low density lipoprotein (LDL) values between groups

During the 12-week period, there was increase in Low Density Lipoprotein (LDL) values in all the groups. The difference in LDL values between the N+DW and N+VO Group was statistically not significant. The difference in LDL values between the HFD+DW and HFD+VO Group was statistically significant at Week 6 and Week 12.

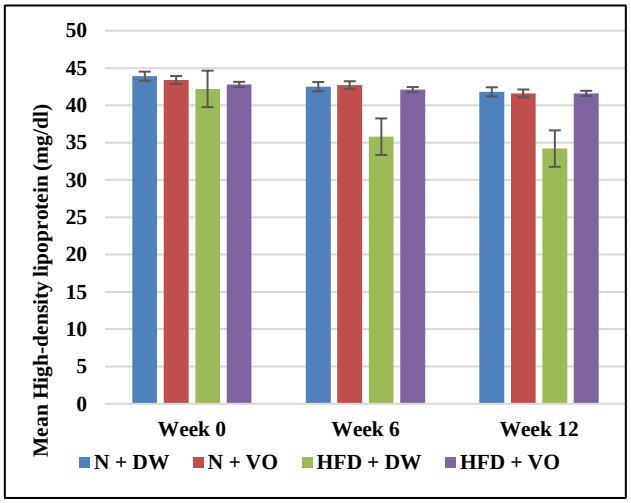

Figure 4: Comparison of mean high density lipoprotein (HDL) values between groups.

During the 12-week period, there was decrease in High Density Lipoprotein (HDL) values in all the groups. The difference in HDL values between the N+DW and N+VO Group was statistically not significant. The difference in HDL values between the HFD+DW and HFD+VO Group was statistically significant at Week 6 and Week 12.

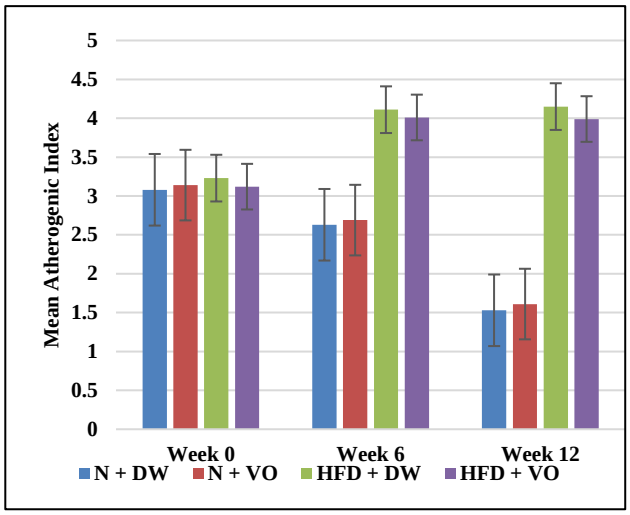

Figure 5: Comparison of mean atherogenic Index values between groups.

The difference in Atherogenic Index values between the N+DW and N+VO Group was statistically not significant. The difference in Atherogenic Index values between the HFD+DW and HFD+VO Group was statistically significant at Week 6 and Week 12.

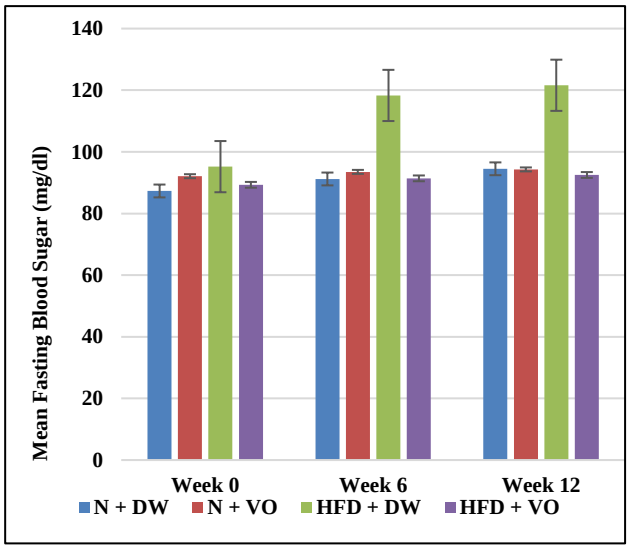

Figure 6: Comparison of mean fasting blood glucose (FBG) levels between groups.

The difference in FBG values between the N+DW and N+VO Group was statistically not significant. The difference in FBG values between the HF+DW and HFD+VO Group was statistically significant at Week 6 and Week 12.

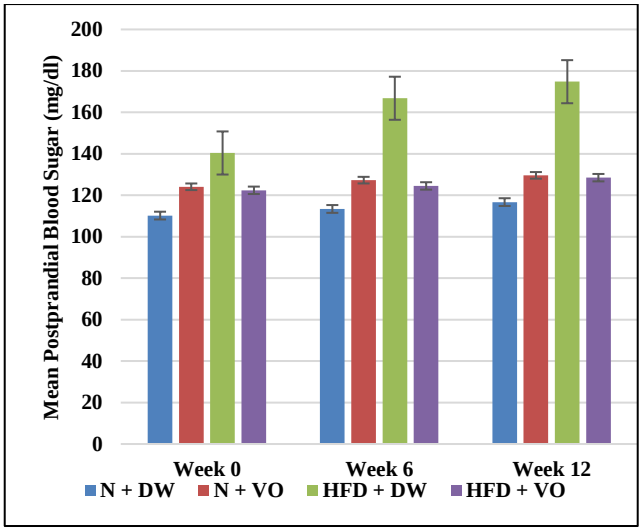

Figure 7: Comparison of mean postprandial blood glucose (PPBG) levels between groups.

The difference in PPBG values between the N+DW and N+VO Group was statistically not significant. The difference in PPBG values between the HFD+DW and HFD+VO Group was statistically significant at Week 6 and Week 12.

DISCUSSION

Obesity is still widely decried as a lifestyle 'choice', but even determined changes in lifestyle may have limited long-term impact on it and, pragmatically, the need for medical intervention is now clear. Psychological consequences of being overweight or obese lowers self-esteem. Abdominal obesity is the most frequently observed component of metabolic syndrome. The metabolic syndrome; clustering of abdominal obesity, dyslipidemia, hyperglycemia and hypertension, is a major public health challenge. The average prevalence of metabolic syndrome is 31% and is associated with a two-fold increase in the risk of coronary heart disease, cerebrovascular disease, and a 1.5 - fold increase in the risk of all-cause mortality.

Voglibose is an alpha glucosidase inhibitor and exerts weight reduction properties through decrease in energy intake and improvement in mitochondrial function, indicating that voglibose has potential therapeutic use in patients with obesity, type 2 diabetes, and related complications.

In this study, administration of voglibose to high fat diet rats could significantly decrease food intake and rise in weight gain as compared to control group. Though there was a decrease in the food intake and the body weight with voglibose in the rats on normal diet, it was not significant.

This is similar to the study of Do JH et al, in which the direct effect of voglibose on body weight in mice was investigated.[8] Pairfed groups were given the same amount of high fat diet as that consumed daily by the VO group

during the 12 weeks periods. Body weights were significantly lower in the voglibose group than those in the control, high fat and pairfed groups. Voglibose groups consumed remarkably less amount of food than the control and high fat groups. The feed efficient ratio was significantly higher in the high fat group than in the control and voglibose groups.

In Moritoh Y et al, study, genetically modified obese (ob/ob) mice were treated with voglibose, pioglitazone, or vehicle for four weeks, and metabolic parameters were analyzed.[9] Average food consumption was significantly decreased in voglibose treated mice, whereas no significant changes were observed in pioglitazone treated mice. After 23 days of treatment, body weight was significantly reduced in voglibose treated group, whereas no significant change was observed in pioglitazone-treated group, compared with vehicle treated mice.

Jones RB et al, study on effect of linagliptin, alone and in combination with voglibose, on glucose control in genetically modified ZDF rats reported that voglibose significantly reduced body weight, and also the body weights of rats given the combination of linagliptin and voglibose were significantly lower than the control, and the linagliptin group.[10] Linagliptin plus voglibose produced a marked increase in GLP-1 (active) at 5 min post-sucrose, compared to linagliptin, possibly because linagliptin prevented the degradation of GLP-1 secreted in response to voglibose. Reduced body weight and markedly increased plasma GLP-1 levels in animals given linagliptin with voglibose, suggests that this combination to be beneficial.

In the study by Fujitaka K et al, (2011) compared the metabolic profiles of pioglitazone versus voglibose in type 2 diabetes mellitus patients associated with metabolic syndrome.[11] They reported significant decrease in body mass index and waist circumference in the voglibose group as compared to pioglitazone.

Another study by Negishi M et al, concluded that voglibose treatment prevented the increase in body weight induced by pioglitazone in type 2 diabetes patients and since it controlled body weight, it may be a potentially useful drug for increasing the benefit of pioglitazone treatment.[12] Study by Do JH et al, studied the effects of the long term administration of voglibose in high fat fed mice preventing diet induced obesity in addition to the hypoglycemic effects in high fat fed mice and further investigated the underlying mechanisms by which voglibose exerts its weight lowering effect.[13] Elevated levels of plasma leptin in high fat diet were significantly reduced with voglibose and voglibose modulated the hypothalamic expressions of leptin receptors and appetite related genes. Voglibose showed the upregulated expressions of Peroxisome proliferator – activated receptor - gamma coactivator (PGC) -1 in the liver and epididymal adipose tissue.

Voglibose improves insulin sensitivity and dyslipidaemic states in non-diabetic hyper insulinaemic subjects too. Administration of voglibose resulted in a significant decline of cholesterol, triglycerides, LDL and in elevation of HDL as seen in this study.

This is consistent with the study of Do JH et al, In the study the mice in the high fat group had elevated levels of total cholesterol, whereas the voglibose significantly reduced total cholesterol levels in the group on high fat diet.[8] It was also reported that the serum triglyceride levels were significantly lower in the voglibose groups than the high fat diet group. In a study by Naik ME et al, administration of voglibose decreased diabetes induced rise in lipid levels and decreased the risks of coronary heart disease.[14] There was significant reduction in the total cholesterol, triglyceride, LDL and elevation in HDL.[14]

Do HJ et al, reported that voglibose showed improved metabolic profiles including blood glucose, triglyceride and free fatty acids. The study by Moritoh Y et al, showed that plasma triglyceride levels were decreased in voglibose treated genetically modified ob/ob mice, compared with vehicle treated mice.[9] Fasting and post prandial blood glucose levels showed significant reduction after the administration of voglibose in both the groups (N+VO and HFD+VO) in this study, which was comparable to the results shown by other studies.

Yasuda K et al, summarised that the postprandial blood glucose levels in voglibose treated rats was significantly lower than in untreated rats.[15] These results indicate that voglibose may improve glucose tolerance since it inhibits activities of disaccharidases in spite of increasing the expression of them on intestine.

Jones RB et al, showed the combination of linagliptin and voglibose significantly reduced body weight, improved glycaemic control compared to linagliptin alone and control in Zucker Diabetic Fatty (ZDF) rats.[10,13] In a study by Vichayanat A et al, Voglibose (0.2mg) and acarbose (100mg), thrice daily, significantly reduced lHbA1c, PPBG and postprandial insulin levels.[16,14]

CONCLUSION

Voglibose prevented weight gain in rats with high fat diet and improvement in metabolic profiles seen. It can be used as an add on therapy with other antidiabetic drugs like sulfonylureas, pioglitazone which are responsible for weight gain, in obese patients with metabolic syndrome to improve metabolic profile, in prediabetic conditions to prevent development of type 2 diabetes mellitus. Further studies are needed to see its potential therapeutic use in obese patients and related complications.

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