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Comparative assessment of the efficacy of voglibose and metformin combined with insulin in patients with type 2 diabetes mellitus

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ABSTRACT

The present study was conducted to assess the efficacy of metformin and voglibose combined with insulin in patients with type II diabetes mellitus. This retrospective study was conducted in tertiary care hospitals of Salem district Tamil Nadu with 120 patients who are taking either metformin and insulin or voglibose and insulin according to the inclusion and exclusion criteria. The total number of patients were divided into two groups each consist of 60. Group A was the patients prescribed with metformin and insulin and group B was the patients prescribed with voglibose and insulin. The average efficacy of metformin and voglibose combined with insulin for 10 days, 20 days, 30 days & 40 days were compared using FBS, PPBS, RBS and HbA1C values. The result shows that patients treated with metformin and insulin, the average efficacy of FBS levels on 10, 20, 30 and 40 days were 22.96%, 27.46%, 30.49% and 36.78% respectively. Whereas in the case of voglibose and insulin the efficacy was 23.48%, 28.38%, 32.57%, 40.47% for 10, 20, 30 and 40 days respectively. In the same way, the PPBS, RBS and HbA1C levels were also calculated. While comparing both the groups of patients, the average efficacy of treatment with voglibose and insulin was more effective than metformin and insulin in the tertiary care Hospitals of Salem district.

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INTRODUCTION

Diabetes mellitus (DM) is a cluster of metabolic disorders characterized by hyperglycemia; which is associated with the abnormalities in the metabolism of carbohydrate, proteins and fats; which leads to chronic complications in macrovascular, microvascular and neuropathic disorders. Controlling the hyperglycemia and its related symptoms are most important. The major challenges in managing the DM patients are preventing or decreasing the complications, improving the quality of life and increasing the life expectancy. Over the past many decades, the efforts in research and development have provided valuable information to improve the outcomes and therapeutic effects in DM patients. In the current population, environmental factors and candidate genes are reported commonly, however, β-cell autoimmunity development occurs in less than 10% of population and progress to DM is less than 1% (DiPiro and Talbert, 2005).

90-95% of the diabetes populations are Type II diabetes, also known as non–insulin-dependent diabetes. The secretion of insulin is flawed in these patients and it is not sufficient to recompense the insulin resistance. The risk of evolving this kind

of diabetes increases with obesity, age and lack of physical activity. Women with prior Gestational DM are more prone to these types of diabetes and also the persons with hypertension and dyslipidemia, and it varies in different ethnic/racial subgroups (Shimazaki et al., 2007).

Worldwide, 8.8% of the adult population had diabetes in the year 2017. It estimates that it may increase to 9.9% in the year 2045 (Aziz et al., 2018). Currently, India represents 49% of the diabetes population of the world and in the year 2017 alone, 72 million new cases. It is also expected, to increase 134 million in the year 2025. The Indian Council of Medical Research sponsored study conducted by the Madras Diabetes Research Foundation reported that 1 out of 10 populations in Tamilnadu is a diabetic. In Tamilnadu, 13.5% of urban and 6.9% of the rural population was affected by DM.

Since the mortality and morbidity are very high in diabetes, the treatment for the above is mandatory. For type I diabetes, Insulin is the only treatment and is also prescribed to type II diabetes Patients, when their blood glucose levels are very high for type II diabetes, the oral hypoglycemic agents such as sulphonylureas (eg. Glipizide, Glimepiride) Biguanides (eg. Metformin), Meglitinides(eg. Repaglinide, Nateglinide), Thiazolidinediones(eg. Pioglitazone) and α- Glucosidase inhibitors (eg. Acarbose) are widely prescribed.

Though several oral antidiabetic drugs are available, we are in need to choose a drug, which is more efficacious in lowering the blood glucose level with less adverse effects. All the oral hypoglycemic agents have a different mechanism of action, and they are prescribed either alone or in combination (Kala et al., 2017).

Metformin is the first-line drug treatment and most commonly prescribed the drug for type II diabetes with the mechanism of decreasing hepatic glucose level and increasing the insulin sensitivity (Luna and Feinglos, 2001) (Yada et al., 2015). Voglibose is the recently identified α- Glucosidase inhibitor, which delays and limits the absorption of glucose. These two agents are widely prescribed to diabetes patients either alone or in combination with insulin. Since there is a limited study on its efficacy in combination (Shinozaki et al., 1996), the present study was focused to find out the efficacy of Metformin and Voglibose combined with Insulin.

MATERIALS AND METHODS

A total of 120 cases were collected from general medicine department of the hospitals during a period of 6 months (Nov 2017 – April 2018) from the various tertiary care hospitals at Salem district, Tamil Nadu. The purpose of the study was to conduct a detailed analysis of prescriptions based on the age and gender distribution, social history of patients, body mass index, duration of disease, the efficacy of Metformin and Voglibose combined with Insulin in respect to FBS, PPBS, RBS and HbA1C values.

Metformin is the first-line drug for the treatment of Type II DM. Recently voglibose is also preferred for some patients those are newly diagnosed with Type II DM (Li et al., 2014) (Chen et al., 2014). Both metformin and voglibose are used as either monotherapy or combined with other oral antidiabetics or insulin for the treatment of Type II DM (Ji et al., 2015). Even in direct comparison, both Metformin and voglibose were showed an equal glucose-lowering effect, but in indirect comparison, Metformin is slightly better than voglibose. The voglibose effect was better in patients of Eastern countries than in Western, where the Metformin showed no difference. However, no study was compared with the efficacy of voglibose and metformin combined with Insulin.

Out of 120 cases, the patients were categorized into five age groups. Majority of them were found to be between 41-60 years of age (60.8%), 22% between 61-80 years of age, 14% between 21-40 years of age and 3% between >80 years of age. Our study correlates with a study Conducted (Shivashankar and Dhandayuthapani, 2011) which showed that most of the patients of age group between 35-60 years were diagnosed with diabetes mellitus. 52% were males and 48% were females prescribed with either metformin and insulin or voglibose and insulin. Majority of the patients (48.3%) were found to be with normal BMI, 22.5% were overweight, 20.8% were underweight and 8.3% were obese.

The majority of patients (53.33%) were found to be taking metformin and insulin for less than five years, followed by 38.33%, 5%, 1.67% and 1.67% in 6-10, 11-15, 16-20 and 21-25 years respectively. Whereas in case of voglibose and insulin, the majority 56.6% was less than 5 years, followed by 33%, 5%, 1.6% and 3.3% in 6-10, 11-15, 16-20 and 21-25 years respectively Table 1.

RESULTS AND DISCUSSION

The efficacy of treatment of metformin with insulin and voglibose with insulin were compared based on percentage improvement of FBS, PPBS, RBS and HbA1C on the number of days undergone treatment like 10 days, 20 days, 30 days & 40 days.

Table 1: Distribution based on duration of diabetes: patient with metformin and voglibose combined with insulin

Duration	Metformin with insulin		Voglibose with insulin	
	No. of patients	Percentage (%)	No. of patients	Percentage (%)
≤5yrs	32	53.33%	34	56.67%
6-10yrs	23	38.33%	20	33.33%
11-15yrs	3	5%	3	5%
16-20yrs	1	1.67%	1	1.67%
21-25yrs	1	1.67%	2	3.33%

Table 2: Percentage reduction of efficacy on treatment with metformin and voglibose with insulin based on FBS, PPBS, RBS, and HbA1C

Duration	Percentage reduction of blood glucose levels							
	FBS		PPBS		RBS		HbA1C	
	Metformin and insulin	Voglibose and insulin	Metformin and insulin	Voglibose and insulin	Metformin and insulin	Voglibose and insulin	Metformin and insulin	Voglibose and insulin
10 days	22.96%	23.48%	20.90%	19.59%	10.70%	15.42%	11.14%	13.24%
20 days	27.46%	28.38%	24.27%	24.38%	26.21%	33.56%	22.39%	25.47%
30 days	30.49%	32.57%	28.25%	27.94%	37.30%	38.00%	27.26%	28.24%
40 days	36.78%	40.47%	39.15%	38.29%	54.20%	52.76%	37.26%	37.55%

The patients undergone treatment with metformin and insulin found their percentage of reduction in FBS was 22.96%, 27.46%, 30.49%, 36.78% respectively. Whereas in the case of voglibose and insulin the percentage of reduction was 23.48%, 28.38%, 32.57%, 40.47% for 10, 20, 30 and 40 days respectively. Hence the percentage improvement of efficacy in FBS level is 0.52%, 0.96%, 2.08%, 3.69% which shows a gradual increase of efficacy in group B.

The values of PPBS for the patient taken with metformin and insulin were 20.90%, 24.27%, 28.25% and 39.15% respectively and with voglibose and insulin was 19.59%, 24.38%, 27.94% and 38.29% respectively. Based on the RBS values from patient with metformin and insulin were found to be 10.7%, 26.21%, 37.30%, and 54.20% for 10, 20, 30 and 40 days respectively and patient with voglibose and insulin were found to be 15.42%, 33.56%, 38%, and 52.76% respectively. The percentage improvement of efficacy in RBS level was 4.72%, 7.35%, 0.7%, 1.44% which shows an increase of efficacy in group B.

Based on HbA1C values from a patient with metformin and insulin were found to be 10.7%, 26.21%, 37.30% and 54.20% for 10, 20, 30 and 40 days respectively and patient with voglibose and insulin were found to be 15.42%, 33.56%, 38% and 52.76%

respectively. The percentage improvement of efficacy in HbA1C level is 2.1%, 3.08%, 0.98%, 0.29% which shows an increase of efficacy in group B.

Hence from this comparison voglibose with insulin shows better percentage of improvement than metformin and insulin. The results are shown in Table 2.

CONCLUSION

Diabetes mellitus (DM) is a group of metabolic disorders characterized by hyperglycemia; is associated with abnormalities in carbohydrate, fat and protein metabolism; and results in chronic complications including microvascular, macrovascular, and neuropathic disorders. Diabetes mellitus is classified as type 1 and type 2 diabetes mellitus.

The present study was carried out to compare the efficacy of metformin with insulin and voglibose with insulin in type 2 diabetes mellitus at tertiary care Hospitals, Salem.

From the above results, it may be concluded that the voglibose with insulin-treated patients was the most effective when compared with the Metformin with insulin group of patients.

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