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Head to head comparison of *Nateglinide* versus *Glimepiride* monotherapy in Type-2 diabetes

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Abstract

Background- Continual hyperglycaemia is a well-known risk factor in type-2 diabetics for the micro- and macrovascular complications. There are a variety of drugs available for the treatment of type-2 diabetes and no fixed regime possible, which fits all. Therefore choosing an appropriate anti-diabetic agent from the available groups is a tricky process for prescribers. To this purpose, we studied the nateglinide versus glimepiride monotherapy in type-2 diabetes patients in a tertiary care hospital.

Method- The present prospective study was conducted to compare the effect of glimepiride and nateglinide in all patients with type – 2 diabetes attending general medicine OPD for three months between March 2011 to May 2011 at tertiary care hospital, Puducherry. The total number of patients was 40, equally divided into two groups. Fasting blood sugar with 140 to 220 mg/dl were included, and patients with diabetic complications and hepatic and renal disorders were excluded from the study. Group I consists of 20 newly diagnosed type – 2 DM taking glimepiride 1 mg and group -2 consists of 20 newly diagnosed type – 2 DM taking Nateglinide monotherapy 60mg once daily laboratory parameters like FBS, PPBS, HbA1c and lipid profile and have been measured before and after study. The study continued for three months and every two weeks; FBS and PPBS were measured. Mean, SD, and percentages were used to describe the data. Chi-square and unpaired "t" test were used appropriately as inferential tools. P value <0.05 was considered statistically significant.

Results- The mean change in FBS was 18.55% with the treatment group taking glimepiride 1mg and the mean change in FBS with nateglinide group was 22.35%. The mean change in PPBS was 16.78% in treatment with glimepiride 1mg group, and the mean change in PPBS in nateglinide was 22%. Mean change in the glycosylated haemoglobin was 10.5% with the group taking glimepiride and was with patient taking nateglinide was 16.49%.

Conclusion- It was obvious that both glimepiride and nateglinide are effective, but the decrease in PPBS and HbA1c% was more with nateglinide. A further study in the large population is essential to assess long-term postprandial glucose control and relationship to diabetic complications.

Keywords: Diabetes Type-2, Glimepiride, Nateglinide

Introduction

Diabetes is a potential epidemic in India with more than sixty-two million diabetic individuals presently diagnosed with the disease [1-2]. The morbidity and mortality due to diabetes and its complications pose significant healthcare burdens on individual families and society [3]. Persistent hyperglycaemia is a well-known risk factor for the micro- and macrovascular complications and especially for cardiovascular disorders [4-5]. Alteration in diet and lifestyle are habitually insufficient to produce fair, long-term metabolic control of diabetes; medication is required for the majority of patients [6]. Also, there are an extensive variety of options for pharmacotherapy of diabetes; there is no fixed regime available, which fits all [7]. Every drug has justification on which it could be considered first-line treatment for type-2 diabetes [8]. Therefore choosing an appropriate anti-diabetic agent from the available groups is a tricky process for prescribers [9]. Nateglinide is a rapid acting insulin-tropic agent unrelated to sulphonylureas [10-11]. Due its action on insulin secretion, Nateglinide has less potential to elicit hypoglycaemia than other sulphonylureas [12]. Furthermore, nateglinide has minimal or no effect on body weight, may be due its insulinotropic effects are limited to the postprandial period [13]. To this purpose, we studied the nateglinide versus glimepiride monotherapy in type-2 diabetes patients in a tertiary care hospital.

Methods

The present prospective study was conducted to compare the effect of glimepiride and nateglinide in the entire patients with type – 2 diabetes attending general medicine OPD for 3 months between March 2011 to May 2011 at Pondicherry Institute of Medical Sciences,

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Puducherry. The total number of patients participated in this study was 40, equally divided into two groups. All the patients with both sex and age group of 30 to 45 with fasting blood sugar 140 to 220 mg/dl were included and patients due to diabetic complications and hepatic and renal disorders were excluded from the study. Ethical committee has approved the study and patient information consent was obtained before conducting the study. Forty patient divided into two groups as per inclusion and exclusion criteria group I consists of 20 newly diagnosed type – 2 DM taking Glimepiride 1 mg and group -2 consists of 20 newly diagnosed type – 2 DM taking Nateglinide monotherapy 60mg once daily laboratory parameters like FBS, PPBS, HbA1c and lipid profile and have

been measured before and after study. The study was conducted for three months and for every 2 weeks FBS and PPBS were measured.

Statistical Analysis: Mean, SD and percentages were used to describe the data. Chi-square and unpaired "t" test were used appropriately as inferential tools. P value <0.05 was considered statistically significant.

Results

After 12week of treatment, all the parameter were repeated, as the patient were asked to undergo fasting and postprandial testing for every 15 days.

Table 1: Effect on FBS and PPBS (BT- Before treatment; AT – After treatment)

FBS	Glimepiride	BT	Mean	SE	T	P
		AT	161.2	7.60		
Nateglinide	Glimepiride	BT	166.4	7.54	6.00	<0.001
		AT	129.6	7.76		
PPBS	Nateglinide	BT	191.6	5.68	6.20	<0.001
		AT	133.6	9.14		
	Glimepiride	BT	201.2	9.0	5.0	<0.01
		AT	157.2	6.00		

Effect on FBS and PPBS

The mean change in FBS was 18.55% with the treatment group taking glimepiride 1mg and the mean change in FBS with nateglinide group was 22.35%.

The mean change in PPBS was 16.78% in treatment with glimepiride 1mg group, and the mean change in PPBS in nateglinide was 22%

Effect on Lipid Profile

The mean change in the serum TG was 5% with glimepiride 1mg and 17.64% with nateglinide group.

The mean change in the serum LDL was 5% in Pt taking glimepiride 1mg and 8% in Repaglinide group.

The mean change in cholesterol with pt taking glimepiride was 15%, but the mean change in cholesterol with nateglinide group was 6%.

The mean change in HDL concentration with Glimepiride group was 15% and whereas HDL with Nateglinide was 8%.

Table 2: Effect on Lipid profile (BT- Before treatment; AT – After treatment)

TG	Glimepiride	BT	Mean	SE	P
		AT	160.00	3.20	
Nateglinide	Glimepiride	BT	170.00	6.43	<0.05
		AT	150.00	8.90	
LDL	Nateglinide	BT	160.00	3.0	<0.05
		AT	140.00	4.14	
	Glimepiride	BT	166.00	3.2	<0.05
		AT	152.00	2.03	
CHOL	Nateglinide	BT	199.00	2.6	<0.001
		AT	170.00	3.42	
	Glimepiride	BT	200.00	2.77	<0.01
		AT	190.00	2.60	
HDL	Nateglinide	BT	42.00	1.26	<0.001
		AT	43.00	1.30	
	Glimepiride	BT	46.00	1.75	<0.05
		AT	46.00	1.70	

Effect on Hba1c

Mean change in the Glycosylated haemoglobin was 10.5% with a group taking Glimepiride and was with patient taking Repaglinide was 16.49%.

Table 3: Effect on Glycosylated haemoglobin (BT- Before treatment; AT – After treatment)

HbA1C	Glimepiride	BT	Mean	SE	P value
		AT	8.50	0.07	
Nateglinide	Glimepiride	BT	7.60	0.06	<0.001
		AT	9.3	0.20	
Nateglinide	Nateglinide	BT	7.3	0.17	<0.001
		AT	9.3	0.20	

Discussion

The major goal in the management of diabetes is to maintain blood sugar level as close to normal as possible [14]. Interestingly, insulin secretion was significantly greater when nateglinide was taken before a meal compared to nateglinide given in the fasted state or in response to just the meal [15]. Nateglinide is associated with a low risk of hypoglycemic events in placebo-controlled or active-controlled studies [16-17]. Nateglinide had more pronounced effects on reducing fasting plasma glucose and glucagon secretion, with no differences in post-prandial glucose and insulin secretion [18].

No major hypoglycaemic episodes and no reported minor hypoglycaemic events were found in the nateglinide group in a randomized, multicenter study, where patients were randomized to receive monotherapy with nateglinide [19].

Conclusion

It was evident that both glimepiride and nateglinide are effective, but the decrease in PPBS and HbA1c% was more with nateglinide. A further study in a large population is essential to assess long-term postprandial glucose control and relationship to diabetic complications.

Conflict of Interest: None

Acknowledgements: Department of Internal Medicine, Department of Biochemistry, PIMS Hospital, Puducherry.

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