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Non-interventional study report	
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An Epidemiological Screening Program to Evaluate the Level of Compensation in Type-2 Diabetes Mellitus Patients on Monotherapy with Oral Glucose-Lowering Agents and Physicians' Satisfaction of Their Use in Routine Practice: An Observational Non-Interventional Study

Time frame for the study conduct:	**Inclusion of the first patient:**
December 2010 – March 2011	December 9, 2010
	Study completion by the last patient: March 28, 2011

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STUDY REPORT SYNOPSIS

An Epidemiological Screening Program to Evaluate the Level of Compensation in Type-2 Diabetes Mellitus Patients on Monotherapy with Oral Glucose-Lowering Agents and Physicians' Satisfaction of Their Use in Routine Practice: An Observational Non-Interventional Study

TIME FRAME FOR THE STUDY CONDUCT

Inclusion of the first patient: December 9, 2010

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STUDY SITES

The study involved 50 study sites in 23 cities of Russia. The study used competitive enrollment of participants among study sites.

GOALS AND OBJECTIVES OF THE STUDY

Study goal

- To evaluate achievement of glycemic control and physicians' satisfaction with the treatment outcomes in T2DM patients on OGLA monotherapy over a treatment period of 6 months to 5 years, taking into account the main provisions of the Federal Program on Diabetes and current clinical practice.

Study objectives

Primary objectives:

- To assess the level of T2DM compensation as measured by HbA_{1c} in patients on OGLA monotherapy
- To assess the target HbA1c (*i.e.* $\leq$ 7%) achievement rate in patients on OGLA monotherapy

Secondary objectives:

- To assess fasting blood glucose levels in T2DM patients on OGLA monotherapy
- To assess postprandial blood glucose levels in T2DM patients on OGLA monotherapy
- To evaluate physicians' satisfaction with the outcomes of OGLA monotherapy in T2DM patients
- To compare outcomes of OGLA monotherapy between different patient groups.

STUDY DESIGN

This study was designed as a multicenter, retrospective, observational, non-interventional trial.

PATIENT ENROLLMENT CRITERIA

Inclusion criteria:

- Patients with an established diagnosis of type-2 diabetes mellitus (ICD-10 code is E.11)
- Age ≥ 40 years
- Patients who have been receiving OGLA monotherapy over a treatment period of 6 months to 5 years at inclusion (substitution of an OGLA for another is allowed within this period)
- Patients who provided their written informed consents to their personal data processing.

Exclusion criteria:

- Evidence of concomitant use of 2 or more OGLAs and/or insulin and/or incretin mimetics (such as exenatide) at any time before enrollment into the study
- No measurement of HbA_{c1} level available, performed within 12 months before the patient's enrollment into the study.

STUDY ENDPOINTS

Primary measured outcomes

- HbA_{1c} levels obtained before (however, within 12 months at the most) the patient's inclusion into the study while on OGLA monotherapy over a treatment period of 6 months to 5 years, and compared to the compensated T2DM values as defined by the National standards of diabetes care
- Proportion of patients (as a percentage of the total number of patients) who achieved the target levels of $HbA_{1c} \leq 7\%$ among T2DM patients on OGLA monotherapy over a treatment period of 6 months to 5 years.

Secondary measured outcomes

- Fasting blood glucose levels (where measured values are available) of T2DM patients on OGLA monotherapy over a treatment period of 6 months to 5 years, compared to the compensated T2DM values as defined by the National standards of diabetes care (see 13.4 for details)
- Postprandial blood glucose levels (where measured values are available) of T2DM patients on OGLA monotherapy over a treatment period of 6 months to 5 years, compared to the compensated T2DM values as defined by the National standards of diabetes care (see 13.4 for details)
- Physicians' satisfaction with the outcomes of OGLA monotherapy over a treatment period of 6 months to 5 years, based on completed Physician Questionnaires

– Comparison of outcomes of OGLA monotherapy between patient subgroups (formed based on gender, age, medications used at the time of HbA_{1c} measurement, dosages of these medications, disease duration, monotherapy duration at the time of HbA_{1c} measurement, and other factors, where necessary) if a particular subgroup is adequate for the purpose.

PATIENT POPULATIONS FOR ANALYSIS

Data were collected for 1,853 patients with T2DM. From those, 1,745 patients were included into the final analysis.

PATIENT DEMOGRAPHICS AND BASELINE CHARACTERISTICS

Parameter	Value	Minimum – maximum values	N
Age (years), average ± SD	60.8 ± 9.2	from 40.0 to 87.0	1735
Gender:		-	1744
Males (n, %)	477 (27.4%)	-	
Females (n, %)	1267 (72.6%)	-	
Body weight (kg), average ± SD	85.40 ± 16.26	from 39.00 to 178.00	1745
Height (m), average ± SD	1.65 ± 0.09	from 1.02 to 1.94	1745
Body mass index (kg/m^2), average ± SD	31.58 ± 5.82	from 15.43 to 95.24	1745

SUMMARY OF RESULTS

1) The levels of glycosylated hemoglobin (**(**HbA_{1c}) were found to be 7.29 ± 1.51% in T2DM patients on OGLA monotherapy over a treatment period of 6 months to 5 years.

2) As many as 52% of the patients achieved the target HbA_{1c} levels consistent with a compensated carbohydrate metabolism while on OGLA monotherapy over a treatment period of 6 months to 5 years. In addition, the remaining 48% of the patients did not achieve the target HbA_{1c} levels, while a third of the study subjects (32.8%) showed HbA_{1c} levels consistent with a decompensated carbohydrate metabolism. These findings are in agreement with literature data indicating that about 40% of diabetes patients on OGLA monotherapy do not achieve the target HbA_{1c} levels [8].

3) Fasting blood glucose levels were of 6.87 ± 1.85 mmol/L in T2DM patients receiving OGLA monotherapy over a treatment period of 6 months to 5 years.

4) Among the study population, 37.3% of the patients achieved the target fasting blood glucose levels consistent with a compensated carbohydrate metabolism (5.0 – 6.0 mmol/L), while the remaining 62.7% failed to achieve the target fasting blood glucose values. Moreover, the majority (47.2%) of the patients demonstrated fasting blood glucose levels consistent with a decompensated carbohydrate metabolism.

5) Postprandial blood glucose levels were found to be 8.2 ± 2.7 mmol/L in T2DM patients on OGLA monotherapy over a treatment period of 6 months to 5 years.

6) As many as 59.6% of the patients showed the target postprandial blood glucose levels consistent with carbohydrate metabolism compensation (7.5 – 8.0 mmol/L), while the remaining 40.4% did not achieve the target postprandial blood glucose values. Furthermore, 26.4% of the patients had postprandial blood glucose levels consistent with a decompensated carbohydrate metabolism.

7) Disease control was inadequate in 30.4% of the patients, assessed by treating endocrinologists as unsatisfactory or none. The physicians reported that they definitely would not use or were not likely to use the current OGLA monotherapy regimen in 22.7% of the patients in the future, while they would not recommend this regimen to their peers in 21.1% of the patients. In the majority of cases, the participating physicians agreed that the use of the current treatment regimen was only justified when combined with other therapeutic regimens. This applied both to using the current treatment regimen (56.0% of the patients) and recommending it to other physicians (64.6%).

8) The analysis of impact of various factors on HbA_{1c} levels did not reveal any correlations between HbA_{1c} levels and the patients' demographics. The study showed a direct correlation between HbA_{1c} levels and the patients' characteristics, such as body mass index, duration of diabetes, and duration of OGLA monotherapy.

9) The analysis of the effect of the last used OGLA on HbA_{1c} levels showed that HbA_{1c} levels were close to the target values in patients receiving metformin (HbA_{1c} = 7.05%), repaglinide (HbA_{1c} = 6.68%) as well as dipeptidyl peptidase-4 inhibitors, such as sitagliptin (HbA_{1c} = 6.60%), and vildagliptin (HbA_{1c} = 6.09%). Those who took sulfonylurea derivatives showed higher HbA_{1c} levels (from 7.33 to 8.31%). In addition, HbA_{1c} levels were found to be significantly higher in patients treated with glibenclamide compared to those who received any other OGLA.