Insulin Detemir vs. Glyburide in gestational diabetes mellitus

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Introduction

Pharmacologic therapy, either by oral hypoglycemic agents or by insulin, is indicated in 15%-30% of GDM cases that cannot be adequately controlled by lifestyle modifications alone (1).

While some randomized controlled trials clearly demonstrated the efficacy and short-term safety of Metformin and Glyburide for the treatment of GDM (2,3), insulin still remains the first-line agent recommended for treatment of GDM in the US.

It was recently published that Glyburide may be associated with a higher rate of neonatal hypoglycemia and macrosomia than insulin or Metformin (4). This may be due to a high concentration of Glyburide in umbilical cord plasma which is approximately 70% of maternal concentration (5).

On 2012 a multinational trial on the safety and efficacy of insulin Detemir for the treatment of women with type 1 diabetes reported reassuring safety and efficacy results (6).

The use of insulin Detemir in GDM has been hitherto only reported in one small study (7).

The purpose of our study was to compare the safety and efficacy of insulin Detemir versus Glyburide in women with GDM.

Materials and Methods

We performed a retrospective cohort analysis of women with singleton pregnancy and GDM, who were treated with either insulin Detemir or Glyburide in two medical centers in Israel.

GDM was diagnosed via the "Tow Step Procedure" of 50g oral glucose solution, followed by 100g oral glucose tolerance test. At least two abnormal values confirmed the diagnosis of GDM.

Pharmacologic treatment was introduced following a fortnight trial of diet if adequate glucose control was not obtained. Glyburide initial dose was 2.5 mg. The initial daily dose of insulin Detemir was 0.1U/kg. Patients were instructed to monitor their blood glucose level on a daily basis.

Maternal characteristics and maternal outcome (preeclampsia, weight gain), as well as neonatal outcome (birth weight and percentile, neonatal hypoglycemia, neonatal jaundice and respiratory morbidity) were compared between the two groups.

Parametric data are expressed as mean ± SD. Nonparametric data are expressed as absolute numbers.

Data analysis was performed with the SPSS v19.0 package (Chicago IL).

Results

Out of 115 women, 67 received insulin Detemir and 48 received Glyburide.

There was no difference in maternal characteristics in both groups.

Maternal weight gain and the incidence of PET were similar in both groups.

Neonatal outcomes were similar as well, apart from the incidence of neonatal hypoglycemia, which was significantly higher in the insulin Detemir group as compared to the group which received Glyburide (37% vs 16.3%, P=0.018).

Maternal characteristic	Glyburide (N=48)	Levemir (N=67)	P value
Age	33 ±5.59	34 ±4.37	0.3
BMI	27.6 ±4.27	29.7 ±6.5	0.07
Gravidity	3.22 ±2.13	3.1 ±1.68	0.799
Parity	1.39 ±1.32	1.46 ±1.28	0.759
. Maternal outcome			
PET	4 (8.3%)	7 (11.9%)	0.75
Weight gain	11.74 ±5.86	13.46 ±17.3	0.64
Neonatal outcome			
Birth weight	3229.9 ±488.2	3266.7 ±468.27	0.68
Percentile	63.6 ±25.7	62.49 ±25.68	0.82
Hypoglycemia	7 (16.3%)	25 (37.3%)	0.018
Neonatal jaundice	10 (23.3%)	11 (16.4%)	0.373
Respiratory morbidity	0	3 (4.5%)	0.279

Conclusions

In women with GDM, there was no difference in maternal outcomes (weight gain and PET) between those treated by Glyburide versus insulin Detemir. The neonatal outcomes were also similar in both groups, except for a significantly higher rate of neonatal hypoglycemia in the women treated by insulin Detemir.

These last results are in contrast to those of Balsells et al. (4), who found a higher rate of neonatal hypoglycemia, as well as macrosomia, in women with GDM who were treated with Glyburide as compared with insulin.

This discrepancy may be accounted for by the different types of insulin used in both studies - NPH by Balsells et al., vs. Detemir in the present study.

However, the number of subjects in this trial is too small to render significant conclusions.

Further trials on the efficacy and safety of insulin Detemir in GDM, of a larger scale, are therefore required.

References

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