DOI: https://doi.org/10.53350/pjmhs2115112928

ORIGINAL ARTICLE

To Compare Metformin Vs Insulin in Gestational Diabetes in Terms of Neonatal Hypoglycemia

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ABSTRACT

Aim: To compare metformin vs insulin in Gestational Diabetes in terms of neonatal hypoglycemia.
Methodology:
Study design: Randomized controlled trial
Setting: Obstetrics / Gynecology Unit-I, Holy Family Hospital, Rawalpindi.
Duration of study: 6 months i.e. 10-11-2017 to 10-05-2018
Data collection procedure: 240 patients were randomly allotted into two groups; A & B. Group A received metformin and group B received regular insulin. Patient was admitted at 36 wks onwards. Neonatal hypoglycemia was measured and entered in structured Performa. All the data was entered and analyzed through SPSS version 22.
Results: In this study, the mean ± sd ages of patients were 28.7±5.05 years in insulin group while 28.01±4.37years in metformin group. Mean neonatal blood sugar level was 51.58±11.77mg/dl in insulin group while 57.37±10.61mg/dl in metformin group. The difference was significant (p<0.05). In this study, neonatal hypoglycemia was noted in 28 (23.3%) cases with insulin while in 1 (0.8%) case with metformin. The difference was significant (p<0.05).
Conclusion: Metformin has better outcome than insulin in terms of less number of neonatal hypoglycemia.
Key words: Gestational Diabetes, Metformin, Insulin, Neonatal Hypoglycemia

INTRODUCTION

Approximately 4% of all pregnancies are complicated by GDM and it is increasing due to rising rates of obesity and more pregnancies in older women[2]. In Pakistan, the incidence of GDM is estimated to be about 3.45%[1]

Treatment of GDM is multidimensional starting with counseling and education regarding nutrition, diet, exercise and drugs; up to 50% of women will require pharmacologic therapy to meet glucose goals. Although insulin remains the only FDA-approved agent to treat GDM, oral hypoglycemic agents are an attractive and increasingly studied alternative in the recent years[3].

Because of the potential side effects with usage of insulin, the oral hypoglycemics are considered to be much required[4]. The use of oral metformin has considered as a cheap, safe and effective alternative to insulin in treating hyperglycemia in pregnancy[5].

The objective of the study was to compare metformin vs insulin in Gestational Diabetes in terms of neonatal hypoglycemia.

METHODOLOGY

This randomized controlled trial was conducted in Obstetrics / Gynecology Unit-I, Holy Family Hospital, Rawalpindi for 6 months i.e. 10-11-2017 to 10-05-2018. Sample size for both study groups was calculated using standard WHO sample size calculator as follows: Level of significance 5%, Power of test 80%**,** and Sample size is 120 in each group. Sampling technique used was non-probability consecutive sampling

Study design: Randomized controlled trial

Inclusion criteria:

1. Age 20-40yrs.
2. Patients between GA 20-28wks diagnosed for the first time as diabetics.
3. Patients with controlled blood sugar levels on the prescribed monotherapy.

Exclusion criteria:

- Patients with multiple gestations.
- Patients with acute severe complications of diabetes like DKA
- Patients having any contraindication to taking metformin.

Data collection procedure: The study was subjected to approval by the IRF of RMC& CPSP. Thorough history, examination, and investigations was done, the patients met the criteria of GDM was admitted both through the OPD and the emergency department. Informed consent was taken from the patients. Group A received metformin and group B received regular insulin. Patients fulfilled the selection criteria were given ID in chronological order and corresponding study group in random ID list were allocated to each patient. Six level blood sugar profiles were maintained for each group for one week during admission and dosage of both drugs adjusted accordingly. Good glycemic control was when the BSF was <90mg/dl and 2hr postprandial level <115mg/dl. All the data was analyzed through SPSS version 22.

RESULTS

Table 1: Age of patients

Age in years	Groups	
	B (Insulin)	A (Metformin)
N	120	120
Mean	28.65	28.01
SD	5.05	4.37
Minimum	20	20
Maximum	39	40

Table 2: Distribution of parity of females

Parity	Group		Total
	B (Insulin)	A (Metformin)	
1	37 (30.8%)	50 (41.7%)	87 (36.3%)
2	42 (35.0%)	40 (33.3%)	82 (34.2%)
3	13 (10.8%)	17 (14.2%)	30 (12.5%)
4	14 (11.7%)	6 (5.0%)	20 (8.3%)
5	7 (5.8%)	7 (5.8%)	14 (5.8%)
6	4 (3.3%)	0 (0.0%)	4 (1.7%)
7	3 (2.5%)	0 (0.0%)	3 (1.3%)
Total	120 (100%)	120 (100%)	240 (100%)

Received on 13-05-2021
Accepted on 27-10-2021

Table 3: Statistics of gestational age

Gestational Age (weeks)	Group	
	B (Insulin)	A (Metformin)
N	120	120
Mean	23.73	23.98
SD	2.31	2.46
Min	20	20
Max	28	28

Table 4: Neonatal hypoglycemia in both groups

Neonatal hypoglycemia	Group		Total
	A (Insulin)	B (Metformin)	
Yes	28	1	29
	23.3%	0.8%	12.1%
No	92	119	211
	76.7%	99.2%	87.9%
Total	120	120	240
	100%	100%	100%

Chi-Square Test = 28.593, p-value = 0.00 (Significant)

DISCUSSION

In this study, the mean age of patients was 28.7±5.05years in insulin group while 28.01±4.37years in metformin group. Data was stratified for age of mothers. In mothers aged 20-30 years, neonatal hypoglycemia was noted in 15(19%) patients in insulin group while 1(1.2%) in metformin group. The difference was significant ($p<0.05$). In mothers aged 31-40 years, neonatal hypoglycemia was noted in 13(31.7%) in insulin group while 0 (0.0%) in metformin group.. The difference was significant ($p<0.05$).

Saleh et al[6] conducted a study to evaluate efficacy of metformin in comparison to insulin for managing GDM. In prospective randomized comparative study, 150 antenatal women with GDM and did not respond to diet alone were recruited. No significant difference in controlling high blood sugar in GDM with the use of metformin or insulin (*P*=0.95, 0.15). Maternal complications in both groups had no significant difference and hypoglycemia occurred more in insulin group with *P* value 0.01. Glycaemic control in GDM can be achieved by using metformin orally without increasing risk of maternal hypoglycemia with satisfying neonatal outcome. In another study, Metformin is an alternative to insulin in the treatment of hyperglycemia during pregnancy. It decreases hepatic gluconeogenesis and improves peripheral glucose uptake[7]. It does not induce hypoglycemia. Evidence supporting the use of metformin in pregnancy is available from studies in patients with polycystic ovary syndrome[8].

CONCLUSION

Metformin has better outcome than insulin in terms of less number of neonatal hypoglycemia.

Conflict of interest: Nil

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