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Comparison of Effects of Different Treatment Modalities for Diabetic Pregnant Patients on Neonatal Complications

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Abstract **Original Research Article**

Background: Comparison of Effects of Different Treatment Modalities for Diabetic Pregnant Patients on Neonatal Complications. ***Patients and Methods:*** observational study among 160 antenatal type2-DM patients attending obstetrics department in lok-nayak hospital, Delhi from 2016-18 and their effects on neonatal complications. ***Results & Discussion:*** DM in pregnancy is associated with higher rates of poor foetal, maternal and perinatal outcomes. In women on Metformin, 19/80 (23.75%) women delivered newborns with birth weight appropriate for gestational age (AGA), none of the delivered newborns were SGA (small for gestational age) and 3/80 (3.75%) delivered newborns with birth weight LGA (large for gestational age). In women on Insulin, 3/80 (3.75%) women delivered newborns with birth weight AGA, none of the delivered newborns were SGA and 1/80(1.25%) delivered newborns with birth weight LGA. In women on Metformin + Insulin, 1/80 (1.25%) women delivered newborns with birth weight AGA, none of the delivered newborns were SGA and 2/80 (2.50%) delivered newborns with birth weight LGA. In both case and control groups, all newborns had APGAR score $\geq$7 at 5 minutes after birth, none of the newborns was admitted in NICU and none of the newborns had any complication like neonatal hypoglycemia, hyperbilirubinemia, asphyxia and early neonatal death. ***Conclusion:*** DM was associated with higher maternal age, gravidity and parity as compared to normal pregnant women. This may be explained by the fact that women with diabetes are older and hence have higher gravidity and parity. In pregnant women with type 2 DM, women who were on insulin and metformin –1/80 (1.25%) had the best results on new born on their birth weight followed by Insulin 3/80 (3.75%), followed by medical nutrition therapy followed by metformin. Which was statistically significant difference in the distribution of birth weight (AGA/SGA/LGA) in cases according to treatment modality which means medical therapy alone should be combined by insulin for best results.

Keywords: DM: Diabetes Mellitus AGA: appropriate for gestational age SGA (small for gestational age) LGA(large for gestational age).

INTRODUCTION

Higher rates of poor fetal, maternal and perinatal outcomes are present in pregnancy with diabetes mellitus (DM) as compared with normal pregnancy [1-3].

Pregnancy with Type 1 DM and type 2 DM are further complicated by congenital defects and fetal growth restriction in case of vasculopathy [4]. Various mechanisms have been postulated for fetal complications in pregnancy with diabetes. Hyperglycaemia during pregnancy leads to changes in maternal–placental blood flow. Hyperglycaemia causes an increase in the thromboxane / prostacyclin ratio in the umbilical vessels as well as the placenta, which leads to increase in placental vascular resistance in pregnancies with DM. As a consequence, redistribution of blood flow occurs from the peripheral vessels to the brain as a compensatory mechanism to the changes in placental hemodynamics Also increase in blood viscosity due to fetal polycythaemia may cause decrease in blood flow velocity through the fetal circulation resulting in adverse fetal outcomes.

MATERIAL AND METHODS

This randomised controlled trial was conducted on pregnant patients enrolled from either antenatal clinic or wards of the study hospital from

November, 2016 to April, 2018. A total of 160 patients were enrolled in this study.

Eighty consecutive diagnosed cases of Diabetes in pregnancy (Gestational Diabetes Mellitus and pre-gestational Diabetes) with period of gestation 34 to 40 weeks with good or excellent dates were enrolled as cases. Another eighty consecutives normal pregnant women with normal glucose tolerance test (GTT) matched for period of gestation (POG) were enrolled as controls. A detailed history and clinical examination were performed.

STATISTICAL EVALUATION

The data obtained was analysed using appropriate statistical test.

- Quantitative variables were determined using student t test or Mann Whitney test. Qualitative variables were determined by Chi-square test or Fisher exact test.
- P value of <0.05 was taken as significant.

DISTRIBUTION OF STUDY POPULATION ACCORDING TO PERIOD OF GESTATION AT DELIVERY

In case group, 7/80 (8.75%) women delivered before 37 weeks of gestation, whereas none of the women in control group delivered before 37 weeks of gestation. In case group 14/80 (17.50%) women delivered between 37-38 weeks, 23/80 (28.75%) women delivered between 38-39 weeks and 36/80 (45%) women delivered between 39-40 weeks. In control group 16/80 (20%) women delivered between 37-38 weeks, 20/80 (25%) women delivered between 38-39 weeks and 44/80 (55%) women delivered between 39-40 weeks. On comparison of both the group, p value was found to be 0.08 which was statistically not significant. Table 30 and Figure 34 depicts Distribution of study population according to period of gestation at delivery.

Table-1: Distribution of study population according to period of gestation at delivery

POG (weeks)	Total Study population (n = 160)		Cases		Controls		p value
	Freq	%age	Freq	%age	Freq	%age	
35-36	2	1.25	2	2.50	0	0.00	0.08
36-37	5	3.12	5	6.25	0	0.00	
37-38	30	18.75	14	17.50	16	20.00	
38-39	43	26.88	23	28.75	20	25.00	
39-40	80	50.00	36	45.00	44	55.00	

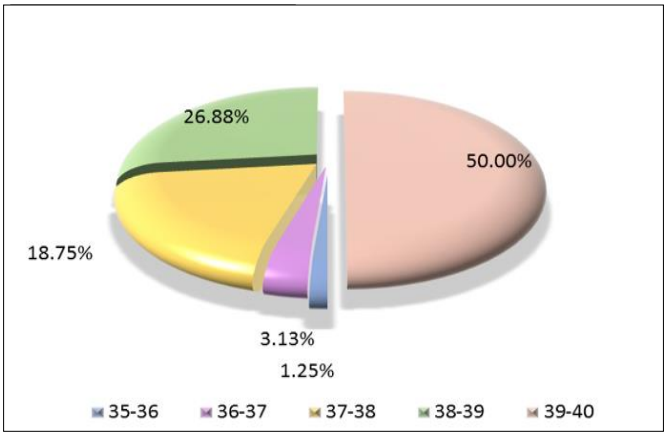

Fig-1: Distribution of period of gestation at delivery

DISTRIBUTION OF CASES AND CONTROLS ACCORDING TO NEONATAL BIRTH WEIGHT

In case group 15/80 (18.75%) women delivered newborn with birth weight < 2500 gms, 28/80 (35%) women delivered newborn with birth weight between 2500-2999 gms, 27/80 (33.75%) women delivered newborn with birth weight between 3000-3499 gms and 10/80 (12.50%) women delivered newborn with birth weight ≥3500 gms. In control group 6/80 (7.50%) women delivered newborn with birth weight < 2500 gms, 51/80 (63.75%) women delivered newborn with birth weight between 2500-2999 gms, 18/80 (22.50%) women delivered newborn with birth weight between 3000-3499 gms and 5/80 (6.25%) women delivered newborn with birth weight ≥3500 gms. On comparison, p value was found to be 0.002. Hence, there was statistically significant difference in the distribution of cases and controls according to neonatal birth weight. Table 32 and Figure 35 depicts distribution of cases and controls according to neonatal birth weight.

Table-2: Distribution of cases and controls according to neonatal birth weight

Birth weight (gms)	Total Study population (n = 160)		Cases		Controls		p value
	Freq	%age	Freq	%age	Freq	%age	
<2500	21	13.12	15	18.75	6	7.50	**0.002**
2500-2999	79	49.38	28	35.00	51	63.75	
3000-3499	45	28.12	27	33.75	18	22.50	
≥3500	15	9.38	10	12.50	5	6.25	

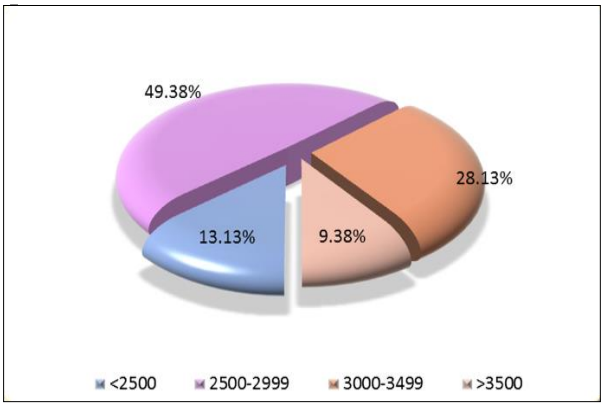

Fig-2: Distribution of neonatal birth weight

DISTRIBUTION OF BIRTH WEIGHT (AGA/SGA/LGA) IN CASES ACCORDING TO TREATMENT MODALITY

In case group, in women on Medical Nutrition Therapy, 44/80 (55%) women delivered newborns with birth weight appropriate for gestational age, 4/80 (5%) delivered newborns with birth weight small for gestational age and 3/80 (3.75%) delivered newborns with birth weight large for gestational age.

In women on Metformin, 19/80 (23.75%) women delivered newborns with birth weight appropriate for gestational age, none of the delivered newborns were small for gestational age and 3/80 (3.75%) delivered newborns with birth weight large for gestational age.

In women on Insulin, 3/80 (3.75%) women delivered newborns with birth weight appropriate for gestational age, none of the delivered newborns were small for gestational age and 1/80(1.25%) delivered newborns with birth weight large for gestational age.

In women on Metformin + Insulin, 1/80 (1.25%) women delivered newborns with birth weight appropriate for gestational age, none of the delivered newborns were small for gestational age and 2/80 (2.50%) delivered newborns with birth weight large for gestational age.

On comparison, p value was found to be 0.03. Hence, there was statistically significant difference in the distribution of birth weight (AGA/SGA/LGA) in cases according to treatment modality. Table-3 depicts distribution of birth weight (AGA/SGA/LGA) in cases according to treatment modality.

Table-3: Distribution of neonatal birth weight (AGA/SGA/LGA) in cases according to treatment modality

Basis of Controlled Blood Sugar Profile	Cases (n = 80)		AGA		SGA		LGA		p value
	Freq	%age	Freq	%age	Freq	%age	Freq	%age	
Medical Nutrition Therapy	51	63.75	44	55.00	4	5.00	3	3.75	**0.03**
Metformin	22	27.50	19	23.75	0	0.00	3	3.75	
Insulin	4	5.00	3	3.75	0	0.00	1	1.25	
Metformin + Insulin	3	3.75	1	1.25	0	0.00	2	2.50	

Distribution of APGAR score of newborn, NICU admission and stay and Neonatal complication

In both case and control groups, all newborns had APGAR score ≥7 at 5 minutes after birth, none of the newborns was admitted in NICU and none of the newborns had any complication like neonatal hypoglycemia, hyperbilirubinemia, asphyxia and early neonatal death.

CONCLUSION

Diabetes mellitus was associated with higher maternal age, gravidity and parity as compared to normal pregnant women (p value for age = 0.01, p value for gravidity = 0.003 and p value for parity = 0.0005). This may be explained by the fact that women with diabetes are older and hence have higher gravidity and parity.

In pregnant women with type 2 DM, women who were on insulin and metformin –(1/80 (1.25%) had the best results on new born on their birthweight followed by Insulin 3/80 (3.75%) , followed by medical nutrition therapy followed by metformin (p-value-0.03).

Which was statistically significant difference in the distribution of birth weight (AGA/SGA/LGA) in cases according to treatment modality which means medical therapy alone should be combined by insulin for best results.

Disclosure of Interests: No

(Including any financial, personal, political, intellectual or religious interests)

Contribution to Authorship

Dr. Aashima Aron: main author of the article who has carried out all the research work and had direct interaction with the patients.

Dr. Ankur Singhal: added help to the author in various technical nuances in the write of this article including statistics and correspondence.

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