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To Compare the Foetaldoppler Studies&Cerebroplacental Ratio (CPR)In Pregnant Women with Diabetes Mellitus (DM) as Compared to Normal Pregnancy at 36 Weeks to 38 Weeks Period of Gestation.

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Abstract
Background:
To compare the foetal doppler studies &CPR in diabetic pregnant patients, as compared to normal pregnancy at 36 weeks to 38 weeks period of gestation
Patients and Methods:
This prospective study has been carried out to investigate the association between pregnancy with diabetes, abnormal Doppler parameters and adverse pregnancy outcome and to compare the data with that of normal pregnancy.
Results& Discussion*:*
*Diabetes mellitus (DM) is one of the most important complication in pregnancy, associated with higher rates of poor foetal, maternal and perinatal outcomes. Therefore, this longitudinal study was conducted in pregnant women attending the antenatal clinic or admitted in the wards of Department of Obstetrics and Gynaecology, Lok Nayak Hospital, New Delhi**. The mean CPR in women with diabetes was 1.77+0.53 whereas it was 1.71+0.43 in normal pregnant women. The mean CPR in women with diabetes was more as compared to control. However, the difference was statistically not significant (p value = 0.43).In our study, the mean CPR was significantly higher in pregnant women with diabetes on hypoglycaemic agents as compared to control group (p value = 0.04).*
In case group two women had CPR<1, out of which 1had NVD and 1 had CS. In case group with CPR>1, 43 women had NVD, whereas 35 had CS. In control group, none of the women had CPR<1. In control group with CPR>1, 52 women had NVD, 24 had CShad vacuum assisted vaginal delivery and 2 had forceps assisted vaginal delivery. On comparison of case and control groups, p value was found to be 0.02 which was statistically significant.
According to our study, 1.7 is the best cut-off of CPR to predict the possibility of LSCS or Instrumental delivery for non-reassuring fetal heart rate.
For cut-off- 1.7, the Sensitivity is 62.10%, Specificity is 57.3%, PPV is 24.3% and NPV is 87.2%. High negative predictive value suggests that a normal CPR is associated with lower possibility for caesarean section.
Conclusion:*The mean CPR in pregnant women with DM was more& the mean CPR was significantly higher in women with diabetes on OHA's.Uncontrolled blood sugar profile in diabetic pregnant women was significantly associated with abnormal CPR values.It was further demonstrated that the mean MCA PI was higher in diabetics, which led to higher CPR.& a normal CPR is associated with lower possibility for caesarean section.*
Keywords*: DM: diabetes mellitus,GDM: gestational diabetes mellitus, UA: umbilical artery, GCA: gross congenital anomaly, MNT:medical nutrition therapy, GTT: Glucose Tolerance Test,OHA: oral hypoglycaemic agent, PI: Pulsatilityindex, RI: resistance index, MCA: Middle cerebral Artery, GA: gestational ag*e

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I. Introduction

Pregnancy with DM is associated with higher rates of poor foetal, maternal and perinatal outcomes compared with normal pregnancy.[i,ii,iii]In India, the prevalence of GDM is estimated to be at 10% to 14.3%.[iv]

Pregnancy with Type 1 DM and type 2 DM are further complicated by congenital defects and foetal growth restriction in case of vasculopathy.[v] Maternal complications include hypertensive disorders, increased rate for caesarean section and elevated risk of developing diabetes later in women. There is no consensus about best method for antepartum foetal surveillance in pregnancy with DM but the use of Doppler studies of the UA has demonstrated to reduce adverse perinatal outcome in diabetic as well as non-diabetic pregnancies.

II. Patients And Methods

- **Study Population:** Patients attending the antenatal clinic or admitted in the wards of Department of Obstetrics and Gynaecology, Lok Nayak Hospital, New Delhi.Cases of Gestational Diabetes mellitus (GDM) as diagnosed by International Association of Diabetes and Pregnancy Study Group (IADPSG) criteria, as defined below:

2-hour oral Glucose Tolerance Test (GTT) with 75 grams glucose[vi]

Plasma Glucose	Glucose Concentration Threshold (mg/ dl)
Fasting	92
One Hour	180
Two Hour	153

Inclusion Criteria for Cases

- Singleton pregnancy with no GCA on level II ultrasound
- Pregnancy with pre-gestational diabetes (Type 1 and Type 2 DM) on medical nutrition therapy (MNT) or any OHAs.

Inclusion Criteria for Controls:

Singleton low risk pregnancy with no GCA on level II ultrasound.

- Period of gestation – 34 to 40* weeks as defined above.
- No history of diabetes mellitus with normal GTT.

Exclusion Criteria For Cases And Controls:

- Foetal Growth Restriction
- Pregnant females with gestational hypertension, pre-eclampsia.
- Pregnant females with any major medical illness e.g. heart disease, chronic kidney disease
- Rh isoimmunisation defined as positive Indirect Coombs Test (ICT) in any titre.

III. Results

Comparison of ultrasound doppler parameters in pregnancy with diabetes v/s control group was measured for Umbilical Artery (UA), Middle cerebral Artery (MCA)&Cerebroplacental ratio as depicted in the following table

TABLE 1: Comparison of ultrasound doppler parameters in pregnancy with diabetes **v/s control group**

Sl. No.	Characteristic	Total Study population (n = 160)		Cases		Controls		p value
		Mean	SD	Mean	SD	Mean	SD	
1.	UA S/D	2.34	0.48	2.44	0.55	2.23	0.38	0.005**(significant)**
2.	UA PI	0.85	0.18	0.88	0.19	0.81	0.16	0.01**(significant)**
3.	UA RI	0.58	0.36	0.62	0.50	0.54	0.08	0.15
4.	MCA S/D	3.99	1.31	4.27	1.41	3.71	1.15	0.006**(significant)**
5.	MCA PI	1.42	0.29	1.50	0.31	1.34	0.23	0.0003**(significant)**
6.	MCA RI	0.72	0.08	0.74	0.08	0.71	0.07	0.01**(significant)**
7.	CPR	1.74	0.49	1.77	0.53	1.71	0.43	0.43

2: COMPARISON OF ULTRASOUND DOPPLER PARAMETERS IN PREGNANCY WITH DIABETES V/S CONTROL GROUP ACCORDING TO AVAILABLE NOMOGRAM FOR THE PERIOD OF GESTATION for Umbilical Artery, Middle Cerebral Artery (MCA)according to available nomogram for the period of gestation.

TABLE 2: Comparison of ultrasound doppler parameters in pregnancy with diabetes v/s control group according to available nomogram for the period of gestation

UA S/D	**Total Study population (n =160)**		**Cases**		**Controls**		**p value**
	Freq	**%age**	**Freq**	**%age**	**Freq**	**%age**	
Normal S/D Ratio (5-95 percentile for GA)	159	99.38	79	98.75	80	100.00	0.60
< 5 percentiles (for GA)	0	0.00	0	0.00	0	0.00	
Increased S/D Ratio (> 95 percentile for GA)	1	0.63	1	1.25	0	0.00	
UA PI	**Total Study population (n =160)**		**Cases**		**Controls**		**p value**
	Freq	**%age**	**Freq**	**%age**	**Freq**	**%age**	
Normal PI (5-95 percentile for GA)	133	83.13	71	88.75	62	77.50	0.05**(significant)**
Abnormal PI (< 5 percentile (for GA)	20	12.50	5	6.25	15	18.75	
Increased PI (> 95 percentile for GA)	7	4.38	4	5.00	3	3.75	
MCA S/D	**Total Study population (n 160)**		**Cases**		**Controls**		**p value**
	Freq	**%age**	**Freq**	**%age**	**Freq**	**%age**	
Normal S/D ratio (5-95 percentile for GA)	153	95.63	76	95.00	77	96.25	0.14
< 5 percentiles (for GA)	2	1.25	0	0.00	2	2.50	
Increased S/D Ratio > 95 percentiles (for GA)	5	3.13	4	5.00	1	1.25	
MCA PI	**Total Study population (n =160)**		**Cases**		**Controls**		**p value**
	Freq	**%age**	**Freq**	**%age**	**Freq**	**%age**	
Normal PI (5 to 95 percentile)	116	72.50	62	77.50	54	67.50	**0.01(significant)**
< 5 percentiles	40	25.00	14	17.50	26	32.50	
Increased PI (> 95 percentile)	4	2.50	4	5.00	0	0.00	

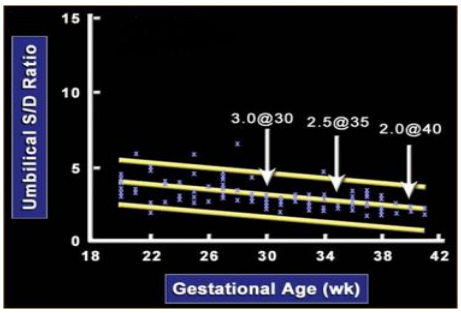

FIGURE 1a: Nomogram for UA S/D ratio

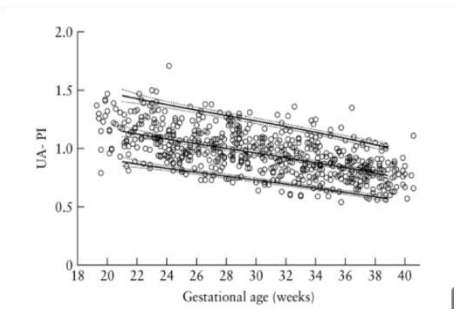

FIGURE 2b: Nomogram for UA PI

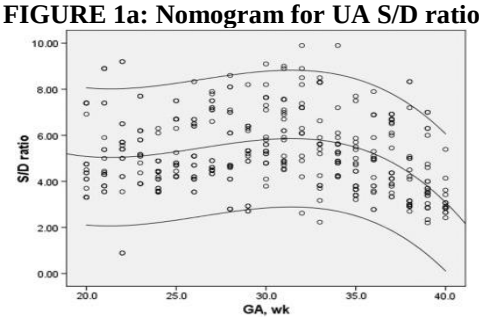

FIGURE 3c: Nomogram for MCA S/D ratio

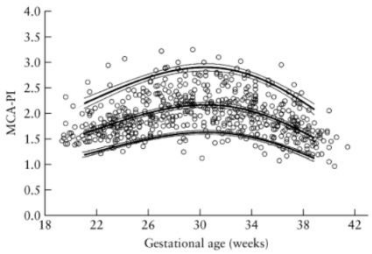

FIGURE 3d: Nomogram for MCA PI

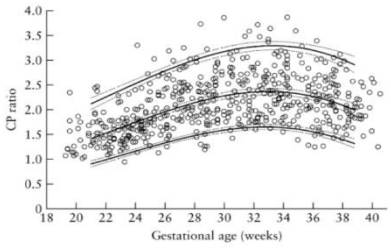

FIGURE 5e: Nomogram for CPR

3. COMPARISON OF ULTRASOUND DOPPLER PARAMETERS IN PREGNANCY WITH DIABETES V/S CONTROL GROUP ACCORDING TO PERCENTILE CALCULATED FROM OUR STUDY in Umbilical Artery (UA), Middle cerebral Artery (MCA)&Cerebroplacental ratio as depicted in the following table

Table 3

Ultrasound Doppler		Pregnancy with diabetes	Control Group	p value
Umbilical Artery	Normal S/D ratio	72	79	**0.04(significant)**
	Increased S/D ratio (>95th percentile)	8	1	
	Normal PI (5th to 95th percentile)	73	73	0.99
	Abnormal PI (<5th percentile)	3	4	
Middle Cerebral Artery	Normal S/D ratio	72	79	**0.04(significant)**
	Increased S/D ratio (>95th percentile)	8	1	
	Normal PI (5th to 95th percentile)	76	70	0.17
	Abnormal PI (<5th percentile)	3	3	
Cerebroplacental Ratio	<1	2	0	0.47
	>=1	78	80	

4. COMPARISON OF ULTRASOUND DOPPLER PARAMETERS IN PREGNANCY WITH DIABETES ON HYPOGLYCAEMIC AGENT V/S CONTROL GROUP in Umbilical Artery (UA), Middle cerebral Artery (MCA)&Cerebroplacental ratio as depicted in the following table:

TABLE 4: Comparison of ultrasound doppler parameters in pregnancy with diabetes on hypoglycaemic agent v/s control group

Ultrasound Doppler		Insulin, Metformin, Insulin + metformin (n=29)	Control Group (n=80)	p value
Umbilical Artery	S/D ratio	4.82+1.81	2.23+0.38	**0.0001(significant)**
	RI	0.77+0.08	0.54+0.08	**0.0001(significant)**
	PI	1.61+0.33	0.81+0.16	**0.0001(significant)**
Middle Cerebral Artery	S/D ratio	2.54+0.56	3.71+1.15	**0.0001(significant)**
	RI	0.59+0.10	0.71+0.07	**0.0001(significant)**
	PI	0.89+0.19	1.34+0.23	**0.0001(significant)**
Cerebroplacental Ratio		1.92+0.61	1.71+0.43	**0.04(significant)**

5. DISTRIBUTION OF CPR IN CASES AND CONTROLS ACCORDING TO MODE OF ONSET OF LABOUR (SPONTANEOUS/ INDUCED) isdepicted in the following table:

TABLE 5: labour (spontaneous/ induced)

Onset of labour	Cases				Controls				P value
	CPR<1		CPR>1		CPR<1		CPR>1		
Spontaneous Labour	1	1.25	32	40.00	0	0.00	56	70.00	**0.0004(significant)**
Induction of labour in view of features of placental insufficiency	0	0.00	36	45.00	0	0.00	22	27.50	**0.03(significant)**

6. DISTRIBUTION OF CPR IN CASES AND CONTROLS BASED ON MODE OF DELIVERY isdepicted in the following table:

TABLE 6: Distribution of CPR in cases and controls according tomode of delivery

Mode of delivery	Total Study population (n = 160)		Cases				Controls				p value
			CPR<1		CPR>1		CPR<1		CPR>1		
	Freq	%	Freq	%	Freq	%	Freq	%	Freq	%	
NVD with EPI	68	42.50	0	0.00	26	16.25	0	0.00	42	26.25	**0.02(significant)**
LSCS	60	37.50	1	0.63	35	21.88	0	0.00	24	15.00	
NVD	18	11.25	1	0.63	10	6.25	0	0.00	7	4.38	
NVD with Tear	9	5.63	0	0.00	7	4.38	0	0.00	2	1.25	
Vacuum with EPI	2	1.25	0	0.00	0	0.00	0	0.00	2	1.25	
Forceps with EPI	2	1.25	0	0.00	0	0.00	0	0.00	2	1.25	
Breech with EPI	1	0.63	0	0.00	0	0.00	0	0.00	1	0.63	

7. DISTRIBUTION OF STUDY POPULATION BASED ON EMERGENCY CAESAREAN SECTION (CS)/ INSTRUMENTAL DELIVERY IN VIEW OF NON-REASSURING FETAL HEART RATE (FHR)

TABLE 8 Distribution of study population based on emergency CS/ instrumental delivery in view of non-reassuring FHR

LSCS FOR NRFHR/ OTHER REASONS	Total Study population (n = 160)		Cases		Controls		p value
	Freq	%age	Freq	%age	Freq	%age	
1	25	15.63	12	15.00	11	13.75	**0.03**
2	35	21.88	24	30.00	13	16.25	
3	97	60.63	44	55.00	53	66.25	
4	3	1.88	0	0.00	3	3.75	

8. RECEIVER OPERATING CHARACTERISTIC CURVE

In our study, when Receiver Operating Characteristic (ROC) curve of CPR was plotted for CS or Instrumental delivery for non-reassuring foetal heart rate, then area under the curve was 0.555 (Figure 36). This shows that in our study, CPR is not a good parameter to predict the possibility of CS or Instrumental delivery for non-reassuring foetal heart rate.

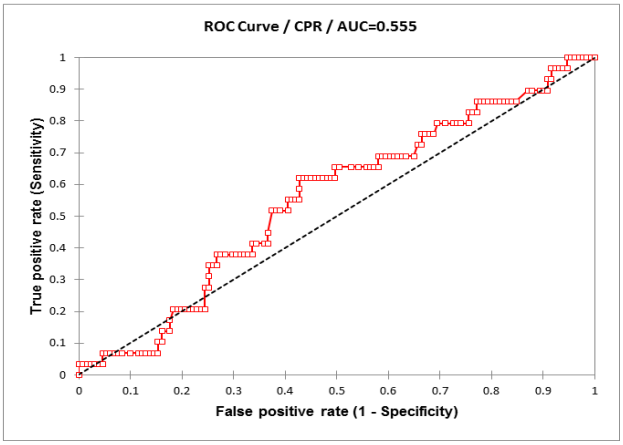

FIGURE 6: ROC curve of CPR predicting CS or instrumental delivery for non-reassuring foetal heart rate

IV. Discussion

Diabetes mellitus (DM) is one of the most important complication in pregnancy, associated with higher rates of poor foetal, maternal and perinatal outcomes compared with normal pregnancies.[1,2,3]

Doppler studieshave emerged as an important predictor of adverse perinatal outcome in situations like FGR and gestational hypertension. CPR is calculated by dividing the Doppler indices of the MCA by the UA.[8] CPR represents the interaction of alterations in blood flow to the brain as manifest by increased diastolic flow due to cerebrovascular dilation resulting from increased placental resistance and decreased diastolic flow of the UA.[9]Therefore, this longitudinal study was conducted in pregnant women attending the antenatal clinic or admitted in the wards of Department of Obstetrics and Gynaecology, Lok Nayak Hospital, New Delhi

i. Mean CPR

The mean CPR in women with diabetes was 1.77+0.53 whereas it was 1.71+0.43 in normal pregnant women. The mean CPR in women with diabetes was more as compared to control. However, the difference was statistically not significant (p value = 0.43).

According to a study conducted by Zanjani et al[6], there was no statistically significant difference in the ratio between the PIs of foetal MCA and UA, CPR, in GDM versus normal pregnancy group. The result of our study was thus comparable to the above study.

ii. Comparing CPR Value with available Nomogram and Percentile Calculated from Our Study

There was no statistically significant difference in CPR between case and control group in our study.

iii. Comparing CPR Between Pregnant Women on Hypoglycaemic Agents and Control Group

In our study, the mean CPR was significantly higher in pregnant women with diabetes on hypoglycaemic agents as compared to control group **(p value = 0.04**). According to the study conducted by

Gibbons et al[17], it was concluded that there was no statistically significant difference in CPR in women with GDM stratified according to treatment by diet, oral hypoglycaemic agent or insulin.

DISTRIBUTION OF CPR IN CASES AND CONTROLS ACCORDING TO MODE OF ONSET OF LABOUR (SPONTANEOUS/ INDUCED)

In case group two women had CPR<1, out of which 1had NVD and 1 had CS. In case group with CPR>1, 43 women had NVD, whereas 35 had CS. In control group, none of the women had CPR<1. In control group with CPR>1, 52 women had NVD, 24 had CShad vacuum assisted vaginal delivery and 2 had forceps assisted vaginal delivery. On comparison of case and control groups, p value was found to be 0.02 which was statistically significant.

MODE OF DELIVERY FOR NON-ASSURING FETAL HEART RATE ACCORDING TO CPR: According to our study, 1.7 is the best cut-off of CPR to predict the possibility of LSCS or Instrumental delivery for non-reassuring foetal heart rate.

For cut-off- 1.7, the Sensitivity is 62.10%, Specificity is 57.3%, PPV is 24.3% and NPV is 87.2%. High negative predictive value suggests that a normal CPR is associated with lower possibility for caesarean section.

V. Conclusion

- The mean CPR in diabetic was more than control. However, the difference was not statistically significant. This can be explained by the fact that the mean MCA PI was higher in diabetics than controls.
- The mean CPR was significantly higher in women with diabetes on hypoglycaemic agents as compared to controls (**p value = 0.04**). This may be explained by the fact that women on hypoglycaemic agents have more severe metabolic changes leading the severe placental insufficiency.
- Uncontrolled blood sugar profile in diabetic pregnant women was significantly associated with abnormal CPR (**p value =0.01**). This may be explained by the fact that hyperglycaemia due to uncontrolled blood sugar profile involves the uterine artery by diabetic vasculopathy and affects the development of an effective utero-placental blood flow.
- It was observed that the mean CPR was significantly higher in pregnant women with diabetes on hypoglycaemic agents as compared to the controls, as diabetic women on hypoglycaemic agents have more severe metabolic changes.
- It was further demonstrated that the mean MCA PI was higher in diabetics, which led to higher CPR. Hence, higher cut-off values of CPR are needed to predict adverse perinatal outcome in pregnancy with diabetes.
- However, further study with larger sample size is needed to establish the role of CPR in pregnancy with diabetes and to assess the correlation between CPR and adverse perinatal outcome.

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(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. SHAKUN TYAGI acted as guide to the main author and planning out of the article and under her observer ship this study was carried out.
DR. Y.M. MALA- acted as co-guide to the main author and planning out of the article and under her observer ship this study was carried out.
DR ANJALI PRAKASH-acted as co-guide to the main author and planning out of the article and under her observer ship this study was carried out.
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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