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A Prospective Cohort Study on Comparison of Umbilical Artery Doppler and Non-Stress Test in Assessment of Fetal Well-Being in Gestational Diabetes Mellitus

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Abstract

Background: *Gestational diabetes mellitus (GDM) is among the most common medical complications of pregnancy. The disease has important health implications for both mother and child. Various studies with fetal Doppler and non-stress tests were done to evaluate early predictors of adverse perinatal outcomes to prevent maternal morbidity and neonatal outcomes, but usually, Middle Cerebral Artery (MCA) Doppler and Umbilical Artery (UA) Pulsatility index were assessed. This study emphasizes on umbilical artery S/D (systolic versus diastolic) ratio in combination with a non-stress test and compares which of these two non-invasive tests in later gestations of pregnancy will be a better predictor for adverse perinatal outcomes in pregnancies affected with GDM.*

Methods: *This prospective cohort study was conducted at a teaching hospital in India spanning over eighteen months. We included women above 18 years of age with singleton intrauterine pregnancy with GDM as per IADPSG criteria at gestation 32-36 weeks as calculated from the last menstrual period. These patients underwent non-Stress tests and transabdominal sonography with Umbilical artery Doppler for the ratio of systolic and diastolic values every 2 weeks till termination of pregnancy. The last assessment just before the termination of pregnancy was considered for comparisons and an assessment of poor fetal outcomes was done. Data were recorded in an MS Excel spreadsheet program and analysis was performed using SPSS v23 (IBM Corp.).*

Results: *Results of this study have shown that the NST was a better modality for fetal assessment than the UA Doppler in the prediction of neonatal outcomes in pregnancy complicated with GDM. The incidence of poor composite fetal outcomes was 13.9%. USG had a sensitivity of 18.2% in predicting poor neonatal outcomes while NST had a sensitivity of 45.5%. NST was found to have a significant association with mode of delivery($p<0.001$) and fetal outcomes in terms of APGAR at 1($p=0.001$) and 5 minutes($p=0.009$), NICU admission($p<0.013$). The specificity of USG was 97.1% and NST was 86.8% for poor fetal outcome. No significant association was found between the UA S/D ratio and poor neonatal outcomes.*

Conclusion: *In this study, we attempted to find an easy and effective tool of assessment for fetal well-being by comparing the famous two methods – UA S/D and NST. This study validates that in pregnancies complicated with gestational diabetes mellitus, NST is a better predictor of poor neonatal outcome in comparison to the umbilical artery S/D ratio.*

Introduction

One of the most common metabolic disorders affecting pregnancy is Gestational Diabetes Mellitus (GDM), defined as impaired carbohydrate tolerance with onset or first recognition in pregnancy(1). Pregnancy confers a state of insulin resistance and hyper-insulinemia that may predispose some women to develop GDM (1). Gestational diabetes mellitus (GDM) occurs when a woman's pancreatic function is inefficient to overcome the diabetogenic state of pregnancy (1). In India, the prevalence rate of GDM in urban areas is reported to be 11-18% and in rural areas, it is around 8-10%(2).

The disease has important health implications for both mother and child (3). The most frequent adverse events include the increased risk of birth trauma to both mother and baby at the time of delivery due to macrosomia and the higher incidence of preterm deliveries, cesarean sections, episodes of neonatal hypoglycemia, hypocalcemia, hypomagnesemia, polycythemia, hyperbilirubinemia and respiratory distress syndrome and prematurity, all of which increases the risk of perinatal morbidity and mortality(4),(5),(6),(7). Infants of diabetic mothers are also predisposed to risk of obesity, diabetes, and cardiovascular disease later in life (8).

Most of the above-mentioned adverse perinatal outcomes are placental-associated. It is confirmed that uterine Doppler evaluation can predict occurrences of most of these adverse perinatal outcomes and thus helps improve these adverse outcomes in near-term pregnancies (9). Non-stress test (NST) is nowadays routinely used as an easy method of fetal monitoring prenatally usually in the third trimester to monitor fetal well-being before delivery in high-risk pregnancies when there is suspicion of fetal hypoxemia (10). Although UA Doppler studies have been shown to be more effective than cardiotocography and biophysical profile for predicting the adverse outcome in diabetic pregnancies, fetal compromise was shown to occur in association with normal Doppler studies in these pregnancies as well (11). Also, NST does not require much expertise and also cost-effective, thus can be easily incorporated as a routine test of fetal surveillance on an out-patient basis in high-risk pregnancies like GDM.

Various studies have been done with the aim to establish a better modality for fetal surveillance and prediction of adverse perinatal outcome in pregnancies complicated with GDM but the differing results open scope for more research and discussion related to this concern. This study compares the umbilical artery S/D (systolic versus diastolic) ratio with non- stress test to look for which among these two non-invasive tests in later gestations of pregnancy will be a better predictor for adverse perinatal outcome in pregnancies affected with GDM.

Materials and Methods

Study design

This was a prospective cohort analytical study conducted over a period of 18 months at a government teaching hospital in Central India.

Inclusion Criteria

All women with GDM of age 18 years and above with singleton pregnancy with intact membranes at period of gestation 32-36 weeks (calculated by LMP by Naegele's rule or by the measurement of fetal crown-rump length at 11-13 weeks or by fetal head circumference at 19-24 weeks). Diagnosis of GDM was done when at least one measurement of OGTT exceed the cut-off. The cut-offs will be a GTT ≥92mg/dl,180mg/dl, and 153mg/dl in fasting, one and two hours after oral intake of 75mg glucose respectively as per IADPSG criteria.

Exclusion Criteria

As per history and evaluation, Pre-existing type 1 or type 2 diabetes mellitus, women with life-threatening medical conditions at the time of participation in the study, and women with fetal anomalies detected in the first half of the pregnancy were excluded from the study. Also, women who did not consent to participate in this study were not included in the study.

Data Collection

Patients meeting the inclusion criteria, had a diagnosis of gestational diabetes mellitus (GDM) as per IADPSG criteria, defined as at least one measurement exceeding the cut-off with a 75gm OGTT and cut-off labeled as ≥92mg/dl, 180mg/dl and 153mg/dl in fasting, one and two hours after oral intake of 75mg glucose respectively. These GDM-labelled patients with period of gestation between 32-36 weeks had undergone non-Stress test and transabdominal sonography with Umbilical artery Doppler for the ratio of systolic and diastolic values at every 2 weeks till termination of pregnancy. History of the period of gestation when GDM was diagnosed in this pregnancy and what treatment she was taking regarding this condition was noted.

UA Systolic/Diastolic ≥3 was considered abnormal. The NST involved 20 minutes of monitoring of FHR and its variation in terms of baseline, beat-to-beat variability, accelerations, and deceleration. The

result of the test was interpreted as reactive or nonreactive. In cases of non-reactive NST, it was extended for another 20 minutes. Women with a non-reactive test were also examined in further tests and interventions regarding oxygenation, left lateral position, hydration, discontinuation of any drugs like oxytocin, etc. Physical examination of each neonate was carried out and the condition was evaluated for any complication.

Adverse perinatal outcomes were considered as delivery before 37 weeks, cesarean deliveries, Apgar scores at 5-min <7, hypoglycemia, neonatal acidosis, hypocalcemia, hyperbilirubinemia requiring phototherapy, admission to the NICU for more than 24 hours, perinatal death, fetal growth restriction (FGR). Poor fetal outcome was considered if hospital stay is prolonged for baby for more or equal to 7 days due to above mentioned factors.

Statistical Analysis

Data were coded and recorded in the Microsoft Excel spreadsheet program. Data analysis was performed using SPSS v23 (IBM Corp.).

Results

A total of 80 patients were included in the study. Out of them 79 had follow up as per the protocol and 1 patient was lost to follow up. The mean Age (Years) of patients was 29.26 ± 4.05. 52.5% of the participants were primigravida and 47.5% of the participants were Multigravida. The mean BMI (Kg/m^2) among participants was 27.67 ± 2.84. 71.2% of patients were diagnosed with GDM at 32-36 weeks of gestation.72.5% were on Medical Nutrition Therapy (MNT) with only 12.5% patients received insulin treatment.77.5% patients have controlled blood sugar levels with treatment.

On regular follow up as per protocol, 94.9% participants had Normal USG and 82.5% participants had reactive NST. The mean POG at Birth (Weeks) was 37.76 ± 1.25. The mean Birth Weight (kg) was 2.83 ± 0.43. The mean APGAR (5 Minutes) was 8.71 ± 0.66. 27 babies had NICU Admission, 13 had IUGR, 10 babies had Acidosis, 10 of babies developed hypoglycemia, 3 developed hypocalcemia and 21 neonates developed Hyperbilirubinemia.

Incidence of poor fetal outcome was 13.9%.

Table 1: Association Between USG Impression and Composite Fetal Outcome (n = 79)

Composite Fetal Outcome	USG Impression			Fisher's Exact Test	
	Normal	Abnormal	Total	χ2	P Value
Good	66 (88.0%)	2 (50.0%)	68 (86.1%)	4.575	0.091
Bad	9 (12.0%)	2 (50.0%)	11 (13.9%)		
Total	75 (100.0%)	4 (100.0%)	79 (100.0%)		

There was no significant difference between the various groups in terms of distribution of Composite Fetal Outcome ($\chi2 = 4.575$, $p = 0.091$).

Table 2: Association Between NST Impression and Composite Fetal Outcome (n = 79)

Composite Fetal Outcome	NST Impression			Fisher's Exact Test	
	Reactive	Non-Reactive	Total	χ2	P Value
Good	59 (90.8%)	9 (64.3%)	68 (86.1%)	6.741	0.021
Bad	6 (9.2%)	5 (35.7%)	11 (13.9%)		
Total	65 (100.0%)	14 (100.0%)	79 (100.0%)		

There was a significant difference between the various groups in terms of distribution of Composite Fetal Outcome ($\chi2 = 6.741$, $p = 0.021$).

Table 3: Description of Variables

Variable	Category(s) Suggesting Outcome Present	Category(s) Suggesting Outcome Absent	Total Positives	True Positives	True Negatives	False Positives	False Negatives
Composite Fetal Outcome	Poor	Good	11 (13.9%)	-	-	-	-
USG Impression	Abnormal	Normal	4 (5.1%)	2 (3%)	66 (84%)	2 (3%)	9 (11%)
NST Impression	Non-Reactive	Reactive	14 (17.7%)	5 (6%)	59 (75%)	9 (11%)	6 (8%)

4 patients had abnormal USG with UA S/D ≥3 and 14 patients had non-reactive NST.

Composite poor fetal outcome was noted in 11 neonates.

Table 4. Primary Diagnostic Parameters

Variable	Sensitivity	Specificity	PPV	NPV	Diagnostic Accuracy
USG Impression	18.2% (2-52)	97.1% (90-100)	50.0% (7-93)	88.0% (78-94)	86.1% (76-93)
NST Impression	45.5% (17-77)	86.8% (76-94)	35.7% (13-65)	90.8% (81-97)	81.0% (71-89)

Sensitivity of NST was 45.5% and USG was 18.2% with diagnostic accuracy of 81% and 86.1% respectively.

Discussion

In our study, there were 11 neonates with poor composite fetal outcome. 5.1% of the participants had abnormal USG over 2 weekly follow up (UA S/D ≥3) and 17.5% participants had non-reactive NST. USG had sensitivity of 18.2% in predicting poor neonatal outcome while NST had sensitivity of 45.5% with diagnostic accuracy of 86.1% and 81% respectively. The specificity of USG was 97.1% and NST was 86.8% for poor fetal outcome. Previously a study done, Zhan et al(12) in 2004 where cases with GDM and control group were taken and abnormal NST was more associated with GDM group ($P<0.05$) and association of abnormal NST with adverse fetal outcome was also noted. Studies like Subramanian et al have shown role of NST as an effective fetal monitoring tool in high-risk pregnancies(13). In this study also, we have observed non-reactive NST are more related to LSCS and poor neonatal outcomes in comparison with reactive NST. Unlike, previous studies like Bracero et al(14), where significant association between UA S/D with adverse neonatal outcome was noted with p value<0.001, in this study no significant association was found between UA S/D and adverse neonatal outcome.

A similar study was done in women with GDM, Niromanesh et al(11), which concluded NST as more powerful than the UA Doppler in the prediction of neonatal outcomes. Our results were consistent with this study and the results of our study demonstrates that the sensitivity and specificity of the NST in the prediction of neonatal outcomes is acceptable with higher sensitivity than the UA Doppler. NST

has significant association with mode of delivery in GDM patients, APGAR at 1 and 5 min, NICU admission and poor composite fetal outcome ($p<0.05$) while UA S/D was not significantly associated with these parameters.

Limitations

The study was undertaken during the COVID-19 pandemic, which resulted in a small sample size. Comparison of these tests are all time related. For example, if NST done 1 day before delivery might have a better sensitivity because it is known that loss of variation and late decelerations necessitate immediate termination and Doppler velocimetry becomes more predictive when there is absent or reverse diastolic flow velocity. Confounding factors like other high-risk factors like hypertension, IHCP and other medical disorder in pregnancy couldn't be eliminated which themselves can affect the perinatal outcome.

Conclusion

Results of this study have shown that the NST was better modality for fetal assessment than the UA Doppler in the prediction of neonatal outcomes in pregnancy complicated with GDM. NST does not require much expertise and also cost-effective, thus can be easily incorporated as routine test of fetal surveillance as an out-patient basis in high-risk pregnancies like GDM. Those with abnormal Doppler with reactive NST could be successfully monitored rather than planning immediate termination and pregnancy can be prolonged so that the sufficient time is available for steroid prophylaxis and fetal maturity. On the contrary, a non-reactive NST with a normal Doppler study warrants to look for cause of non-reactive NST and in most cases immediate termination of pregnancy is planned if NST continued to be non-reactive despite interventions. But considering the high false-positive rate of NST, it will be better to wait before planning termination of pregnancy and take a wise decision to avoid unnecessary caesarean sections. Each test reflects different aspects of maternal and fetal pathophysiology and it is advisable to repeat the test and combine with other modes of fetal surveillance before making decision based on single test alone in high-risk pregnancies to improve the perinatal outcome and for better prediction of adverse events.

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