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Comparison of Outcome in Women with Non-Reactive Cardiotocography versus Non-Reactive Cardiotocography and Fetal Scalp Blood Sampling

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ABSTRACT

Background: Intrapartum assessment of the fetus is a challenging task. And a good fetal surveillance during labour often entails monitoring the fetal heart rate with cardiotocography (CTG). The fetal heart rate pattern is an indicator of medullary response of fetal brain to the acidemia, blood volume changes and hypoxemia, as the brain modulates the fetal heart rate. But specificity of CTG is low that's why generally intrapartum cardiotocography is combined with a second variable, such as Fetal Scalp Blood sampling, to improve its specificity. The increased intervention rates associated with non-reactive cardiotocography can be reduced with the use of fetal scalp blood sampling. **Objectives:** To compare frequency of caesarean section with use of non- reactive Cardiotocography versus non-reactive Cardiotocography and fetal scalp blood sampling. To determine the immediate neonatal outcome in terms of death, Apgar score and need for intensive care unit admission after delivery. **Study Design:** This study was cross sectional analytical study. **Settings:** Obstetrics and Gynaecology department, Unit-I, Lady Willingdon Hospital, Lahore, affiliated with King Edward Medical University. **Duration:** The duration of study was 1 year. **Methodology:** The non-probablity purposive sampling technique was used in this study. 100 patients in labour at term presented to labour room of Lady Willingdon Hospital, and fulfilling the inclusion criteria were enrolled in this study. After taking informed written consent, the patients were divided into two groups (A and B). In group A, 50 cases having non-reactive Cardiotocography were taken and according to fetal assessment by Cardiotocography all were taken for caesarean section. In group B, 50 cases having non-reactive Cardiotocography were taken and fetal assessment was done by continuous Cardiotocography as well as fetal scalp blood sampling. In group B, fetal hypoxia was assessed by fetal blood pH. Only those cases in group B underwent caesarean section, where fetal hypoxia was confirmed by fetal blood pH (pH=<7.20). Apgar score at 1 min and 5 min and admission to neonatal intensive care unit (NICU) was noted for postnatal fetal assessment in both the groups. Data was entered and analyzed through SPSS version 21. To calculate sensitivity, specificity, Positive predictive value (PPV), negative predictive value (NPV) and fetal scalp blood pH 2x2 tables were generated, taking pH as gold standard. **Results:** In this study among 100 patients, the mean age of the patients was noted as 27.64±4.38 years and the mean gestational age was noted as 39.30±1.05 weeks. The mean Apgar score at 1 minute of the baby was noted as 5.62±1.39, whereas at 5 minutes was noted as 6.76±2.09. In group B among 50 cases the mean pH value of fetal scalp blood was noted as 7.25±0.048. Fetal scalp blood sampling was normal in 20/50 (40%) patients, borderline in 24/50 (48%) patients, whereas it was abnormal in 6/50 (12%) patients. In group A, among 50 cases all underwent lower segment Caesarean section (LSCS). In group B, among 50 cases, 30/50 (60%) cases underwent LSCS while 20/50 (40%) underwent spontaneous vaginal delivery. In group A, 28/50 (56%) cases had Apgar <7 at 5 minutes while in group B, 18/50 (36%) cases had Apgar <7 at 5 minutes. In group A, 4/50 (8%) cases died while in group B, no mortality was observed. There was significant difference observed between group A and cases in group B for all these factors. In group A, 10/50 (20%) cases had NICU admission while in group B, only 6/50(12%) cases had NICU admission. There was no significant difference observed between two groups in NICU admission. **Conclusion:** It was concluded that CTG coupled with fetal blood sampling for fetal pH versus carditocography alone is an accurate method for assessment of fetal condition in labour to decide the mode of delivery and neonatal outcome after birth.

Keywords: *Caesarean Section, Non-reactive Cardiotocography, Fetal scalp blood Sampling*

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INTRODUCTION

Monitoring of fetal heart rate with cardiotocography (CTG) is generally considered as a good fetal surveillance test during labour. Cardiotocography (CTG) is a continuous electronic record of the fetal heart rate obtained via an ultrasound transducer placed on the mother's abdomen. It is the most commonly used test for antepartum and intrapartum fetal surveillance in the majority of hospitals of developed countries. This technology was first developed in 1950 and became commercially available in 1960.[1]

Normal results of cardiotocography indicate that the fetus is getting enough oxygen.[2] In nearly half of all tracings, however, the results are not reassuring.[3] Cardiotocography is highly sensitive but has low specificity. It means that normal trace is good to identify non-hypoxic fetus but abnormal trace does not mean that the fetus is necessarily hypoxic.[4] The cardiotocography has low positive predictive value for adverse outcome but high negative predictive value, due to which cardiotocography has been associated with increased caesarean section rate.[5]

There is widespread agreement that the intrapartum cardiotocography needs to be combined with a second variable to improve its specificity.[6] The increased intervention rates associated with non-reactive cardiotocography can be reduced with the use of fetal scalp blood sampling. Fetal scalp blood sampling for pH evaluation can be performed as an adjunct to non-reactive cardiotocography.[7]

In 1962 Saling introduced fetal scalp blood sampling during labour to analyze pH as an indicator of hypoxia.[8] Biochemical assessment of fetal blood pH, with the use of scalp or umbilical cord blood, is often viewed as the "gold standard" against which other indicators of fetal distress must be judged.[9]

In general, low pH suggests that the fetus does not have enough oxygen, which means that the fetus is not tolerating labour very well. The analysis of pH needs 30 to 50µl of blood and there is 11 to 20 percent sampling failure rate.[10] Fetal scalp blood sampling is usually performed by inserting a blood lancet through vaginal route by making a shallow incision on fetal scalp, after which a capillary tube is applied to collect the sample through capillary action.[11]

Rationale of this study is to reduce unnecessary caesarean section rate due to non-reassuring cardiotocography because it is not specific enough in detecting fetal hypoxia and it is frequently poorly interpreted so additional test such as fetal scalp blood sampling in labour is required to increase its specificity.

According to the Current NICE and RCOG guideline, with the following pH response, following strategy should be followed:[12]

- If pH is less than or equal to 7.25 – repeat of FSBS is indicated if cardiotocography (CTG) abnormalities persist.

If pH is between 7.21 to 7.24 - repeat FSBS within 30 minutes or if there has been a rapid fall in pH as compared to the previous sample consider for delivery.

If pH is below or equal to 7.20 – urgent delivery.

All the results of pH sampling should be compared with the previous sample results, maternal and fetal clinical features and the rate of progress of labour.

METHODOLOGY

Study Design: The cross sectional analytical study design

Place of Study: This study has been conducted at Obstetrics and Gynaecology department, Unit-I, Lady Willingdon Hospital, Lahore, affiliated with King Edward Medical University

Duration of Study: December 2015 to November 2016.

Method:

The cross sectional analytical study design has been used with sample size of 97 (approximate 100) cases was calculated with 95% confidence level, 5% margin of error and taking expected percentage of decreased scalp pH that is 6.8%(11) in labouring patient with non-reactive cardiotocography by following formula (63)

$$n = \frac{Z^2_{1-\alpha/2}\, P(1-P)}{d^2}$$

Where P is 6.8%, d is 5%, Z is 1.96 and sample has been carried out using non-probability consecutive sampling.

Patients included in the study were

- Booked cases,
- Patient in labour at term. Gestational age 37-42wks (through LMP) with ruptured membrane, clear liquor and cervical dilatation of at least 3cm (on vaginal examination).
- Cephalic presentation on Ultrasonography.
- Patient with non-reactive cardiotocography (suspicious and pathological)

Patients excluded from the study were those having

- Clear evidence of serious fetal compromise from continuous external fetal heart rate monitoring.
- Normal cardiotocography.
- Impending delivery within 15 minutes (fully dilated)
- Placenta previa on ultrasonography.
- Placental abruption on ultrasonography.
- Intrauterine growth retardation on ultrasonography.
- PIH (BP>140/90mmHg), pre-eclampsia, eclampsia.
- Gestational or known diabetes
- Previous ≥1 caesarean sections.
- Maternal infection e.g. hepatitis viruses, HIV diagnosed from antenatal visits.

One hundred booked patients at term presenting in labour to Lady Willingdon Hospital labour room 1 and fulfilling the inclusion criteria were enrolled for this study. After taking informed written consent, these patients were divided into two groups (A and B). In group A, 50 cases having non-reactive cardiotocography were taken and according to fetal assessment by cardiotocography, all underwent caesarean section. In group B, 50 cases having non-reactive cardiotocography traces, fetal assessment was done by continuous cardiotocography as well as fetal scalp blood sampling. Fetal blood samples were assessed for pH (pH)* value and subsequent action was taken.

- Normal pH (= >7.25) → sample was repeated after 1 hour if the fetal heart rate abnormality persisted as before or sooner if there were further abnormalities.

If pH remained normal after 2nd sample, a third or further sample was deferred unless there was further abnormality in the CTG trace and normal vaginal delivery was considered.

- Borderline pH (7.21 – 7.24) → sample was repeated within 30 minutes after resuscitation by encouraging mother to lie in left lateral position, by checking BP, O2 inhalation was given, giving 500ml crystalloid if appropriate. If the fetal heart rate abnormality persisted delivery by caesarean section was considered if rapid fall in pH since last sample.
- Abnormal (pH=< 7.20) → caesarean section within 30 min.

All the results of pH samples of fetal scalp blood sampling were compared to the previous sample results. The rate of progress of labour and maternal and fetal clinical features was taken in account like meconium-stained liquor, abnormal fetal heart rate and maternal pyrexia.

- In case of failure of fetal blood sampling or if it is not possible, delivery was accomplished within 30 minutes by caesarean section.

Once patient delivered, Apgar score at 1 min and 5 min was assessed by pediatrician, admission to neonatal intensive care unit was noted and neonatal follow-up was done after 1 week in OPD for postnatal assessment.

The patient who required an FBS was assessed by vaginal examination for suitability of the procedure like cervical dilatation, presentation, and station of the presenting part. Under aseptic measures, the amnioscope was passed into the vagina and positioned against the fetal head. Fetal scalp was cleaned with the dry cotton wool using sponge holding forceps, spray of ethylene chloride was used to promote capillary action. A small nick was given on the fetal scalp and when a drop was formed 2 samples were collected in heparinized capillary tube. Pressure was applied over the puncture site for 3-5 minutes to ensure hemostasis. The blood sample was immediately analyzed with blood gas analyzer (Nova Biomedical) for pH and base excess, at clinical laboratory of LWH, Lahore.

Data was entered and analyzed through SPSS (Statistical Package for Social Science) version 21 computer software program. Data master sheets were generated for variables under study. Quantitative Variables like age of mother, gestational age, and scalp blood pH, Apgar score at 1 min and at 5 min were presented as mean and standard deviation and qualitative variable like gravidity, Apgar score (low, normal) were calculated as frequency and percentage. Both groups were compared by using chi-square test. P-value $\leq$ 0.05 was taken as significant.

RESULTS

Total 100 patients were enrolled in this study. The mean age was noted as 27.64±4.38 years with minimum and maximum age of 19 and 37 years respectively. The mean gestational age was noted as 39.30±1.05 weeks with minimum and maximum gestational age of 37 & 41 weeks respectively. In group A among 50 cases having non-reactive CTG, non-reassuring baseline was found in 18 cases and abnormal baseline was in 7 cases, non-reassuring variability was in 12 cases and abnormal variability was in 25 cases, deceleration was found in 17 cases and acceleration was absent in all cases. In group B among 50 cases having non-reactive CTG non-reassuring baseline was found in 18 cases and abnormal baseline was in 7 cases, non-reassuring variability was in 21 cases and abnormal variability was in 19 cases, deceleration was found in 11 cases and acceleration was absent in all cases.

All the patients in group A underwent LSCS due to pathological CTG. While patients in group B were further managed by FSB sampling. The results of pH values in group B were as shown in table 1. The mode of delivery in both groups is shown in table 2. The fetal outcome in the form of APGAR scores in 1 and 5 min and NICU admission is shown in table 3.

Table 1: Results of pH values from first and final attempt of fetal scalp blood sampling, in group B (n=50)

pH Sampling	First Attempt		Final Attempt	
	No. of pt.	Percent	No. of pt.	Percent
Abnormal (<7.20)	2	4	6	12
Borderline (7.21 – 7.24)	34	68	24	48
Normal (>7.25)	14	28	20	40
Total	**50**	**100**	**50**	**100**

In group B, among 50 cases, at first attempt of fetal scalp blood sampling, 14 cases had normal pH (7.25-7.35), 34 cases had borderline pH(7.21-7.24) and 2 cases had abnormal pH(=<7.20).

In group B, among 50 cases, 14 cases with normal pH, scalp sample was repeated after 1 hour all cases remained normal. 34 cases with borderline pH, scalp sample was repeated after 30mins, 24 cases remained borderline, 6 cases converted to normal and 4 cases converted to abnormal, and finally 20 cases had normal pH (7.25-7.35), 24 cases had borderline pH(7.21-7.24) and 6 cases had abnormal pH(=<7.20).

Table 2: Comparison of mode of delivery between both study groups

		Study group (n=100)		p-value
		GROUP A(n=50)	GROUP B(n=50)	
Mode of Delivery	**LSCS**	50 (100%)	30 (60%)	**0.0001**
	SVD	0 (0%)	20 (40%)	
Total		**50** (100%)	**50** (100%)	

Chi-square = 25.000 p-value = 0.0001 (Significant)

In group A, all cases 50/50 (100%) underwent LSCS. In group B, 30/50 (60%) cases underwent LSCS while 20/50 (40%) cases underwent SVD. There was significant difference observed between two groups and cases in group B had less chance of LSCS as compared to group A.

Table 3: Fetal Outcome between both study groups

		Study Groups					Study Groups		
		Group A n=50	Group B n=50				Group A n=50	Group B n=50	
Apgar score	**<7**	28 (56%)	18 (36%)	0.045	**NICU admission**	Yes	10 (20%)	6 (12%)	0.275
	≥7	22 (44%)	32 (64%)			No	40 (80%)	44 (88%)	
Total		**50/50 (100%)**	**50/50 (100%)**		**Total**		**50/50 (100%)**	**50/50 (100%)**	

Chi-square = 4.026
Chi-square = 1.190
p-value = 0.045 (Significant)
p-value = 0.275 (Insignificant)

In group A, 28/50 (56%) cases had Apgar <7 after 5 minutes while in group B, 18/50 (36%) cases had Apgar <7 after 5 minutes. There was significant difference observed between two groups and cases in group B had less chances of Apgar <7 as compared to group A. (p value 0.045)
In group A, among 50 cases, 10/50 (20%) cases had NICU admission while in group B, among 50 cases, only 6/50 (12%) cases had NICU admission. There was insignificant difference observed between two groups. (p value 0.275)

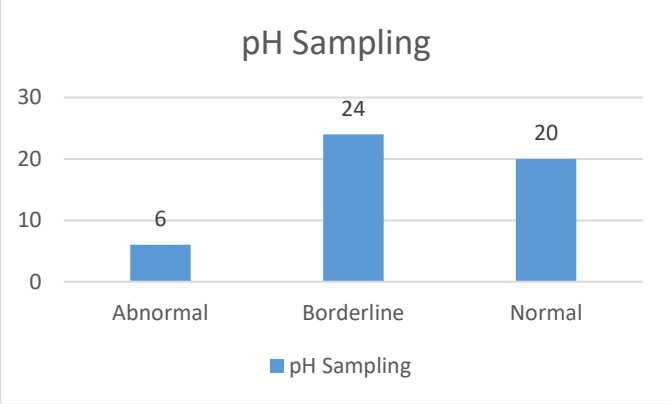

Figure 1: Group-B, Distribution of pH sampling results

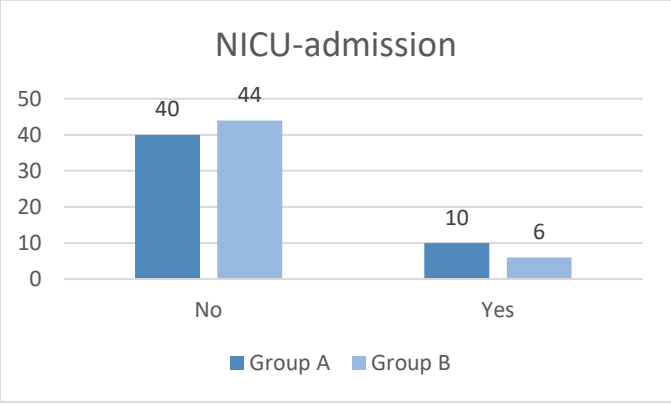

Figure 2: Comparison of Neonatal ICU admission in both groups

Scalp blood sampling was done in 50 patients of group B among which 20 cases had normal pH (7.25-7.35), 24 cases had borderline pH (7.21-7.24) and 6 cases had abnormal pH (=<7.20).
In group A, among 50 cases NICU admissions was observed in 10/50 (20%) cases while in group B, among 50 cases NICU admissions was observed in 6/50 (12%) cases. Similarly, in group A, 40/50 (80%) neonates did not require NICU admissions while in group B, 44/50 (88%) neonates did not require NICU admissions

DISCUSSION

This cross sectional analytical study was conducted at Obstetrics and Gynecology Department, Unit-I, Lady Willingdon Hospital, Lahore, affiliated with King Edward Medical University to compare frequency of caesarean section in women with non-reactive CTG versus non-reactive CTG and fetal scalp blood sampling. Also, the fetal outcome of prolonging labour by FBS was studied.
One hundred patients were included in this study with the mean age of 27.64±4.38 years. The mean gestational age was observed as 39.30±1.05 weeks (37-41 weeks), the mean Apgar score at 1 minute was 5.62±1.39 which was improved to 6.76±2.09 at 5 minutes.
The patients were divided in two groups (A and B) each group had 50 patients. In group A, fetal assessment was done by CTG only and all patients underwent cesarean section directly only on the basis of non-reactive CTG while in group B, fetal assessment was done by CTG and fetal scalp blood sampling and, the mean pH value was 7.25±0.048. Among cases of group B, out of 50 cases, fetal scalp blood sampling was normal in 20/50 (40%) patients, borderline in 24/50 (48%) cases, abnormal in 6/50 (12%) patients.
In group A among 50 case, all 50/50 (100%) cases underwent cesarean section while in group B, among 50 cases 30/50 (60%) cases underwent cesarean section and 20/50 (40%) cases underwent normal vaginal delivery. There was significant difference observed between two groups as cases in group B had less chances of having cesarean section as compared to group A (p-value=0.0001). Same result was shown in a study by Ali L et al[13]. In their study the impact of pathological CTG on incidence of caesarean section rate was determined and it showed that CTG alone increases the cesarean section rate.

Cases with abnormal and borderline pH had more chances of having LSCS as compared to normal pH.

In a study done by Reif P et al[14] to show the impact of fetal blood sampling on reducing the number of caesarean sections in cases with suspicious, non-reassuring or pathological fetal heart rate tracing. They found that operative delivery could be avoided in 6.4% of the study population, in spite of the non-reassuring fetal heart rate trace and concluded that fetal blood analysis still is an effective tool to reduce unnecessary operative deliveries. In our study the caesarean section rate was reduced by 40% in Group B due to FBS.

Holzmann M et al[15] has done a secondary analysis of data from a trial of 2992 women, who were, when indicated, randomized to either lactate or pH analyses by FBS. Severe intrapartum acidemia (pH < 7.17) was present in 69/1008 (6.8%) cases with pH analyses. This result is higher than our study group B, in which out of 50 cases severe acidemia (pH ≤ 7.2) was found in 6 (12%) cases only.

In group A, among 50 cases 28 (56%) had Apgar <7 at 5 minutes while in group B, 18 (36%) cases had Apgar <7 at 5 minutes. There was significant difference observed between two groups (p-value=0.045). These results are comparable to results of a study by Khursheed et al[16] who studied CTG in women admitted in labour ward and showed that 66 women (31.42%) had non-reactive pattern of CTG out of which 29 (46.77%) babies were born with good Apgar score while 33 (53.22%) were born with low Apgar score (p=0.008).

Kavitha et al[17] in their study showed that in patient with non-reactive CTG poor Apgar score (<7) at 1 minute was 16.7% while at 5 minute it was 5.6% only. By these studies it was concluded that adjunctive methods are required to improve the sensitivity and specificity of fetal monitoring if unnecessary interventions are to be avoided.

In group A, 10/50 (20%) cases had NICU admission while in group B only 6/50 (12%) cases had NICU admission. There was insignificant difference observed between two groups (p-value=0.275) and cases in group B had less chances of NICU admission as compared to group A reported that in patient with non-reactive CTG NICU admission was 44.4%.

In a study done by Rahman H[18] in 2012, they evaluated the predictive value of the admission cardiotocogram (CTG) in detecting fetal hypoxia and perinatal outcome in high-risk obstetric cases. They found that in non-reactive CTG group incidence of fetal distress, thick meconium stained liquor and neonatal intensive care unit (NICU) admission was significantly more.

The limitation of this study is small sample size especially with respect to the number of deliveries in our hospital. Comparable studies conducted by Chandraharan[19] had more than 300 patients included. But still the overall frequencies observed were comparable to other studies. Evaluating the results of our study it can be said that FBS is an effective diagnostic tool to predict the possibility of low APGAR score and NICU admission in the new born. Bhide et al [20] study results also confirm the significance of FSB in detecting fetal acidosis.

CONCLUSION

The frequency of caesarean section is low in women monitored by fetal scalp blood sampling and cardiotocography in labour than women who are monitored by cardiotocography alone, without adversely affecting the fetal outcome.

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