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Original Research Article

Correlation of Cardiotocography with neonatal outcome in term pregnancies at a tertiary care centre in Bihar, India: A prospective observational study

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ABSTRACT

Introduction: Early recognition of foetal distress by intrapartum cardiotocography (CTG) has a pivotal role in the improvement of perinatal outcome. So, the aim of this study was to correlate the findings of CTG with neonatal outcome.

Materials and Methods: This Prospective Observational study was conducted on 300 pregnant women in labour having singleton term pregnancy with cephalic presentation. Intrapartum cardiotocography was done. CTG pattern was correlated with neonatal outcomes by analysing Apgar score, NICU admission and neonatal mortality rate. Statistical analysis was done by using chi square test and Fisher Exact test and p value < 0.05 was considered as statistically significant.

Results: Out of 300 patients, reactive CTG pattern was observed in 67% while suspicious and pathological pattern was observed in 22% and 11% of pregnancies respectively. The percentage of caesarean deliveries were significantly more among abnormal CTG group as compared to reactive group (p value < 0.0001). The sensitivity and specificity of CTG for predicting foetal distress and NICU admission was 80 % and 78.75% respectively. There was high NPV of 94.03%, and the diagnostic accuracy of test was 79%.

Conclusions: Reactive CTG is more predictive of favourable neonatal outcomes while Pathological CTG tracing requires immediate intervention. Suspicious CTG requires close observation during intrapartum period after correcting underlying causes and taking conservative measures and Immediate delivery is not required unless it became pathological and hence caesarean section rate can be reduced in this group. Overall, intrapartum CTG is an important screening tool for early identification of foetal distress.

1. Introduction

Monitoring of the foetal well being during labour is important to minimize foetal death due to asphyxia and the neurological sequelae of the intrapartum hypoxic insult, usually secondary to high-risk pregnancies or even seen in low-risk pregnancy also. The basic goal of intrapartum foetal monitoring is to assess foetal well-being and early detection of impending foetal hypoxia and thus preventing subsequent academia and its consequences so that a good perinatal outcome is anticipated by appropriate and timely intervention. Electronic foetal monitoring in the form of cardiotocography (CTG) is routinely used now a day for the intrapartum surveillance of foetus.

CTG is a graphical presentation that simultaneously records foetal heart rate (FHR), foetal movement and uterine contraction. The basis of CTG is that the uterine contraction during labour causes physiological stress by temporarily curtailing the blood flow containing oxygen and nutrients to the foetus. This compromise in circulation resulting in transient hypoxia is sensed by the foetal brain with the help of various stimuli such as chemoreceptor's, baroreceptors, and direct effect of metabolic changes within the brain itself. This results in alteration of FHR leading to decreased

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oxygen consumption and redistribution of blood flow to the vital organs as a compensatory mechanism. These changes or alterations in the FHR are thus recorded on the CTG. Thus, recording CTG helps us to determine the ability of the foetus to cope up the stress of labour.

CTG was introduced into obstetrical practice in the 1960's, primarily to monitor complicated pregnancies.[1,2] However FHR changes, foetal hypoxia and acidosis may occur with same frequency in low-risk patients as in high risk one.[3]

Interpretation of the cardiotocography includes the description of frequency, intensity and duration of uterine contractions, baseline foetal heart rate, baseline foetal heart rate variability, presence of accelerations, periodic or episodic decelerations and accordingly cardiotocography will be normal, suspicious or pathological.[4]

Studies indicate that number of stillbirths and early neonatal deaths are higher among nonreactive CTG group as compared to reactive group.[5–7] Consequently, a good perinatal outcome is expected when CTG results are normal, but not when they are abnormal. The Sensitivity and Specificity of CTG for predicting neonatal morbidity was 81.25% and 82.2%, while it's PPV and NPV was 66.6% and 90.9%.[8] In the study conducted by Rajlekshmi etal Out of 26 NICU admissions, 1.1% were in normal CTG group, 12.3 % in abnormal and 47.4 % in pathological trace.[9]

We hence conducted this study to determine the role of CTG in intrapartum foetal monitoring and neonatal outcomes.

2. Aims and Objectives

1. To correlate intrapartum CTG findings with Apgar score and neonatal outcome.
2. To evaluate positive and negative predictive value of CTG for foetal distress.

3. Materials and Methods

3.1. Study design and area

This prospective observational study was conducted in the Department of Obstetrics and Gynaecology at IGIMS, Sheikhpura, and Patna from December 2019 to November 2020. Ethical clearance was obtained for the study from the Institutional Ethical Committee. A written informed consent was taken from all the participants fulfilling the selection criteria.

3.2. Sample size

A total of 300 pregnant women in labour, either spontaneous or induced.

3.3. Sample size calculation

As per previous study (ref: IOSR Journal of Dental and Medical Sciences.2018;17(6):42-50) the sensitivity and specificity of CTG for predicting abnormal outcome was 96% and 63% respectively. Taking these values as reference, the minimum required sample size with desired precision of 10%, 95% power of study and 5% level of significance will be calculated as:

3.3.1. Sensitivity

H_0: Se=96 versus Se≠96 (Se_1)

With 95% confidence level and 95% power for detection of difference of 10% from a Se of 96%, sample size calculated is: -

N = ((1.96*sqrt (.96*(1-.96)) +(1.645*sqrt(.86*(1-.86))^2/(.1*.1)

= 91.18=92(approx.)

3.3.2. Specificity

H_0: Sp=63 versus Sp≠63 (Sp_1)

With 95% confidence level and 95% power for detection of difference of 10% from a Sp of 63%, sample size calculated is: -

N = ((1.96*sqrt(.63*(1-.63))+(1.645*sqrt (.73*(1-.73))^2/(.1*.1)

= 281.10=282(approx.)

So, for a minimum of 282 patients to be included in this study, and to reduce margin of error total sample size taken is 300.

3.4. Inclusion criteria

Singleton pregnancy ≥ 37 weeks of gestation, irrespective of the parity in labour with cephalic presentation, both high and low risk pregnancy.

3.5. Exclusion criteria

Pregnancy<37 weeks of gestation, pregnancy with known congenital anomalies in foetus, multiple pregnancies, malpresentation and intrauterine death.

3.6. Ethical approval

Informed consent was obtained from all individual participants included in the study and ethical approval was obtained from the institution where the study was carried out.

3.7. Data collection and procedure

3.7.1. Data source

The data was taken from Labour room of Obstetrics and Gynaecology department, IGIMS, Sheikhpura, Patna. Woman's detailed history including age, parity, obstetrical,

medical and family history was documented.

3.7.2. Examination methods

General physical and obstetrical examination was done. CTG was performed. Two belts were placed around patient's abdomen, the foetal transducer was placed at the location where the foetal heart was best localised and the toco-transducer was placed at the Fundus of the uterus and CTG tracing was recorded for a span of 20 minutes. The FHR tracing by cardiotocography obtained were labelled as per national institute of clinical excellence (NICE) guidelines 2017 as normal, suspicious or pathological.

3.7.3. Procedure and monitoring

If interpretation of Cardiotocography came under reactive category, rest of the labour event was monitored by intermittent auscultation till delivery. But at any time during progression of labour if there was clinical suspicion regarding non reactivity of foetus like meconium or blood-stained liquor, bradycardia or tachycardia or dips in FHR during intermittent auscultation then repeat CTG was done. If CTG trace was suspicious, conservative management was given to the patients (left lateral position, oxygen inhalation, intravenous fluid administration, discontinuation of Oxytocin if being used, artificial rupture of membrane if membrane present / use of terbutaline if uterus was hypertonic.) and CTG tracing was further extended for 20 minutes. If CTG remain suspicious or became abnormal at any time during labour events, then delivery was expedited either in the form of operative vaginal delivery or emergency caesarean section depending on stage of labour.

Immediately after the delivery of the baby, Apgar score at 1 and 5 minutes was noted for all babies and for non-vigorous baby who needed NICU admission were followed. Reasons for NICU admission and duration of NICU stay was noted. Neonatal mortality rate was calculated with the cause.

3.8. Statistical analysis

The presentation of the Categorical variables was done in the form of number and percentage (%). The association of the variables which were qualitative in nature were analyzed using Chi-Square test/Fisher's Exact test. Diagnostic test was used to find out sensitivity, specificity, PPV and NPV. The data entry was done in the Microsoft EXCEL spreadsheet and the final analysis was done with the use of Statistical Package for Social Sciences (SPSS) software version 21.0. For statistical significance, p value of less than 0.05 was considered as significant.

4. Results

In our study, 156 (52%) women had one or more high risk factors while 144 (48%) women were of low risk.Figure 1

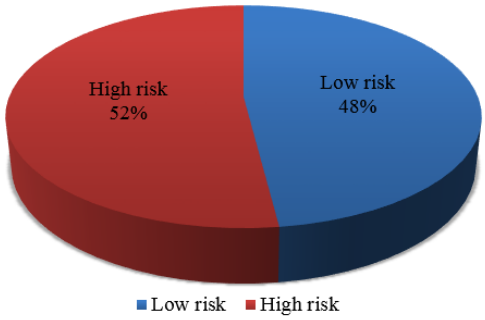

Fig. 1: Distribution ofstudy population according to their risk factors.

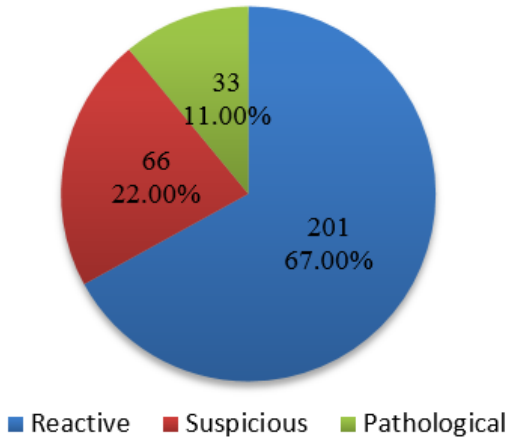

Fig. 2: Distribution of CTG tracing of study subjects

Application of Fisher exact test showed that both suspicious and pathological CTG group was significantly associated with higher incidence of caesarean section ($p<0.0001$).Table 1

Association of low 5-minute Apgar score (≤7) with pathological CTG group was statistically significant ($p<0.0001$).Table 2

Application of Fisher-Exact test showed that the association of meconium-stained liquor (moderate/thick) with pathological CTG group was statistically significant ($p<0.0001$).

NICU admission was higher in pathological CTG groups (87.88%) as compared to reactive and suspicious group (5.97% and 28.79%). Application of chi-square test showed that this difference was statistically significant ($p<0.0001$).

In the pathological CTG group, common indications for NICU admission were graver such as RDS (36.36%), birth asphyxia (24.24%) and MAS (12.12%). In suspicious group, RDS (7.58%) and neonates for observation (6.06%) was more frequent reason for NICU admission. While birth asphyxia and MAS was seen in 1.52% and 3.03% respectively. Among reactive CTG group, TTN (1.99%),

Table 1: Association of mode of delivery with CTG status

Mode of Delivery	Reactive (n=201)	Suspicious (n=66)	Pathological (n=33)	Total
Spontaneous Vaginal delivery	135(67.16%)	10(15.15%)	3(9.09%)	148(49.33%)
Instrumental vaginal delivery(ventouse/forceps)	6(2.99%)	6(9.09%)	6(18.18%)	18(6%)
Caesarean section	60(29.85%)	50(75.76%)	24(72.73%)	134(44.67%)
Total	201(100%)	66(100%)	33(100%)	300(100%)

Value < 0 0001

Table 2: Association of neonatal outcome with CTG status

Neonatal Outcome	Reactive (n=201)	Suspicious (n=66)	Pathological (n=33)	Total	P Value	Test Performed
Apgar score ≤7 at 5 minute	9 (4.48%)	11 (16.67%)	25 (75.76%)	45 (15%)	<.0001	Chi square test,113.143
			Colour of liquor			
Clear	156(77.61%)	42(63.64%)	11(33.33%)	210(70%)		
Moderate/thick meconium stained	43(21.39%)	24(36.36%)	20(60.61%)	87(29%)	<.0001	Fisher Exact test
Blood stained	2(1.00%)	0(0.00%)	2(6.06%)	4(1.33%)		
NICU admission	12 (5.97%)	19 (28.79%)	29 (87.88%)	60 (20%)	<.0001	Chi square test,122.944
			NICU stay duration			
< 24 hour	4(1.99%)	6(9.09%)	6(18.18%)	16(5.33%)		
24-48 hour	5(2.49%)	6(9.09%)	10(30.30%)	21(7%)	0.754	Fisher Exact test
> 48 hour	3(1.49%)	7(10.61%)	13(39.39%)	23(7.67%)		
			Reasons for NICU admission			
For observation	6(2.99%)	4(6.06%)	2(6.06%)	12(4%)	0.330	Fisher Exact test
IUGR	1(0.50%)	1(1.52%)	2(6.06%)	4(1.33%)	0.036	Fisher Exact test
TTN	4(1.99%)	2(3.03%)	1(3.03%)	7(2.33%)	0.583	Fisher Exact test
LBW	2(1.00%)	1(1.52%)	2(6.06%)	5(1.67%)	0.108	Fisher Exact test
NNH	4(1.99%)	2(3.03%)	2(6.06%)	8(2.67%)	0.262	Fisher Exact test
Hypoglycaemia	0(0.00%)	0(0.00%)	2(6.06%)	2(0.67%)	0.012	Fisher Exact test
RDS	3(1.49%)	5(7.58%)	12(36.36%)	20(6.67%)	<.0001	Fisher Exact test
MAS	1(0.50%)	2(3.03%)	4(12.12%)	7(2.33%)	0.001	Fisher Exact test
Birth asphyxia	1(0.50%)	1(1.52%)	8(24.24%)	10(3.33%)	<.0001	Fisher Exact test
Neonatal mortality	1 (0.50%)	0 (0%)	3 (9.09%)	4 (1.33%)	0.007	Fisher Exact test

IUGR: Intrauterine Growth Retardation, TTN: Transient Tachypnoea of New-born, LBW: Low Birth Weight, NNH: Neonatal Hyperglycaemia, RDS: Respiratory Distress Syndrome, MAS: Meconium Aspiration Syndrome

neonates for observation (2.99%) and NNH (1.99%) were contributed to more common indication for NICU admission while RDS, birth asphyxia and MAS were seen in 1.49 %, 0.5% and 0.5% respectively.

Correlation of pathological CTG group with more grave complication of neonates were found to be significant ($p \leq 0.001$).

Application of Fisher-Exact test showed that the association of neonatal mortality with pathological CTG group was statistically significant (p=0.007).

The sensitivity, specificity, positive predictive value and negative predictive value of CTG for fetal distress and NICU was found to be 80%, 78.75%, 48.48% and 94.03% respectively. Table 3

Table 3: Diagnostic parameters of CTG for foetal distress and NICU admission.

Diagnostic parameters of CTG	
Sensitivity(95% CI)	80% (67.67%to89.22%)
Specificity(95% CI)	78.75% (73.03%to83.75%)
AUC(95% CI)	0.79 (0.74to0.84)
Positive Predictive Value(95% CI)	48.48% (38.32%to58.75%)
Negative Predictive Value(95% CI)	94.03% (89.80% to 96.88%)
Diagnostic accuracy	79.00%

5. Discussion

In our study, out of 300 enrolled antenatal women, majority belonged to the age group of 21-25 years (50%), followed

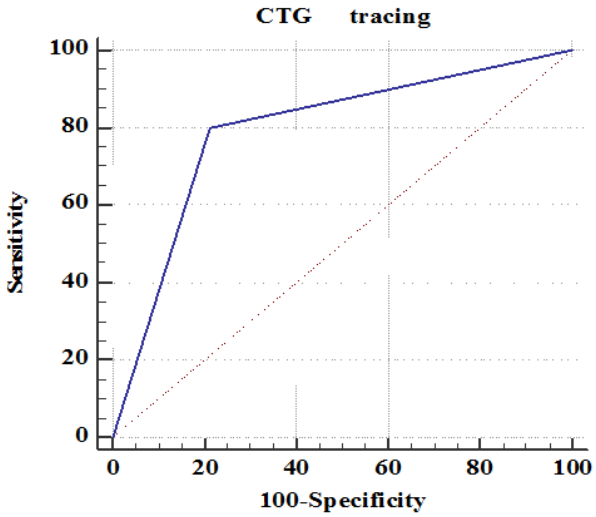

Fig. 3: ROC curve of CTG

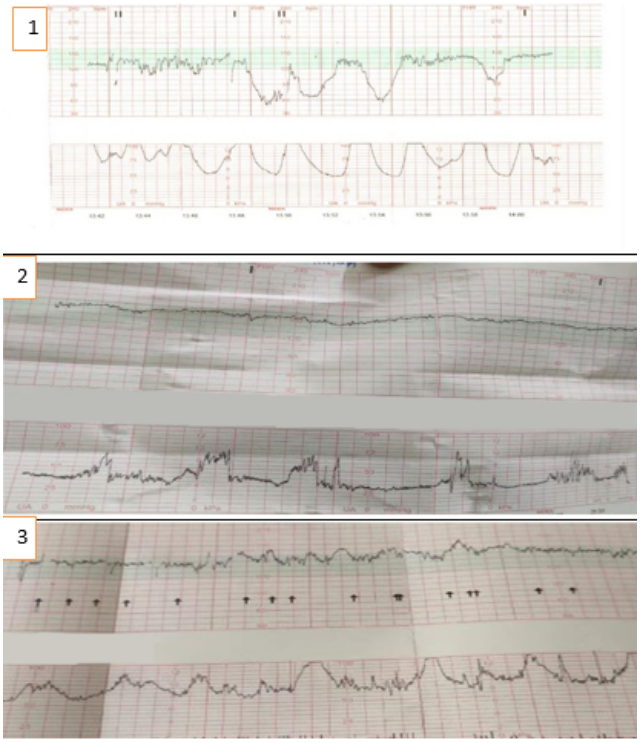

Fig. 4: CTG Patterns in study population according to nice guidelines.
Pathological CTG[1], Suspicious CTG[2], Reactive CTG[3]

by 26-30 years' age group (37.66%). Most of the study subjects were Primigravida (49.66%). The mean birth weight of neonate was 2.89±0.48 kilogram.

Majority of the patients (52%) were having high risk factors like post-datism (16%), Previous Caesarean (16%), Hypothyroidism (8%), Moderate/ Thick meconium (7.66%), pregnancy induced hypertension (7%), Intrauterine growth retardation (5.33%), Oligohydramnios (4.66%), premature rupture of membrane (4%), Diabetes mellitus (2.33%), heart disease (2%), Antepartum haemorrhage (2%), Cholestasis of pregnancy (1.66%), Rh negative (1.66%), IgA nephropathy (0.33%) and Lupus nephritis (0.33%). Low risk patients contributed to 48% of total study population.

In the current era, intrapartum foetal monitoring by CTG is being used in all pregnant women irrespective of their risk factors. Though wide use of CTG had significantly increased the number of caesarean sections for foetal indication but at the same time resulted in good perinatal outcome. So, a normal CTG trace gives reassurance to obstetrician and help them in making decision regarding continuation of labour safely.

In this study, out of 300 cases, 201 (67%) patients had reactive CTG tracing, 66(22)% had suspicious and 33 cases (11%) had pathological CTG tracing.

Similarly, Joshi H et al conducted a study on 100 pregnant women and showed that CTG was reactive in 67%, suspicious in 21% and pathological in 12% of women.[3]

Dhakare J. T et al conducted a study on 105 high risk pregnant patients and showed that incidence of the reactive trace was 62.9%, while suspicious and pathological patterns were observed in 13.3% and 23.8% respectively.[8]

Out of 201 patients with reactive CTG, 135 patients (67.16%) delivered vaginally, 6(2.99%) patients underwent instrumental vaginal delivery while 60 (29.85%) patients were delivered by caesarean section. Of the 66 patients with suspicious CTG, 10(15.15%) delivered vaginally, 6(9.09%) patients had instrumental vaginal delivery and 50(75.76%) underwent caesarean section. Among 38 patients who had pathological CTG, 24(72.73%) delivered by caesarean section, while 9.09% delivered vaginally and 18.18% had instrumental delivery. Hence the incidence of vaginal deliveries were more common among reactive CTG group. On the other hand, caesarean sections rate was high with similar incidence in suspicious and pathological CTG group (75.76% and 72.73%). Correlation of modes of delivery with different CTG groups were found to be statistically significant ($p<0.0001$).

This result was comparable to a study conducted by Joshi H et al.[3] In the study conducted by Thapa et al, 27.4% patients with reactive CTG had caesarean delivery, while 75% patients with non-reactive CTG underwent caesarean section.[10] Banu S et al in their study on 100 pregnant women found that percentage of various mode of delivery

among suspicious and pathological CTG group did not show significant difference with p value 0.663, which was similar to our study.[11]

In our study, Apgar score ≤7 at 5 minutes was observed in 16.67% of suspicious group and in 75.76% of pathological tracing group, while in only 4.48% cases with reactive CTG group. This showed that pathological CTG is important in predicting low Apgar score (p<0.0001). In the study carried out by Qureshi A et al, almost all the new-borns of the patients with reactive CTG have an excellent APGAR score, whereas significant number of new-borns of patients with pathological CTG trace had an APGAR <6 at 0, 1 and 5 minutes of birth.[12] Gupta M et al, in their study found that out of 74 non-reactive cases, 27 (36.5%) had Apgar score between 0-4 and 60.8% had Apgar score ≤7 at 5 minutes.[13]

In our study, MSL (moderate/thick) and blood-stained liquor was more common among pathological CTG group (60.61%) as compared to suspicious and reactive group (36.36% and 21.39%) while incidence of clear liquor was more in reactive CTG group (77.61%). correlation of different pattern of CTG trace with colour of liquor was found be statistically significant (p <0.0001). Meconium/ blood-stained liquor has been found to be associated with foetal distress and poor neonatal outcome. Similarly, a study conducted by Gupta M et al, out of 74 non-reactive cases, 66.2% had meconium-stained liquor, 9.5% had fresh blood-stained liquor and 24.3% had clear liquor (p<0.001).[13]

In this study, 28.79% babies of suspicious group and 87.88% babies of pathological group needed NICU admission while NICU admission was needed in only 5.97% babies of reactive CTG group. This study was comparable to those of Panda et al, in their study reassuring CTG group had 9.3% NICU admission and 78.57% NICU admission was seen in non-reassuring group.[14] while in the study by Dr. K. Sowmya et al, NICU admission rate was 27.08% in non-reassuring CTG group and 34.6% in abnormal CTG group.[15] Thus the incidence of foetal distress and NICU admission was more in the patients with ominous CTG and had similar results to our study.

Correlation of NICU stay duration with different CTG group was statistically insignificant (p = 0.754).

Reasons for NICU admission were graver among pathological CTG group: RDS (36.36%), birth asphyxia (24.24%) and MAS (12.12%) as compared to suspicious group: RDS (7.58%), birth asphyxia (1.52%) and MAS (3.03%) and reactive CTG group: RDS (1.49%), birth asphyxia (0.5%) and MAS (0.5%). Similarly, the study conducted by Salma U et al showed that the proportion of birth asphyxia was significantly more in non- reassuring (72.5%) than sreassuring (30.6%) on CTG.[6]

Perinatal mortality was seen in 1 (0.5%) case of reactive CTG group and the cause of death was severe birth asphyxia. Three (9.09%) perinatal mortality was seen in pathological CTG group, 2 died due to severe birth asphyxia and RDS and remaining one due to MAS. There was no perinatal mortality in suspicious CTG group. (p value = 0.007). Overall perinatal mortality rate was low in pathological CTG group. Early intervention in the case of a pathological CTG led to favourable neonatal outcome by minimizing the duration of foetal hypoxemia and acidosis.

In our study, CTG has high sensitivity and specificity (80% and 78.75%) in predicting foetal distress and NICU admission. Thus, abnormal CTG could diagnose 80% of subjects who had foetal distress and specificity of 78.75% showed that CTG also had a good ability to identify those who did not have foetal distress. There was high negative predictive value of CTG (94.03%), which showed that reactive CTG trace is well correlated with good neonatal outcome. This study was comparable to those of Gupta M etal, in their study, the sensitivity of CTG for NICU admission was 75.7%, specificity was 77.2%, and a high negative predictive value of 84.5% was seen.[13] On the other hand, in the study carried out by Bogdanovic Gordana et al, sensitivity and specificity of the pathological CTG records as a diagnostic test of intrauterine asphyxia was 66% and 27% respectively; and the positive predictive value of CTG was 80%.[16]

In our study, high caesarean section rate among abnormal CTG group might be attributed to firstly, being a tertiary care institute with super-speciality departments most of the patients were high risk and referral cases. Secondly, Further studies are suggested for making decision regarding pregnancy continuation or termination in case CTG remain suspicious for more than 40 minutes as immediate termination of pregnancy was considered in our study which was manifested as more number of caesarean section in this group.

6. Conclusions

In this study, the following conclusions were drawn:

1. High negative predictive value of CTG showed that Reactive CTG is more predictive of favourable neonatal outcome.
2. Operative interventions in the form of operative vaginal deliveries and caesarean section were observed significantly more among abnormal CTG tracings (suspicious and pathological CTG) group as compared to reactive group.
3. Pathological CTG tracing is significantly associated with grave neonatal complications (birth asphyxia, RDS, MAS) and NICU admission, hence immediate intervention is required in pathological group.
4. Neonatal outcomes among suspicious CTG group are more comparable to reactive group and is not much associated with Grave neonatal complications as it was in pathological CTG group.

5. Suspicious CTG should be followed up more during intrapartum period after correcting underlying causes such as hypotension or uterine hyper stimulation and taking conservative measures. Though close observation is required during intrapartum period but Immediate delivery is not required unless it became pathological.
6. 0verall intrapartum foetal monitoring with CTG serve as a good screening tool for timely identification and rescue of the foetus at risk of adverse neonatal outcomes from intrapartum hypoxic insult.

7. Conflicts of Interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and or publication of this article.

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