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Relationship Between Cardiotocography Categories and Labor Outcomes in Saudi Arabia: A Correlational Study Design

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Abstract

The labor process is a stressful period for the fetus in which fetal heart rate monitoring is crucial. Cardiotocograph (CTG) is a common method for intrapartum fetal heart rate monitoring. However, accurate interpretation of the traces is equally important. To examine the relationship between CTG categories and labor outcomes in Saudi Arabia. A descriptive correlational design was used to conduct the study at the labor and delivery unit in East Jeddah Hospital. A total of 350 laboring women were recruited in convenience for the study. The inclusion criteria were pregnant women who were ≥ 18 years old, admitted to the labor and delivery unit, in active or transition phase, with cephalic presentation, single fetus, and term pregnancy (38 to 41 weeks), as well as willing to participate in the study. A structured checklist developed by the researchers was used for data collection. The mean age of the participants was 28.3 ±5.1 years, the mean gravidity was 3.3 ±2.0, and the mean parity was 1.9 ±1.8. The mode of delivery was spontaneous vaginal birth for 91.4%, cesarean section with spinal anesthesia for 5.1%, and vacuum-assisted vaginal birth for 3.5% of the participants. CTG category was I for 89.1%, II for 6.9%, and III for 4% of the participants. Most of the newborns (99.4%) had 7-10 Apgar scores in 1st minute, and all of them had 7-10 Apgar scores in the 5th minute. Only 0.3% of newborns had been admitted to the neonatal intensive care unit (NICU). Mode of delivery, Apgar score at 1st and 5th minutes, and admission to NICU were significantly associated with the CTG categories (P= 0.001, 0.04 & 0.011). CTG categories were significantly related to labor outcomes in terms of mode of delivery, Apgar score at 1st and 5th minute, and NICU admission.
Keywords: *CTG categories, electronic fetal monitoring, intrapartum fetal monitoring, labor outcomes, neonatal outcomes, Saudi Arabia.*

INTRODUCTION

Labor and delivery are periods of significant metabolic stress for both the woman and her fetus. However, this stressor is easily tolerated by majority of women, and perfect labor outcomes are achieved. Conversely, disruption of oxygenation is poorly tolerated by some fetuses leading to a degree of acidosis with a risk of multi-organ dysfunction or even death. Therefore, fetal monitoring during labor whether intermittent or continuous is a crucial intervention to detect fetal compromise. In this context, the midwife should keep an accurate record of FHR changes during childbirth. Although there are recommendations and guidelines concerning intrapartum fetal monitoring, providers' views differ regarding what is optimal [1, 2].

CTG is a common method for monitoring fetal well-being, and many obstetricians rely on it to decide the mode of delivery and improve perinatal outcome [3]. It was first adopted in the 1960s and has been a primary aspect of women's care during labor since then [4]. In this perspective, the National Institute of Child Health and Human Development (NICHD) introduced the three-tiered category system, which helps healthcare providers interpret the CTG trace accurately and make their clinical decision accordingly in which category I indicates a normal trace, category II represents an indeterminate trace, and category III shows abnormal trace [5, 6].

Although fetal heart rate monitoring and CTG interpretation are common practices, they have some flaws that can be attributed to lack of relevant rigorous clinical studies, high subjectivity, and inter-and intra-observer variation [5, 6]. Moreover, misinterpretation of CTG traces may occur if clinicians based their decisions on declarative patterns rather than understanding fetal physiology. So they neither take the whole clinical picture into account nor act upon the abnormal CTG trace in a timely fashion [7]. In turn, interventions such as emergency cesarean sections and operative vaginal births had been widely used [8, 9]. Indeed, CTG itself is not diagnostic and should be described as a screening tool to aid the clinician's decision-making when fetal hypoxia/ acidosis is suspected [4].

Nonetheless, false positive or false negative results are commonly recorded. Where false-positive records indicate a pathological trace, and an undepressed fetus is born with a good Apgar score and without acidosis. Whereas false-negative records show normal CTG trace and yet depressed fetus born with low Apgar score [10]. Moreover, applying CTG can irritate women in labor by putting belts across their abdomen as well as limiting their freedom to move or walk and holding them in bed in a left lateral position to avoid losing contact in the tracing where mobilization through labor should be facilitated. Further, it restricts provision of midwifery care in terms of non-pharmacological pain relief measures and changing positions as well as adopting variety of delivery positions rather than lithotomy position [10, 11, 12].

Although continuous fetal monitoring is only recommended in high-risk pregnancy, most settings apply it to all laboring women. In this regard, the practice of continuous CTG monitoring and relying on it to decide on the mode of delivery and predict neonatal outcomes should be reconsidered. As, it should not be the only diagnostic tool for fetal distress and further measurements such as fetal scalp pH need be employed to distinguish hypoxic from non-hypoxic fetuses with abnormal CTG and reduce the rate of unnecessary cesarean sections [13].

In this perspective, some researchers found a significant association between CTG categories, and the status of the new-borns evaluated by 1st and 5th minutes Apgar score, umbilical cord artery blood pH, and NICU admission rate among women with abnormal test results [10, 11, 12]. Furthermore, CTG categories had been significantly associated with early labor outcomes as mothers with category II CTG were more likely to undertake operative delivery and cesarean delivery, compared to those with category I CTG (51.4% vs. 25.3%, p = 0.005) [14]. However, minimal studies were found in Saudi Arabia, assessing the relationship between CTG categories and labor outcomes. In this context, the current study examined the relationship between CTG categories and labor outcomes in terms of delivery mode, Apgar score at 1st and 5th minutes, and NICU admission.

Conceptual framework
The Donabedian model provides a framework for evaluating and improving the quality of healthcare. The model encompasses three main constructs: structure, process, and outcome. Donabedian's assumed that structures of health care systems affect processes, which in turn affect outcomes. In the current study, applying continuous fetal monitoring as a part of routine care for laboring women, policy and procedure, and staff training regarding CTG in the study setting are considered care structure. The researcher examined the relationship between interpretation of CTG categories based on NICDH as a process of care on labor outcomes in terms of mode of delivery, 1st and 5th minute Apgar score, and admission rate in NICU [15] (Figure 1).

First, health care structure in the form of physical and organizational aspects of care, is represented in the current study as applying continuous CTG monitoring to all laboring women. Second, the care processes sit in the middle of the diagram because they rely on the structures to employ resources and mechanisms for participants to carry out patient care activities. In the current study, the process of care is represented as interpreting CTG categories based on NICHD and health outcomes are specified as labor outcomes.
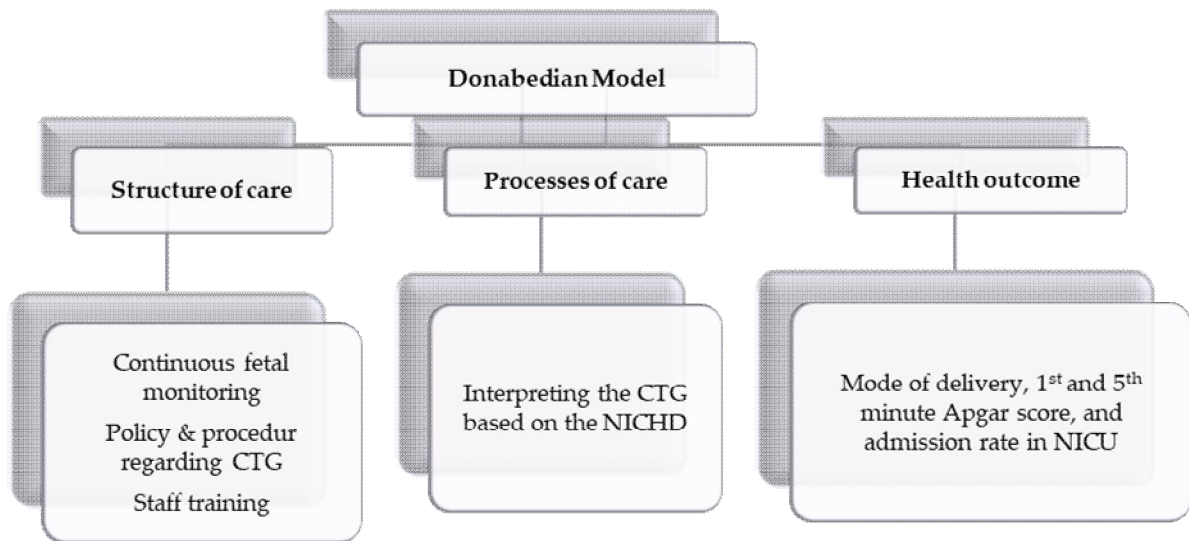
Figure 1: Adapted Donabedian Model

MATERIAL AND METHODS
Aim of the Study
This study aims to examine the relationship between CTG categories and labor outcomes in Saudi Arabia.
Research Design, Setting and Population
A descriptive correlational design was used in the current study as it suits its nature. The study was conducted at East Jeddah Hospital in the labor and delivery unit. All laboring women who are ≥ 18 years old and admitted to the Labor and Delivery Unit were recruited in the current study. The inclusion criteria were active or transition phases of the first stage, single fetus, cephalic presentation, term pregnancy (38 to 40+6 weeks), and willingness to participate in the study. In contrast, the exclusion criteria were women having a high-risk pregnancy (Pre-eclampsia toxemia (PET), gestational diabetes mellitus (GDM), cardiac disease, placenta previa or abruption placenta), induced or augmented labor, elective cesarean section, or malposition.
Sampling and Sampling Techniques
The estimated sample size was 334, using Raosoft® online calculator, which was increased to 350 participants to increase representativeness of study findings. The input data involved the population size, which was 2534 in one year [16], while the acceptable margin of error was 5.0% with a confidence level of 95% and a response rate of 50%. Laboring women who met the inclusion criteria and were willing to participate in the current study were recruited in inconvenience.
Data Collection Process
Data were collected by observing laboring women starting from the 1st stage of labor till the first 24 hours after delivery. Besides, data on age, obstetrical history, and admission to NICU were obtained from medical records. The observation was done in the background without any interference with healthcare provision. The researcher introduced herself and explained the purpose of the study to each woman who met the inclusion criteria. Then, written informed consent to participate in the current study was obtained from them.

The researcher observed the CTG for 40 minutes during the active or transition phase of the first stage of labor. Then, the researcher asked an experienced midwife (At least four years of experience) or the obstetrician to interpret the CTG according to NICHD 2008 criteria system which was already used in the study setting. If any changes occurred in the CTG pattern, the midwife or the obstetrician was asked to re-interpret the CTG. The researcher considered and recorded the last interpretation category before women's delivery. The Umbilical cord blood was obtained immediately after birth in a pre-heparinized container and analyzed within 5-10 minutes. After that, the pediatrician interpreted the printed result. Normal cord pH was defined as 7.25 or above while neonatal acidosis was defined as cord blood pH of 7.20 or less (NICE, 2020).
Data Collection Methods
A structured checklist was developed by the researchers after an extensive literature review [14, 17, 18, 13] to collect the needed data in relation to the study objectives. The checklist included three main

sections in addition to the women's ages. The first section included the participants' previous obstetrical history as parity and gravidity. The second section is about the history of the current pregnancy, such as status of liquor, CTG characteristics in terms of uterine contractions, FHR baseline rate, variability, acceleration, deceleration, categories, and who interpreted it and mode of delivery. Finally, the third section encompassed neonatal outcomes of interest, such as birth weight, Apgar score at 1st and 5th minutes, and NICU admission.

Data Analysis

Obtained data were entered, coded, and analyzed using the statistical package for social sciences (SPSS) version 25. Data were described using frequencies and percentages and presented in tables and graphs. Mean and standard deviations were utilized for continuous variables. Inferential statistics as Chi-square and ANOVA tests were used to test the relationship between variables. The level of statistical significance was considered at p-value <0.05 throughout the study.

Validity and Reliability

The checklist was reviewed by experts in obstetrics and gynecology field for relevancy and appropriateness to the current study aim, recommended modifications were done.

Reliability was assessed through the pilot testing on 20% of the estimated sample size (70 participants) who met the inclusion criteria. The results showed a strong association between CTG categories and the mode of delivery using Phi and Crammer tests (P=0.001).

Ethical Consideration

The study was conducted after being approved by the College of Nursing Research Unit, King Abdullah International Medical Research Centre (KAIMRC), and the Institutional Review Board (IRB), at King Abdulaziz Medical City-Western Region in addition to Ministry of Health's IRB. The researcher then explained the study's aim and nature to each woman who met the inclusion criteria to gain her written consent to participate in the current study with emphasis on voluntary participation, confidentiality, and anonymity.

RESULTS

Description of The Participants and CTG Characteristics

The age of the participants ranged between 18 and 41 years, with a mean of 28.3 ±5.1 years, and 40% of them were in the age group 25 – 29 years. Gravidity ranged between 1 and 10, with a mean of 3.3 ±2.0. Moreover, parity ranged between 0 and 9, with a mean of 1.9 ±1.8 (Table 1).

Table 1. Description of the participants

Variable	n=350	%
Age		
< 20	4	1.2
20-24	85	24.4
25-29	140	40
30-34	70	20
35-40	46	13.2
40 +	5	1.2
Range	18 - 41	
Mean ± SD	28.3 ± 5.1	
Gravidity		
Range	1 - 10	
Mean ± SD	3.3 ± 2.0	
Parity		
Range	0 - 9	
Mean ± SD	1.9 ± 1.8	

Out of the 350 participants included in the study, 82.3% had clear liquor, 17.1% had meconium-stained liquor, and only 0.6% of them had bloody liquor with query abruptio placenta. Concerning CTG characteristics, 99.7% of the participants had 3 - 4 uterine contractions/ 10 min, and 0.3% of them had more than 5 uterine contractions/ 10 min. Baseline FHR was 110 – 160 b/min for 96.6 % of the participants, the results also showed that 95.7% of the participants had normal beats variability (5-15 b/min), 4.0% of them had reduced beats variability (2-4 b/min), and only 0.3 % had flat beats variability (0-1 b/min) and about 87.1% of the participants showed acceleration.

Further, according to NICHD 2008 guidelines, 89.1 % of the participants had CTG category I, 6.9% had category II, while 4% of them had category III. Seventy-two-point nine percent of the CTGs were interpreted by midwives, 16.3% by residents, 5.7% by specialists, and 5.1% by senior specialists (Table 2) (Figure 2).

Table 2. History of the current labor and CTG characteristics

| Variable	n=350	%
Liquor		
Bloody	2	0.6
Clear	288	82.3
Meconium	60	17.1
Uterine contractions/ 10 min		
≥ 5	1	0.3
3-4	349	99.7
Baseline FHR		
< 110 beat/minute	11	3.1
Normal 110 – 160 beat/minute	338	96.6
>160 beat/minute	1	0.3
Variability		
Flat 0-1 beats	1	0.3
Reduced 2- 4 beats	14	4.0
Normal 5-15 beats	335	95.7
Acceleration		
No	45	12.9
Yes	305	87.1
CTG categories		
I	312	89.1
II	24	6.9
III	14	4.0
Interpretation done by		
Resident	57	16.3
Midwife	255	72.9
Specialist	20	5.7
Senior Specialist	18	5.1
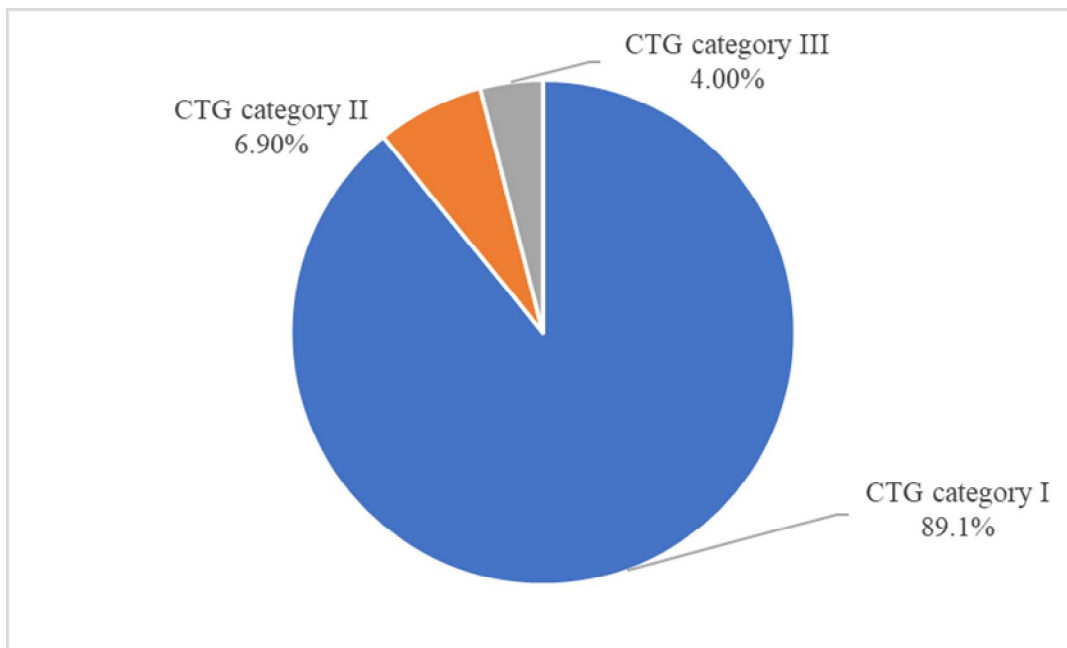
Figure 2: CTG categories distribution

***Labor Outcomes*:**
Most of the participants had spontaneous vaginal birth (91.4%), (5.1%) had cesarean section with spinal anesthesia, and (3.5%) had vacuum-assisted vaginal birth. Regarding the new-borns, 99.7% of them weighed 2.5 to 4 kg, 99.4% had 7-10 Apgar score at the 1st minute, while all of them had 7-10 Apgar score at the 5th minute. Cord pH was done for (8.3%) of the new-borns, of those the results showed normal pH (7.25 or above) for 96.7% new-borns and acidosis (7.20 or less) for only 3.3 %. Only 0.3% of the new-borns had been admitted to NICU for further respiratory assessment and close observation (Table 3).

Table 3. Labor outcomes of the participants

Variable	n=350	%
Mode of delivery		
C/S Spinal Anastasia	18	5.1
Spontaneous vaginal birth	320	91.4
Vacuum assisted vaginal birth	12	3.5
New-borns weight		
2.5-4.0 kg	349	99.7
More than 4 kg	1	0.3
Apgar score at 1st minute		
4–6 as moderate asphyxia	2	0.6
7–10 as reassuring	348	99.4
Apgar score at 5th minute		
4–6 as moderate asphyxia	0	0
7–10 as reassuring	350	100
Cord pH (n=30)		
Acidosis (≤ 7.20)	1	3.3
Normal pH (≥ 7.25)	29	96.7
Admission to NICU		
No	349	99.7
Yes	1	0.3

Relationship Between CTG Categories, History of The Participants and Labor Outcomes
The study showed no statistically significant relationship between CTG categories and age. However, gravidity, parity and state of liquor were significantly associated with CTG categories *(P=0.008, P=0.019 & P=0.006),* respectively (Table 4).

Table 4. Relationship between CTG categories and history of the participants

Variable	n	CTG categories I n= (312)	II n= (24)	III n= (14)	P-value
Mean age		28.5	27.4	28.7	0.598
Mean gravidity		3.4	2.1	2.9	0.008**
Mean parity		2.1	1.0	1.7	0.019*
Liquor					
Bloody	2	0	0	2 (14.3%)	0.006**
Clear	288	264 (84.9%)	17 (70.8%)	7 (50.0%)	
Meconium	60	48 (15.1%)	7 (29.2%)	5 (35.7%)	

Mode of delivery was found to be significantly related to the CTG categories using the Fisher Freeman-Halton test *(P=0.001).* Most of the participants with CTG category I had spontaneous vaginal birth represented 99.7% and only 0.3% of them had vacuum-assisted vaginal birth. Forty-one-point seven percent of the participants with CTG category II had cesarean delivery with spinal anesthesia, 29.2%, of them had spontaneous vaginal birth and 29.1% of them had vacuum-assisted vaginal birth. Fifty-seven-point one percent of the participants with CTG category III had a cesarean delivery with spinal anesthesia, while 28.6% of the participants had a vacuum-assisted vaginal birth, and 14.3% of them had spontaneous vaginal birth (Table 5) (Figure 3).
Moreover, a significant relationship was identified between CTG categories and Apgar score at 1st minute. All new-borns with CTG category I, had a reassuring Apgar score. Most new-borns with CTG category II had a reassuring Apgar score presented as 95.6% while only 4.4% of them had moderate asphyxia. Whereas 92.9% of the new-borns with CTG category III had a reassuring Apgar score however, 7.1% of them had moderate asphyxia (Table 5) (Figure 4). In addition, a significant relationship was identified

between CTG categories and cord pH. Cord pH was not done for all new-borns with CTG category I. For newborns with CTG category II, 69.6% of them had a normal pH (≥ 7.25) while 30.4% were not screened. Moreover, 85.7 % of the new-borns with CTG category III, had a normal pH (≥ 7.25), 7.1% had acidosis (≤ 7.20), and 7.2 % were not screened (Table 5) (Figure 5). Further, this study showed a significant association between the CTG categories and admission to NICU. All new-borns who had CTG category I and II were not admitted to NICU. Also, most new-borns with CTG category III were not admitted to NICU; only 7.1 % of them admitted to NICU (Table 5) (Figure 6).

Table 5. Relationship between CTG categories and labor outcomes

| Variable	n (%)	CTG categories			P-value
		I n=312 (89.1%)	II n=24 (6.9)	III n=14 (4%)	
Mode of delivery					
C/S Spinal anesthesia	18 (5.1%)	0	10 (41.7%)	8 (57.1%)	0.001**
Spontaneous vaginal birth	320 (91.4 %)	311 (99.7%)	7 (29.2%)	2 (14.3%)	
Vacuum assisted vaginal birth	12 (3.5%)	1 (0.3%)	7 (29.1%)	4 (28.6%)	
Apgar score at 1st minute					
4–6 as moderate asphyxia	2 (%)	0	1 (4.4%)	1(7.1%)	0.011*
7–10 as reassuring	348 (%)	312 (100%)	23 (95.6%)	13 (92.9%)	
Cord pH					
Acidosis. (7.20 or less)	1 (0.3%)	0	0	1(7.1%)	0.001**
Normal pH. (7.25 or above)	29 (8.6%)	0	17 (69.6%)	12 (85.7%)	
Not done	320 (91.4%)	312 (100%)	7 (30.4)	1(7.2%)	
Admission to NICU					
No	349 (99.7%)	312 (100%)	24 (100%)	13 (92.9%)	0.040*
Yes	1 (0.3%)	0	0	1 (7.1%)	
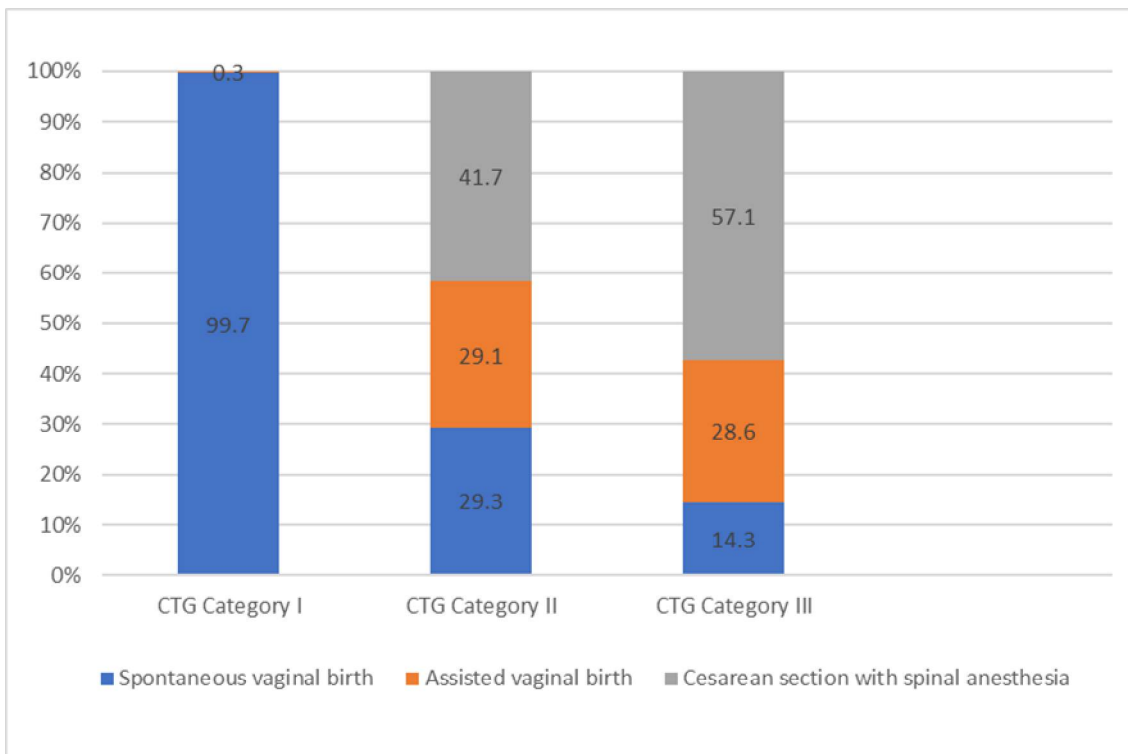
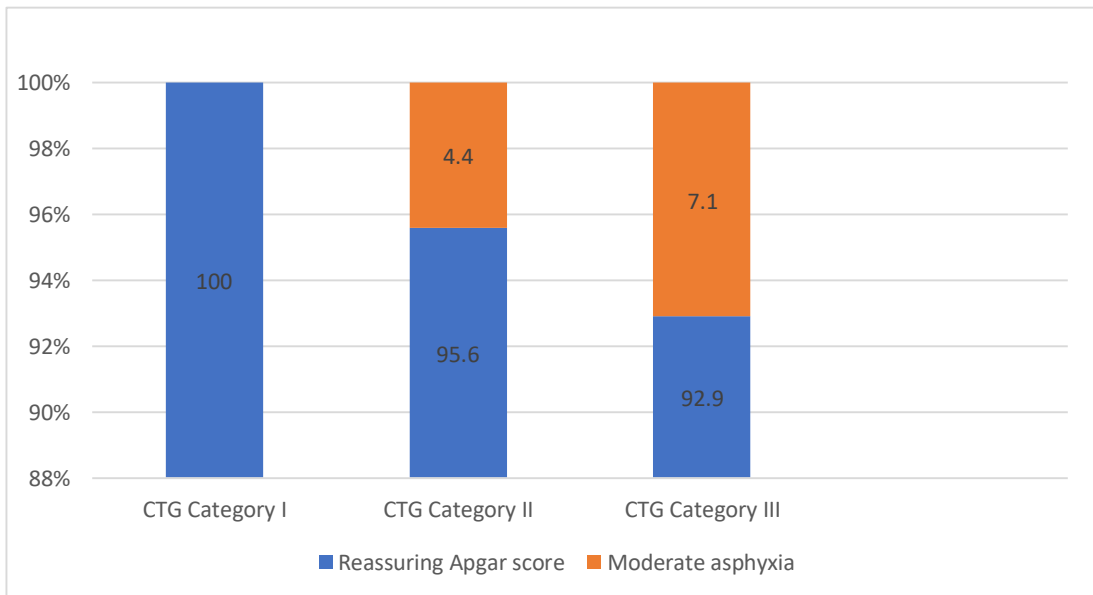**Figure 3:** Relationship between CTG categories and mode of delivery

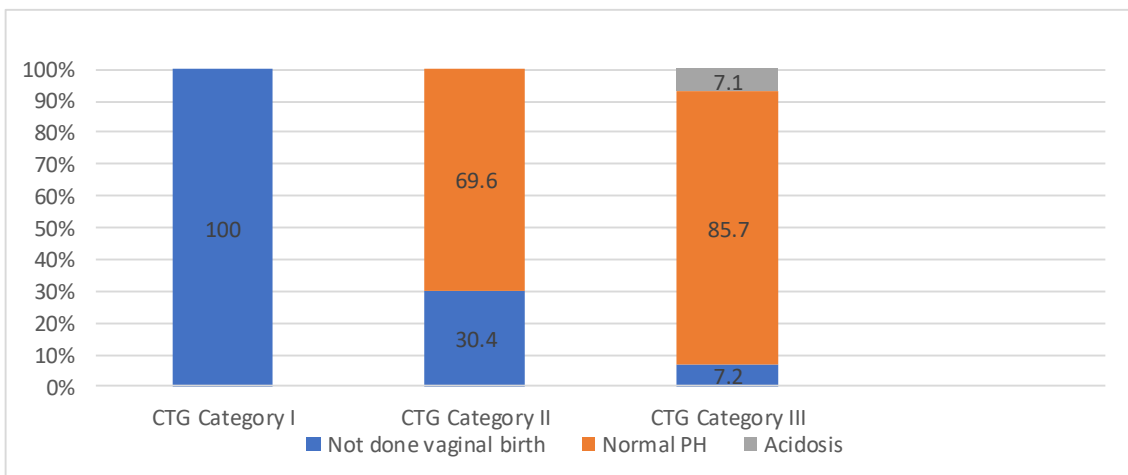**Figure 4:** Relationship between CTG categories and Apgar score at 1st minute

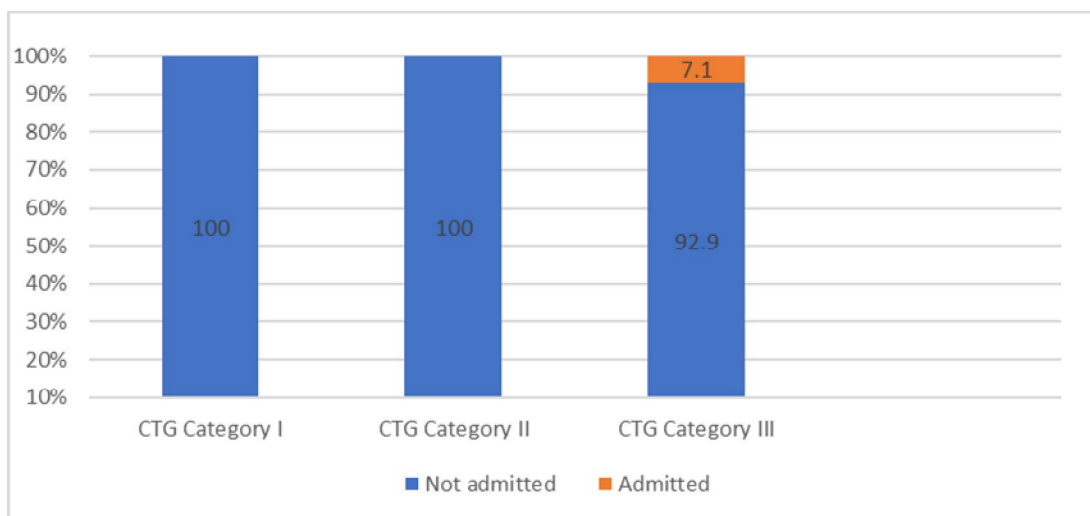**Figure 5:** Relationship between CTG categories and cord PH

Figure 6: Relationship between CTG categories and NICU admission

DISCUSSION

The current study showed that, majority of the participants had CTG category I. Concerning the relationship between CTG categories and personal characteristics of the participants, age was not significantly related however gravidity and parity were significantly related. In the same line, previous studies showed that, more than two thirds of the participants had CTG category I [11, 14]. Similar relationship in relation to age of the participants was found in a study investigated the association between intrapartum cardio-tocogram categories based on the NICHD 2008 and early neonatal outcomes but not for gravidity and parity [14].

This study revealed a statistically significant relationship between CTG categories and state of liquor where majority of the participants with CTG category I, had clear liquor and about two-thirds of the participants with meconium-stained liquor had CTG categories II and III, and less the one third of them had CTG category I. These findings agreed with previous studies [14, 19].

This study showed a significant statistical association between CTG categories and mode of delivery *(P < 0.001).* These findings agreed with another study showed that, two thirds of the participants delivered by vaginal delivery (66.7%), followed by cesarean delivery (24.2%), vacuum extraction (8.3%), and forceps extraction (0.8%). Additionally, participants with CTG category II were more likely to undertake cesarean delivery (32.4%), vacuum (16.2%), and forceps extraction (2.7%). Whereas, less than half of the participants with CTG category II had normal delivery, compared to more than two-thirds of the participants who had normal vaginal delivery were with CTG category I *(P = 0.005)* [14]. In the same line, it was reported that, vaginal delivery was the mode of delivery for 99.7% of the participants with CTG category I, while cesarean sections was the mode of delivery for 57.1% of the participants with CTG category III with a statistical significant relationship *(P < 0.05) (*Joshi et al., 2019*)*. Moreover, another study used only two classification system of CTG categories, normal for category I and abnormal for category II and III identified that, 83.3% of the participants who had normal CTG, delivered vaginally, and only 13.4% of them had cesarean section. While mode of delivery for the participants having abnormal CTG was cesarean section for 66.7%, assisted vaginal birth for 10%, and spontaneous vaginal delivery for 23% of them [13].

With regards the neonatal outcomes, the current study reveled a significant statistical relationship between CTG categories and 1st minute Apgar score *(P < 0.011).* In the same line, a previous study revealed that all new-borns with CTG category I had reassuring at 1st minute Apgar score. However, 8.1% of new-borns with CTG category II had moderate asphyxia. Further, all new-borns with CTG category I and II, had a reassuring 5th minute Apgar score [14]. Differently was found in another study where 86.7% of the new-borns with CTG category I had a reassuring 1st minute Apgar score and 90% of them had a reassuring 5th minute Apgar score. While 63.4% of the new-borns with CTG category II and III, had a reassuring 1st minute Apgar score. This difference may be attributed to the small sample size (n=60) [13]. Additionally, another study revealed that, two-thirds of the new-borns who had moderate asphyxia at the 5th minute after delivery were with CTG category III while, the vast majority of the new-borns who had reassuring 5th minute Apgar score were with CTG category I [11].

This study showed a statistically significant relationship between CTG categories and cord pH (P 0.001). In the same line, other studies reported a statistically significant association between intrapartum CTG categories and umbilical cord pH where new-borns with CTG category II were more likely to develop neonatal acidosis than those with category I *(P <0.001*) [14, 12]. Moreover, it was found that, only 2% of the participants with CTG category I had acidic umbilical cord blood pH, 22% with CTG category II had acidic umbilical cord blood pH and, 44% with CTG category III had acidic umbilical cord blood pH [20].

The current study reveled a statistically significant relationship between CTG categories and NICU admission (P < 0.040). These findings were consistent with a former study, which showed that, most of the new-borns admitted to NICU, had CTG category III [14]. Furthermore, NICU admissions were found to be more among newborns with the CTG category II (28.6%) and III (66.7%), as compared to CTG category I (7.5%) [11]. Additionally, another study revealed that about one-third of the new-borns admitted to NICU were with CTG category I while, about two-thirds were with category II and III. The difference may be attributed to the low percentage of CTG category II (6.9%) and III (4.0%) among the participants in the current study [13].

CONCLUSIONS

In summary, the current study revealed that CTG categories have a significant relationship with labor outcomes in terms of mode of delivery, Apgar score at 1st and 5th minute, and NICU admission. Although the study provided to some extent an insight on the relationship between CTG categories and labor outcomes, the researcher was not able to obtain the result of cord pH sampling for all new-borns, as it is

not a routine investigation to all new-borns in EJH and taken only up to pediatrician order. Moreover, using convenience sampling technique lowers representativeness of the population in comparison with other sampling techniques. Furthermore, participants recruited in the study were low risk pregnant women so, generalizability of the findings to high-risk mothers may be limited.

Implications for Nursing:

The study provided some insight on the relationship between CTG categories and labor outcome, however further studies using systematic reviews and meta-analysis is recommended to summarizes best evidence regarding CTG practice and interpretation. In addition to, organizing refreshing courses on interpretation of CTG traces using NICHD categories and incorporating them into orientation program for junior nurses. Moreover, other fetal monitoring measures such as fetal scalp blood sampling should be considered to detect hypoxic fetus, enhance predication of labor outcomes, aid into a proper clinical decision making and avoid unnecessary interventions or delay of necessary interventions. Further stakeholders and policy maker in hospitals need to rethink about the indication of continuous fetal monitoring.

Data availability: The supporting data will be available when needed.

Conflict of interests: The authors declare that there is no conflict of interest.

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