Validation of readings of locally made cardiotocogram (RxBox 2) model 2 compared with standard equipment*

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ABSTRACT

Background: The RxBox 2 Model 2 is a portable device developed by the National TeleHealth Center capable of measuring various physiologic signals including fetal heart beat and uterine contractions, making it able to act as a cardiotocogram. The first model of the RxBox 2 was used in an observational cross-sectional study and was noted to have a low accuracy compared with the standard cardiotocogram. An adjustment was made with the objective of improving the sensitivity and specificity.

Objective: The objective of this diagnostic cross-sectional study is to validate the RxBox 2 Model 2 by comparing its sensitivity and specificity with that of the standard cardiotocogram in detecting Category II traces.

Results: The results of this study exhibited an improvement in the sensitivity (77% versus 60%) and specificity (71% versus 61%). In terms of accuracy, there is no significant difference between the high risk and non-high risk groups. These contribute to the validity of RxBox 2 Model 2 as an acceptable screening tool.

Recommendation: Further studies may still be done to improve the correlation of each component of the trace to that of the standard cardiotocogram. Detailed analysis of the interpretations with corresponding interventions and perinatal outcomes may aid in validating the device.

Keywords: telemedicine, perinatology, perinatal care, maternal health

INTRODUCTION

Maternal and neonatal morbidity and mortalityremain to be growing public health concerns in the Philippines. There is an apparent need to assist the rural areas in terms of human and material resources to improve detection of cases that require immediate intervention and prompt referral to tertiary hospitals. The National TeleHealth Center (NTHC) responded to this demand through the National TeleHealth Service Program (NTSP). The development of the RxBox, a portable telemedicine device more affordable than the standard cardiotocogram, capable of measuring and transmitting basic physiologic signals is a part of this program.

The device has 5 sensors: the blood pressure monitor, the pulse oximeter, an electrocardiogram, skin surface temperature probe and fetal heart monitor with maternal tocometer. The first model of the RxBox 2 was used in an observational cross-sectional study and was noted to have a sensitivity of 60% and a specificity of 61%.[1] It was deemed that the discrepancy in the accuracy was due to the scale of tracing, thus, an adjustment was made with the objective of improving the sensitivity and specificity of the RxBox 2.

REVIEW OF LITERATURE

Cardiotocography

Cardiotocography is the electronic monitoring of fetal heart rate (FHR) pattern and uterine contractions. It is derived from the words kardia, meaning heart, and tokos, meaning labor or childbirth.[2] Because the parasympathetic and sympathetic forces that control FHR are affected by the degree of oxygenation, the pattern can serve as a reflection of fetal well-being. The use of electronic fetal monitoring is not limited to high-risk patients and is one of the most widely-used obstetrical procedure.[2]

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Cardiotocography and Perinatal Outcomes

The computed sensitivity and specificity of cardiotocography in predicting fetal asphyxia were 66% and 27% respectively. In the presence of bradycardia of less than 100 beats/minute, tachycardia more than 180 beats/min, silent-type curve and late decelerations, there is fetal asphyxia in up to 80% of the cases.[3]

Among the various components of a pathological trace, late decelerations are most often associated with fetal acidosis, as well as bradycardia and tachycardia. Variable decelerations are more often associated with normal pH.[3] A study by Georgiva further assessed this association by computing for the phase-rectified signal averaging. They concluded that increased decelerative capacity and short-term variation values are related to acidemia at birth; however, this parameter is not reliable in isolation and is locally not yet used.[4]

Another consequence of prolonged oxygen deprivation and metabolic acidosis is hypoxic-ischemic encephalopathy (HIE). HIE is a clinically defined syndrome characterized by abnormal neurologic function manifesting as change in the level of consciousness or seizures.[5] Up to 79% of newborns with HIE were found to have an abnormal cardiotocogram, usually with narrow variability or late decelerations.[6] A study done in 2014 did not find a specific FHR abnormality more predictive of HIE, but they identified an increased rate of non-reactive tracings and late decelerations.[7]

The APGAR score may be used to predict asphyxia, hypoxic-ischemic encephalopathy, cerebral palsy and cognitive impairment in later years. A 2012 study in Brazil evaluated the different factors that may predict the APGAR score, including obstetric factors. Among the different factors evaluated, repeated late decelerations and prolonged second stage of labor, with odds ratios of 2.4 and 3.3 respectively, were associated with an APGAR score of < 7 on the 5th minute.[8]

In 2013, a Cochrane review concluded that continuous cardiotocography is associated with a decrease in the incidence of neonatal seizures and also leads to an increase in caesarean section rates. The relationship of continuous cardiotocography to other outcomes such as perinatal death, neonatal hypoxic brain injury, adverse neurodevelopmental outcomes, cerebral palsy and need for analgesia were not statistically significant.[9]

Cardiotocography and Different Patient Profiles

In the Cochrane study, analysis did not note subgroup differences of high clinical importance that could affect the overall results. There is no evidence that continuous cardiotocography has a different influence on caesarean section and neonatal seizures in low and high-risk populations.[9]

A 2005 systematic review concluded that the use of cardiotocography among low risk patients results to more interventions without improving pregnancy outcomes. It does not recommend the use of cardiotocography as a screening test.[10]

In a 2007 study, cardiotocography had a sensitivity of 66.7%, specificity of 93.3% and a positive predictive value of 53.3% for predicting an Apgar score < 5 at birth among high risk patients. They concluded that cardiotocography can be used to accurately predict adverse fetal outcomes in this group of patients.[11] In a 2012 Australasian study, they found out that among those with ominous results, the incidence of fetal distress, meconium staining and neonatal intensive care unit (NICU) admission was significantly more frequent. It concluded that the use of carditocography is an effective way to screen for adverse outcomes among high-risk obstetric patients.[12] A study in 2013 established that biophysical profile and cardiotocography or non-stress test alone were not good predictors of neonatal outcomes among patients whose pregnancy is complicated with preeclampsia.[13] Likewise, among pregnant patients with diabetes mellitus, antenatal cardiotocography, non-stress test, biophysical profile or Doppler studies should be utilized.[14]

SIGNIFICANCE OF THE STUDY

Validating a locally-made cardiotocogram will improve accessibility of electronic monitoring of the FHR, contributing to a more vigilant approach to fetal assessment during labor, avoidance of unnecessary obstetric interventions and, ultimately, to the reduction of perinatal morbidity and mortality and improvement of overall maternal health.

OBJECTIVES

A. General Objective

To determine the sensitivity and specificity of the RxBox 2 Model 2 in detecting suspicious (Category II) traces compared with the standard cardiotocogram as the gold standard, with subgroup analysis for non-high risk pregnant patients and high risk pregnant patients

B. Specific Objectives

1. To determine the sensitivity, specificity, positive predictive value and negative predictive value in detecting (Category II) traces using the RxBox 2 Model 2 compared with standard cardiotocogram among non-high risk pregnant patients
2. To determine the sensitivity, specificity, positive predictive value and negative predictive value in detecting (Category II) traces using the

RxBox 2 Model 2 compared with standard cardiotocogram among high risk pregnant patients
3. To compare and analyze the differences between the two groups

MATERIALS AND METHODS

1. Definition of Terms

A. Classification of Traces

- **Normal (Category I)**
  - o Baseline: 110–160 beats per minute
  - o Variability: 5–25 beats per minute
  - o Decelerations: No repetitive decelerations
- **Suspicious (Category II)**
  - o Basline, Variability and Decelerations: Lacking at least one characteristics of normality, but with no pathological features
- **Pathological (Category III)**
  - o Baseline: <100 beats per minute
  - o Variability: Reduced variability, increased variability, or sinusoidal pattern
  - o Decelarations: Repetitive late or prolonged deceleratuons during > 30 minutes or 20 minutes if redueced variability, or one prolonged deceleration with > 5 minutes

B. Prenatal and Intrapartum High Risk Screening

The risk assessment system is shown in Appendix C. A total score of 10 divides patients into a low-risk (≤9) or a high-risk (≥10) category.[15]

2. Research Design

This is a diagnostic cross-sectional study to determine the accuracy of the RxBox 2 Model 2 in detecting Category II traces compared to the standard cardiotocogram.

3. Study Population

All pregnant women admitted in the Obstetrics and Gynecology Admitting Section (OBAS) with the following characteristics:

Inclusion criteria:

- Singleton
- Completed 37 weeks
- Cephalic
- >/= 3 centimeters cervical dilatation or with rupture membranes
- Able to provide informed consent

Exclusion criteria:

- Multifetal gestation
- Presence of fetal congenital anomally
- Contraindications to vaginal delivery
- Indications for immediate delivery

4. Sample Size Calculation

The desired total sample size is 210. The expected sensitivity of the RxBox 2 Model 2 is 0.99, the desired lower confidence limit is 0.9, with level of significance (alpha) of 0.05, power of 0.8, and an estimated prevalence of suspicious traces of 0.2. The calculations were performed in R statistical software (R version 3.2.4 (2016-03-10)) using the "power.diagnostic.test" function in the "MKmisc" package.[16,17]

5. Description of Study Procedure

All pregnant women who satisfy the inclusion and exclusion criteria were recruited in the study. The purposes and procedure of the study were explained upon admission. An informed consent was taken after explaining the methodology and objectives of the study. Upon agreement, the patients were hooked to the standard cardiotocogram for the initial tracing. All patients with an initial Category I or Category II trace were hooked to the RxBox for another tracing. If the initial trace was Category III, the patient was excluded from the study. The sequence of the patients on whom intrapartal monitoring was done was determined by the residents-on-duty and was not affected by the study. The interventions done after the initial tracing, including the decision to use analgesia, resuscitation, and delivery were determined by the residents-on-duty and were not affected by the study. All of the initial traces were read by a perinatology fellow. At the end of the study period, all of the traces were read by a perinatology consultant who was blinded to the source of the tracing. The maternal data and fetal outcomes were not disclosed to the perinatology fellow and consultant. A flow chart of the procedure is demonstrated in Figure 1.

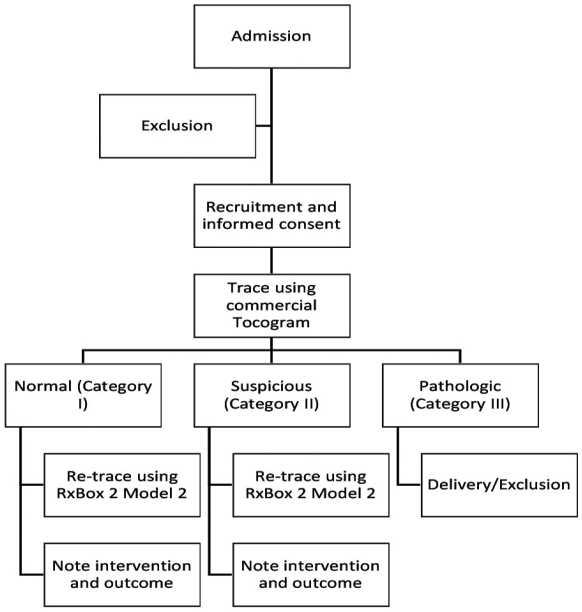

Figure 1. Flow Chart of the Study Procedure

Table 1. Maternal Characteristics, Intervention Details and Perinatal Outcomes

Maternal Characteristics		
Variables	**Non-High Risk**	**High Risk**
Maternal Age		
<20	29	13
20-29	70	33
30-39	28	27
40-49	5	5
>50	0	0
Marital Status		
Single	109	54
Married	23	24
Parity		
0	82	40
1	19	17
2-5	28	19
6-9	3	2
>/= 10	0	0
Amniotic Fluid		
Not stained	132	61
Thinly-stained	0	2
Thickly-stained	0	15
Cervical Dilatation		
≤4	67	59
5	27	13
≥6	38	6
Intervention Details		
Variables	**Non-High Risk**	**High Risk**
Route of Delivery		
Spontaneous vaginal	66	27
Instrumental vaginal	11	12
Caesarean section	55	39
Type of anesthesia		
Spinal	34	33
Epidural	41	25
General	1	1
None	56	19
Perinatal Outcomes		
Variables	**Non-High Risk**	**High Risk**
1st minute APGAR		
0-3	2	1
4-6	3	2
7-8	5	3
9	122	72
5th minute APGAR		
0-3	0	0
4-6	0	0
7-8	4	2
9	128	76
Neonatal Intensive Care Unit (NICU) Admission		
Yes	3	5
No	129	73
Weight		
AGA	126	74
SGA	2	3
LGA	4	1
Neonatal death		
Yes	0	0
No	132	78

RESULTS AND DISCUSSION

The total number of patients included in the study is 210. 132 patients were considered non-high risk, while 78 were high risk. Table 1 shows the breakdown of maternal factors, intervention details and perinatal outcomes.

In the series of two-by-two tables elucidated in Table 2, normal or Category I traces are regarded as "no disease", while suspicious or Category II traces are the "disease" states. Category II traces detected by both the standard cardiotocogram and the RxBox 2 are the true positive results, while category I traces detected by both the standard cardiotocogram and the RxBox 2 are the true negative results. Category II traces incorrectly identified by the RxBox 2 but not by the standard cardiotocogram are the false positive results, while the category II traces detected by the standard cardiotocogram but not by the RxBox 2 are the false negative results.

In this comparative study using the standard cardiotocogram as gold standard, the overall sensitivity of the RxBox 2 Model 2 in detecting Category II traces is 77% while the specificity is 71%. These values are higher compared to the initial study done by Hurtado, et al[1] in which the sensitivity was 60% and the specificity was 61%. In the initial study[1], it was noted that the variability of the traces greatly affected the number of Category II traces detected. Enhancing the scale of the traces in the RxBox 2 Model 2, and consequently the appearance of the variability, might have contributed to the improvement of the sensitivity and specificity. The computed accuracy of the RxBox 2 Model 2 is 74% which is also higher compared to the initial study (60%). Comparing the accuracy and the no information rate, the difference is statistically significant with a p-value of $9.855x10^{12}$, which shows that using the RxBox 2 Model 2 is better than randomly guessing in the detection of Category II traces. The sensitivity of the standard cardiotocogram in detecting fetal acidosis may be as high as 95.0%[18].

Comparing the two subgroups, the accuracy of the RxBox 2 Model 2 among non-high risk patients is 73% while it is 77% among high risk patients. Although the sensitivity is much higher among high risk patients (91% compared to 71%), further analysis of the accuracy shown in Table 4 clarifies that the difference between the two groups is not statistically significant (p-value = 0.6109). This is consistent with the Cochrane study[9] where subgroup analysis between low risk and high risk patients did not show any differences. A February 2017 revision of the Cochrane database also supported this. According to the update, data for both low risk and high risk patients including preterm pregnancy and high-quality trial subgroups were consistent with the overall results of the trial[19]. The comparable accuracy of the RxBox 2 Model

Table 2. Two-By-Two Tables

Comparison of the RxBox 2 Model 2 versus Standard Cardiotocogram			
Outcome of the diagnostic test	Standard Cardiotocogram (Gold standard)		
RxBox 2 (Model 2)	Suspicious/ Category II (Disease)	Normal/ Category I (No Disease)	Row Total
Suspicious/ Category II (Positive)	79 (True positives)	31 (False positives)	110
Normal/ Category I (Negative)	23 (False negatives)	77 (True negatives)	100
Column total	102	108	210
Comparison of the RxBox 2 Model 2 versus Standard Cardiotocogram Among Non-High Risk Patients			
Outcome of the diagnostic test	Standard Cardiotocogram (Gold standard)		
RxBox 2 (Model 2)	Suspicious/ Category II (Disease)	Normal/ Category I (No Disease)	Row Total
Suspicious/ Category II (Positive)	48 (True positives)	16 (False positives)	64
Normal/ Category I (Negative)	20 (False negatives)	48 (True negatives)	68
Column total	68	64	132
Comparison of the RxBox 2 Model 2 versus Standard Cardiotocogram Among High Risk Patients			
Outcome of the diagnostic test	Standard Cardiotocogram (Gold standard)		
RxBox 2 (Model 2)	Suspicious/ Category II (Disease)	Normal/ Category I (No Disease)	Row Total
Suspicious/ Category II (Positive)	31 (True positives)	15 (False positives)	46
Normal/ Category I (Negative)	3 (False negatives)	29 (True negatives)	32
Column total	34	44	78

2 between the two groups is promising because a number of studies support the benefit of cardiotocography in both low risk and high risk patients. In an article written by Ali et al, the percentage of patients who had a pathological trace

Table 3. Diagnostic Accuracy Characteristics

All Patients		
		95% CI
Accuracy	74%	68%, 80%
No Information Rate	51%	
P-Value [Acc > NIR]	9.86E-12	
Kappa	0.49	
Mcnemar's Test P-Value	0.34	
Sensitivity	77%	68%, 85%
Specificity	71%	62%, 80%
Positive predictive value	72%	62%, 80%
Negative predictive value	77%	68%, 85%
Prevalence	49%	42%, 56%
Detection rate	38%	
Detection prevalence	52%	45%, 59%
Balanced accuracy	74%	
All Patients (Fellow-In-Training)		
		95% CI
Accuracy	60%	54%, 67%
No Information Rate	58%	
P-Value [Acc > NIR]	0.27	
Kappa	0.20	
Mcnemar's Test P-Value	0.51	
Sensitivity	57%	46%, 67%
Specificity	63%	54%, 72%
Positive predictive value	53%	42%, 63%
Negative predictive value	67%	58%, 75%
Prevalence	42%	35%, 49%
Detection rate	24%	
Detection prevalence	45%	38%, 52%
Balanced accuracy	60%	54%, 67%
Non-High Risk Patients		
		95% CI
Accuracy	73%	64%, 80%
No Information Rate	52%	
P-Value [Acc > NIR]	5.26E-07	
Kappa	0.46	
Mcnemar's Test P-Value	0.62	
Sensitivity	71%	58%, 81%
Specificity	75%	63%, 85%
Positive predictive value	71%	63%, 85%
Negative predictive value	71%	58%, 81%
Prevalence	52%	43%, 60%
Detection rate	36%	
Detection prevalence	48%	40%, 57%
Balanced accuracy	73%	
High Risk Patients		
		95% CI
Accuracy	77%	66%, 87%
No Information Rate	56%	
P-Value [Acc > NIR]	1.36E-04	
Kappa	0.55	
Mcnemar's Test P-Value	0.01	
Sensitivity	91%	76%, 98%
Specificity	66%	50%, 80%
Positive predictive value	67%	52%, 80%
Negative predictive value	91%	75%, 98%
Prevalence	44%	32%, 55%
Detection rate	40%	
Detection prevalence	59%	47%, 70%
Balanced accuracy	79%	

Table 4. Summary Table: Overall Accuracy and Comparison of Components of Traces (RxBox 2 Model 2 versus Standard Cardiotocogram)

	Overall	Non-High Risk Patients	High Risk Patients
Sensitivity	77%	71%	91%
Specificity	71%	75%	66%
Positive Predictive Value	72%	71%	67%
Negative Predictive Value	77%	71%	91%
Accuracy in Non-High Risk Group		73%	
Accuracy in High Risk Group		77%	
X-squared = 0.2589, df = 1, p-value = 0.6109			
alternative hypothesis: two sided			

		p-value
Baseline FHR (minimum)	Pearson correlation coefficient r: 0.59	2.20 x 10-16
Baseline FHR (maximum)	Pearson correlation coefficient r: 0.60	2.20 x 10-16
Variability	Cramers V: 0.13	0.31
Acceleration	Cramers V: 0.03	0.67
Deceleration	Cramers V: 0.16	0.34
Intensity of contractions	Contingency coefficient: 0.392	0.00145341

among the low risk group is considerably lower compared to the high risk group (7.8% versus 22.8%) but 18.86% of babies born to low risk mothers had low APGAR scores (≤7). It concluded that using cardiotocography as a screening method is beneficial even among low risk patients because the number of women having pathologic intrapartal monitoring in low risk pregnancies is not negligible[20]. Its value among high risk patients is more evident. In addition to the study done by Sandhu et al11 described in the review of related literature where in the test had a sensitivity of 66.7%, specificity of 93.3% and a positive predictive value of 53.3% for predicting an Apgar score < 5 at birth, a more recent study by Gupta done among high risk patients showed a strong correlation of non-reactive traces with neonatal ICU admission, poor APGAR scores (<7) and perinatal mortality, with p-values <0.001. It also reported a significant increase in cesarean section rate (82.4% among those with non-reactive traces versus 20.5% among those with reactive traces (p-value <0.001).[21]

Table 4 also shows the statistical analysis for the different components of the traces. The Pearson correlation coefficients (normally ranging from -1 to +1) for the minimum and maximum baseline FHR are 0.59 and 0.60, respectively. In terms of the baseline FHR, the readings of the RxBox 2 Model 2 compared with the standard cardiotocogram has a moderate positive correlation. The p-values are small which means that the coefficients are statistically different from 0. For the variability, acceleration and deceleration, the values of Cramer's V, which is a measure of association between nominal or categorical variables, are 0.13, 0.03 and 0.16 respectively. These values also show a positive but weak correlation. Additionally, the p-values for these parameters are large, which means that there are no statistically significant associations. The contingency coefficient (normally ranging from 0 (no association) to 1 (maximum association)) for the intensity of the contractions is 0.392, with a p-value of 0.001. There is a weak to moderate correlation in this aspect, and that the value is statistically significant from 0.

The single-arm nature of the methodology may also increase the bias. False negative cases may arise because after a Category II trace is detected by the standard cardiotocogram, resuscitative measures will be given to the patient. This will consequently improve the fetal status and may result to a Category I reading by the time the patient is monitored using the RxBox 2 Model 2. This bias could have been reduced if the patients will be randomized into 2 groups, where in one group will be monitored using the RxBox 2 Model 2 first, while the other group using the standard cardiotocogram first, as what was done in the study of Hurtado, et al1. However, since necessary interventions (resuscitation and delivery) could not be done based on the readings of the RxBox 2 Model 2, monitoring the patient first using the RxBox 2 Model 2 would result to a delay in the management. This is important because even a 20-minute deferral of an intervention may result to a perinatal morbidity or mortality.

Based on these findings, it can be concluded that with regards to accuracy, there was some improvement between the RxBox 2 Model 2 in comparison to the first model, with a sensitivity of 77% and a specificity of 71%. There is no significant difference between the high risk and non-high risk groups. The difference between the accuracy and the no information rate is statistically significant. These two factors contribute to the validity of RxBox 2 Model 2 as an acceptable screening tool. However, as to the different components of the trace, there is room for improvement for the RxBox 2 Model 2 especially for the acceleration, which shows the weakest correlation among all the different variables.

Figure 2. The RxBox 2 Model 2

RECOMMENDATIONS

If at all possible, using the RxBox 2 Model 2 simultaneously with the standard cardiotocogram (i.e. constructing smaller probes that would fit in the same belt), as opposed to using one device after the other, may be a better study to compare the accuracy. In this setting, a more similar reading is expected, if not identical. The ability of the RxBox 2 Model 2 to detect each component of the trace can be further scrutinized and the aspect that needs fine-tuning the most can be differentiated. The consultant reader can also interpret each tracing more than once to decrease intraobserver variability. Detailed analysis of the interpretations of the RxBox 2 Model 2 and the corresponding interventions and perinatal outcomes may also aid in the validation of the device.

ETHICAL CONSIDERATIONS

The research protocol was approved by the University of the Philippines-Manila Research Ethics Board (UPMREB) PGH Review Panel prior to data collection. Informed consent was acquired from each patient. Patient confidentiality was kept by assigning a control number. All gathered data were seen only by the research assistants, resident, fellow and consultants directly involved in the research. All the finances required in the study was covered by the NTHC, through the aid of the National Institutes of Health. The participants of the study did not receive any form of financial compensation and they did not directly benefit from the research. There were no expected risks associated with the use of the device; at most, skin irritation from the probes of the cardiotocogram or from the elastic belt may occur, but is not usual and was not observed in the study. Prompt referrals and interventions were done as needed. ■

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