African Journal of FetoMaternal Medicine

Original

Handheld Doppler Versus Pinard Stethoscope for Intrapartum Foetal Monitoring at A Tertiary Centre in Nigeria: A Randomised Controlled Trial

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ABSTRACT

Background: Stillbirth is a major contributor to perinatal mortality rate, majority of which occur intrapartum. Intermittent auscultation is the method of choice in low-risk pregnant women and mostly available in the West African sub-Saharan region. **General objective:** This study aimed at comparing the use of Pinard stethoscope and handheld Doppler in foetal monitoring during labour. **Methods:** The study was carried out in the labour ward of the Federal Medical Centre Katsina. It consisted of 220 low risk pregnant women randomized to either handheld Doppler or intermittent auscultation with Pinard Stethoscope for foetal monitoring in labour. The outcome measures were studied. Significant p values were set at <0.05. Data was analysed using SPSS version 20.0. **Results:** There were no statistically significant difference between the two groups in the socio demographic characteristics except for religion, obstetric there is no statistically significant difference in characteristics, rate of abnormal foetal heart rate detection (Fisher's exact test, p = 0.667), mode of delivery, (X^2 = 0.096, p = 0.953), foetal birth weight (X^2 = 3.12, p = 0.128), admission into the neonatal special care baby unit (X^2 = 1.019, p = 0.622) and APGAR score at 5minutes (X^2 = 0.338, p = 1.000). There was higher level of maternal satisfaction in the Handheld doppler group, Likert scale (X^2 = 24.029, p = < 0.001) and Ordinal logistic regression. **Conclusion**: Handheld doppler is comparable to Pinard stethoscope in terms of foetal heart rate abnormality detection, foetal and maternal outcomes with higher maternal satisfaction in the Handheld doppler group.

Keywords: Handheld Doppler, Pinard stethoscope, Intrapartum foetal monitoring, low risk pregnancy.

INTRODUCTION

Stillbirths account for more than half of the world's six million perinatal deaths which occur mostly in low and middle-income countries where annually about three million still birth occur in the third trimester.[1,2]

Foetal heart rate monitoring and use of partograph in labour have become essential for early screening and identification of existing complications, so that early decision can be made regarding additional interventions.[2,3] Intermittent auscultation is the recommended method of foetal heart rate monitoring during normal labour except in high risk patients.[4,5] Intermittent auscultation was recommended for safety and reduction in operative interventions.[7–11]

This study aims at comparing the ability to detect intrapartum foetal heart rate

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abnormalities between Pinard stethoscope and handheld Doppler.

SUBJECTS AND METHODS

The study was carried out in the labour room of Federal Medical Centre Katsina Nigeria over four-month period from 12th September 2018 to 24th January 2019. This was a randomized controlled trial that enrolled 224 low risk pregnant women from 37 completed weeks and up to 42 weeks of gestation in active stage of labour who consented and met the inclusion criteria. The subjects were randomized to either of two groups. The first group (control group) consisted of 112 subjects who were monitored with Pinard stethoscope. The second group (study group) consisted of 112 subjects who were monitored with Handheld doppler. The patients were briefed about the study during antenatal visits.

The randomisation was done via random number generator software available on Microsoft excel, which was used to allocate patients to either of the 2 groups as they presented to the labour ward and met the inclusion criteria. Exclusion criteria include, non-consenting women, women who present in second stage of labour, twin gestation, diagnosis of foetal distress on admission, contraindications to vaginal delivery, diagnosis of intrauterine foetal death on admission, any woman with diagnosis of Eclampsia or antepartum haemorrhage, foetal presentation other than cephalic, obesity and polyhydramnios.

Two hundred and twenty-four brown envelopes of the same size were obtained. Two hundred and twenty-four sheets of standard size papers were divided into two sets. On one set of 112 Treatment A (Pinard stethoscope) and on the second set Treatment B (Handheld Doppler) was written. The envelops were numbered 1 to 224 and filled with the corresponding sheets either A or B according to the already generated random numbers.

The progress of labour in the consenting women was recorded in a partograph which was marked at the top as Pinard or Handheld Doppler. A base line foetal heart rate of 110 beats per minute to 160 beats per minute was regarded as normal. A foetal heart rate of less than 110bpm regarded as bradycardia while a heart rate of more than 160bpm was considered as tarchycardia.[11] Abnormalities in foetal heart rate detected were further confirmed by a cardiotocography (CTG). Foetal heart rate tachycardia or bradycardia, reduced baseline variability, atypical variable or late deceleration were considered abnormal. In the event abnormal heart rate is detected, intrapartum resuscitative measures (hydration, left lateral position and oxygen) were taken, and appropriate line of action was then taken by the team on call. Measures of primary outcome include Abnormal foetal heart rate and APGAR score of < 7 at 5minute for the fetus then Vaginal delivery, Instrumental delivery, and Caesarean section for the mother.

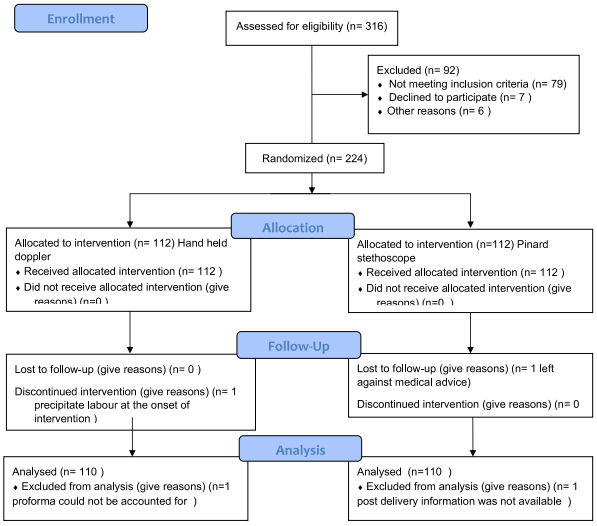

Fig. 1. CONSORT 2010 Flow Diagram

The data was obtained with the aid of an interviewer administered proforma, partograph and records from neonatal intensive care unit up to the seventh day of admission in babies who were admitted.

The data obtained was checked for completeness and then entered serially into the SPSS software package version 20.0, for analysis using mean and standard deviation of variables. Categorical data were expressed as frequencies and percentages and were analysed by chi -square test. Normally distributed continuous data was described using mean and standard deviation and was analysed by using student t-test. Comparisons of outcome measures was made with P values set at < 0.05.

Ethical approval of the Health

Research and Ethics Committee of the hospital was obtained with reference number FMCNHREC.REG.N003/082012.

RESULTS

A total of 224 participants were enrolled and 220 were analysed. The mean age of the patients in the handheld doppler group was 27.00 ±7.01years while mean age in the Pinard group was 28.68 ±6.40 years. There was no statistically significant difference in the mean age of the patients (t = -1.85, p = 0.066). The differences were statistically significant in the religious group between the two arms (X^2 = 4.806) p =0.028). In general, there was no statistically significant difference in the socio demographic characteristics of the patients in the two groups.

Table 1: Socio- Demographic Characteristics of the Patients

Variable	Hand-held Doppler (n=110)	Pinar (n=110)	Test	P-value
Mean age ± SD (years)	27.00(7.01)	28.68(6.40)	t- test t = -1.85	0.066
Tribe				
Hausa	90(81.8%)	75(68.2%)		
Fulani	10(9.1%)	15(13.6%)		
Others	10(9.1%)	20(18.2%)	X^2= 5.697	0.058
Religion				
Islam	101(91.8%)	90(81.8%)		
Christianity/ Others	9(8.2%)	20(18.2%)	**X^2= 4.806***	0.028
Educational level				
Qura'nic	34(30%)	23(20.9)		
Primary	5(4.5%)	10(9.1%)	X^2=4.660	0.190
Secondary	25(22.7%)	32(29.1%)		
Tertiary	46(41%)	45(40.9%)		
Occupation				
House wife	75(68.2%)	73(66.4%)		
Civil servant	17(15.5%)	19(17.3%)	X^2=0.588	0.899
Business	9(8.2%)	7(6.4%)		
Others	9(8.2%)	11(10.0%)		
Booking status	74(67.3%)	87(79.1%)	X^2=3.914	0.067
Booked	36(32.7%)	23(20.9%)		
Unbooked				

The modal parity in both groups was para 0 meaning that primigravidity had the highest frequency. The mean gestational age at delivery was (38.8±1.392) weeks and (38.9 ±1.673) weeks the difference in the mean gestational age at delivery was not statistically significant (t= -0.745 p = 0.457). There was no significant difference between the two groups in the rate of augmentation of labour (X^2 = 0.656, p = 0.418)

In the handheld doppler group six patients (5.5%) had abnormal foetal heart rate compared to four patients (3.6%) in the Pinard group.

Table 2: Obstetric Characteristics

Variable	Hand-held Doppler(n=110)	Pinard(n-110)	Test	p- value
Modal parity	0	0		
Mean gestational age(weeks) ± SD	38.8(1.392)	38.9(1.673)	**t= -0.745**	**0.457**
Augmentation of labour	27(24%)	22(20%)	**X^2** = 0.656	**0.418**

Table 3: Distribution of Abnormal Foetal Heart Rate

Variable	Hand-held Doppler (n=6)	Pinard(n=4)	Test	P value
CTG				
Normal	5(83%)	3(75%)	Fisher's exact test	0.667
Abnormal	1(17%)	1(25%)		

Table 4: Foetal/ Neonatal Outcome

Variable	Hand-held Doppler(n=110)	Pinard(n=110)	X^2	P value
Weight in kg				
< 2.5	5(4.5%)	12(10.9%)	X^2=3.12	0.128
≥ 2.5	105(95.5%)	98(89.1%)		
Admission to SCBU				
Yes	3(2.7%)	1(0.9%)	X^2 = 1.019	0.622
No	107(97%)	102(99.1%)		
APGAR score				
< 7	1(0.9%)	2(1.8%)	X^2 = 0.338	1.00
≥ 7	109(99.1%)	108(98.2%)		

TABLE 5: MATERNAL OUTCOME

Variable	Hand-held Doppler(n=110)	Pinard(n=110)	Test	P value
Mean duration of labour(Hrs)	5.6(2.522)	5.73(2.044)	t= 0.285	0.776
Mode of delivery				
Spontaneous vaginal delivery	104(94.5%)	103(93.6%)	X^2 = 0.096	0.953
Instrumental vaginal delivery	1(0.9%)	1(0.9%)		
Caesarean section	5(4.6%)	6(5.5%)		
Level of maternal satisfaction				
Very dissatisfied	0(0.0%)	5(4.5%)		
Dissatisfied	0(0.0%)	1(0.9%)	**X^2 = 24.029***	< 0.001
Neutral	7(6.4%)	29(26.4)		
Satisfied	61(55.56)	42(38.2%)		
Very satisfied	42(38.2%)	33(30.0%)		

The abnormal heart rate was further confirmed with CTG (Fishers exact test, p = 0.667). The difference in foetal heart rate abnormality detection was not statistically significant.

Table 6: Ordinal Logistic Regression of Maternal Satisfaction

Maternal Satisfaction	Handheld Doppler (n = 110)	Pinnard (n = 110)	Exp B (Odds Ratio)	95% Confidence Interval		P Value
				Lower	Upeer	
Very dissatisfied	0 (0.0%)	5 (4.5%)	0.033	0.013	0.082	<0.001*
Dissatisfied	0 (0.0%)	1 (0.9%)	0.040	0.017	0.091	<0.001*
Neutral	7 (6.4%)	29 (26.4%)	0.356	0.240	0.528	<0.001*
Satisfied	61 (55.4%)	42 (38.2%)	3.172	2.123	4.740	<0.001*
Very Satisfied	42 (38.2%)	33 (30.0%)	2.366	1.420	3.942	0.001*

The difference in fetal weight was not statistically significant X^2 =3.12 p = 0.128. There was also no statistically significant difference in APGAR score (X^2 = 0.338 p =1.00). and admission into special care baby unit between the two groups. (X^2 = 1.019, p =0.622).

Table 7: Summary of the Foetuses With Abnormal Heart Rate

Variable	Handheld doppler (n=6)	Pinard (n= 4)	Total
Time of onset of abnormal heart rate			
First stage	0	0	
Second stage	6(60%)	4(40%)	10
CTG			
Normal	5(83.3%)	3(75%)	8
Abnormal	1(16.7%)	1(25%)	2
Mode of delivery			
Spontaneous vaginal delivery	4(66.6%)	2(50%)	6
Instrumental vaginal delivery	1(16.6%)	1(25%)	2
Caesarean section	1(16.6%)	1(25%)	2

The difference in the mode of delivery was not statistically significant X^2 = 0.096, p = 0.953. However, in the level of maternal satisfaction the difference is statistically significant, with more women preferring handheld doppler (X^2 = 24.029 p = < 0.001). The level of maternal satisfaction was further confirmed by a univariate ordinal logistic regression. The handheld doppler group were 2 times more likely to be very satisfied with the method of auscultation than the doppler group.

DISCUSSION

This was a randomized trial that compared two different methods of intermittent auscultation the handheld doppler and Pinard stethoscope in the labour ward of Federal Medical Centre Katsina. There was no statistically significant difference in the socio demographic characteristics of the two groups except for the religion. There was also no statistically significant difference in the obstetric characteristics between the two groups, this also makes the two groups similar and reduced confounders. This means the two groups are similar in this respect therefore any difference observed in the outcome of the mothers, or the babies were most likely due to the difference between the two methods.

From this study the handheld doppler was able to pick 5.5% and the Pinard detected 3.6% as having abnormal foetal heart rate (Fisher's exact test, p = 0.667). This finding was not statistically significant. This result is contrary to what was obtained by Byaruhanga et al where the detection of abnormal foetal heart rate by hand held doppler was 7.6% against Pinard 4.7% and the difference was statistically significant.[11] This difference could be due to a larger number of study participants and the longer duration of data collection in that study. Over 2000 participants were enrolled in the study by Byaruhanga et al which was ten times the number of participants in this study. Also Kamala BA et al in Dar es Salam had found abnormal heart rate of 6.0% in the hand held doppler and 3.9% in the Pinard group which was also statistically significant.[12] This could be explained by the fact that in the Dar es Salam study 2.7% foetal heart rate abnormality detection for Pinard stethoscope and 5% foetal heart rate abnormality detection by handheld doppler were considered significant contrary to this study were abnormal foetal heart rate detection rates of 10% and 25% were considered significant for Pinard and Hand held Doppler respectively. Therefore, there has to be quite a higher number of foetal heart abnormality detection by the Handheld Doppler (2.5 times that of Pinard) before an increased detection becomes significant in this study. The previous study also

had larger number of participants and was carried out over a two- and half-year period.

There was no statically significant difference between the handheld doppler group and Pinard group in the foetal and neonatal outcomes in terms of foetal birth weight, admission into the neonatal special care baby unit and APGAR score at 5minutes. This is similar to what was found in Kampala and the Dar es Salaam studies.[9,10] The Hararen study did not find any statistically significant difference in the APGAR score at 5 minutes between various methods of intermittent auscultation.[13] In the previous studies increased detection of abnormal foetal heart rate by hand held doppler did not lead to a better foetal and neonatal outcome,[9,10] In this study there was no record of still birth or neonatal seizure in any of the two groups. This could be explained by the fact that there were reports of delays in the interventions given to the foetuses with abnormal foetal heart rate in the previous studies.[13] However, in this study majority of the abnormal heart rate picked did not persist after resuscitative measures were instituted. There was also prompt delivery of the few foetuses that had persistent abnormal heart rate.

This study did not show any statistically significant difference in the mean duration of labour, between the handheld doppler group and the Pinard group (duration of labour which in this study only takes account of the admission to delivery interval). This finding is similar to what was found in other studies.[10,11] In this study there was no statistically significant difference in the mode of delivery between the hand held doppler and the Pinard group. This is similar to was found in previous studies.[9,10] However Mohammed et al found higher caesarean section rate among those monitored with doppler and electronic monitoring compared to pianrd.[13]This may be because in this study, CTG was done and resuscitative measures were successful in restoring normal fetal heart rate patterns, thereby allowing labour to continue in most of the patients in the 2 groups.

There was statistically significant difference in the level of maternal satisfaction using Likert scale and ordinal logistic regression which shows higher satisfaction by the women in the handheld doppler group than the Pinard group. This is similar to was found in Cape town South Africa where the most preferred method of foetal heart rate monitoring for the pregnant women was the hand held doppler followed by CTG then Pinard.[14] Although in this study the women's reasons for being satisfied with either of the two method was not asked, the higher satisfaction level with hand held Doppler may be attributed to the fact that they can hear the foetal heart rate and that gives them further reassurance.

There were ten foetuses with abnormal foetal heart rate 6 in the doppler group and 4 in the pinard group. The abnormality was found in the second stage of labour. The abnormal foetal heart rate that was not confirmed by CTG could be explained by the occurrence of typical variable deceleration which could happen when there is cord compression and is picked by intermittent auscultation as bradycardia. Rarely maternal pulse could be erroneously recorded by intermittent auscultation as foetal bradycardia which will not be confirmed by CTG. Only two foetuses one from each group had persistent foetal heart rate abnormality which prompted assisted vaginal delivery in the form of vacuum extraction. The main aim of intrapartum monitoring is to identify those foetuses at risk of hypoxia/acidemia and salvage them.[8] The two foetuses however had normal APGAR scores at five minutes. However, in a British Columbian Study the incidence of Low APGAR score was found to be very low among neonates delivered by caesarean section for non-reassuring fetal heart rate.[15]

Recommendations

Based on the findings of this study the following are recommended

1. Handheld doppler can be used in place of Pinard stethoscope for intarapartum foetal monitoring. This is because it is associated with similar outcomes and better maternal satisfaction than Pinard.
2. A similar but larger multi- centre randomised controlled trial should be done among low-risk pregnant women to compare the two methods of intermittent auscultation.

Limitations

1. Lack of blinding.
2. Due to ethical concerns intrauterine resuscitation was instituted before CTG could be done, therefore the CTG might not have been a true representation of the foetal condition, since the acute distress might have resolved, making the CTG to appear normal.
3. It was not possible to compare both the two methods on the same patient to further clarify the reasons for the difference in the level of maternal satisfaction

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