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Use of wind-up fetal Doppler versus Pinard for fetal heart rate intermittent monitoring in labour: a randomised clinical trial

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ABSTRACT

Objectives: In resource-poor settings, the standard of care to inform labour management is the partograph plus Pinard stethoscope for intermittent fetal heart rate (FHR) monitoring. We compared FHR monitoring in labour using a novel, robust wind-up handheld Doppler with the Pinard as a primary screening tool for abnormal FHR on perinatal outcomes.

Design: Prospective equally randomised clinical trial.

Setting: The labour and delivery unit of a teaching hospital in Kampala, Uganda.

Participants: Of the 2042 eligible antenatal women, 1971 women in active term labour, following uncomplicated pregnancies were randomised to either the standard of care, or not.

Intervention: Intermittent FHR monitoring using Doppler.

Primary outcome measures: Incidence of FHR abnormality detection, intrapartum stillbirth and neonatal mortality prior to discharge.

Results: Age, parity, gestational age, mode of delivery, and newborn weight were similar between study groups. In the Doppler group, there was a significantly higher rate of FHR abnormalities detected (Incidence Rate Ratio (IRR)=1.61, 95%CI 1.13 to 2.30). However, in this group there were also higher though not statistically significant rate of intrapartum stillbirths (IRR=3.94, 0.44 to 35.24) and neonatal deaths (IRR=1.38, 0.44 to 4.34).

Conclusion: Routine monitoring with a handheld Doppler increased the identification of FHR abnormalities in labour; however, our trial did not find evidence that this lead to a decrease the incidence of intrapartum stillbirth or neonatal death.

Trial registration: ClinicalTrails.gov (1000031587)

TEXT BOXES

1. Strengths and limitations of this study

- This is the first study to use current monitoring guidelines to compare evaluated Doppler versus Pinard in improving stillbirth and neonatal outcomes.
- A major strength of this study includes the prospective and randomisation design.
- We were unable to perform secondary screening of suspected fetal hypoxia through the use of cardiotography; nor confirm for the presence of fetal hypoxia acidemia via fetal blood scalp sampling, and cord blood gases; therefore we were unable to assess if the identification (or lack of identification) of abnormal FHR was correlated with the presence of fetal hypoxia acidemia.
- We were unable to exclude some cases where the underlying cause of death was other than fetal hypoxia (e.g. congenital anomalies, early onset sepsis) due to diagnostic limitations in differentially diagnosing these cases.

2. Training

Helping Babies Survive Labour is the training programme that was used to train the midwives in Nsambya hospital. It was developed by Powerfree Education and Technology in Cape Town in collaboration with Save the Children and health professionals from Nsambya Hospital Kampala (Figure 3).

Many training methods and guidelines are written in high income countries and are simply transferred for use in low income countries, although the healthcare workers in these countries may face very different challenges. Input was solicited from both the healthcare workers and academics in the target country in the preparation of these training materials.

The material first provides a section of evidence-based theory that will help health workers to understand why monitoring of the fetal heart is important. This is followed by practical lessons on how to monitor fetal well-being, how to interpret observations and recordings and most importantly, gives guidelines on what to do when something is wrong. The training is developed in such a way that it can be used along side the Helping Babies Breath training material, which focuses on neonatal resuscitation.

Before this trial started, midwives and doctors were trained. Fifty-two people attended the training and 42 completed both the pre- and post-test. The average score for the pre-test was 49.7% (median 50%). The average score for the post-test was 67.9% (median 69%). It does reveal the low baseline knowledge on appropriate intrapartum care and illustrates the need for continuous quality improvement.

For link to the manual and its references
http://www.healthynewbornnetwork.org/sites/default/files/resources/HBSL%20training%20booklet.pdf

INTRODUCTION

Approximately 44% of all child deaths under the age of 5 years occur in neonates (<28 days of age).[1] The third largest cause of neonatal mortality is intrapartum-related hypoxia (formerly called `birth asphyxia') resulting in an estimated 660 000 neonatal deaths per year globally[1] and an additional 414,000 children who survive with disability.[2] There are also an estimated 1.02 million intrapartum stillbirths almost all in low and middle income countries.[3] This burden is highest in areas of the world where the probability of quality of care at birth is the lowest.[4] In order to reduce the incidence of intrapartum-related stillbirths and neonatal deaths, it is necessary to assess fetal well-being in labour with routine monitoring of the fetal heart rate (FHR), linked to rapid and effective management with resuscitative measures or prompt delivery, and provision of neonatal resuscitation if needed.

Characteristic FHR changes often precede brain injury via a process of progressive fetal hypoxic acidemia.[5] Intermittent auscultation as a primary screening tool to monitor fetal well-being is the recommended standard of care for women experiencing uncomplicated deliveries.[6-9] One method of intermittent auscultation uses the Pinard Fetal Stethoscope (Pinard), a trumpet shaped horn, to monitor the FHR and is widely adopted as the standard of care in resource-poor settings since it is low cost and does not require a power source or repairs. The difficulties posed in using a Pinard are generally not conducive to a busy labour ward. It requires additional time to precisely locate the fetal heart as the heart is only audible within a very narrow area of the woman's abdomen, it requires that the surrounding area be quiet in order to hear the fetal heart, the reading can be unreliable in obese women, and it requires the midwife to place her ear in close proximity to the woman's pubic area. In addition the midwife usually counts the FHR for short time, such as 15 seconds, and multiplies to reach beats/minute, further decreasing accuracy and introducing arithmetic errors. The handheld Doppler ultrasound fetal heart rate monitor (Doppler) detects FHR and provides a steady state number per minute, as well as audible auscultation of the FHR. It requires a reliable power source and may need repairs, and is more costly than a Pinard. However, it permits the midwife to quickly locate the FHR, allows others including the mother to hear the FHR, permits the woman to remain in any comfortable position while being assessed, permits the midwife to both assess the FHR and communicate to the woman the status of her baby, and has been shown to be preferred by women over the use of the Pinard.[8,10] A rugged, wind-up, handheld Doppler fetal heart rate monitor (Doppler) developed by Power-free Education Technology (Pet.og.za) showed in initial field tests to be accurate and acceptable to both mother and midwives in low-resource settings.[11,12] It uses a hand crank to generate 2:30 minutes of use for every 30 seconds of cranking.

While there have been several studies showing reduced intervention and no improved outcomes in the use of the intermittent (Pinard or Doppler) versus continuous cardiotocography (CTG) monitoring as the primary screening tool in uncomplicated deliveries,[6,13] there is little research on outcomes in intermittent monitoring comparing Doppler versus Pinard. A single study by Mohamed et al using a monitoring protocol of 10 minutes every half-hour found higher detection of FHR abnormalities and better perinatal outcomes in the intermittent auscultation Doppler group compared with the Pinard group.[14]

We aimed to use a randomised trial design to compare the primary screening methods of FHR monitoring (Doppler as intervention versus Pinard as standard of care) on incidence of detection of FHR abnormalities, and on the incidence of intrapartum stillbirth and neonatal mortality in the first 24 hours after delivery.

METHODS

Study design and participants

We undertook this randomised controlled trial at San Raphael of St. Francis Nsambya Hospital, a peri-urban private not-for-profit hospital in Kampala, Uganda. It is a teaching hospital that manages 7 500 deliveries annually. CTG and fetal blood gas sampling to support labour management, and epidural pain medication are not available. Oxytocin augmentation and Caesarean delivery rates are 40% and 20% respectively. The standard of care for intrapartum FHR monitoring is by intermittent auscultation using the Pinard.

Women were requested to participate during an antenatal care appointment. This consent was reconfirmed in labour provided that they presented in labour with a singleton pregnancy, in a cephalic position, at term or post-term (>37 weeks gestation). Women were excluded if they were already in second stage of labour upon admission or had a high risk pregnancy, such as preeclampsia or antepartum hemorrhage; if there was a diagnosis of intrauterine fetal death upon admission; or if the woman was admitted for an elective Caesarean delivery. Participants were presented with information about the study, and agreeing participants provided written consent. This study was approved by Sickkids Research Ethics Board, Nsambya Internal Review Board, as well as the Uganda National Council for Science and Technology. Registration of our protocol with ClinicalTrials.gov occurred before participant enrolment started, but due to an administrative error with our institution's Clinical Research Services Unit, the protocol was only released to the public after the completion of the study. Documentation from the Chair of our independent Research Ethics Board was provided to BMJ Open attesting to the version of the protocol provided to them prior to the start of enrolment.

Randomisation

Women were equally randomised to one of the two study methods using sequentially numbered, opaque sealed envelopes. Study participants and care providers where not blinded to the intervention. Data were collected from the patient's partograph and from the hospital's routine neonatal mortality audit data, when applicable.

Procedures

The standard of care for intrapartum monitoring relied on partograph and FHR monitoring with the Pinard. Our pre-study training address deficiencies in monitoring standards (acceptable range for FHR, recognition of accelerations, decelerations, and change in baseline). We developed a training module entitled "Helping Babies Survive Labour" modeling on the "Helping Babies Breathe" visual materials and learning approach. The technical basis was from World Health Organisation (WHO) and Canadian Obstetric Society protocols.[5] All midwives and doctors were then given this in-service training for half a day. FHR monitoring was undertaken every 30 minutes in first stage of labour; every 15 minutes in second stage before pushing; and every 5 minutes in second stage when pushing and for 1 minute immediately after a contraction. The baseline FHR was recorded as a single number rather than a range, in the unit of beats per minute (bpm). The FHR rhythm (regular or irregular) and absence or presence of accelerations or decelerations were also documented. The maternal pulse was simultaneously palpated to differentiate it with the FHR.

When FHR abnormalities are identified the standard of care would be to switch from intermittent auscultation to CTG. Since CTG is not available in Nsambya Hospital, any noted FHR abnormalities were reported by the research midwife to the doctor on duty for assessment. Management following this assessment was either closer intermittent monitoring, or intra-uterine

resuscitation with re-assessment of the FHR. Intra-uterine resuscitation consisted of maternal position change, administration of oxygen by mask to mother, initiation of intravenous infusion, discontinuation of oxytocin augmentation, and consider prompt delivery (assisted vaginal if imminent, otherwise by Caesarean).

Outcomes

The primary outcome measures of interest were detection of FHR abnormality in labour (defined below), intrapartum stillbirth, and neonatal deaths in the first 24 hours of life. Fetal heart rate abnormality is defined as tachycardia, bradycardia, or atypical variable, late or prolonged decelerations. Tachycardia and bradycardia are defined as baselines of >160 bpm and <110 bpm, respectively. Some features of atypical variable decelerations are abrupt fetal heart rate decelerations, lasting >2 minutes, slow return to baseline, or in the presence of tachycardia. Late decelerations are a repetitive, gradual decrease in the FHR and return to baseline, commencing after the onset of the contraction, and return to baseline after the end of the contraction. Prolonged decelerations are a decrease from baseline of >15 bpm lasting from 2-10 minutes. Secondary outcomes were Apgar score less than 7 at 5 minutes, admission to special care unit for intrapartum-related complications (intrapartum hypoxia, neonatal encephalopathy, or meconium aspiration syndrome), diagnosis of neonatal encephalopathy (NE), and delivery by Caesarean. A validated and simplified scoring method was used for grading mild, moderate and severe NE.[15,16]

Statistical analysis

Estimating that the use of the Doppler would reduce intrapartum stillbirth by 30% compared to the Pinard (based on the results of Mohamed et al 1994),[14] with 80% power to detect at least a 30% reduction in stillbirths with 95% confidence, we would need to enroll 840 participates in each of the two comparison groups. We added 20% to the sample size for each study arm to account for loss to follow-up and statistical adjustments and stratification, resulting in 1008 participants required for each comparison group.

Data were double entered from the partograph and, where applicable, the hospital's routine neonatal mortality audit document. An interim analysis was conducted by the data safety and monitoring board at the mid-point of the data collection period. Descriptive statistics were used to describe the characteristics of the participants and their outcomes under each study arm.

We used population-averaged generalized Poisson regression modeling to compare methods of FHR monitoring with Doppler versus Pinard on incidence rate ratio (IRR) of detection of FHR abnormalities, intrapartum stillbirth, and neonatal mortality. We conducted a sub-group analysis and qualitative reporting on the intrapartum stillbirths and a pre-discharge neonatal deaths within 24 hours and those fetuses with detected abnormal FHR.

All analyses were conducted using Stata/SE (StataCorp. 2011. Stata Statistical Software: Release 12. College Station, TX: StataCorp LP).

Role of funding source

The sponsor had no role in designing the study, analysing data, collecting data, interpreting the results, writing the report, or the decision to submit the paper for publication. The corresponding author had complete access to all the data.

RESULTS

From July 2012 to December 2013, we screened 2042 women antenatally. Fifty-three women were ineligible (50 planned to deliver elsewhere, 3 planned Caesarean delivery); 2 women declined to

participate; 1987 were enrolled (Figure 1). After assignment to a monitoring method, 8 of the 987 in the Pinard arm were excluded from analysis (1 lost to follow up, 1 delivered before the partograph was started, 2 undiagnosed breech births, 4 undiagnosed multiple births); and 8 of the 1000 in the Doppler arm were excluded (3 delivered before the partograph was started, 3 undiagnosed breech births, 2 undiagnosed multiple births). The final study group was n=979 in the Pinard arm and n=992 in the Doppler arm.

Of the 1971 women analyzed, the median maternal age was 26 years (IQR 24-30) (Table 1). There were a slightly higher though not statistically significant number of post-term women (≥42 weeks of gestational age) in the Doppler versus the Pinard arm (54/992 (5.4%) versus 41/979 (4.2%), p=0.193). A similar proportion of women in the Doppler versus the Pinard arm were primiparous (395/992 (39.8%) versus 413/979 (42.2%)), with similar median gestational age (39 weeks, IQR 38-40), and similar median newborn weight (3300g, IQR 3000-3500g).

Table 1: Demographic, clinical and perinatal characteristics

		Pinard (n=979)	Doppler (n=992)	p-value
Maternal age (years)	Median (IQR)	26 (23-30)	27 (24-30)	0.95
Marital status	Married	816 (83.4)	818 (82.5)	0.60
	Single	163 (16.7)	174 (17.5)	
Maternal education	None	9 (0.9)	7 (0.7)	0.62
	Primary	93 (9.5)	94 (9.5)	
	Secondary	385 (39.3)	423 (42.6)	
	Vocational	235 (24.0)	224 (22.6)	
	University	257 (26.3)	243 (24.5)	
	Missing		1 (0.1)	
Maternal occupation	Housewife	357 (36.5)	377 (38.0)	0.80
	Skilled worker	84 (8.6)	75 (7.6)	
	Self-employed	271 (27.7)	260 (26.2)	
	Professional	252 (25.7)	262 (26.4)	
	Other	15 (1.5)	18 (1.8)	
No. of ANC visits	Median (IQR)	4 (3-5)	4 (3-5)	0.58
Complication noted in pregnancy	Yes	17 (98.3)	24 (2.4)	0.29
	No	962 (1.7)	968 (97.6)	
Gravity	1	334 (34.1)	332 (33.5)	0.64
	2	422 (43.1)	416 (41.9)	
	≥3	223 (22.8)	244 (24.6)	
Parity	0	413 (42.2)	395 (39.8)	0.31
	1	238 (24.3)	232 (23.4)	
	≥2	328 (33.5)	365 (36.8)	
Previous perinatal death	Yes	24 (2.5)	29 (2.9)	0.52
	No	955 (97.6)	963 (97.1)	
Malarial IPTp	Yes	914 (93.4)	923 (93.0)	0.78
	No	65 (6.6)	69 (7.0)	
Syphilis	Negative	830 (84.8)	869 (87.6)	0.14
	Positive	11 (1.1)	6 (0.6)	
	Missing	138 (14.1)	117 (11.8)	
HIV Status	Negative	887 (90.6)	892 (89.9)	0.55
	Positive	46 (4.7)	57 (5.6)	
	Missing	46 (4.7)	43 (4.3)	
Gestational age at delivery (weeks)	Median (IQR)	39 (38-40)	39 (38-40)	0.80
Postterm gestation (≥42 weeks)	Yes	41 (4.2)	54 (5.4)	0.19
	No	938 (95.8)	938 (94.6)	
Newborn weight (g)	Median (IQR)	3300 (3000-3500)	3300 (3000-3500)	0.70

Data are n (%) or median (IQR); IPTp - Intermittent preventative treatment in pregnancy; HIV - Human immunodeficiency virus

Table 2: Secondary outcomes by treatment group

		Pinard (n=979)	Doppler (n=992)	p-value
Management of FHR abnormality	IU resuscitation	15 (1.5)	30 (3.0)	0.04
	Assisted	7 (0.7)	4 (0.4)	
	Cesarean	39 (4.0)	55 (5.5)	
	Not applicable	918 (93.8)	903 (91.1)	
Length of 1st stage	(hh:mm)	6:30 (4:15-8:20)	6:30 (4:12-8:06)	0.64
Length of 2nd stage	(hh:mm)	0:10 (00:05-00:15)	0:10 (00:5-00:15)	0.37
Oxytocin augmentation	Yes	407 (41.9)	402 (40.5)	0.42
	No	520 (53.6)	554 (55.8)	
	Missing	52 (5.4)	36 (3.6)	
Amniotic fluid	Clear	768 (78.5)	758 (76.4)	0.28
	Meconium	211 (21.5)	234 (23.6)	
Apgar <7 at 5 min	<7	17 (1.7)	23 (2.3)	0.40
	≥7	961 (98.2)	969 (97.7)	
	Missing	1 (0.1)	0 (0.0)	
Type of delivery	Vaginal	813 (83.0)	817 (82.4)	0.69
	Caesarean	166 (17.0)	175 (17.6)	
Admission to NICU*	Yes	36 (3.7)	48 (4.8)	0.20
	No	943 (96.3)	944 (95.2)	

Data are n (%) or median (IQR); FHR - fetal heart rate; IU - intrauterine resuscitation; NICU - neonatal intensive care unit; *for asphyxia, neonatal encephalopathy, or meconium aspiration syndrome

Similar proportions of women in the Doppler versus Pinard arm had Caesarean deliveries (175/992 (17.6%) versus 166/979 (17.0%), p=0.695) (Table 2). Data on duration of ruptured membranes were not collected.

There were a significantly higher number of FHR abnormalities detected in the Doppler versus Pinard arm (75/992 (7.6%) versus 46/979 (4.7%), p=0.008, IRR=1.61, 95%CI 1.13-2.30) (Table 3). There were a higher though not statistically significant number of intrapartum stillbirths in the Doppler versus Pinard arm (4/988 (0.4%) versus 1/977 (0.1%), p=0.184, IRR=3.94, 95%CI 0.44-35.24), and higher number of neonatal deaths prior to discharge (7/985 (0.7%) versus 5//973 (0.5%), p=0.579, IRR=1.38, 95%CI 0.44-4.34).

There were 121 cases of abnormal FHR detected in labour (Figure 2). Of the 17 deaths in total (intrapartum stillbirths and neonatal deaths prior to discharge), 5 were associated with the detection of abnormal FHR in labour. In a subgroup analysis of those cases where abnormal FHR was detected, there were a higher though not statistically significant proportion of deaths in the Doppler versus Pinard arm (4/71 (5.3%) vs 1/45 (2.2%), IRR=2.45 95%CI 0.28-21.47). The remaining 12 deaths who had a normal FHR reported; 3 had missing cause of death, and 1 had a congenital anomaly, and cause of death for the remaining 8 was intrauterine hypoxia, respiratory distress, or neonatal encephalopathy, suggesting that an abnormal FHR was a missed diagnosis in labour for these 8 deaths.

Table 3: Primary outcomes by treatment group

		Pinard (n=979)	Doppler (n=992)	p value	IRR* (95% CI)	p value
Abnormality detected	Yes	46 (4.7)	75 (7.6)	0.008	1.61 (1.13 to 2.30)	0.009
	No	933 (95.3)	917 (92.4)			
Intrapartum stillbirth	Yes	1 (0.1)	4 (0.4)	0.184	3.94** (0.44 to 35.24)	0.219
	No	977 (99.9)	988 (99.6)			
	Missing	1	0			
Neonatal death prior to discharge	Yes	5 (0.5)	7 (0.7)	0.579	1.38** (0.44 to 4.34)	0.552
	No	973 (99.5)	985 (99.3)			
	Missing	1				

IRR - incidence rate ratio; * not adjusted, significant baseline characteristics (p value <0.2) were tested and did not influence measure of effect in the model **excludes missing from analysis

DISCUSSION

Detection of abnormal FHR in labour is essential for identifying the fetus in need of responsive management such as prompt delivery. We report that intermittent auscultation with a Doppler identifies 60% more in need of prompt delivery (IRR=1.61); however, we did not find that this identification resulted in a significant decrease in mortality, although one would expect that higher detection should lead to prompt delivery and improved outcomes.

We propose a number of explanations for this lack of detected impact. We considered that there may have been a learning curve for staff using the Doppler as a new technology; however, we found no difference in outcomes over time or between groups (data not shown). Secondly, it is possible that use of technology such as the Doppler lead to false reassurance that FHR was being closely monitored, delayed involvement of senior staff and subsequent delivery, or there may simply have been delay between recognition and action that, by chance, had more deleterious effects in the intervention group. Thirdly this study sample size and power was based on the Mohamed 1994 study, aiming to detect a 30% reduction in intrapartum stillbirth in the Doppler compared to the Pinard group and this may be optimistic, necessitating a larger sample size to demonstrate any improved outcomes given the improved detection rates in the Doppler group.

Some study limitations include that we were unable to perform secondary screening of suspected fetal hypoxia through the use of cardiotography; nor confirm for the presence of fetal hypoxia acidemia via fetal blood scalp sampling, and cord blood gases; therefore we were unable to assess if the identification (or lack of identification) of abnormal FHR was correlated with the presence of fetal hypoxia acidemia. In addition, we were unable to exclude some cases where the underlying cause of death was other than fetal hypoxia (e.g. congenital anomalies, early onset sepsis) due to diagnostic limitations in differentially diagnosing these cases. Finally, the screening process was all linked to the partograph which has well recognized limitations.[17]

In conclusion, routine monitoring with a handheld Doppler increases the proportion of fetuses identified in need of prompt delivery via the identification of FHR abnormalities in labour. The care providers and the women expressed preferences for the Doppler, however, we did not find evidence that this lead to a decrease in the incidence of intrapartum stillbirth or neonatal death. This study demonstrates the need for further larger study with linkage to rapid response for abnormal FHR, including caesarean section to ensure that increased detection leads to decreased

death and disability.

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Figure 1: Trial profile

Figure 2: Flow diagram for outcome by fetal heart rate and management
FHR - fetal heart rate; CS/IU/Ass't - Caesarean delivery, intrauterine resuscitation, assisted delivery

Contributorship statement: All authors designed the study. RB DGB AJ PM did data collection. DGB and AM did analysis and wrote the first draft of the manuscript. All authors reviewed and provided feedback on the manuscript draft.

Competing interests: We have read and understood BMJ policy on declaration of interests and declare the following interests: AJ is a paid employ[1]ee of Powerfree, the not-for-profit designers of the handheld Doppler used in this study.

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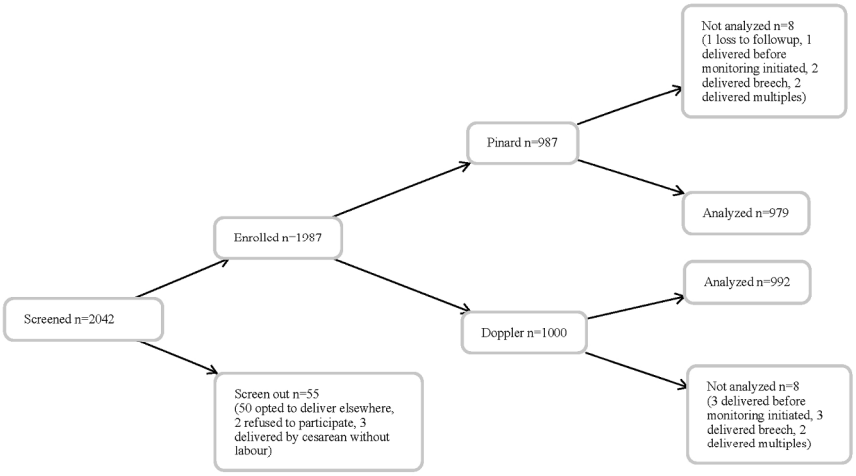
Data sharing: No additional data available

REFERENCES

1 Lawn JE, Blencowe H, Oza S, et al (2014) Every Newborn: progress, priorities, and potential beyond survival. Lancet 384: 189-205.
2 Lee AC, Kozuki N, Blencowe H, et al (2013) Intrapartum-related neonatal encephalopathy incidence and impairment at regional and global levels for 2010 with trends from 1990. Pediatr Res 74 Suppl 1: 50-72.
3 Lawn JE, Blencowe H, Pattinson R, et al (2011) Stillbirths: Where? When? Why? How to make the data count? Lancet 377: 1448-1463.
4 Lawn JE, Kinney M, Lee AC, et al (2009) Reducing intrapartum-related deaths and disability: can the health system deliver? Int J Gynaecol Obstet 107 Suppl 1: S123-40, S140-2.
5 SOGC (2013) Advances in labour and risk management. Ottawa: Society of Obstetricians and Gynaecologists of Canada.
6 NICE (2003) The Use of electronic fetal monitoring. NHS Clinical Guideline C 23807: 1-17.
7 Liston R, Sawchuck D, Young D (2007) Fetal health surveillance: antepartum and intrapartum consensus guideline. J Obstet Gynaecol Canada 29: S3-56.
8 Hofmeyr GJ, Haws RA, Bergström S, et al (2009) Obstetric care in low-resource settings: what, who, and how to overcome challenges to scale up? Int J Gynaecol Obstet 107 Suppl 1: S21-44, S44-5.
9 Alfirevic Z, Devane D, Gyte GM (2013) Continuous cardiotocography (CTG) as a form of electronic fetal monitoring (EFM) for fetal assessment during labour. Cochrane Database Syst Rev 5.
10 Mangesi L, Hofmeyr GJ, Woods D (2009) Assessing the preference of women for different methods of monitoring the fetal heart in labour. S Afr J Obstet Gynaecol 15.

11 Bezuidenhout H, Woods D, Wyatt J, et al (2006) Does fetal heart rate count? Developing a low cost, alternative powered doppler fetal heart monitor for use in low resource high mortality settings. 4th IET Seminar on Appropriate Healthcare Technologies for Developing Countries : 155-159.
12 Woods D (2009) Appropriate technology and education for improved intrapartum care in underresourced countries. S Afr J Obstet Gynaecol 15.
13 Devane D, Lalor JG, Daly S, et al (2012) Cardiotocography versus intermittent auscultation of fetal heart on admission to labour ward for assessment of fetal wellbeing. Cochrane Database Syst Rev 2.
14 Mahomed K, Nyoni R, Mulambo T, et al (1994) Randomised controlled trial of intrapartum fetal heart rate monitoring. BMJ 308: 497-500.
15 Ellis M, Manandhar N, Manandhar DS, et al (2000) Risk factors for neonatal encephalopathy in Kathmandu, Nepal, a developing country: unmatched case-control study. BMJ 320: 1229-1236.
16 Amiel-Tison C (2002) Update of the Amiel-Tison neurologic assessment for the term neonate or at 40 weeks corrected age. Pediatr Neurol 27: 196-212.
17 Lavender T, Hart A, Smyth RM (2013) Effect of partogram use on outcomes for women in spontaneous labour at term. Cochrane Database Syst Rev 7: CD005461.



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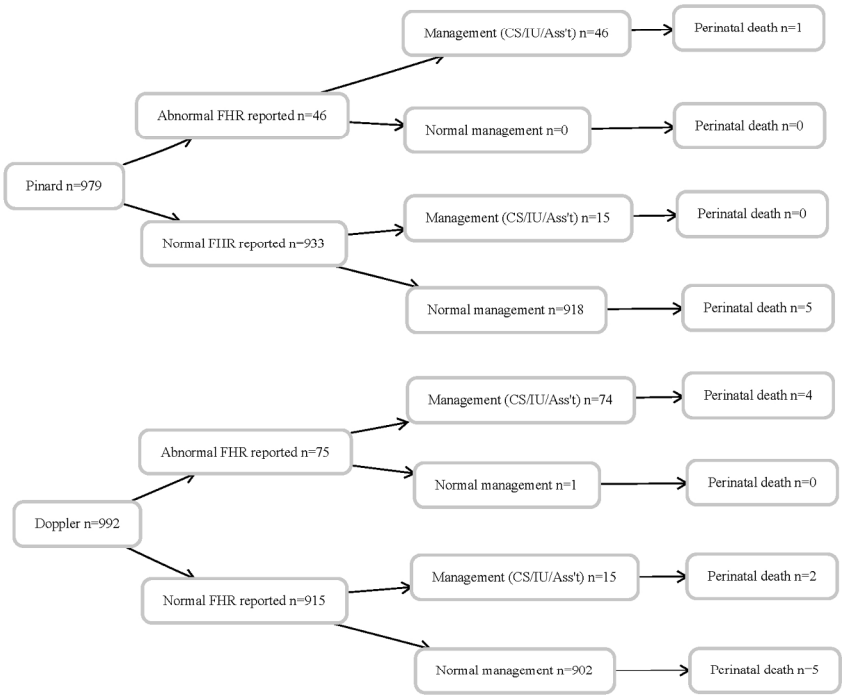

254x216mm (200 x 200 DPI)

342x196mm (96 x 96 DPI)

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	not applicable
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	not applicable
Sample size	7a	How sample size was determined	6
	7b	When applicable, explanation of any interim analyses and stopping guidelines	6
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	not reported
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	5

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	5
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	6
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	6
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1, 6-7
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1, 6-7
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6
	14b	Why the trial ended or was stopped	6
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	8
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	8
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	10
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	10
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	9
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Table 2, 9
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	10
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	10
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	10
Other information			
Registration	23	Registration number and name of trial registry	2
Protocol	24	Where the full trial protocol can be accessed, if available	2
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	2

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Use of wind-up fetal Doppler versus Pinard for fetal heart rate intermittent monitoring in labour: a randomised clinical trial

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Use of wind-up fetal Doppler versus Pinard for fetal heart rate intermittent monitoring in labour: a randomised clinical trial

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TITLE: Use of wind-up fetal Doppler versus Pinard for fetal heart rate intermittent monitoring in labour: a randomized clinical trial

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ABSTRACT

Objectives: In resource-poor settings, the standard of care to inform labour management is the partograph plus Pinard stethoscope for intermittent fetal heart rate (FHR) monitoring. We compared FHR monitoring in labour using a novel, robust wind-up handheld Doppler with the Pinard as a primary screening tool for abnormal FHR on perinatal outcomes.

Design: Prospective equally randomised clinical trial.

Setting: The labour and delivery unit of a teaching hospital in Kampala, Uganda.

Participants: Of the 2042 eligible antenatal women, 1971 women in active term labour, following uncomplicated pregnancies were randomised to either the standard of care, or not.

Intervention: Intermittent FHR monitoring using Doppler.

Primary outcome measures: Incidence of FHR abnormality detection, intrapartum stillbirth and neonatal mortality prior to discharge.

Results: Age, parity, gestational age, mode of delivery, and newborn weight were similar between study groups. In the Doppler group, there was a significantly higher rate of FHR abnormalities detected (Incidence Rate Ratio (IRR)=1.61, 95%CI 1.13 to 2.30). However, in this group there were also higher though not statistically significant rate of intrapartum stillbirths (IRR=3.94, 0.44 to 35.24) and neonatal deaths (IRR=1.38, 0.44 to 4.34).

Conclusion: Routine monitoring with a handheld Doppler increased the identification of FHR abnormalities in labour; however, our trial did not find evidence that this lead to a decrease the incidence of intrapartum stillbirth or neonatal death.

Trial registration: ClinicalTrails.gov (1000031587)

TEXT BOXES

1. Strengths and limitations of this study

- This is the first study to use current monitoring guidelines to compare evaluated Doppler versus Pinard in improving stillbirth and neonatal outcomes.
- A major strength of this study includes the prospective and randomisation design.
- We were unable to perform secondary screening of suspected fetal hypoxia through the use of cardiotography; nor confirm for the presence of fetal hypoxia acidemia via fetal blood scalp sampling, and cord blood gases; therefore we were unable to assess if the identification (or lack of identification) of abnormal FHR was correlated with the presence of fetal hypoxia acidemia.
- We were unable to exclude some cases where the underlying cause of death was other than fetal hypoxia (e.g. congenital anomalies, early onset sepsis) due to diagnostic limitations in differentially diagnosing these cases.

2. Training

Helping Babies Survive Labour is the training programme that was used to train the midwives in Nsambya hospital. It was developed by Powerfree Education and Technology in Cape Town in collaboration with Save the Children and health professionals from Nsambya Hospital Kampala (Figure 3).

Many training methods and guidelines are written in high income countries and are simply transferred for use in low income countries, although the healthcare workers in these countries may face very different challenges. Input was solicited from both the healthcare workers and academics in the target country in the preparation of these training materials.

The material first provides a section of evidence-based theory that will help health workers to understand why monitoring of the fetal heart is important. This is followed by practical lessons on how to monitor fetal well-being, how to interpret observations and recordings and most importantly, gives guidelines on what to do when something is wrong. The training is developed in such a way that it can be used along side the Helping Babies Breath training material, which focuses on neonatal resuscitation.

Before this trial started, midwives and doctors were trained. Fifty-two people attended the training and 42 completed both the pre- and post-test. The average score for the pre-test was 49.7% (median 50%). The average score for the post-test was 67.9% (median 69%). It does reveal the low baseline knowledge on appropriate intrapartum care and illustrates the need for continuous quality improvement.

For link to the manual and its references
http://www.healthynewbornnetwork.org/sites/default/files/resources/HBSL%20training%20booklet.pdf

INTRODUCTION

Approximately 44% of all child deaths under the age of 5 years occur in neonates (<28 days of age).[1] The third largest cause of neonatal mortality is intrapartum-related hypoxia (formerly called `birth asphyxia') resulting in an estimated 660 000 neonatal deaths per year globally[1] and an additional 414,000 children who survive with disability.[2] There are also an estimated 1.02 million intrapartum stillbirths almost all in low and middle income countries.[3] This burden is highest in areas of the world where the probability of quality of care at birth is the lowest.[4] In order to reduce the incidence of intrapartum-related stillbirths and neonatal deaths, it is necessary to assess fetal well-being in labour with routine monitoring of the fetal heart rate (FHR), linked to rapid and effective management with resuscitative measures or prompt delivery, and provision of neonatal resuscitation if needed.

Characteristic FHR changes often precede brain injury via a process of progressive fetal hypoxic acidemia.[5] Intermittent auscultation as a primary screening tool to monitor fetal well-being is the recommended standard of care for women experiencing uncomplicated deliveries.[6-9] One method of intermittent auscultation uses the Pinard Fetal Stethoscope (Pinard), a trumpet shaped horn, to monitor the FHR and is widely adopted as the standard of care in resource-poor settings since it is low cost and does not require a power source or repairs. The difficulties posed in using a Pinard are generally not conducive to a busy labour ward. It requires additional time to precisely locate the fetal heart as the heart is only audible within a very narrow area of the woman's abdomen, it requires that the surrounding area be quiet in order to hear the fetal heart, the reading can be unreliable in obese women, and it requires the midwife to place her ear in close proximity to the woman's pubic area. In addition the midwife usually counts the FHR for short time, such as 15 seconds, and multiplies to reach beats/minute, further decreasing accuracy and introducing arithmetic errors. The handheld Doppler ultrasound fetal heart rate monitor (Doppler) detects FHR and provides a steady state number per minute, as well as audible auscultation of the FHR. It requires a reliable power source and may need repairs, and is more costly than a Pinard. However, it permits the midwife to quickly locate the FHR, allows others including the mother to hear the FHR, permits the woman to remain in any comfortable position while being assessed, permits the midwife to both assess the FHR and communicate to the woman the status of her baby, and has been shown to be preferred by women over the use of the Pinard.[8,10] A rugged, wind-up, handheld Doppler fetal heart rate monitor (Doppler) developed by Power-free Education Technology (Pet.og.za) showed in initial field tests to be accurate and acceptable to both mother and midwives in low-resource settings.[11,12] It uses a hand crank to generate 2:30 minutes of use for every 30 seconds of cranking.

While there have been several studies showing reduced intervention and no improved outcomes in the use of the intermittent (Pinard or Doppler) versus continuous cardiotocography (CTG) monitoring as the primary screening tool in uncomplicated deliveries,[6,13] there is little research on outcomes in intermittent monitoring comparing Doppler versus Pinard. A single study by Mohamed et al using a monitoring protocol of 10 minutes every half-hour found higher detection of FHR abnormalities and better perinatal outcomes in the intermittent auscultation Doppler group compared with the Pinard group.[14]

We aimed to use a randomised trial design to compare the primary screening methods of FHR monitoring (Doppler as intervention versus Pinard as standard of care) on incidence of detection of FHR abnormalities, and on the incidence of intrapartum stillbirth and neonatal mortality in the first 24 hours after delivery.

METHODS

Study design and participants

We undertook this randomised controlled trial at San Raphael of St. Francis Nsambya Hospital, a peri-urban private not-for-profit hospital in Kampala, Uganda. It is a teaching hospital that manages 7 500 deliveries annually. CTG and fetal blood gas sampling to support labour management, and epidural pain medication are not available. Oxytocin augmentation and Caesarean delivery rates are 40% and 20% respectively. The standard of care for intrapartum FHR monitoring is by intermittent auscultation using the Pinard.

Women were requested to participate during an antenatal care appointment. This consent was reconfirmed in labour provided that they presented in labour with a singleton pregnancy, in a cephalic position, at term or post-term (>37 weeks gestation). Women were excluded if they were already in second stage of labour upon admission or presented with a condition that, according to the doctor on duty, contra-indicated labouring (e.g. antepartum hemorrhage); if there was a diagnosis of intrauterine fetal death upon admission; or if the woman was admitted for an elective Caesarean delivery. Participants were presented with information about the study, and agreeing participants provided written consent. This study was approved by Sickkids Research Ethics Board, Nsambya Internal Review Board, as well as the Uganda National Council for Science and Technology. Registration of our protocol with ClinicalTrials.gov occurred before participant enrolment started, but due to an administrative error with our institution's Clinical Research Services Unit, the protocol was only released to the public after the completion of the study. Documentation from the Chair of our independent Research Ethics Board was provided to BMJ Open attesting to the version of the protocol provided to them prior to the start of enrolment.

Randomisation

Women were equally randomised to one of the two study methods using sequentially numbered, opaque sealed envelopes. Study participants and care providers where not blinded to the intervention. Data were collected from the patient's partograph and from the hospital's routine neonatal mortality audit data, when applicable.

Procedures

The standard of care for intrapartum monitoring relied on partograph and FHR monitoring with the Pinard. Our pre-study training address deficiencies in monitoring standards (acceptable range for FHR, recognition of accelerations, decelerations, and change in baseline). We developed a training module entitled "Helping Babies Survive Labour" modeling on the "Helping Babies Breathe" visual materials and learning approach. The technical basis was from World Health Organisation (WHO) and Canadian Obstetric Society protocols.[5] All midwives and doctors were then given this in-service training for half a day. FHR monitoring was undertaken every 30 minutes in first stage of labour; every 15 minutes in second stage before pushing; and every 5 minutes in second stage when pushing and for 1 minute immediately after a contraction. The baseline FHR was recorded as a single number rather than a range, in the unit of beats per minute (bpm). The FHR rhythm (regular or irregular) and absence or presence of accelerations or decelerations were also documented. The maternal radial pulse was simultaneously palpated to differentiate it with the FHR.

When FHR abnormalities are identified the standard of care would be to switch from intermittent auscultation to CTG. Since CTG is not available in Nsambya Hospital, any noted FHR abnormalities were reported by the research midwife to the doctor on duty for assessment.

Management following this assessment was either closer intermittent monitoring, or intra-uterine resuscitation with re-assessment of the FHR. Intra-uterine resuscitation consisted of maternal position change, administration of oxygen by mask to mother, initiation of intravenous infusion, discontinuation of oxytocin augmentation, and consider prompt delivery (assisted vaginal if imminent, otherwise by Caesarean).

Outcomes

The primary outcome measures of interest were detection of FHR abnormality in labour (defined below), intrapartum stillbirth, and neonatal deaths in the first 24 hours of life. Fetal heart rate abnormality is defined as tachycardia, bradycardia, or atypical variable, late or prolonged decelerations. Tachycardia and bradycardia are defined as baselines of >160 bpm and <110 bpm, respectively. Some features of atypical variable decelerations are abrupt fetal heart rate decelerations, lasting >2 minutes, slow return to baseline, or in the presence of tachycardia. Late decelerations are a repetitive, gradual decrease in the FHR and return to baseline, commencing after the onset of the contraction, and return to baseline after the end of the contraction. Prolonged decelerations are a decrease from baseline of >15 bpm lasting from 2-10 minutes. Secondary outcomes were Apgar score less than 7 at 5 minutes, admission to special care unit for intrapartum-related complications (intrapartum hypoxia, neonatal encephalopathy, or meconium aspiration syndrome), diagnosis of neonatal encephalopathy (NE), and delivery by Caesarean. A validated and simplified scoring method was used for grading mild, moderate and severe NE.[15,16] Indications for Caesarean delivery were failure to progress (as indicated by crossing of the action line on the partograph), abnormal FHR unresponsive to uterine resuscitation, and identification of malpresentation in labour (e.g. conversion from vertex to brow or mentum posterior).

Statistical analysis

Estimating that the use of the Doppler would reduce intrapartum stillbirth by 30% compared to the Pinard (based on the results of Mohamed et al 1994),[14] with 80% power to detect at least a 30% reduction in stillbirths with 95% confidence, we would need to enroll 840 participates in each of the two comparison groups. We added 20% to the sample size for each study arm to account for loss to follow-up and statistical adjustments and stratification, resulting in 1008 participants required for each comparison group.

Data were double entered from the partograph and, where applicable, the hospital's routine neonatal mortality audit document. An interim analysis was conducted by the data safety and monitoring board at the mid-point of the data collection period. Descriptive statistics were used to describe the characteristics of the participants and their outcomes under each study arm.
We used population-averaged generalized Poisson regression modeling with robust variance to compare methods of FHR monitoring with Doppler versus Pinard on incidence rate ratio (IRR) of detection of FHR abnormalities, intrapartum stillbirth, and neonatal mortality (see Barros et al for details of this choice over logistic regression [17]). We conducted a sub-group analysis and qualitative reporting on the intrapartum stillbirths and pre-discharge neonatal deaths within 24 hours and those fetuses with detected abnormal FHR.

All analyses were conducted using Stata/SE (StataCorp. 2011. Stata Statistical Software: Release 12. College Station, TX: StataCorp LP).

Role of funding source

The sponsor had no role in designing the study, analysing data, collecting data, interpreting the results, writing the report, or the decision to submit the paper for publication. The corresponding author had complete access to all the data.

RESULTS

From July 2012 to December 2013, we screened 2042 women antenatally. Fifty-three women were ineligible (50 planned to deliver elsewhere, 3 planned Caesarean delivery); 2 women declined to participate; 1987 were enrolled (Figure 1). After assignment to a monitoring method, 8 of the 987 in the Pinard arm were excluded from analysis (1 lost to follow up, 1 delivered before the partograph was started, 2 undiagnosed breech births, 4 undiagnosed multiple births); and 8 of the 1000 in the Doppler arm were excluded (3 delivered before the partograph was started, 3 undiagnosed breech births, 2 undiagnosed multiple births). The final study group was n=979 in the Pinard arm and n=992 in the Doppler arm.

Of the 1971 women analyzed, the median maternal age was 26 years (IQR 24-30) (Table 1). There were a slightly higher though not statistically significant number of post-term women (≥42 weeks of gestational age) in the Doppler versus the Pinard arm (54/992 (5.4%) versus 41/979 (4.2%), p=0.193). A similar proportion of women in the Doppler versus the Pinard arm were primiparous (395/992 (39.8%) versus 413/979 (42.2%)), with similar median gestational age (39 weeks, IQR 38-40), and similar median newborn weight (3300g, IQR 3000-3500g).

Table 1: Demographic, clinical and perinatal characteristics

		Pinard (n=979)	Doppler (n=992)	p-value
Maternal age (years)	Median (IQR)	26 (23-30)	27 (24-30)	0.95
Marital status	Married	816 (83.4)	818 (82.5)	0.60
	Single	163 (16.7)	174 (17.5)	
Maternal education	None	9 (0.9)	7 (0.7)	0.62
	Primary	93 (9.5)	94 (9.5)	
	Secondary	385 (39.3)	423 (42.6)	
	Vocational	235 (24.0)	224 (22.6)	
	University	257 (26.3)	243 (24.5)	
	Missing		1 (0.1)	
Maternal occupation	Housewife	357 (36.5)	377 (38.0)	0.80
	Skilled worker	84 (8.6)	75 (7.6)	
	Self-employed	271 (27.7)	260 (26.2)	
	Professional	252 (25.7)	262 (26.4)	
	Other	15 (1.5)	18 (1.8)	
No. of ANC visits	Median (IQR)	4 (3-5)	4 (3-5)	0.58
Complication noted in pregnancy	Yes	17 (98.3)	24 (2.4)	0.29
	No	962 (1.7)	968 (97.6)	
Gravity	1	334 (34.1)	332 (33.5)	0.64
	2	422 (43.1)	416 (41.9)	
	≥3	223 (22.8)	244 (24.6)	
Parity	0	413 (42.2)	395 (39.8)	0.31
	1	238 (24.3)	232 (23.4)	
	≥2	328 (33.5)	365 (36.8)	
Previous perinatal death	Yes	24 (2.5)	29 (2.9)	0.52
	No	955 (97.6)	963 (97.1)	
Malarial IPTp	Yes	914 (93.4)	923 (93.0)	0.78
	No	65 (6.6)	69 (7.0)	
Syphilis	Negative	830 (84.8)	869 (87.6)	0.14
	Positive	11 (1.1)	6 (0.6)	
	Missing	138 (14.1)	117 (11.8)	
HIV Status	Negative	887 (90.6)	892 (89.9)	0.55
	Positive	46 (4.7)	57 (5.6)	
	Missing	46 (4.7)	43 (4.3)	
Gestational age at delivery (weeks)	Median (IQR)	39 (38-40)	39 (38-40)	0.80
Postterm gestation (≥42 weeks)	Yes	41 (4.2)	54 (5.4)	0.19
	No	938 (95.8)	938 (94.6)	
Newborn weight (g)	Median (IQR)	3300 (3000-3500)	3300 (3000-3500)	0.70

Data are n (%) or median (IQR); IPTp - Intermittent preventative treatment in pregnancy; HIV - Human immunodeficiency virus

There were no differences between the study arms in Apgar score <7 at 5 minutes (23 (2.3%) in the Doppler versus 17(1.7%) the Painard, p=0.40) or admission to neonatal intensive care unit for any reason (48(4.8%) in the Doppler versus 36(3.7%) the Pinard, p=0.20). Similar proportions of women in the Doppler versus Pinard arm had Caesarean deliveries (175/992 (17.6%) versus 166/979 (17.0%), p=0.695).

There were a significantly higher number of FHR abnormalities detected in the Doppler versus Pinard arm (75/992 (7.6%) versus 46/979 (4.7%), p=0.008, IRR=1.61, 95%CI 1.13-2.30) (Table 2). There were a higher though not statistically significant number of intrapartum stillbirths in the Doppler versus Pinard arm (4/988 (0.4%) versus 1/977 (0.1%), p=0.184, IRR=3.94, 95%CI 0.44-35.24), and higher number of neonatal deaths prior to discharge (7/985 (0.7%) versus 5//973 (0.5%), p=0.579, IRR=1.38, 95%CI 0.44-4.34).

There were 121 cases of abnormal FHR detected in labour (Figure 2). Of the 17 deaths in total (intrapartum stillbirths and neonatal deaths prior to discharge), 5 were associated with the detection of abnormal FHR in labour. In a subgroup analysis of those cases where abnormal FHR was detected, there were a higher though not statistically significant proportion of deaths in the Doppler versus Pinard arm (4/71 (5.3%) vs 1/45 (2.2%), IRR=2.45 95%CI 0.28-21.47). The remaining 12 deaths who had a normal FHR reported; 3 had missing cause of death, and 1 had a congenital anomaly, and cause of death for the remaining 8 was intrauterine hypoxia, respiratory distress, or neonatal encephalopathy, suggesting that an abnormal FHR was a missed diagnosis in labour for these 8 deaths.

Table 2: Primary outcomes by treatment group

		Pinard (n=979)	Doppler (n=992)	p value	IRR* (95% CI)	p value
Abnormality detected	Yes	46 (4.7)	75 (7.6)	0.008	1.61 (1.13 to 2.30)	0.009
	No	933 (95.3)	917 (92.4)			
Intrapartum stillbirth	Yes	1 (0.1)	4 (0.4)	0.184	3.94** (0.44 to 35.24)	0.219
	No	977 (99.9)	988 (99.6)			
	Missing	1	0			
Neonatal death prior to discharge	Yes	5 (0.5)	7 (0.7)	0.579	1.38** (0.44 to 4.34)	0.552
	No	973 (99.5)	985 (99.3)			
	Missing	1				

IRR - incidence rate ratio; *not adjusted, significant baseline characteristics (p value <0.2) were tested and did not influence measure of effect in the model **excludes missing from analysis

DISCUSSION

Detection of abnormal FHR in labour is essential for identifying the fetus in need of responsive management such as prompt delivery. We report that intermittent auscultation with a Doppler identifies 60% more in need of prompt delivery (IRR=1.61); however, we did not find that this identification resulted in a significant decrease in mortality, although one would expect that higher

detection should lead to prompt delivery and improved outcomes.

We propose a number of explanations for this lack of detected impact. We considered that there may have been a learning curve for staff using the Doppler as a new technology; however, we found no difference in outcomes over time or between groups (data not shown). Secondly, it is possible that use of technology such as the Doppler lead to false reassurance that FHR was being closely monitored, delayed involvement of senior staff and subsequent delivery, or there may simply have been delay between recognition and action that, by chance, had more deleterious effects in the intervention group. Thirdly this study sample size and power was based on the Mohamed 1994 study, aiming to detect a 30% reduction in intrapartum stillbirth in the Doppler compared to the Pinard group and this may be optimistic, necessitating a larger sample size to demonstrate any improved outcomes given the improved detection rates in the Doppler group.

Some study limitations include that we were unable to perform secondary screening of suspected fetal hypoxia through the use of cardiotography; nor confirm for the presence of fetal hypoxia acidemia via fetal blood scalp sampling, and cord blood gases; therefore we were unable to assess if the identification (or lack of identification) of abnormal FHR was correlated with the presence of fetal hypoxia acidemia. In addition, we were unable to exclude some cases where the underlying cause of death was other than fetal hypoxia (e.g. congenital anomalies, early onset sepsis) due to diagnostic limitations in differentially diagnosing these cases. Finally, the screening process was all linked to the partograph which has well recognized limitations.[18]

In conclusion, routine monitoring with a handheld Doppler increases the proportion of fetuses identified in need of prompt delivery via the identification of FHR abnormalities in labour; however, we did not find evidence that this lead to a decrease in the incidence of intrapartum stillbirth or neonatal death. While assessing user satisfaction was not the objective of this study, the care providers and the women expressed preference for the Doppler, and given that the Doppler performed no worse than the Pinard in detecting abnormal FHR or in newborn survival, this should be an area of further research. Finally, this study demonstrates the need for a larger study with linkage to rapid response for abnormal FHR, including caesarean section to ensure that increased detection using the Doppler leads to decreased death and disability.

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Figure 1: Trial profile

Figure 2: Flow diagram for outcome by fetal heart rate and management
FHR - fetal heart rate; CS/IU/Ass't - Caesarean delivery, intrauterine resuscitation, assisted delivery

Contributorship statement: All authors designed the study. RB DGB AJ PM did data collection. DGB and AM did analysis and wrote the first draft of the manuscript. All authors reviewed and provided feedback on the manuscript draft.

Competing interests: We have read and understood BMJ policy on declaration of interests and declare the following interests: AJ is a paid employee of Powerfree, the not-for-profit designers of the handheld Doppler used in this study.

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REFERENCES

1 Lawn JE, Blencowe H, Oza S, et al (2014) Every Newborn: progress, priorities, and potential beyond survival. Lancet 384: 189-205.
2 Lee AC, Kozuki N, Blencowe H, et al (2013) Intrapartum-related neonatal encephalopathy incidence and impairment at regional and global levels for 2010 with trends from 1990. Pediatr Res 74 Suppl 1: 50-72.
3 Lawn JE, Blencowe H, Pattinson R, et al (2011) Stillbirths: Where? When? Why? How to make the data count? Lancet 377: 1448-1463.
4 Lawn JE, Kinney M, Lee AC, et al (2009) Reducing intrapartum-related deaths and disability: can the health system deliver? Int J Gynaecol Obstet 107 Suppl 1: S123-40, S140-2.
5 SOGC (2013) Advances in labour and risk management. Ottawa: Society of Obstetricians and Gynaecologists of Canada.
6 NICE (2003) The Use of electronic fetal monitoring. NHS Clinical Guideline C 23807: 1-17.
7 Liston R, Sawchuck D, Young D (2007) Fetal health surveillance: antepartum and intrapartum consensus guideline. J Obstet Gynaecol Canada 29: S3-56.
8 Hofmeyr GJ, Haws RA, Bergström S, et al (2009) Obstetric care in low-resource settings: what, who, and how to overcome challenges to scale up? Int J Gynaecol Obstet 107 Suppl 1: S21-44, S44-5.
9 Alfirevic Z, Devane D, Gyte GM (2013) Continuous cardiotocography (CTG) as a form of electronic fetal monitoring (EFM) for fetal assessment during labour. Cochrane Database Syst Rev 5.
10 Mangesi L, Hofmeyr GJ, Woods D (2009) Assessing the preference of women for different methods of monitoring the fetal heart in labour. S Afr J Obstet Gynaecol 15.
11 Bezuidenhout H, Woods D, Wyatt J, et al (2006) Does fetal heart rate count? Developing a low cost, alternative powered doppler fetal heart monitor for use in low resource high mortality settings. 4th IET Seminar on Appropriate Healthcare Technologies for Developing Countries : 155-159.
12 Woods D (2009) Appropriate technology and education for improved intrapartum care in underresourced countries. S Afr J Obstet Gynaecol 15.
13 Devane D, Lalor JG, Daly S, et al (2012) Cardiotocography versus intermittent auscultation of fetal heart on admission to labour ward for assessment of fetal wellbeing. Cochrane Database Syst Rev 2.
14 Mahomed K, Nyoni R, Mulambo T, et al (1994) Randomised controlled trial of intrapartum fetal heart rate monitoring. BMJ 308: 497-500.
15 Ellis M, Manandhar N, Manandhar DS, et al (2000) Risk factors for neonatal encephalopathy in Kathmandu, Nepal, a developing country: unmatched case-control study. BMJ 320: 1229-1236.
16 Amiel-Tison C (2002) Update of the Amiel-Tison neurologic assessment for the term neonate or at 40 weeks corrected age. Pediatr Neurol 27: 196-212.
17 Barros AJ, Hirakata VN (2003) Alternatives for logistic regression in cross-sectional studies: an empirical comparison of models that directly estimate the prevalence ratio. BMC Med Res Methodol 3: 21.
18 Lavender T, Hart A, Smyth RM (2013) Effect of partogram use on outcomes for women in

spontaneous labour at term. Cochrane Database Syst Rev 7: CD005461.

Use of wind-up fetal Doppler versus Pinard for fetal heart rate intermittent monitoring in labour: a randomised clinical trial

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ABSTRACT

Objectives: In resource-poor settings, the standard of care to inform labour management is the partograph plus Pinard stethoscope for intermittent fetal heart rate (FHR) monitoring. We compared FHR monitoring in labour using a novel, robust wind-up handheld Doppler with the Pinard as a primary screening tool for abnormal FHR on perinatal outcomes.

Design: Prospective equally randomised clinical trial.

Setting: The labour and delivery unit of a teaching hospital in Kampala, Uganda.

Participants: Of the 2042 eligible antenatal women, 1971 women in active term labour, following uncomplicated pregnancies were randomised to either the standard of care, or not.

Intervention: Intermittent FHR monitoring using Doppler.

Primary outcome measures: Incidence of FHR abnormality detection, intrapartum stillbirth and neonatal mortality prior to discharge.

Results: Age, parity, gestational age, mode of delivery, and newborn weight were similar between study groups. In the Doppler group, there was a significantly higher rate of FHR abnormalities detected (Incidence Rate Ratio (IRR)=1.61, 95%CI 1.13 to 2.30). However, in this group there were also higher though not statistically significant rate of intrapartum stillbirths (IRR=3.94, 0.44 to 35.24) and neonatal deaths (IRR=1.38, 0.44 to 4.34).

Conclusion: Routine monitoring with a handheld Doppler increased the identification of FHR abnormalities in labour; however, our trial did not find evidence that this lead to a decrease the incidence of intrapartum stillbirth or neonatal death.

Trial registration: ClinicalTrails.gov (1000031587)

TEXT BOXES

1. Strengths and limitations of this study

- This is the first study to use current monitoring guidelines to compare evaluated Doppler versus Pinard in improving stillbirth and neonatal outcomes.
- A major strength of this study includes the prospective and randomisation design.
- We were unable to perform secondary screening of suspected fetal hypoxia through the use of cardiotography; nor confirm for the presence of fetal hypoxia acidemia via fetal blood scalp sampling, and cord blood gases; therefore we were unable to assess if the identification (or lack of identification) of abnormal FHR was correlated with the presence of fetal hypoxia acidemia.
- We were unable to exclude some cases where the underlying cause of death was other than fetal hypoxia (e.g. congenital anomalies, early onset sepsis) due to diagnostic limitations in differentially diagnosing these cases.

2. Training

Helping Babies Survive Labour is the training programme that was used to train the midwives in Nsambya hospital. It was developed by Powerfree Education and Technology in Cape Town in collaboration with Save the Children and health professionals from Nsambya Hospital Kampala (Figure 3).

Many training methods and guidelines are written in high income countries and are simply transferred for use in low income countries, although the healthcare workers in these countries may face very different challenges. Input was solicited from both the healthcare workers and academics in the target country in the preparation of these training materials.

The material first provides a section of evidence-based theory that will help health workers to understand why monitoring of the fetal heart is important. This is followed by practical lessons on how to monitor fetal well-being, how to interpret observations and recordings and most importantly, gives guidelines on what to do when something is wrong. The training is developed in such a way that it can be used along side the Helping Babies Breath training material, which focuses on neonatal resuscitation.

Before this trial started, midwives and doctors were trained. Fifty-two people attended the training and 42 completed both the pre- and post-test. The average score for the pre-test was 49.7% (median 50%). The average score for the post-test was 67.9% (median 69%). It does reveal the low baseline knowledge on appropriate intrapartum care and illustrates the need for continuous quality improvement.

For link to the manual and its references
http://www.healthynewbornnetwork.org/sites/default/files/resources/HBSL%20training%20booklet.pdf

INTRODUCTION

Approximately 44% of all child deaths under the age of 5 years occur in neonates (<28 days of age).[1] The third largest cause of neonatal mortality is intrapartum-related hypoxia (formerly called `birth asphyxia') resulting in an estimated 660 000 neonatal deaths per year globally[1] and an additional 414,000 children who survive with disability.[2] There are also an estimated 1.02 million intrapartum stillbirths almost all in low and middle income countries.[3] This burden is highest in areas of the world where the probability of quality of care at birth is the lowest.[4] In order to reduce the incidence of intrapartum-related stillbirths and neonatal deaths, it is necessary to assess fetal well-being in labour with routine monitoring of the fetal heart rate (FHR), linked to rapid and effective management with resuscitative measures or prompt delivery, and provision of neonatal resuscitation if needed.

Characteristic FHR changes often precede brain injury via a process of progressive fetal hypoxic acidemia.[5] Intermittent auscultation as a primary screening tool to monitor fetal well-being is the recommended standard of care for women experiencing uncomplicated deliveries.[6-9] One method of intermittent auscultation uses the Pinard Fetal Stethoscope (Pinard), a trumpet shaped horn, to monitor the FHR and is widely adopted as the standard of care in resource-poor settings since it is low cost and does not require a power source or repairs. The difficulties posed in using a Pinard are generally not conducive to a busy labour ward. It requires additional time to precisely locate the fetal heart as the heart is only audible within a very narrow area of the woman's abdomen, it requires that the surrounding area be quiet in order to hear the fetal heart, the reading can be unreliable in obese women, and it requires the midwife to place her ear in close proximity to the woman's pubic area. In addition the midwife usually counts the FHR for short time, such as 15 seconds, and multiplies to reach beats/minute, further decreasing accuracy and introducing arithmetic errors. The handheld Doppler ultrasound fetal heart rate monitor (Doppler) detects FHR and provides a steady state number per minute, as well as audible auscultation of the FHR. It requires a reliable power source and may need repairs, and is more costly than a Pinard. However, it permits the midwife to quickly locate the FHR, allows others including the mother to hear the FHR, permits the woman to remain in any comfortable position while being assessed, permits the midwife to both assess the FHR and communicate to the woman the status of her baby, and has been shown to be preferred by women over the use of the Pinard.[8,10] A rugged, wind-up, handheld Doppler fetal heart rate monitor (Doppler) developed by Power-free Education Technology (Pet.og.za) showed in initial field tests to be accurate and acceptable to both mother and midwives in low-resource settings.[11,12] It uses a hand crank to generate 2:30 minutes of use for every 30 seconds of cranking.

While there have been several studies showing reduced intervention and no improved outcomes in the use of the intermittent (Pinard or Doppler) versus continuous cardiotocography (CTG) monitoring as the primary screening tool in uncomplicated deliveries,[6,13] there is little research on outcomes in intermittent monitoring comparing Doppler versus Pinard. A single study by Mohamed et al using a monitoring protocol of 10 minutes every half-hour found higher detection of FHR abnormalities and better perinatal outcomes in the intermittent auscultation Doppler group compared with the Pinard group.[14]

We aimed to use a randomised trial design to compare the primary screening methods of FHR monitoring (Doppler as intervention versus Pinard as standard of care) on incidence of detection of FHR abnormalities, and on the incidence of intrapartum stillbirth and neonatal mortality in the first 24 hours after delivery.

METHODS

Study design and participants

We undertook this randomised controlled trial at San Raphael of St. Francis Nsambya Hospital, a peri-urban private not-for-profit hospital in Kampala, Uganda. It is a teaching hospital that manages 7 500 deliveries annually. CTG and fetal blood gas sampling to support labour management, and epidural pain medication are not available. Oxytocin augmentation and Caesarean delivery rates are 40% and 20% respectively. The standard of care for intrapartum FHR monitoring is by intermittent auscultation using the Pinard.

Women were requested to participate during an antenatal care appointment. This consent was reconfirmed in labour provided that they presented in labour with a singleton pregnancy, in a cephalic position, at term or post-term (>37 weeks gestation). Women were excluded if they were already in second stage of labour upon admission or presented with a condition that, according to the doctor on duty, contra-indicated labouring (e.g. ~~had a high risk pregnancy, such as preeclampsia or~~ antepartum hemorrhage); if there was a diagnosis of intrauterine fetal death upon admission; or if the woman was admitted for an elective Caesarean delivery. Participants were presented with information about the study, and agreeing participants provided written consent. This study was approved by Sickkids Research Ethics Board, Nsambya Internal Review Board, as well as the Uganda National Council for Science and Technology. Registration of our protocol with ClinicalTrials.gov occurred before participant enrolment started, but due to an administrative error with our institution's Clinical Research Services Unit, the protocol was only released to the public after the completion of the study. Documentation from the Chair of our independent Research Ethics Board was provided to BMJ Open attesting to the version of the protocol provided to them prior to the start of enrolment.

Randomisation

Women were equally randomised to one of the two study methods using sequentially numbered, opaque sealed envelopes. Study participants and care providers where not blinded to the intervention. Data were collected from the patient's partograph and from the hospital's routine neonatal mortality audit data, when applicable.

Procedures

The standard of care for intrapartum monitoring relied on partograph and FHR monitoring with the Pinard. Our pre-study training address deficiencies in monitoring standards (acceptable range for FHR, recognition of accelerations, decelerations, and change in baseline). We developed a training module entitled "Helping Babies Survive Labour" modeling on the "Helping Babies Breathe" visual materials and learning approach. The technical basis was from World Health Organisation (WHO) and Canadian Obstetric Society protocols.[5] All midwives and doctors were then given this in-service training for half a day. FHR monitoring was undertaken every 30 minutes in first stage of labour; every 15 minutes in second stage before pushing; and every 5 minutes in second stage when pushing and for 1 minute immediately after a contraction. The baseline FHR was recorded as a single number rather than a range, in the unit of beats per minute (bpm). The FHR rhythm (regular or irregular) and absence or presence of accelerations or decelerations were also documented. The maternal radial pulse was simultaneously palpated to differentiate it with the FHR.

When FHR abnormalities are identified the standard of care would be to switch from intermittent auscultation to CTG. Since CTG is not available in Nsambya Hospital, any noted FHR

abnormalities were reported by the research midwife to the doctor on duty for assessment. Management following this assessment was either closer intermittent monitoring, or intra-uterine resuscitation with re-assessment of the FHR. Intra-uterine resuscitation consisted of maternal position change, administration of oxygen by mask to mother, initiation of intravenous infusion, discontinuation of oxytocin augmentation, and consider prompt delivery (assisted vaginal if imminent, otherwise by Caesarean).

Outcomes

The primary outcome measures of interest were detection of FHR abnormality in labour (defined below), intrapartum stillbirth, and neonatal deaths in the first 24 hours of life. Fetal heart rate abnormality is defined as tachycardia, bradycardia, or atypical variable, late or prolonged decelerations. Tachycardia and bradycardia are defined as baselines of >160 bpm and <110 bpm, respectively. Some features of atypical variable decelerations are abrupt fetal heart rate decelerations, lasting >2 minutes, slow return to baseline, or in the presence of tachycardia. Late decelerations are a repetitive, gradual decrease in the FHR and return to baseline, commencing after the onset of the contraction, and return to baseline after the end of the contraction. Prolonged decelerations are a decrease from baseline of >15 bpm lasting from 2-10 minutes. Secondary outcomes were Apgar score less than 7 at 5 minutes, admission to special care unit for intrapartum-related complications (intrapartum hypoxia, neonatal encephalopathy, or meconium aspiration syndrome), diagnosis of neonatal encephalopathy (NE), and delivery by Caesarean. A validated and simplified scoring method was used for grading mild, moderate and severe NE.[15,16] Indications for Caesarean delivery were failure to progress (as indicated by crossing of the action line on the partograph), abnormal FHR unresponsive to uterine resuscitation, and identification of malpresentation in labour (e.g. conversion from vertex to brow or mentum posterior).

Statistical analysis

Estimating that the use of the Doppler would reduce intrapartum stillbirth by 30% compared to the Pinard (based on the results of Mohamed et al 1994),[14] with 80% power to detect at least a 30% reduction in stillbirths with 95% confidence, we would need to enroll 840 participates in each of the two comparison groups. We added 20% to the sample size for each study arm to account for loss to follow-up and statistical adjustments and stratification, resulting in 1008 participants required for each comparison group.

Data were double entered from the partograph and, where applicable, the hospital's routine neonatal mortality audit document. An interim analysis was conducted by the data safety and monitoring board at the mid-point of the data collection period. Descriptive statistics were used to describe the characteristics of the participants and their outcomes under each study arm. ~~[17]~~

We used population-averaged generalized Poisson regression modeling with robust variance to compare methods of FHR monitoring with Doppler versus Pinard on incidence rate ratio (IRR) of detection of FHR abnormalities, intrapartum stillbirth, and neonatal mortality (see Barros et al for details of this choice over logistic regression [17]). We conducted a sub-group analysis and qualitative reporting on the intrapartum stillbirths and pre-discharge neonatal deaths within 24 hours and those fetuses with detected abnormal FHR.

All analyses were conducted using Stata/SE (StataCorp. 2011. Stata Statistical Software: Release 12. College Station, TX: StataCorp LP).

Role of funding source

The sponsor had no role in designing the study, analysing data, collecting data, interpreting the results, writing the report, or the decision to submit the paper for publication. The corresponding

author had complete access to all the data.

RESULTS

From July 2012 to December 2013, we screened 2042 women antenatally. Fifty-three women were ineligible (50 planned to deliver elsewhere, 3 planned Caesarean delivery); 2 women declined to participate; 1987 were enrolled (Figure 1). After assignment to a monitoring method, 8 of the 987 in the Pinard arm were excluded from analysis (1 lost to follow up, 1 delivered before the partograph was started, 2 undiagnosed breech births, 4 undiagnosed multiple births); and 8 of the 1000 in the Doppler arm were excluded (3 delivered before the partograph was started, 3 undiagnosed breech births, 2 undiagnosed multiple births). The final study group was n=979 in the Pinard arm and n=992 in the Doppler arm.

Of the 1971 women analyzed, the median maternal age was 26 years (IQR 24-30) (Table 1). There were a slightly higher though not statistically significant number of post-term women (≥42 weeks of gestational age) in the Doppler versus the Pinard arm (54/992 (5.4%) versus 41/979 (4.2%), p=0.193). A similar proportion of women in the Doppler versus the Pinard arm were primiparous (395/992 (39.8%) versus 413/979 (42.2%)), with similar median gestational age (39 weeks, IQR 38-40), and similar median newborn weight (3300g, IQR 3000-3500g).

Table 1: Demographic, clinical and perinatal characteristics

		Pinard (n=979)	Doppler (n=992)	p-value
Maternal age (years)	Median (IQR)	26 (23-30)	27 (24-30)	0.95
Marital status	Married	816 (83.4)	818 (82.5)	0.60
	Single	163 (16.7)	174 (17.5)	
Maternal education	None	9 (0.9)	7 (0.7)	0.62
	Primary	93 (9.5)	94 (9.5)	
	Secondary	385 (39.3)	423 (42.6)	
	Vocational	235 (24.0)	224 (22.6)	
	University	257 (26.3)	243 (24.5)	
	Missing		1 (0.1)	
Maternal occupation	Housewife	357 (36.5)	377 (38.0)	0.80
	Skilled worker	84 (8.6)	75 (7.6)	
	Self-employed	271 (27.7)	260 (26.2)	
	Professional	252 (25.7)	262 (26.4)	
	Other	15 (1.5)	18 (1.8)	
No. of ANC visits	Median (IQR)	4 (3-5)	4 (3-5)	0.58
Complication noted in pregnancy	Yes	17 (98.3)	24 (2.4)	0.29
	No	962 (1.7)	968 (97.6)	
Gravity	1	334 (34.1)	332 (33.5)	0.64
	2	422 (43.1)	416 (41.9)	
	≥3	223 (22.8)	244 (24.6)	
Parity	0	413 (42.2)	395 (39.8)	0.31
	1	238 (24.3)	232 (23.4)	
	≥2	328 (33.5)	365 (36.8)	
Previous perinatal death	Yes	24 (2.5)	29 (2.9)	0.52
	No	955 (97.6)	963 (97.1)	
Malarial IPTp	Yes	914 (93.4)	923 (93.0)	0.78
	No	65 (6.6)	69 (7.0)	
Syphilis	Negative	830 (84.8)	869 (87.6)	0.14
	Positive	11 (1.1)	6 (0.6)	
	Missing	138 (14.1)	117 (11.8)	
HIV Status	Negative	887 (90.6)	892 (89.9)	0.55
	Positive	46 (4.7)	57 (5.6)	
	Missing	46 (4.7)	43 (4.3)	
Gestational age at delivery (weeks)	Median (IQR)	39 (38-40)	39 (38-40)	0.80
Postterm gestation (≥42 weeks)	Yes	41 (4.2)	54 (5.4)	0.19
	No	938 (95.8)	938 (94.6)	
Newborn weight (g)	Median (IQR)	3300 (3000-3500)	3300 (3000-3500)	0.70

Data are n (%) or median (IQR); IPTp - Intermittent preventative treatment in pregnancy; HIV - Human immunodeficiency virus

There were no differences between the study arms in Apgar score <7 at 5 minutes (23 (2.3%) in the Doppler versus 17(1.7%) the Painard, p=0.40) or admission to neonatal intensive care unit for any reason (48(4.8%) in the Doppler versus 36(3.7%) the Pinard, p=0.20). Similar proportions of women in the Doppler versus Pinard arm had Caesarean deliveries (175/992 (17.6%) versus 166/979 (17.0%), p=0.695).

There were a significantly higher number of FHR abnormalities detected in the Doppler versus Pinard arm (75/992 (7.6%) versus 46/979 (4.7%), p=0.008, IRR=1.61, 95%CI 1.13-2.30) (Table 2). There were a higher though not statistically significant number of intrapartum stillbirths in the Doppler versus Pinard arm (4/988 (0.4%) versus 1/977 (0.1%), p=0.184, IRR=3.94, 95%CI 0.44-35.24), and higher number of neonatal deaths prior to discharge (7/985 (0.7%) versus 5//973 (0.5%), p=0.579, IRR=1.38, 95%CI 0.44-4.34).

There were 121 cases of abnormal FHR detected in labour (Figure 2). Of the 17 deaths in total (intrapartum stillbirths and neonatal deaths prior to discharge), 5 were associated with the detection of abnormal FHR in labour. In a subgroup analysis of those cases where abnormal FHR was detected, there were a higher though not statistically significant proportion of deaths in the Doppler versus Pinard arm (4/71 (5.3%) vs 1/45 (2.2%), IRR=2.45 95%CI 0.28-21.47). The remaining 12 deaths who had a normal FHR reported; 3 had missing cause of death, and 1 had a congenital anomaly, and cause of death for the remaining 8 was intrauterine hypoxia, respiratory distress, or neonatal encephalopathy, suggesting that an abnormal FHR was a missed diagnosis in labour for these 8 deaths.

Table 2~~3~~: Primary outcomes by treatment group

		Pinard (n=979)	Doppler (n=992)	p value	IRR* (95% CI)	p value
Abnormality detected	Yes	46 (4.7)	75 (7.6)	0.008	1.61 (1.13 to 2.30)	0.009
	No	933 (95.3)	917 (92.4)			
Intrapartum stillbirth	Yes	1 (0.1)	4 (0.4)	0.184	3.94** (0.44 to 35.24)	0.219
	No	977 (99.9)	988 (99.6)			
	Missing	1	0			
Neonatal death prior to discharge	Yes	5 (0.5)	7 (0.7)	0.579	1.38** (0.44 to 4.34)	0.552
	No	973 (99.5)	985 (99.3)			
	Missing	1				

IRR - incidence rate ratio; *not adjusted, significant baseline characteristics (p value <0.2) were tested and did not influence measure of effect in the model **excludes missing from analysis

DISCUSSION

Detection of abnormal FHR in labour is essential for identifying the fetus in need of responsive management such as prompt delivery. We report that intermittent auscultation with a Doppler identifies 60% more in need of prompt delivery (IRR=1.61); however, we did not find that this identification resulted in a significant decrease in mortality, although one would expect that higher

detection should lead to prompt delivery and improved outcomes.

We propose a number of explanations for this lack of detected impact. We considered that there may have been a learning curve for staff using the Doppler as a new technology; however, we found no difference in outcomes over time or between groups (data not shown). Secondly, it is possible that use of technology such as the Doppler lead to false reassurance that FHR was being closely monitored, delayed involvement of senior staff and subsequent delivery, or there may simply have been delay between recognition and action that, by chance, had more deleterious effects in the intervention group. Thirdly this study sample size and power was based on the Mohamed 1994 study, aiming to detect a 30% reduction in intrapartum stillbirth in the Doppler compared to the Pinard group and this may be optimistic, necessitating a larger sample size to demonstrate any improved outcomes given the improved detection rates in the Doppler group.

Some study limitations include that we were unable to perform secondary screening of suspected fetal hypoxia through the use of cardiotography; nor confirm for the presence of fetal hypoxia acidemia via fetal blood scalp sampling, and cord blood gases; therefore we were unable to assess if the identification (or lack of identification) of abnormal FHR was correlated with the presence of fetal hypoxia acidemia. In addition, we were unable to exclude some cases where the underlying cause of death was other than fetal hypoxia (e.g. congenital anomalies, early onset sepsis) due to diagnostic limitations in differentially diagnosing these cases. Finally, the screening process was all linked to the partograph which has well recognized limitations.[18]

In conclusion, routine monitoring with a handheld Doppler increases the proportion of fetuses identified in need of prompt delivery via the identification of FHR abnormalities in labour; ~~The care providers and the women expressed preferences for the Doppler,~~ however, we did not find evidence that this lead to a decrease in the incidence of intrapartum stillbirth or neonatal death. While assessing user satisfaction was not the objective of this study, the care providers and the women expressed preference for the Doppler, and given that the Doppler performed no worse than the Pinard in detecting abnormal FHR or in newborn survival, this should be an area of further research. Finally, t~~T~~his study demonstrates the need for a ~~further~~ larger study with linkage to rapid response for abnormal FHR, including caesarean section to ensure that increased detection using the Doppler leads to decreased death and disability.

Acknowledgements
We would like to thank all the midwives and staff of Nsymabya Hopsital maternity care services for their enthusiastic participation and all the women for their willingness to be part of the trial. We are grateful to Hanifah Senguendo, Patrick Aligyira of Saving Newborn Lives, Save the Children Uganda and the members of Ugandan Obstetric Society and other colleagues for valuable inputs to the training materials. We appreciate the insights and helpful comments of Kate Kerber and Dave Woods.

Figure 1: Trial profile

Figure 2: Flow diagram for outcome by fetal heart rate and management
FHR - fetal heart rate; CS/IU/Ass't - Caesarean delivery, intrauterine resuscitation, assisted delivery

Contributorship statement: All authors designed the study. RB DGB AJ PM did data collection. DGB and AM did analysis and wrote the first draft of the manuscript. All authors reviewed and provided feedback on the manuscript draft.

Competing interests: We have read and understood BMJ policy on declaration of interests and declare the following interests: AJ is a paid employee of Powerfree, the not-for-profit designers of the handheld Doppler used in this study.

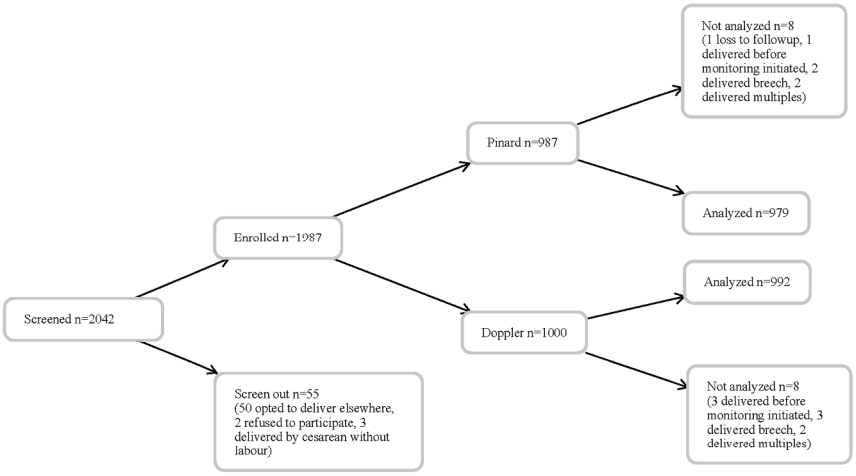
Funding: Grand Challenges Canada for the trial and Laerdal Foundation for the training module "Helping Babies Survive Labour".

Data sharing: No additional data available

REFERENCES

1 Lawn JE, Blencowe H, Oza S, et al (2014) Every Newborn: progress, priorities, and potential beyond survival. Lancet 384: 189-205.
2 Lee AC, Kozuki N, Blencowe H, et al (2013) Intrapartum-related neonatal encephalopathy incidence and impairment at regional and global levels for 2010 with trends from 1990. Pediatr Res 74 Suppl 1: 50-72.
3 Lawn JE, Blencowe H, Pattinson R, et al (2011) Stillbirths: Where? When? Why? How to make the data count? Lancet 377: 1448-1463.
4 Lawn JE, Kinney M, Lee AC, et al (2009) Reducing intrapartum-related deaths and disability: can the health system deliver? Int J Gynaecol Obstet 107 Suppl 1: S123-40, S140-2.
5 SOGC (2013) Advances in labour and risk management. Ottawa: Society of Obstetricians and Gynaecologists of Canada.
6 NICE (2003) The Use of electronic fetal monitoring. NHS Clinical Guideline C 23807: 1-17.
7 Liston R, Sawchuck D, Young D (2007) Fetal health surveillance: antepartum and intrapartum consensus guideline. J Obstet Gynaecol Canada 29: S3-56.
8 Hofmeyr GJ, Haws RA, Bergström S, et al (2009) Obstetric care in low-resource settings: what, who, and how to overcome challenges to scale up? Int J Gynaecol Obstet 107 Suppl 1: S21-44, S44-5.
9 Alfirevic Z, Devane D, Gyte GM (2013) Continuous cardiotocography (CTG) as a form of electronic fetal monitoring (EFM) for fetal assessment during labour. Cochrane Database Syst Rev 5.
10 Mangesi L, Hofmeyr GJ, Woods D (2009) Assessing the preference of women for different methods of monitoring the fetal heart in labour. S Afr J Obstet Gynaecol 15.
11 Bezuidenhout H, Woods D, Wyatt J, et al (2006) Does fetal heart rate count? Developing a low cost, alternative powered doppler fetal heart monitor for use in low resource high mortality settings. 4th IET Seminar on Appropriate Healthcare Technologies for Developing Countries : 155-159.
12 Woods D (2009) Appropriate technology and education for improved intrapartum care in underresourced countries. S Afr J Obstet Gynaecol 15.
13 Devane D, Lalor JG, Daly S, et al (2012) Cardiotocography versus intermittent auscultation of fetal heart on admission to labour ward for assessment of fetal wellbeing. Cochrane Database Syst Rev 2.
14 Mahomed K, Nyoni R, Mulambo T, et al (1994) Randomised controlled trial of intrapartum fetal heart rate monitoring. BMJ 308: 497-500.
15 Ellis M, Manandhar N, Manandhar DS, et al (2000) Risk factors for neonatal encephalopathy in Kathmandu, Nepal, a developing country: unmatched case-control study. BMJ 320: 1229-1236.
16 Amiel-Tison C (2002) Update of the Amiel-Tison neurologic assessment for the term neonate or at 40 weeks corrected age. Pediatr Neurol 27: 196-212.
17 Barros AJ, Hirakata VN (2003) Alternatives for logistic regression in cross-sectional studies: an empirical comparison of models that directly estimate the prevalence ratio. BMC Med Res Methodol 3: 21.
18 Lavender T, Hart A, Smyth RM (2013) Effect of partogram use on outcomes for women in

spontaneous labour at term. Cochrane Database Syst Rev 7: CD005461.



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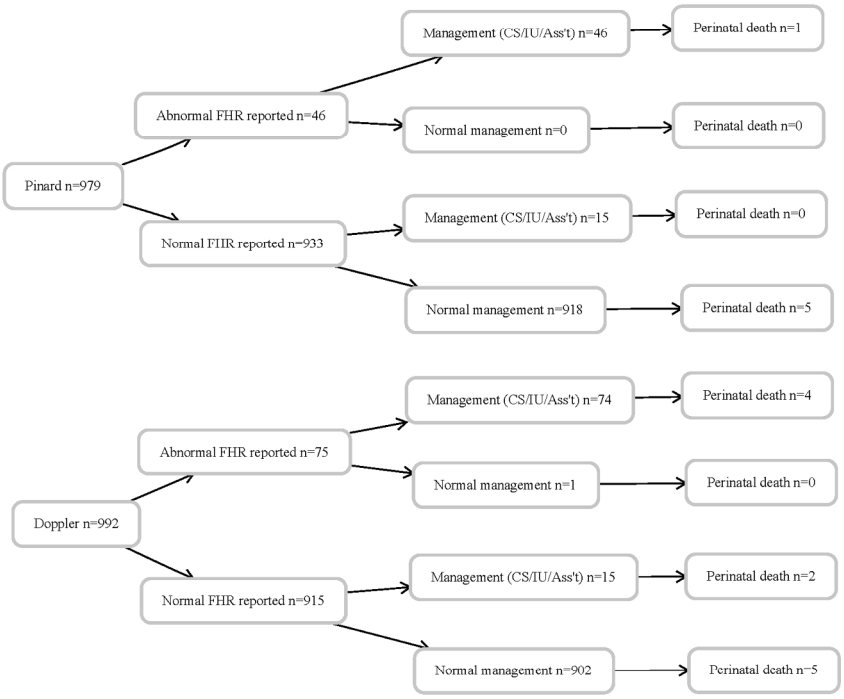

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	not applicable
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	not applicable
Sample size	7a	How sample size was determined	6
	7b	When applicable, explanation of any interim analyses and stopping guidelines	6
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	not reported
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	5

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	5
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	6
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	6
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1, 6-7
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1, 6-7
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6
	14b	Why the trial ended or was stopped	6
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	8
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	8
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	10
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	10
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	9
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Table 2, 9
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	10
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	10
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	10
Other information			
Registration	23	Registration number and name of trial registry	2
Protocol	24	Where the full trial protocol can be accessed, if available	2
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	2

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Use of wind-up fetal Doppler versus Pinard for fetal heart rate intermittent monitoring in labour: a randomised clinical trial

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Use of wind-up fetal Doppler versus Pinard for fetal heart rate intermittent monitoring in labour: a randomised clinical trial

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TITLE: Use of wind-up fetal Doppler versus Pinard for fetal heart rate intermittent monitoring in labour: a randomized clinical trial

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ABSTRACT

Objectives: In resource-poor settings, the standard of care to inform labour management is the partograph plus Pinard stethoscope for intermittent fetal heart rate (FHR) monitoring. We compared FHR monitoring in labour using a novel, robust wind-up handheld Doppler with the Pinard as a primary screening tool for abnormal FHR on perinatal outcomes.

Design: Prospective equally randomised clinical trial.

Setting: The labour and delivery unit of a teaching hospital in Kampala, Uganda.

Participants: Of the 2042 eligible antenatal women, 1971 women in active term labour, following uncomplicated pregnancies were randomised to either the standard of care, or not.

Intervention: Intermittent FHR monitoring using Doppler.

Primary outcome measures: Incidence of FHR abnormality detection, intrapartum stillbirth and neonatal mortality prior to discharge.

Results: Age, parity, gestational age, mode of delivery, and newborn weight were similar between study groups. In the Doppler group, there was a significantly higher rate of FHR abnormalities detected (Incidence Rate Ratio (IRR)=1.61, 95%CI 1.13 to 2.30). However, in this group there were also higher though not statistically significant rate of intrapartum stillbirths (IRR=3.94, 0.44 to 35.24) and neonatal deaths (IRR=1.38, 0.44 to 4.34).

Conclusion: Routine monitoring with a handheld Doppler increased the identification of FHR abnormalities in labour; however, our trial did not find evidence that this lead to a decrease the incidence of intrapartum stillbirth or neonatal death.

Trial registration: ClinicalTrails.gov (1000031587)

TEXT BOXES

1. Strengths and limitations of this study

- This is the first study to use current monitoring guidelines to compare evaluated Doppler versus Pinard in improving stillbirth and neonatal outcomes.
- A major strength of this study includes the prospective and randomisation design.
- We were unable to perform secondary screening of suspected fetal hypoxia through the use of cardiotography; nor confirm for the presence of fetal hypoxia acidemia via fetal blood scalp sampling, and cord blood gases; therefore we were unable to assess if the identification (or lack of identification) of abnormal FHR was correlated with the presence of fetal hypoxia acidemia.
- We were unable to exclude some cases where the underlying cause of death was other than fetal hypoxia (e.g. congenital anomalies, early onset sepsis) due to diagnostic limitations in differentially diagnosing these cases.

2. Training

Helping Babies Survive Labour is the training programme that was used to train the midwives in Nsambya hospital. It was developed by Powerfree Education and Technology in Cape Town in collaboration with Save the Children and health professionals from Nsambya Hospital Kampala (Figure 3).

Many training methods and guidelines are written in high income countries and are simply transferred for use in low income countries, although the healthcare workers in these countries may face very different challenges. Input was solicited from both the healthcare workers and academics in the target country in the preparation of these training materials.

The material first provides a section of evidence-based theory that will help health workers to understand why monitoring of the fetal heart is important. This is followed by practical lessons on how to monitor fetal well-being, how to interpret observations and recordings and most importantly, gives guidelines on what to do when something is wrong. The training is developed in such a way that it can be used along side the Helping Babies Breath training material, which focuses on neonatal resuscitation.

Before this trial started, midwives and doctors were trained. Fifty-two people attended the training and 42 completed both the pre- and post-test. The average score for the pre-test was 49.7% (median 50%). The average score for the post-test was 67.9% (median 69%). It does reveal the low baseline knowledge on appropriate intrapartum care and illustrates the need for continuous quality improvement.

For link to the manual and its references
http://www.healthynewbornnetwork.org/sites/default/files/resources/HBSL%20training%20booklet.pdf

INTRODUCTION

Approximately 44% of all child deaths under the age of 5 years occur in neonates (<28 days of age).[1] The third largest cause of neonatal mortality is intrapartum-related hypoxia (formerly called `birth asphyxia') resulting in an estimated 660 000 neonatal deaths per year globally[1] and an additional 414,000 children who survive with disability.[2] There are also an estimated 1.02 million intrapartum stillbirths almost all in low and middle income countries.[3] This burden is highest in areas of the world where the probability of quality of care at birth is the lowest.[4] In order to reduce the incidence of intrapartum-related stillbirths and neonatal deaths, it is necessary to assess fetal well-being in labour with routine monitoring of the fetal heart rate (FHR), linked to rapid and effective management with resuscitative measures or prompt delivery, and provision of neonatal resuscitation if needed.

Characteristic FHR changes often precede brain injury via a process of progressive fetal hypoxic acidemia.[5] Intermittent auscultation as a primary screening tool to monitor fetal well-being is the recommended standard of care for women experiencing uncomplicated deliveries.[6-9] One method of intermittent auscultation uses the Pinard Fetal Stethoscope (Pinard), a trumpet shaped horn, to monitor the FHR and is widely adopted as the standard of care in resource-poor settings since it is low cost and does not require a power source or repairs. The difficulties posed in using a Pinard are generally not conducive to a busy labour ward. It requires additional time to precisely locate the fetal heart as the heart is only audible within a very narrow area of the woman's abdomen, it requires that the surrounding area be quiet in order to hear the fetal heart, the reading can be unreliable in obese women, and it requires the midwife to place her ear in close proximity to the woman's pubic area. In addition the midwife usually counts the FHR for short time, such as 15 seconds, and multiplies to reach beats/minute, further decreasing accuracy and introducing arithmetic errors. The handheld Doppler ultrasound fetal heart rate monitor (Doppler) detects FHR and provides a steady state number per minute, as well as audible auscultation of the FHR. It requires a reliable power source and may need repairs, and is more costly than a Pinard. However, it permits the midwife to quickly locate the FHR, allows others including the mother to hear the FHR, permits the woman to remain in any comfortable position while being assessed, permits the midwife to both assess the FHR and communicate to the woman the status of her baby, and has been shown to be preferred by women over the use of the Pinard.[8,10] A rugged, wind-up, handheld Doppler fetal heart rate monitor (Doppler) developed by Power-free Education Technology (Pet.og.za) showed in initial field tests to be accurate and acceptable to both mother and midwives in low-resource settings.[11,12] It uses a hand crank to generate 2:30 minutes of use for every 30 seconds of cranking.

While there have been several studies showing reduced intervention and no improved outcomes in the use of the intermittent (Pinard or Doppler) versus continuous cardiotocography (CTG) monitoring as the primary screening tool in uncomplicated deliveries,[6,13] there is little research on outcomes in intermittent monitoring comparing Doppler versus Pinard. A single study by Mohamed et al using a monitoring protocol of 10 minutes every half-hour found higher detection of FHR abnormalities and better perinatal outcomes in the intermittent auscultation Doppler group compared with the Pinard group.[14]

We aimed to use a randomised trial design to compare the primary screening methods of FHR monitoring (Doppler as intervention versus Pinard as standard of care) on incidence of detection of FHR abnormalities, and on the incidence of intrapartum stillbirth and neonatal mortality in the first 24 hours after delivery.

METHODS

Study design and participants

We undertook this randomised controlled trial at San Raphael of St. Francis Nsambya Hospital, a peri-urban private not-for-profit hospital in Kampala, Uganda. It is a teaching hospital that manages 7 500 deliveries annually. CTG and fetal blood gas sampling to support labour management, and epidural pain medication are not available. Oxytocin augmentation and Caesarean delivery rates are 40% and 20% respectively. The standard of care for intrapartum FHR monitoring is by intermittent auscultation using the Pinard.

Women were requested to participate during an antenatal care appointment. This consent was reconfirmed in labour provided that they presented in labour with a singleton pregnancy, in a cephalic position, at term or post-term (>37 weeks gestation). Women were excluded if they were already in second stage of labour upon admission or presented with a condition that, according to the doctor on duty, contra-indicated labouring (e.g. antepartum hemorrhage); if there was a diagnosis of intrauterine fetal death upon admission; or if the woman was admitted for an elective Caesarean delivery. Participants were presented with information about the study, and agreeing participants provided written consent. This study was approved by Sickkids Research Ethics Board, Nsambya Internal Review Board, as well as the Uganda National Council for Science and Technology. Registration of our protocol with ClinicalTrials.gov occurred before participant enrolment started, but due to an administrative error with our institution's Clinical Research Services Unit, the protocol was only released to the public after the completion of the study. Documentation from the Chair of our independent Research Ethics Board was provided to BMJ Open attesting to the version of the protocol provided to them prior to the start of enrolment.

Randomisation

Women were equally randomised to one of the two study methods using sequentially numbered, opaque sealed envelopes. Study participants and care providers where not blinded to the intervention. Data were collected from the patient's partograph and from the hospital's routine neonatal mortality audit data, when applicable.

Procedures

The standard of care for intrapartum monitoring relied on partograph and FHR monitoring with the Pinard. Our pre-study training address deficiencies in monitoring standards (acceptable range for FHR, recognition of accelerations, decelerations, and change in baseline). We developed a training module entitled "Helping Babies Survive Labour" modeling on the "Helping Babies Breathe" visual materials and learning approach. The technical basis was from World Health Organisation (WHO) and Canadian Obstetric Society protocols.[5] All midwives and doctors were then given this in-service training for half a day. FHR monitoring was undertaken every 30 minutes in first stage of labour; every 15 minutes in second stage before pushing; and every 5 minutes in second stage when pushing and for 1 minute immediately after a contraction. The baseline FHR was recorded as a single number rather than a range, in the unit of beats per minute (bpm). The FHR rhythm (regular or irregular) and absence or presence of accelerations or decelerations were also documented. The maternal radial pulse was simultaneously palpated to differentiate it with the FHR.

When FHR abnormalities are identified the standard of care would be to switch from intermittent auscultation to CTG. Since CTG is not available in Nsambya Hospital, any noted FHR abnormalities were reported by the research midwife to the doctor on duty for assessment.

Management following this assessment was either closer intermittent monitoring, or intra-uterine resuscitation with re-assessment of the FHR. Intra-uterine resuscitation consisted of maternal position change, administration of oxygen by mask to mother, initiation of intravenous infusion, discontinuation of oxytocin augmentation, and consider prompt delivery (assisted vaginal if imminent, otherwise by Caesarean).

Outcomes

The primary outcome measures of interest were detection of FHR abnormality in labour (defined below), intrapartum stillbirth, and neonatal deaths in the first 24 hours of life. Fetal heart rate abnormality is defined as tachycardia, bradycardia, or atypical variable, late or prolonged decelerations. Tachycardia and bradycardia are defined as baselines of >160 bpm and <110 bpm, respectively. Some features of atypical variable decelerations are abrupt fetal heart rate decelerations, lasting >2 minutes, slow return to baseline, or in the presence of tachycardia. Late decelerations are a repetitive, gradual decrease in the FHR and return to baseline, commencing after the onset of the contraction, and return to baseline after the end of the contraction. Prolonged decelerations are a decrease from baseline of >15 bpm lasting from 2-10 minutes. Secondary outcomes were Apgar score less than 7 at 5 minutes, admission to special care unit for intrapartum-related complications (intrapartum hypoxia, neonatal encephalopathy, or meconium aspiration syndrome), diagnosis of neonatal encephalopathy (NE), and delivery by Caesarean. A validated and simplified scoring method was used for grading mild, moderate and severe NE.[15,16] Indications for Caesarean delivery were failure to progress (as indicated by crossing of the action line on the partograph), abnormal FHR unresponsive to uterine resuscitation, and identification of malpresentation in labour (e.g. conversion from vertex to brow or mentum posterior).

Statistical analysis

Estimating that the use of the Doppler would reduce intrapartum stillbirth by 30% compared to the Pinard (based on the results of Mohamed et al 1994),[14] with 80% power to detect at least a 30% reduction in stillbirths with 95% confidence, we would need to enroll 840 participates in each of the two comparison groups. We added 20% to the sample size for each study arm to account for loss to follow-up and statistical adjustments and stratification, resulting in 1008 participants required for each comparison group.

Data were double entered from the partograph and, where applicable, the hospital's routine neonatal mortality audit document. An interim analysis was conducted by the data safety and monitoring board at the mid-point of the data collection period. Descriptive statistics were used to describe the characteristics of the participants and their outcomes under each study arm.
We used population-averaged generalized Poisson regression modeling with robust variance to compare methods of FHR monitoring with Doppler versus Pinard on incidence rate ratio (IRR) of detection of FHR abnormalities, intrapartum stillbirth, and neonatal mortality (see Barros et al for details of this choice over logistic regression [17]). We conducted a sub-group analysis and qualitative reporting on the intrapartum stillbirths and pre-discharge neonatal deaths within 24 hours and those fetuses with detected abnormal FHR.

All analyses were conducted using Stata/SE (StataCorp. 2011. Stata Statistical Software: Release 12. College Station, TX: StataCorp LP).

Role of funding source

The sponsor had no role in designing the study, analysing data, collecting data, interpreting the results, writing the report, or the decision to submit the paper for publication. The corresponding author had complete access to all the data.

RESULTS

From July 2012 to December 2013, we screened 2042 women antenatally. Fifty-three women were ineligible (50 planned to deliver elsewhere, 3 planned Caesarean delivery); 2 women declined to participate; 1987 were enrolled (Figure 1). After assignment to a monitoring method, 8 of the 987 in the Pinard arm were excluded from analysis (1 lost to follow up, 1 delivered before the partograph was started, 2 undiagnosed breech births, 4 undiagnosed multiple births); and 8 of the 1000 in the Doppler arm were excluded (3 delivered before the partograph was started, 3 undiagnosed breech births, 2 undiagnosed multiple births). The final study group was n=979 in the Pinard arm and n=992 in the Doppler arm.

Of the 1971 women analyzed, the median maternal age was 26 years (IQR 24-30) (Table 1). There were a slightly higher though not statistically significant number of post-term women (≥42 weeks of gestational age) in the Doppler versus the Pinard arm (54/992 (5.4%) versus 41/979 (4.2%), p=0.193). A similar proportion of women in the Doppler versus the Pinard arm were primiparous (395/992 (39.8%) versus 413/979 (42.2%)), with similar median gestational age (39 weeks, IQR 38-40), and similar median newborn weight (3300g, IQR 3000-3500g).

Table 1: Demographic, clinical and perinatal characteristics

		Pinard (n=979)	Doppler (n=992)	p-value
Maternal age (years)	Median (IQR)	26 (23-30)	27 (24-30)	0.95
Marital status	Married	816 (83.4)	818 (82.5)	0.60
	Single	163 (16.7)	174 (17.5)	
Maternal education	None	9 (0.9)	7 (0.7)	0.62
	Primary	93 (9.5)	94 (9.5)	
	Secondary	385 (39.3)	423 (42.6)	
	Vocational	235 (24.0)	224 (22.6)	
	University	257 (26.3)	243 (24.5)	
	Missing		1 (0.1)	
Maternal occupation	Housewife	357 (36.5)	377 (38.0)	0.80
	Skilled worker	84 (8.6)	75 (7.6)	
	Self-employed	271 (27.7)	260 (26.2)	
	Professional	252 (25.7)	262 (26.4)	
	Other	15 (1.5)	18 (1.8)	
No. of ANC visits	Median (IQR)	4 (3-5)	4 (3-5)	0.58
Complication noted in pregnancy	Yes	17 (98.3)	24 (2.4)	0.29
	No	962 (1.7)	968 (97.6)	
Gravity	1	334 (34.1)	332 (33.5)	0.64
	2	422 (43.1)	416 (41.9)	
	≥3	223 (22.8)	244 (24.6)	
Parity	0	413 (42.2)	395 (39.8)	0.31
	1	238 (24.3)	232 (23.4)	
	≥2	328 (33.5)	365 (36.8)	
Previous perinatal death	Yes	24 (2.5)	29 (2.9)	0.52
	No	955 (97.6)	963 (97.1)	
Malarial IPTp	Yes	914 (93.4)	923 (93.0)	0.78
	No	65 (6.6)	69 (7.0)	
Syphilis	Negative	830 (84.8)	869 (87.6)	0.14
	Positive	11 (1.1)	6 (0.6)	
	Missing	138 (14.1)	117 (11.8)	
HIV Status	Negative	887 (90.6)	892 (89.9)	0.55
	Positive	46 (4.7)	57 (5.6)	
	Missing	46 (4.7)	43 (4.3)	
Gestational age at delivery (weeks)	Median (IQR)	39 (38-40)	39 (38-40)	0.80
Postterm gestation (≥42 weeks)	Yes	41 (4.2)	54 (5.4)	0.19
	No	938 (95.8)	938 (94.6)	
Newborn weight (g)	Median (IQR)	3300 (3000-3500)	3300 (3000-3500)	0.70

Data are n (%) or median (IQR); IPTp - Intermittent preventative treatment in pregnancy; HIV - Human immunodeficiency virus

There were no differences between the study arms in Apgar score <7 at 5 minutes (23 (2.3%) in the Doppler versus 17(1.7%) the Painard, p=0.40) or admission to neonatal intensive care unit for any reason (48(4.8%) in the Doppler versus 36(3.7%) the Pinard, p=0.20). Similar proportions of women in the Doppler versus Pinard arm had Caesarean deliveries (175/992 (17.6%) versus 166/979 (17.0%), p=0.695).

There were a significantly higher number of FHR abnormalities detected in the Doppler versus Pinard arm (75/992 (7.6%) versus 46/979 (4.7%), p=0.008, IRR=1.61, 95%CI 1.13-2.30) (Table 2). There were a higher though not statistically significant number of intrapartum stillbirths in the Doppler versus Pinard arm (4/988 (0.4%) versus 1/977 (0.1%), p=0.184, IRR=3.94, 95%CI 0.44-35.24), and higher number of neonatal deaths prior to discharge (7/985 (0.7%) versus 5//973 (0.5%), p=0.579, IRR=1.38, 95%CI 0.44-4.34).

There were 121 cases of abnormal FHR detected in labour (Figure 2). Of the 17 deaths in total (intrapartum stillbirths and neonatal deaths prior to discharge), 5 were associated with the detection of abnormal FHR in labour. In a subgroup analysis of those cases where abnormal FHR was detected, there were a higher though not statistically significant proportion of deaths in the Doppler versus Pinard arm (4/71 (5.3%) vs 1/45 (2.2%), IRR=2.45 95%CI 0.28-21.47). The remaining 12 deaths who had a normal FHR reported; 3 had missing cause of death, and 1 had a congenital anomaly, and cause of death for the remaining 8 was intrauterine hypoxia, respiratory distress, or neonatal encephalopathy, suggesting that an abnormal FHR was a missed diagnosis in labour for these 8 deaths.

Table 2: Primary outcomes by treatment group

		Pinard (n=979)	Doppler (n=992)	p value	IRR* (95% CI)	p value
Abnormality detected	Yes	46 (4.7)	75 (7.6)	0.008	1.61 (1.13 to 2.30)	0.009
	No	933 (95.3)	917 (92.4)			
Intrapartum stillbirth	Yes	1 (0.1)	4 (0.4)	0.184	3.94** (0.44 to 35.24)	0.219
	No	977 (99.9)	988 (99.6)			
	Missing	1	0			
Neonatal death prior to discharge	Yes	5 (0.5)	7 (0.7)	0.579	1.38** (0.44 to 4.34)	0.552
	No	973 (99.5)	985 (99.3)			
	Missing	1				

IRR - incidence rate ratio; *not adjusted, significant baseline characteristics (p value <0.2) were tested and did not influence measure of effect in the model **excludes missing from analysis

DISCUSSION

Detection of abnormal FHR in labour is essential for identifying the fetus in need of responsive management such as prompt delivery. We report that intermittent auscultation with a Doppler identifies 60% more in need of prompt delivery (IRR=1.61); however, we did not find that this identification resulted in a significant decrease in mortality, although one would expect that higher

detection should lead to prompt delivery and improved outcomes.

We propose a number of explanations for this lack of detected impact. We considered that there may have been a learning curve for staff using the Doppler as a new technology; however, we found no difference in outcomes over time or between groups (data not shown). Secondly, it is possible that use of technology such as the Doppler lead to false reassurance that FHR was being closely monitored, delayed involvement of senior staff and subsequent delivery, or there may simply have been delay between recognition and action that, by chance, had more deleterious effects in the intervention group. Thirdly this study sample size and power was based on the Mohamed 1994 study, aiming to detect a 30% reduction in intrapartum stillbirth in the Doppler compared to the Pinard group and this may be optimistic, necessitating a larger sample size to demonstrate any improved outcomes given the improved detection rates in the Doppler group.

Some study limitations include that we were unable to perform secondary screening of suspected fetal hypoxia through the use of cardiotography; nor confirm for the presence of fetal hypoxia acidemia via fetal blood scalp sampling, and cord blood gases; therefore we were unable to assess if the identification (or lack of identification) of abnormal FHR was correlated with the presence of fetal hypoxia acidemia. In addition, we were unable to exclude some cases where the underlying cause of death was other than fetal hypoxia (e.g. congenital anomalies, early onset sepsis) due to diagnostic limitations in differentially diagnosing these cases. Finally, the screening process was all linked to the partograph which has well recognized limitations.[18]

In conclusion, routine monitoring with a handheld Doppler increases the proportion of fetuses identified in need of prompt delivery via the identification of FHR abnormalities in labour; however, we did not find evidence that this lead to a decrease in the incidence of intrapartum stillbirth or neonatal death. While assessing user satisfaction was not the objective of this study, the care providers and the women expressed preference for the Doppler, and given that the Doppler performed no worse than the Pinard in detecting abnormal FHR or in newborn survival, this should be an area of further research. Finally, this study demonstrates the need for a larger study with linkage to rapid response for abnormal FHR, including caesarean section to ensure that increased detection using the Doppler leads to decreased death and disability.

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Figure 1: Trial profile

Figure 2: Flow diagram for outcome by fetal heart rate and management
FHR - fetal heart rate; CS/IU/Ass't - Caesarean delivery, intrauterine resuscitation, assisted delivery

Contributorship statement: All authors designed the study. RB DGB AJ PM did data collection. DGB and AM did analysis and wrote the first draft of the manuscript. All authors reviewed and provided feedback on the manuscript draft.

Competing interests: We have read and understood BMJ policy on declaration of interests and declare the following interests: AJ is a paid employee of Powerfree, the not-for-profit designers of the handheld Doppler used in this study.

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REFERENCES

1 Lawn JE, Blencowe H, Oza S, et al (2014) Every Newborn: progress, priorities, and potential beyond survival. Lancet 384: 189-205.
2 Lee AC, Kozuki N, Blencowe H, et al (2013) Intrapartum-related neonatal encephalopathy incidence and impairment at regional and global levels for 2010 with trends from 1990. Pediatr Res 74 Suppl 1: 50-72.
3 Lawn JE, Blencowe H, Pattinson R, et al (2011) Stillbirths: Where? When? Why? How to make the data count? Lancet 377: 1448-1463.
4 Lawn JE, Kinney M, Lee AC, et al (2009) Reducing intrapartum-related deaths and disability: can the health system deliver? Int J Gynaecol Obstet 107 Suppl 1: S123-40, S140-2.
5 SOGC (2013) Advances in labour and risk management. Ottawa: Society of Obstetricians and Gynaecologists of Canada.
6 NICE (2003) The Use of electronic fetal monitoring. NHS Clinical Guideline C 23807: 1-17.
7 Liston R, Sawchuck D, Young D (2007) Fetal health surveillance: antepartum and intrapartum consensus guideline. J Obstet Gynaecol Canada 29: S3-56.
8 Hofmeyr GJ, Haws RA, Bergström S, et al (2009) Obstetric care in low-resource settings: what, who, and how to overcome challenges to scale up? Int J Gynaecol Obstet 107 Suppl 1: S21-44, S44-5.
9 Alfirevic Z, Devane D, Gyte GM (2013) Continuous cardiotocography (CTG) as a form of electronic fetal monitoring (EFM) for fetal assessment during labour. Cochrane Database Syst Rev 5.
10 Mangesi L, Hofmeyr GJ, Woods D (2009) Assessing the preference of women for different methods of monitoring the fetal heart in labour. S Afr J Obstet Gynaecol 15.
11 Bezuidenhout H, Woods D, Wyatt J, et al (2006) Does fetal heart rate count? Developing a low cost, alternative powered doppler fetal heart monitor for use in low resource high mortality settings. 4th IET Seminar on Appropriate Healthcare Technologies for Developing Countries : 155-159.
12 Woods D (2009) Appropriate technology and education for improved intrapartum care in underresourced countries. S Afr J Obstet Gynaecol 15.
13 Devane D, Lalor JG, Daly S, et al (2012) Cardiotocography versus intermittent auscultation of fetal heart on admission to labour ward for assessment of fetal wellbeing. Cochrane Database Syst Rev 2.
14 Mahomed K, Nyoni R, Mulambo T, et al (1994) Randomised controlled trial of intrapartum fetal heart rate monitoring. BMJ 308: 497-500.
15 Ellis M, Manandhar N, Manandhar DS, et al (2000) Risk factors for neonatal encephalopathy in Kathmandu, Nepal, a developing country: unmatched case-control study. BMJ 320: 1229-1236.
16 Amiel-Tison C (2002) Update of the Amiel-Tison neurologic assessment for the term neonate or at 40 weeks corrected age. Pediatr Neurol 27: 196-212.
17 Barros AJ, Hirakata VN (2003) Alternatives for logistic regression in cross-sectional studies: an empirical comparison of models that directly estimate the prevalence ratio. BMC Med Res Methodol 3: 21.
18 Lavender T, Hart A, Smyth RM (2013) Effect of partogram use on outcomes for women in

spontaneous labour at term. Cochrane Database Syst Rev 7: CD005461.

Use of wind-up fetal Doppler versus Pinard for fetal heart rate intermittent monitoring in labour: a randomised clinical trial

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TITLE: Use of wind-up fetal Doppler versus Pinard for fetal heart rate intermittent monitoring in labour: a randomized clinical trial

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ABSTRACT

Objectives: In resource-poor settings, the standard of care to inform labour management is the partograph plus Pinard stethoscope for intermittent fetal heart rate (FHR) monitoring. We compared FHR monitoring in labour using a novel, robust wind-up handheld Doppler with the Pinard as a primary screening tool for abnormal FHR on perinatal outcomes.

Design: Prospective equally randomised clinical trial.

Setting: The labour and delivery unit of a teaching hospital in Kampala, Uganda.

Participants: Of the 2042 eligible antenatal women, 1971 women in active term labour, following uncomplicated pregnancies were randomised to either the standard of care, or not.

Intervention: Intermittent FHR monitoring using Doppler.

Primary outcome measures: Incidence of FHR abnormality detection, intrapartum stillbirth and neonatal mortality prior to discharge.

Results: Age, parity, gestational age, mode of delivery, and newborn weight were similar between study groups. In the Doppler group, there was a significantly higher rate of FHR abnormalities detected (Incidence Rate Ratio (IRR)=1.61, 95%CI 1.13 to 2.30). However, in this group there were also higher though not statistically significant rate of intrapartum stillbirths (IRR=3.94, 0.44 to 35.24) and neonatal deaths (IRR=1.38, 0.44 to 4.34).

Conclusion: Routine monitoring with a handheld Doppler increased the identification of FHR abnormalities in labour; however, our trial did not find evidence that this lead to a decrease the incidence of intrapartum stillbirth or neonatal death.

Trial registration: ClinicalTrails.gov (1000031587)

TEXT BOXES

1. Strengths and limitations of this study

- This is the first study to use current monitoring guidelines to compare evaluated Doppler versus Pinard in improving stillbirth and neonatal outcomes.
- A major strength of this study includes the prospective and randomisation design.
- We were unable to perform secondary screening of suspected fetal hypoxia through the use of cardiotography; nor confirm for the presence of fetal hypoxia acidemia via fetal blood scalp sampling, and cord blood gases; therefore we were unable to assess if the identification (or lack of identification) of abnormal FHR was correlated with the presence of fetal hypoxia acidemia.
- We were unable to exclude some cases where the underlying cause of death was other than fetal hypoxia (e.g. congenital anomalies, early onset sepsis) due to diagnostic limitations in differentially diagnosing these cases.

2. Training

Helping Babies Survive Labour is the training programme that was used to train the midwives in Nsambya hospital. It was developed by Powerfree Education and Technology in Cape Town in collaboration with Save the Children and health professionals from Nsambya Hospital Kampala (Figure 3).

Many training methods and guidelines are written in high income countries and are simply transferred for use in low income countries, although the healthcare workers in these countries may face very different challenges. Input was solicited from both the healthcare workers and academics in the target country in the preparation of these training materials.

The material first provides a section of evidence-based theory that will help health workers to understand why monitoring of the fetal heart is important. This is followed by practical lessons on how to monitor fetal well-being, how to interpret observations and recordings and most importantly, gives guidelines on what to do when something is wrong. The training is developed in such a way that it can be used along side the Helping Babies Breath training material, which focuses on neonatal resuscitation.

Before this trial started, midwives and doctors were trained. Fifty-two people attended the training and 42 completed both the pre- and post-test. The average score for the pre-test was 49.7% (median 50%). The average score for the post-test was 67.9% (median 69%). It does reveal the low baseline knowledge on appropriate intrapartum care and illustrates the need for continuous quality improvement.

For link to the manual and its references
http://www.healthynewbornnetwork.org/sites/default/files/resources/HBSL%20training%20booklet.pdf

INTRODUCTION

Approximately 44% of all child deaths under the age of 5 years occur in neonates (<28 days of age).[1] The third largest cause of neonatal mortality is intrapartum-related hypoxia (formerly called `birth asphyxia') resulting in an estimated 660 000 neonatal deaths per year globally[1] and an additional 414,000 children who survive with disability.[2] There are also an estimated 1.02 million intrapartum stillbirths almost all in low and middle income countries.[3] This burden is highest in areas of the world where the probability of quality of care at birth is the lowest.[4] In order to reduce the incidence of intrapartum-related stillbirths and neonatal deaths, it is necessary to assess fetal well-being in labour with routine monitoring of the fetal heart rate (FHR), linked to rapid and effective management with resuscitative measures or prompt delivery, and provision of neonatal resuscitation if needed.

Characteristic FHR changes often precede brain injury via a process of progressive fetal hypoxic acidemia.[5] Intermittent auscultation as a primary screening tool to monitor fetal well-being is the recommended standard of care for women experiencing uncomplicated deliveries.[6-9] One method of intermittent auscultation uses the Pinard Fetal Stethoscope (Pinard), a trumpet shaped horn, to monitor the FHR and is widely adopted as the standard of care in resource-poor settings since it is low cost and does not require a power source or repairs. The difficulties posed in using a Pinard are generally not conducive to a busy labour ward. It requires additional time to precisely locate the fetal heart as the heart is only audible within a very narrow area of the woman's abdomen, it requires that the surrounding area be quiet in order to hear the fetal heart, the reading can be unreliable in obese women, and it requires the midwife to place her ear in close proximity to the woman's pubic area. In addition the midwife usually counts the FHR for short time, such as 15 seconds, and multiplies to reach beats/minute, further decreasing accuracy and introducing arithmetic errors. The handheld Doppler ultrasound fetal heart rate monitor (Doppler) detects FHR and provides a steady state number per minute, as well as audible auscultation of the FHR. It requires a reliable power source and may need repairs, and is more costly than a Pinard. However, it permits the midwife to quickly locate the FHR, allows others including the mother to hear the FHR, permits the woman to remain in any comfortable position while being assessed, permits the midwife to both assess the FHR and communicate to the woman the status of her baby, and has been shown to be preferred by women over the use of the Pinard.[8,10] A rugged, wind-up, handheld Doppler fetal heart rate monitor (Doppler) developed by Power-free Education Technology (Pet.og.za) showed in initial field tests to be accurate and acceptable to both mother and midwives in low-resource settings.[11,12] It uses a hand crank to generate 2:30 minutes of use for every 30 seconds of cranking.

While there have been several studies showing reduced intervention and no improved outcomes in the use of the intermittent (Pinard or Doppler) versus continuous cardiotocography (CTG) monitoring as the primary screening tool in uncomplicated deliveries,[6,13] there is little research on outcomes in intermittent monitoring comparing Doppler versus Pinard. A single study by Mohamed et al using a monitoring protocol of 10 minutes every half-hour found higher detection of FHR abnormalities and better perinatal outcomes in the intermittent auscultation Doppler group compared with the Pinard group.[14]

We aimed to use a randomised trial design to compare the primary screening methods of FHR monitoring (Doppler as intervention versus Pinard as standard of care) on incidence of detection of FHR abnormalities, and on the incidence of intrapartum stillbirth and neonatal mortality in the first 24 hours after delivery.

METHODS

Study design and participants

We undertook this randomised controlled trial at San Raphael of St. Francis Nsambya Hospital, a peri-urban private not-for-profit hospital in Kampala, Uganda. It is a teaching hospital that manages 7 500 deliveries annually. CTG and fetal blood gas sampling to support labour management, and epidural pain medication are not available. Oxytocin augmentation and Caesarean delivery rates are 40% and 20% respectively. The standard of care for intrapartum FHR monitoring is by intermittent auscultation using the Pinard.

Women were requested to participate during an antenatal care appointment. This consent was reconfirmed in labour provided that they presented in labour with a singleton pregnancy, in a cephalic position, at term or post-term (>37 weeks gestation). Women were excluded if they were already in second stage of labour upon admission or presented with a condition that, according to the doctor on duty, contra-indicated labouring (e.g. ~~had a high risk pregnancy, such as preeclampsia or~~ antepartum hemorrhage); if there was a diagnosis of intrauterine fetal death upon admission; or if the woman was admitted for an elective Caesarean delivery. Participants were presented with information about the study, and agreeing participants provided written consent. This study was approved by Sickkids Research Ethics Board, Nsambya Internal Review Board, as well as the Uganda National Council for Science and Technology. Registration of our protocol with ClinicalTrials.gov occurred before participant enrolment started, but due to an administrative error with our institution's Clinical Research Services Unit, the protocol was only released to the public after the completion of the study. Documentation from the Chair of our independent Research Ethics Board was provided to BMJ Open attesting to the version of the protocol provided to them prior to the start of enrolment.

Randomisation

Women were equally randomised to one of the two study methods using sequentially numbered, opaque sealed envelopes. Study participants and care providers where not blinded to the intervention. Data were collected from the patient's partograph and from the hospital's routine neonatal mortality audit data, when applicable.

Procedures

The standard of care for intrapartum monitoring relied on partograph and FHR monitoring with the Pinard. Our pre-study training address deficiencies in monitoring standards (acceptable range for FHR, recognition of accelerations, decelerations, and change in baseline). We developed a training module entitled "Helping Babies Survive Labour" modeling on the "Helping Babies Breathe" visual materials and learning approach. The technical basis was from World Health Organisation (WHO) and Canadian Obstetric Society protocols.[5] All midwives and doctors were then given this in-service training for half a day. FHR monitoring was undertaken every 30 minutes in first stage of labour; every 15 minutes in second stage before pushing; and every 5 minutes in second stage when pushing and for 1 minute immediately after a contraction. The baseline FHR was recorded as a single number rather than a range, in the unit of beats per minute (bpm). The FHR rhythm (regular or irregular) and absence or presence of accelerations or decelerations were also documented. The maternal radial pulse was simultaneously palpated to differentiate it with the FHR.

When FHR abnormalities are identified the standard of care would be to switch from intermittent auscultation to CTG. Since CTG is not available in Nsambya Hospital, any noted FHR

abnormalities were reported by the research midwife to the doctor on duty for assessment. Management following this assessment was either closer intermittent monitoring, or intra-uterine resuscitation with re-assessment of the FHR. Intra-uterine resuscitation consisted of maternal position change, administration of oxygen by mask to mother, initiation of intravenous infusion, discontinuation of oxytocin augmentation, and consider prompt delivery (assisted vaginal if imminent, otherwise by Caesarean).

Outcomes

The primary outcome measures of interest were detection of FHR abnormality in labour (defined below), intrapartum stillbirth, and neonatal deaths in the first 24 hours of life. Fetal heart rate abnormality is defined as tachycardia, bradycardia, or atypical variable, late or prolonged decelerations. Tachycardia and bradycardia are defined as baselines of >160 bpm and <110 bpm, respectively. Some features of atypical variable decelerations are abrupt fetal heart rate decelerations, lasting >2 minutes, slow return to baseline, or in the presence of tachycardia. Late decelerations are a repetitive, gradual decrease in the FHR and return to baseline, commencing after the onset of the contraction, and return to baseline after the end of the contraction. Prolonged decelerations are a decrease from baseline of >15 bpm lasting from 2-10 minutes. Secondary outcomes were Apgar score less than 7 at 5 minutes, admission to special care unit for intrapartum-related complications (intrapartum hypoxia, neonatal encephalopathy, or meconium aspiration syndrome), diagnosis of neonatal encephalopathy (NE), and delivery by Caesarean. A validated and simplified scoring method was used for grading mild, moderate and severe NE.[15,16] Indications for Caesarean delivery were failure to progress (as indicated by crossing of the action line on the partograph), abnormal FHR unresponsive to uterine resuscitation, and identification of malpresentation in labour (e.g. conversion from vertex to brow or mentum posterior).

Statistical analysis

Estimating that the use of the Doppler would reduce intrapartum stillbirth by 30% compared to the Pinard (based on the results of Mohamed et al 1994),[14] with 80% power to detect at least a 30% reduction in stillbirths with 95% confidence, we would need to enroll 840 participates in each of the two comparison groups. We added 20% to the sample size for each study arm to account for loss to follow-up and statistical adjustments and stratification, resulting in 1008 participants required for each comparison group.

Data were double entered from the partograph and, where applicable, the hospital's routine neonatal mortality audit document. An interim analysis was conducted by the data safety and monitoring board at the mid-point of the data collection period. Descriptive statistics were used to describe the characteristics of the participants and their outcomes under each study arm. ~~[17]~~

We used population-averaged generalized Poisson regression modeling with robust variance to compare methods of FHR monitoring with Doppler versus Pinard on incidence rate ratio (IRR) of detection of FHR abnormalities, intrapartum stillbirth, and neonatal mortality (see Barros et al for details of this choice over logistic regression [17]). We conducted a sub-group analysis and qualitative reporting on the intrapartum stillbirths and pre-discharge neonatal deaths within 24 hours and those fetuses with detected abnormal FHR.

All analyses were conducted using Stata/SE (StataCorp. 2011. Stata Statistical Software: Release 12. College Station, TX: StataCorp LP).

Role of funding source

The sponsor had no role in designing the study, analysing data, collecting data, interpreting the results, writing the report, or the decision to submit the paper for publication. The corresponding

author had complete access to all the data.

RESULTS

From July 2012 to December 2013, we screened 2042 women antenatally. Fifty-three women were ineligible (50 planned to deliver elsewhere, 3 planned Caesarean delivery); 2 women declined to participate; 1987 were enrolled (Figure 1). After assignment to a monitoring method, 8 of the 987 in the Pinard arm were excluded from analysis (1 lost to follow up, 1 delivered before the partograph was started, 2 undiagnosed breech births, 4 undiagnosed multiple births); and 8 of the 1000 in the Doppler arm were excluded (3 delivered before the partograph was started, 3 undiagnosed breech births, 2 undiagnosed multiple births). The final study group was n=979 in the Pinard arm and n=992 in the Doppler arm.

Of the 1971 women analyzed, the median maternal age was 26 years (IQR 24-30) (Table 1). There were a slightly higher though not statistically significant number of post-term women (≥42 weeks of gestational age) in the Doppler versus the Pinard arm (54/992 (5.4%) versus 41/979 (4.2%), p=0.193). A similar proportion of women in the Doppler versus the Pinard arm were primiparous (395/992 (39.8%) versus 413/979 (42.2%)), with similar median gestational age (39 weeks, IQR 38-40), and similar median newborn weight (3300g, IQR 3000-3500g).

Table 1: Demographic, clinical and perinatal characteristics

		Pinard (n=979)	Doppler (n=992)	p-value
Maternal age (years)	Median (IQR)	26 (23-30)	27 (24-30)	0.95
Marital status	Married	816 (83.4)	818 (82.5)	0.60
	Single	163 (16.7)	174 (17.5)	
Maternal education	None	9 (0.9)	7 (0.7)	0.62
	Primary	93 (9.5)	94 (9.5)	
	Secondary	385 (39.3)	423 (42.6)	
	Vocational	235 (24.0)	224 (22.6)	
	University	257 (26.3)	243 (24.5)	
	Missing		1 (0.1)	
Maternal occupation	Housewife	357 (36.5)	377 (38.0)	0.80
	Skilled worker	84 (8.6)	75 (7.6)	
	Self-employed	271 (27.7)	260 (26.2)	
	Professional	252 (25.7)	262 (26.4)	
	Other	15 (1.5)	18 (1.8)	
No. of ANC visits	Median (IQR)	4 (3-5)	4 (3-5)	0.58
Complication noted in pregnancy	Yes	17 (98.3)	24 (2.4)	0.29
	No	962 (1.7)	968 (97.6)	
Gravity	1	334 (34.1)	332 (33.5)	0.64
	2	422 (43.1)	416 (41.9)	
	≥3	223 (22.8)	244 (24.6)	
Parity	0	413 (42.2)	395 (39.8)	0.31
	1	238 (24.3)	232 (23.4)	
	≥2	328 (33.5)	365 (36.8)	
Previous perinatal death	Yes	24 (2.5)	29 (2.9)	0.52
	No	955 (97.6)	963 (97.1)	
Malarial IPTp	Yes	914 (93.4)	923 (93.0)	0.78
	No	65 (6.6)	69 (7.0)	
Syphilis	Negative	830 (84.8)	869 (87.6)	0.14
	Positive	11 (1.1)	6 (0.6)	
	Missing	138 (14.1)	117 (11.8)	
HIV Status	Negative	887 (90.6)	892 (89.9)	0.55
	Positive	46 (4.7)	57 (5.6)	
	Missing	46 (4.7)	43 (4.3)	
Gestational age at delivery (weeks)	Median (IQR)	39 (38-40)	39 (38-40)	0.80
Postterm gestation (≥42 weeks)	Yes	41 (4.2)	54 (5.4)	0.19
	No	938 (95.8)	938 (94.6)	
Newborn weight (g)	Median (IQR)	3300 (3000-3500)	3300 (3000-3500)	0.70

Data are n (%) or median (IQR); IPTp - Intermittent preventative treatment in pregnancy; HIV - Human immunodeficiency virus

There were no differences between the study arms in Apgar score <7 at 5 minutes (23 (2.3%) in the Doppler versus 17(1.7%) the Painard, p=0.40) or admission to neonatal intensive care unit for any reason (48(4.8%) in the Doppler versus 36(3.7%) the Pinard, p=0.20). Similar proportions of women in the Doppler versus Pinard arm had Caesarean deliveries (175/992 (17.6%) versus 166/979 (17.0%), p=0.695).

There were a significantly higher number of FHR abnormalities detected in the Doppler versus Pinard arm (75/992 (7.6%) versus 46/979 (4.7%), p=0.008, IRR=1.61, 95%CI 1.13-2.30) (Table 2). There were a higher though not statistically significant number of intrapartum stillbirths in the Doppler versus Pinard arm (4/988 (0.4%) versus 1/977 (0.1%), p=0.184, IRR=3.94, 95%CI 0.44-35.24), and higher number of neonatal deaths prior to discharge (7/985 (0.7%) versus 5//973 (0.5%), p=0.579, IRR=1.38, 95%CI 0.44-4.34).

There were 121 cases of abnormal FHR detected in labour (Figure 2). Of the 17 deaths in total (intrapartum stillbirths and neonatal deaths prior to discharge), 5 were associated with the detection of abnormal FHR in labour. In a subgroup analysis of those cases where abnormal FHR was detected, there were a higher though not statistically significant proportion of deaths in the Doppler versus Pinard arm (4/71 (5.3%) vs 1/45 (2.2%), IRR=2.45 95%CI 0.28-21.47). The remaining 12 deaths who had a normal FHR reported; 3 had missing cause of death, and 1 had a congenital anomaly, and cause of death for the remaining 8 was intrauterine hypoxia, respiratory distress, or neonatal encephalopathy, suggesting that an abnormal FHR was a missed diagnosis in labour for these 8 deaths.

Table 2~~3~~: Primary outcomes by treatment group

		Pinard (n=979)	Doppler (n=992)	p value	IRR* (95% CI)	p value
Abnormality detected	Yes	46 (4.7)	75 (7.6)	0.008	1.61 (1.13 to 2.30)	0.009
	No	933 (95.3)	917 (92.4)			
Intrapartum stillbirth	Yes	1 (0.1)	4 (0.4)	0.184	3.94** (0.44 to 35.24)	0.219
	No	977 (99.9)	988 (99.6)			
	Missing	1	0			
Neonatal death prior to discharge	Yes	5 (0.5)	7 (0.7)	0.579	1.38** (0.44 to 4.34)	0.552
	No	973 (99.5)	985 (99.3)			
	Missing	1				

IRR - incidence rate ratio; *not adjusted, significant baseline characteristics (p value <0.2) were tested and did not influence measure of effect in the model **excludes missing from analysis

DISCUSSION

Detection of abnormal FHR in labour is essential for identifying the fetus in need of responsive management such as prompt delivery. We report that intermittent auscultation with a Doppler identifies 60% more in need of prompt delivery (IRR=1.61); however, we did not find that this identification resulted in a significant decrease in mortality, although one would expect that higher

detection should lead to prompt delivery and improved outcomes.

We propose a number of explanations for this lack of detected impact. We considered that there may have been a learning curve for staff using the Doppler as a new technology; however, we found no difference in outcomes over time or between groups (data not shown). Secondly, it is possible that use of technology such as the Doppler lead to false reassurance that FHR was being closely monitored, delayed involvement of senior staff and subsequent delivery, or there may simply have been delay between recognition and action that, by chance, had more deleterious effects in the intervention group. Thirdly this study sample size and power was based on the Mohamed 1994 study, aiming to detect a 30% reduction in intrapartum stillbirth in the Doppler compared to the Pinard group and this may be optimistic, necessitating a larger sample size to demonstrate any improved outcomes given the improved detection rates in the Doppler group.

Some study limitations include that we were unable to perform secondary screening of suspected fetal hypoxia through the use of cardiotography; nor confirm for the presence of fetal hypoxia acidemia via fetal blood scalp sampling, and cord blood gases; therefore we were unable to assess if the identification (or lack of identification) of abnormal FHR was correlated with the presence of fetal hypoxia acidemia. In addition, we were unable to exclude some cases where the underlying cause of death was other than fetal hypoxia (e.g. congenital anomalies, early onset sepsis) due to diagnostic limitations in differentially diagnosing these cases. Finally, the screening process was all linked to the partograph which has well recognized limitations.[18]

In conclusion, routine monitoring with a handheld Doppler increases the proportion of fetuses identified in need of prompt delivery via the identification of FHR abnormalities in labour; ~~The care providers and the women expressed preferences for the Doppler,~~ however, we did not find evidence that this lead to a decrease in the incidence of intrapartum stillbirth or neonatal death. While assessing user satisfaction was not the objective of this study, the care providers and the women expressed preference for the Doppler, and given that the Doppler performed no worse than the Pinard in detecting abnormal FHR or in newborn survival, this should be an area of further research. Finally, t~~T~~his study demonstrates the need for a ~~further~~ larger study with linkage to rapid response for abnormal FHR, including caesarean section to ensure that increased detection using the Doppler leads to decreased death and disability.

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Figure 1: Trial profile

Figure 2: Flow diagram for outcome by fetal heart rate and management
FHR - fetal heart rate; CS/IU/Ass't - Caesarean delivery, intrauterine resuscitation, assisted delivery

Contributorship statement: All authors designed the study. RB DGB AJ PM did data collection. DGB and AM did analysis and wrote the first draft of the manuscript. All authors reviewed and provided feedback on the manuscript draft.

Competing interests: We have read and understood BMJ policy on declaration of interests and declare the following interests: AJ is a paid employee of Powerfree, the not-for-profit designers of the handheld Doppler used in this study.

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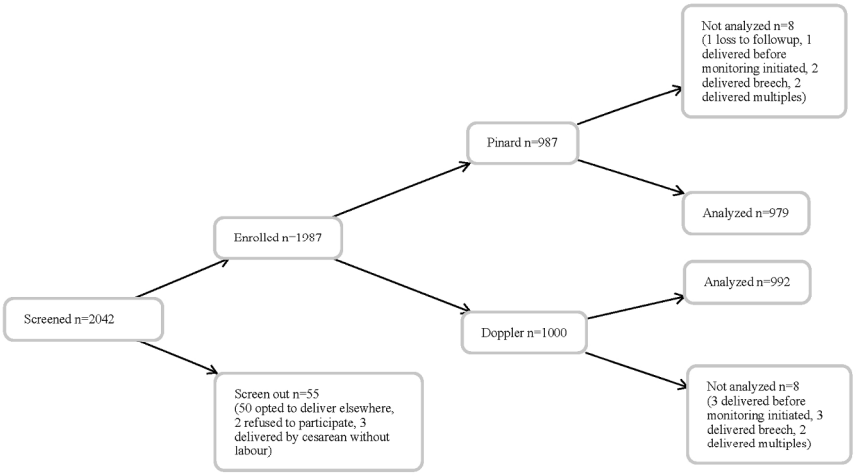
Data sharing: No additional data available

REFERENCES

1 Lawn JE, Blencowe H, Oza S, et al (2014) Every Newborn: progress, priorities, and potential beyond survival. Lancet 384: 189-205.
2 Lee AC, Kozuki N, Blencowe H, et al (2013) Intrapartum-related neonatal encephalopathy incidence and impairment at regional and global levels for 2010 with trends from 1990. Pediatr Res 74 Suppl 1: 50-72.
3 Lawn JE, Blencowe H, Pattinson R, et al (2011) Stillbirths: Where? When? Why? How to make the data count? Lancet 377: 1448-1463.
4 Lawn JE, Kinney M, Lee AC, et al (2009) Reducing intrapartum-related deaths and disability: can the health system deliver? Int J Gynaecol Obstet 107 Suppl 1: S123-40, S140-2.
5 SOGC (2013) Advances in labour and risk management. Ottawa: Society of Obstetricians and Gynaecologists of Canada.
6 NICE (2003) The Use of electronic fetal monitoring. NHS Clinical Guideline C 23807: 1-17.
7 Liston R, Sawchuck D, Young D (2007) Fetal health surveillance: antepartum and intrapartum consensus guideline. J Obstet Gynaecol Canada 29: S3-56.
8 Hofmeyr GJ, Haws RA, Bergström S, et al (2009) Obstetric care in low-resource settings: what, who, and how to overcome challenges to scale up? Int J Gynaecol Obstet 107 Suppl 1: S21-44, S44-5.
9 Alfirevic Z, Devane D, Gyte GM (2013) Continuous cardiotocography (CTG) as a form of electronic fetal monitoring (EFM) for fetal assessment during labour. Cochrane Database Syst Rev 5.
10 Mangesi L, Hofmeyr GJ, Woods D (2009) Assessing the preference of women for different methods of monitoring the fetal heart in labour. S Afr J Obstet Gynaecol 15.
11 Bezuidenhout H, Woods D, Wyatt J, et al (2006) Does fetal heart rate count? Developing a low cost, alternative powered doppler fetal heart monitor for use in low resource high mortality settings. 4th IET Seminar on Appropriate Healthcare Technologies for Developing Countries : 155-159.
12 Woods D (2009) Appropriate technology and education for improved intrapartum care in underresourced countries. S Afr J Obstet Gynaecol 15.
13 Devane D, Lalor JG, Daly S, et al (2012) Cardiotocography versus intermittent auscultation of fetal heart on admission to labour ward for assessment of fetal wellbeing. Cochrane Database Syst Rev 2.
14 Mahomed K, Nyoni R, Mulambo T, et al (1994) Randomised controlled trial of intrapartum fetal heart rate monitoring. BMJ 308: 497-500.
15 Ellis M, Manandhar N, Manandhar DS, et al (2000) Risk factors for neonatal encephalopathy in Kathmandu, Nepal, a developing country: unmatched case-control study. BMJ 320: 1229-1236.
16 Amiel-Tison C (2002) Update of the Amiel-Tison neurologic assessment for the term neonate or at 40 weeks corrected age. Pediatr Neurol 27: 196-212.
17 Barros AJ, Hirakata VN (2003) Alternatives for logistic regression in cross-sectional studies: an empirical comparison of models that directly estimate the prevalence ratio. BMC Med Res Methodol 3: 21.
18 Lavender T, Hart A, Smyth RM (2013) Effect of partogram use on outcomes for women in

spontaneous labour at term. Cochrane Database Syst Rev 7: CD005461.



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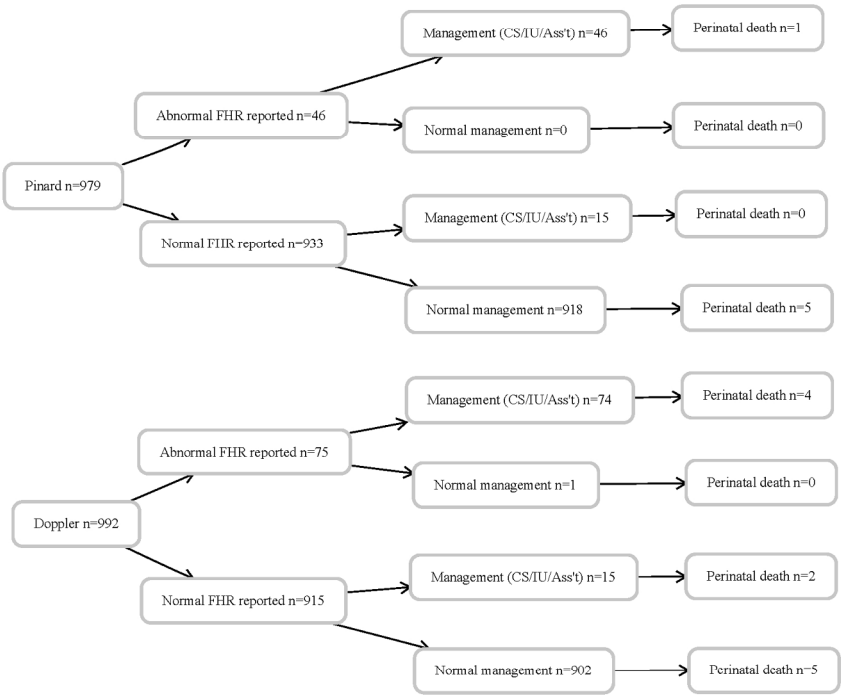

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	not applicable
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	not applicable
Sample size	7a	How sample size was determined	6
	7b	When applicable, explanation of any interim analyses and stopping guidelines	6
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	not reported
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	5

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	5
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	6
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	6
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1, 6-7
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1, 6-7
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6
	14b	Why the trial ended or was stopped	6
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	8
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	8
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	10
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	10
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	9
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Table 2, 9
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	10
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	10
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	10
Other information			
Registration	23	Registration number and name of trial registry	2
Protocol	24	Where the full trial protocol can be accessed, if available	2
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	2

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.