Reducing newborn deaths by improving intrapartum fetal heart rate monitoring using the Moyo device in a low resource setting

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Introduction

Globally, half of the stillbirths and one third of the early neonatal deaths are attributed to the intrapartum period [1]. Intrapartum fetal heart rate monitoring (FHRM) to detect fetal distress, followed by appropriate and timely interventions can reduce perinatal morbidity and mortality [2-4]. In Uganda, half of the 26,000 perinatal deaths audited and reported in 2021/2022 were due to birth asphyxia caused by obstructed labour (90%) [5]. In Mbale hospital, the caesarean section rate is high at 35% [6, 7], but the institutional perinatal mortality rate is twice the national average of 48 per 1,000 total births [8]. In a study on pre-operative sodium bicarbonate infusion in obstructed labour at Mbale hospital by Musaba et al., [6, 7], 34% of the newborns had an Apgar score less than 7, and 12% were early neonatal deaths despite being resuscitated. Thus, neonates had suffered severe intrapartum hypoxia, and caesarean section and standard neonatal resuscitation was too little and too late for adequate recovery. Furthermore, two thirds of the children born to women in that cohort had a neurodevelopmental delay at two years of age [9].

Early intervention through detection of fetal distress is heavily dependent on intrapartum FHRM [4]. Currently in most low resource settings, intrapartum FHRM is done intermittently using a pinard fetoscope or a hand-held ultrasound doppler and the fetal heart rate is plotted on a partograph [10-12]. However, this evidence-based practice of intrapartum surveillance using the partograph is labour intensive, requires adequate staffing, resources, skills and equipment in the obstetric facility, which are not readily available in several low resource settings [13]. Therefore, introduction of the low cost MOYO device for continuous FHRM, might improve this practice and ultimately reduce perinatal mortality. The MOYO device is a low cost, simple-to-use compact digital fetal monitor for both intermittent and continuous fetal heart monitoring [13, 14]. The MOYO device has various benefits including; it has a 9-crystal sensor that accurately detects the fetal heart rate (FHR) within seconds and dual electrodes that differentiate the maternal from the fetal heart rate. It is light and portable and can monitor the FHR continuously, even while the mother is moving around. This MOYO device also gives a longer heart rate history that informs health workers of the situation, a 30-minute histogram displays the FHR, and an audio-visual alarm is activated if abnormal FHR is detected [15]. This could lead to early intervention through accurate detection of fetal distress in the intrapartum period.

Studies have shown that the MOYO device has great potential in identifying babies with fetal distress at risk of birth asphyxia among low-risk patients in similar settings [4, 13, 15], but it is not known if its use can improve neonatal outcomes among women with high-risk pregnancies in a resource limited setting. We hypothesize that improved intrapartum fetal heart rate monitoring using the MOYO device will reduce early neonatal mortality at Mbale hospital by at least 40% from the current 10% [7] to 6%. Our aim is to explore implementation of the MOYO device for intrapartum FHRM and inform development of a larger study of clinical effectiveness. Our primary objectives are:

1). To assess the effect of introducing the MOYO device as a means of continuous intrapartum fetal heart rate monitoring on the reduction of intrapartum perinatal mortality.

2). To assess the effect of introducing the MOYO device as a means of continuous intrapartum fetal heart rate monitoring on the detection of abnormal FHR patterns.

3). To explore the acceptability of using the MOYO for intrapartum FHRM in Mbale hospital.

Methods and materials

Study design

This will be a pre and post quasi experimental study, with both qualitative and quantitative methods of data collection, over a period of 12 months.

Study setting

The study will be conducted at Mbale hospital in eastern Uganda. Mbale hospital is a busy regional referral hospital in eastern Uganda with a catchment population of over 4-5 million people. The hospital records an estimated 10,000 births annually and has a caesarean section rate of 35%. The current practice of fetal heart monitoring at the maternity wards in this hospital is intermittent fetal heart monitoring using a pinard fetoscope or a hand-held ultrasound doppler.

Study population

We plan to use the MOYO device on all birthing mothers with a Robson classification (≥2), or otherwise identified with an increased risk of a poor outcome. We will also include health care providers who will have used the MOYO for FHR monitoring. However, mothers with the

following conditions will be excluded: absence of a fetal heart (IUFD), multiple pregnancy, mothers who do not have the capacity to give informed consent at the time of approach, women who are in late stages of labour, and women who have reduced capacity to comprehend due to the administration of pain relief or illness. There will be no control group because we know that continuous FHR monitoring is superior to the current practice. So, it would be unethical to randomise some patients into a control group.

Study procedures

We plan to run this project for over a period of 12 months. In the **pre-implementation phase, we will conduct a one-day refresher training for all healthcare providers on intrapartum FHRM**. This will be followed by a six-month period of observing practice and collecting information from patient case notes using a checklist (Appendix 1). Fetal heart rate will be monitored according to existing department routines of FHRM. In the **post-implementation phase, the MOYO fetal heart rate monitor will be introduced. It will take two weeks to train all the healthcare workers to use the MOYO.** We will observe practice for a further six months using the same checklist in appendix 1. Fetal heart rate will be monitored as follows; 1) Minimum 20 min continuous monitoring every hour during 1st stage of labor and 2) Continuous monitoring during 2nd stage of labor.

Sample size estimation and sampling

Perinatal mortality at MRRH among high risk mothers was 10% according to a study by Musaba et al., [7]. Assuming that the introduction of Moyo device would reduce perinatal mortality by at least 40% to a perinatal mortality of 6%. We plan to observe a minimum of 772 in the pre and post implementation period (1544 mothers in total). This would give us 80% power with and alpha level of 0.05. At our hospital, based on the current practice of intrapartum FHR monitoring (standard of care), we are able to detect abnormal FHR in 13% of the women [7]. With the above sample size (**1,544**), we will have 80% power to observer an increase in detection rate of abnormal FHR of at least 40% in this high-risk population. Participants will be recruited by consecutive sampling until the required sample size is reached.

Outcome measures

The primary quantitative outcome measure will be perinatal mortality at 7 days postnatal (Early Neonatal Period). While the secondary outcomes will include: Number of babies with Apgar under 7 at 5 and 10 minutes, Number of women breastfeeding within 1 hour of birth, Rate of exclusive breastfeeding at discharge home, Rate of referral to the neonatal unit for admission, Number of staffs trained in the use of MOYO for intrapartum FHRM, The time from detection of abnormal FHR to childbirth, The proportion of mothers monitored who have either a normal or abnormal FHR, The percentage of mothers requiring intrapartum FHRM for whom the MOYO devices were unavailable and the proportion of women requiring EMCS following detection of abnormal fetal heart rate monitoring. The qualitative outcome measures will include: 1). Healthcare workers' experiences of using the MOYO for intrapartum FHRM, 2). Healthcare workers' satisfaction with using the MOYO for intrapartum FHRM, 3). Mothers' experiences of using the MOYO for intrapartum FHRM, 4) Healthcare workers' views on strengths and limitations of using the MOYO for intrapartum FHRM.

Recruitment

All eligible pregnant mothers attending the study site for labour care will be approached by a member of the clinical care team (a trained midwife) during early stages of their labour and only when they have been assessed and are considered comfortable and competent enough to be approached. The mother will be informed by the midwife that this study is seeking to explore women's experience of continuous FHRM using the MOYO device. The mother will then be asked for written consent to participate in the study. She will also be informed that a researcher may approach her after the birth to seek formal consent to the use of the data collected during the birth, as well as an interview about her experience. Based on the current number of births in the facility, we anticipate that there will be about six patients that meet the inclusion criteria every day. If the woman does not agree to take part, she will receive the current standard of care. After the birth, the researcher will only approach the mother when the clinical staff member (usually a midwife) has assessed the mother and considers her to be comfortable and competent enough to be approached. This will be a minimum of two hours after birth. She will be asked for a formal, written consent for an interview to discuss her experience. Data will be collected by research assistants (qualified midwives), trained in data collection. These will be available day and night.

For the healthcare workers, a workshop will take place to inform them about the study. Those that show interest in knowing more will be trained on how to use the MOYO. A written informed consent will be obtained by a research team member for the healthcare provider to be interviewed, and attend a focus group to discuss their experiences of implementation of the MOYO for FHRM. Qualitative data will be collected using focus group discussion and interviews with the study participants. Mothers will be purposively sampled to maximize diversity in participant characteristics (e.g. maternal age, parity, educational levels, etc.).

Data collection

We will use the same checklist to collect quantitative data in both the pre and post implementation periods. These will include newborn outcomes, which will be collected using KoBo Toolbox. KoBo Toolbox is an open-source software developed by the Harvard Humanitarian Initiative with support from United Nations agencies, CISCO, and partners to support data management by researchers and humanitarian organizations (https://www.kobotoolbox.org/). The servers are secure and encrypted with strong safe guards and protection against data loss. The FHR tracings will be uploaded automatically using an application call "Liveborn', developed by Laerdal Global Health. These will be downloaded by the PI after the data collection for analysis.

For qualitative data, we anticipate conducting two focus group discussions with 4–8 healthcare workers who will have used the MOYO device for intrapartum FHRM. We also expect to conduct 30 – 60 exit interviews with mothers monitored using the MOYO or until theoretical saturation, has been reached. The interviews will be transcribed verbatim and translated into English by the research assistants.

Data analysis plan

The quantitative outcome measures will be compared descriptively, using frequencies and percentages for categorical variables and means, standard deviations, medians and ranges for continuous variables. Proportions will be computed and compared across the pre and post implementation periods using prevalence ratios as the measure of association. Data on various confounders will be collected and controlled for at analysis using stratification. Data will be analyzed in Stata version 17.0.

Interviews will be audio-recorded on a digital voice recorder. All voice recordings will be carefully transcribed in English by an individual with an excellent command of both English and at least one of the local languages (Lumasaba, Luganda,Ateso, and Lugwere). A translator not involved in the interviews or transcribing will check the quality of translation for all interviews, by comparing the transcript with the recording. If there are any errors which alter the meaning derived, then further quality checks will be conducted and adjustments made to improve quality. The transcripts will be analysed thematically using Computer-Aided Qualitative Analysis Software such as NVivo. Two researchers will independently code the first few interviews and will then meet to agree on a coding framework. Interviews will be coded using a combination of deductive and inductive approaches, in order to determine the major emerging themes.

Ethical considerations

Ethical approval will be sought from the Busitema University Research and Ethics Committee (REC), and the Uganda National Council for Science and Technology (UNCST). Administrative clearance to conduct the study will be obtained from the Mbale regional referral hospital. The Ministry of Health and hospital protocols will be followed in management of emergencies such as neonatal resuscitation during the study [16]. For those participants admitted in active labour by the attending health provider, informed consent will be obtained in two steps as suggested in the differed consent pathway for intrapartum research [17]. In step one, a research team member will inform all patients and their attendants while in the waiting/admission area about the ongoing study. Those who will express interest in knowing more about the study will be taken through the process of obtaining a short verbal consent (Appendix 3). We will keep an inventory of those that decline to participate at this stage, they will not be approached again and their deliveries will not be observed by our research team in case the neonate requires resuscitation. In step two, after delivery, the formal informed consent process will be completed in the postpartum period, when the emergency has been addressed. From past experience in this same labour ward this might be the scenario for most of the participants. In the case of illiterate participants, an independent witness will also be asked to witness the consent process and sign the consent form besides the participants thumb print. Pregnant women below 18 years of age will be included as emancipated minors, who can give a valid informed consent as per the national guidelines [18].

For the health providers, written informed consent will be obtained before recruitment into the study as participants for the interviews. All the data collected will be kept anonymous. We will not use the data for any other purposes than those for which the participants have given consent. The video recording will be restricted to the procedure of neonatal resuscitation using the intervention and will not identify the midwife nor the mother. Any visible identification from the video footage shall be scrambled using video editing software to ensure that none of the participants can be identified. As per the hospital protocols, all newborn that undergo resuscitation are admitted to the neonatal unit for observation before discharge.

Budget

Budget and Justification						
Budget Category Totals	**Unit price**	**No of units**	**Frequency**	**First 12 mo. Budget period**	**second budget period up to 12, if applicable**	**Total, USD**
Personnel costs (including fringe)						
Full time research assistants	400	2	12	9,600	0	9,600
Consultants	0	0	0	0	0	0
Supplies (Training workshops for healthcare providers on MOYO	640	1	2	640	640	1,280
Travel	553	1	1	1	553	553
Patient Care costs	11	300	1	2000	1300	3,300
Equipment						
Moyo Device	370	10	1	3,700	0	3,700
Participant compensation -UNCST	4	1,544	1	2,000	3,867	5,867
Contractual Costs						
Ethical approvals	700	1	1	700	0	700
Indirect costs - Busitema University						
Administrative cost (7%)	-	-	-	732	1000	1,701
Total for entire proposed project:	`					**26,701**

Study work plan

Activity	2023	2024

	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
REC & UNCST Approvals																		
Recruitment of staff																		
Procurements																		
Data collection																		
Data analysis																		
Dissemination and Publications																		

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Appendices

Appendix 1: Interview topic guide for mothers whose intrapartum fetal heart rate monitoring was done using the MOYO device

Participant Identification number: _____

Opportunity to ask questions and sign consent form

Introduce self, thank participant for taking part and confirm agrees to interview taking place. Ensure environment is comfortable. Discuss the following issues:

i. Review the nature and purpose of the research.

ii. No right or wrong answers, aim to understand experiences or perspectives.

iii. Confidentiality, use of data.

iv. Researcher aware that discussion might bring up difficult memories, explain can decline to answer any question or prompt; can ask to stop at any time if feels need to.

v. Expected duration of interview.

vi. Do you understand and agree with everything I have said?

If yes: Read consent form with participant and ask to sign or make a thumb print

vii. Is it ok to start the interview now?

viii. I am going to turn on the tape recorder now and we can start. Explain the use of data recorder, transcription, use of pseudonym (invite to choose), use of verbatim quotes, will be taking field notes.

1. Can you tell me about yourself?

Sociodemographic and clinical characteristics of the mother (Fill in)

1. Age in complete years _____ _____

2. What is your marital status?

i. Single

ii. Married/cohabiting

iii. Separated/divorced

iv. Widowed

3. What is the highest level of education attained?

i. No education

ii. Primary

iii. Secondary

iv. Tertiary

4. What is your current occupation/source of income?

i. Unemployed

ii. Housewife

iii. Peasant farmer

iv. Salaried employment

v. Self-employment`

5. How would you describe the area where you stay?

i. Rural

ii. Urban

6. What is your religion?

i. Anglican

ii. Catholic

iii. Pentecostal

iv. Moslem

v. Others

7. Obstetric history

7.1 When was the first day of your last normal menstrual period? _____ (Ask mother when was the first day of her last normal menstrual period. Also, cross check with medical records; ANC card, Ultrasound scan to confirm. In case the mother does not remember the actual date of the month and has no ultrasound scan to cross check with, put 1/mm/yyyy if the mother says at the beginning of the month, 15/mm/yyyy if the mother says mid-month and 28/mm/yyyy if the mother says end month.)

7.2 What is the gestation age of the current pregnancy? _____

7.3 Gravidity……

7.4 Parity…….

7.5 History of pregnancy loss

i. Abortion/miscarriage

ii. Still birth

8. What was the date of admission to Mbale hospital? _____

9. Were you admitted as a referral in labour? _____

i. Yes

ii. No

If Yes, what was the source of the referral

i. Government facility

ii. Private facility

iii. TBA

iv. Other (please specify)……

10. Did you use any herbs during the process of labour?

i. Yes

ii. No

11. Obstetric complications

i. Hypertensive disorder

ii. Antepartum hemorrhage

iii. Preterm labour

iv. Obstructed labour

v. Prolonged labour

vi. Sepsis

vii. None

viii. Other (please specify)

12. Medical conditions

i. Hypertension

ii. Diabetes mellitus

iii. HIV

iv. None

iv. Other (please specify)

Checklist

1. Cervical dilatation on first examination…….(cm)

2. Intrapartum complications

i. Malpresentation

ii. Cord presentation

iii. Hypertensive disorder

iv. Fetal distress

v. Obstructed labour

vi. Prolonged labour

vii. APH

iv. Other (please specify)

3. Meconium-stained amniotic fluid

i. Yes

ii. No

4. Postpartum hemorrhage

i. Yes

ii. No

4. Date and time of delivery of the birth?

i. Date _____

ii. Time _____

5.1 Time of administration of the uterotonic drug _____:_____Hours

5. 2 Time of cord clamping _____:_____Hours

5.3 Time of starting controlled cord traction (CCT) to deliver the placenta?

5.4 Time of starting massage of the uterine fundus after the placenta is delivered?

6. Sex of the baby

i. Male

ii. Female

7. Birth weight of the baby in kg? _____

8. Apgar score?

i. At 1 minute_____

ii. At 5 minutes _____

9. Did the baby cry immediately after child birth?

i. Yes

ii. No

10. Birth outcomes

i. Transferred to postnatal ward

ii. Transferred to NNU

iii. Fresh still birth

iv. Early neonatal death (heart rate detected, but no spontaneous breathing)

10. Mode of delivery?

i. Spontaneous vertex delivery (SVD)

ii. Assisted vaginal delivery

iii. Caesarean section

11. Who conducted the delivery?

i. Doctor

ii. Midwife

iii. Student

iv. Other (please specify)

12. Was the MOYO device used for intrapartum fetal heart rate monitoring?

i. Yes

ii. No

13. 1 Continuous FHRM during first stage

From _____:_____Hours to _____:_____Hours

Fetal Heart Rate was between _____ to _____ bpm

13. 2 Was an abnormal fetal heart rate detected at any time by the MOYO device during intrapartum fetal heart monitoring in the first stage?

i. Yes

ii. No

If yes, at what time? _____:_____Hours

If yes, at what time did the health care team intervene (conduct caesarean section)?

_____:_____Hours

13. 1 Continuous FHRM during second stage

From _____:_____Hours to _____:_____Hours

Fetal Heart Rate was between _____ to _____ bpm

13. 2 Was an abnormal fetal heart rate detected at any time by the MOYO device during intrapartum fetal heart monitoring?

i. Yes

ii. No

If yes, at what time? _____:_____Hours

14. Did the health provider use the MOYO device correctly?

i. Yes

ii. No

15. Did the health provider encounter any challenges using the MOYO device?

i. Yes

ii. No

16. If yes, list some of the challenges encountered

……

…….

Domain	**Topic and Probes**
Perspectives of intrapartum fetal heart rate monitoring	What is your view towards intrapartum monitoring of the fetal heart rate? Probes: Do you have any experience? Have they monitored your baby's fetal heart rate during the intrapartum period before? How did you

	feel about it? Are you aware of any challenges in our current delivery suites for intrapartum fetal heart rate monitoring? Probes: Nature of the delivery beds? Number of women in delivery suites? Space? Do you think that there might be benefits or challenges with intrapartum monitoring of your baby's fetal heart rate? Probes: How would you feel about intrapartum monitoring of your baby's fetal heart rate? How would you feel about your baby's fetal heart rate being monitored continuously? Which of these two approaches would you prefer?
Perception of MOYO device	Was the MOYO device used to monitor your baby's fetal heart rate? What is your experience of the MOYO device being used in your birth? How did you feel about it? Probes: What problems could you foresee and what ways do you think these might be solved?

Appendix 2: Interview guide for health workers who conducted intrapartum fetal heart rate monitoring was done using the MOYO device

Participant Identification number: _____

Opportunity to ask questions and sign consent form

Introduce self, thank participant for taking part and confirm agrees to interview taking place. Ensure environment is comfortable. Discuss the following issues:

i. Review the nature and purpose of the research.

ii. No right or wrong answers, aim to understand experiences or perspectives.

iii. Confidentiality, use of data.

iv. Researcher aware that discussion might bring up difficult memories, explain can decline to answer any question or prompt; can ask to stop at any time if feels need to.

v. Expected duration of interview.

vi. Do you understand and agree with everything I have said?

If yes: Read consent form with participant and ask to sign or make a thumb print

vii. Is it ok to start the interview now?

viii. I am going to turn on the tape recorder now and we can start. Explain the use of data recorder, transcription, use of pseudonym (invite to choose), use of verbatim quotes, will be taking field notes.

1. Sociodemographic characteristics of the health provider

1.1 How old are you (in completed years)? _____

1.2 For how long have you been in practice (in completed years)? _____

1.3 What is your highest level of training?

i. Certificate in nursing/midwifery

ii. Diploma in nursing/midwifery

iii. Degree in nursing/midwifery

iv. Masters in nursing/midwifery

v. MD

Domain	**Topic and Probes**
Perspectives of intrapartum fetal heart rate monitoring	Can you tell me about your experiences with intrapartum fetal heart rate monitoring I. Allow participant to describe their role and experiences. II. Allow participant to respond uninterrupted and use open prompts if required to explore aspects of their experiences in depth. Are you aware of any challenges in our current delivery suites for intrapartum fetal heart rate monitoring? Probes: Nature of the delivery beds? Number of women in delivery suites? Space? How do you feel about continuous intrapartum fetal heart rate monitoring as opposed to intermittent fetal heart rate monitoring? Which of these two approaches would you prefer?
Perception of MOYO device	Have you used the MOYO device for intrapartum fetal heart rate monitoring? What is your experience with the MOYO device? Probes: What are some of the facilitators and barriers you envisage if this approach to

	intrapartum fetal heart rate monitoring was to be adopted in this facility and others country wide?