Assessment of foetal heart rate monitoring devices in referral hospitals in Tanzania

Towards improved quality of intrapartum care

by

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Dedication

*To my late grandfather, **Petro Kamala 'Kabalitoija'**, the cornerstone of our family education achievement*

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Abbreviations

BEmONC	Basic Emergency Obstetric and New-born Care
CEmONC	Comprehensive Emergency Obstetric and New-born Care
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Forms
CTG	Cardiotocograph
DHS	Demographic and Health Survey
EFM	Electronic Foetal Heart Rate Monitor
ENAP	Every New-born Action Plan
END	Early Neonatal Death
FHR	Foetal Heart Rate
FSB	Fresh Stillbirth
GA	Gestation age
GBD	Global Burden of Diseases
HIC	High Income Countries
LIC	Low Income Countries
LMIC	Low Middle Income countries
MDGs	Millennium Development Goals
MHIC	Middle- and High-Income Countries
NPV	Negative Predictive Value
MOHCDGEC	Ministry of Health Community Development Gender Elderly and Children
PHSDP	Primary Healthcare Service Delivery Program
PO-RALG	Presidents Officer Regional Authority and Local Government
PPV	Positive predictive Value
RCH	Reproductive and Child Health
RCHS	Reproductive and Child Health Section
RMNCAH	Reproductive Maternal Newborn Child Adolescent Health
SBR	Stillbirth Rates
SDG	Sustainable Development Goals
STROBE	Strengthening the Reporting of Observational Studies in Epidemiology
UNICEF	United Nations International Children’s Emergency Fund
WHO	World Health Organisation

Definitions of key terms

Neonatal period: period from birth to 28 days of life

Perinatal period: period immediately before and after birth including the 1st week of life

Birth asphyxia: failure to initiate and sustain breathing at birth secondary to intrauterine oxygen deprivation

Intrapartum period: period from the onset of labour to the end of the third stage of labour.

Stillbirth: a foetal death at or after 28 weeks of gestation but before birth

Fresh stillbirth: a baby born dead without signs of skin disintegration (death occurs mostly less than 12hrs prior to birth)

Macerated stillbirth: a baby born dead with skin disintegration (death assumed to occur more than 12hrs prior to birth)

Quality of care: the extent to which health care services provided to individual and patient populations improve desired health outcome

Preterm: baby born before 36 complete weeks of gestation

Summary

Background: There are 2.5 million neonatal deaths that occur globally each year: 25% of them secondary to labour complications (intrapartum related). In addition, 2.6 million stillbirths occur globally each year, 40% of them intrapartum related termed as fresh stillbirth (FSB). Moreover, more than 80% of neonatal deaths occur in low-income countries (LICs). Almost 50% occur in Sub-Saharan Africa, where the supply of service does not match with the demand of service provision. These deaths can be substantially reduced by improving quality of care around time of labour and childbirth. Intrapartum foetal heart rate (FHR) monitoring and partograph use form an important component of quality of care provision. In LICs, where most births occur, FHR assessment is mostly done intermittently and mainly using Pinard stethoscope and rarely with hand-held Doppler devices. The effectiveness of assessment devices to detect FHR abnormalities in relation to the improvement of quality of intrapartum care is scarcely documented. An FHR monitor called Moyo, was designed for low-resource settings. The monitor can be used intermittently or strapped on for continuous FHR monitoring during labour.

Aims: The overall aim of this PhD project was to compare the effectiveness of different FHR monitoring devices and the associated improvement in quality of intrapartum care at two urban referral hospitals in Dar es Salaam, Tanzania.

Methods: We conducted three studies from 2013 to 2017. The studies included singleton women in the active phase of the first stage of labour who had normal baseline FHR on admission. Study I applied a randomized controlled study design between April 2013 through September 2015 at Muhimbili National Hospital. Hand-held Doppler (n=1,421) and Pinard stethoscope (n=1,423) arms were compared in their effectiveness to detect abnormal baseline FHR. Secondary outcomes

were time to childbirth, mode of childbirth, and perinatal outcomes, including Apgar score, bag mask ventilation, admission to neonatal unit, FSB and 24-hour neonatal deaths. Study II was a follow-up of Study I and applied a randomized controlled design at Muhimbili between February 2016 through September 2017. Strap-on automatic FHR monitor, Moyo (*n*=1,479) and intermittent Hand-held Doppler (*n*=1,494) arms were compared in their effectiveness to detect abnormal baseline FHR. Secondary outcomes were time intervals in labour, mode of childbirth and perinatal outcomes (as in Study I). Study III was a pre- and post-implementation study design, conducted at Temeke Regional Referral Hospital, concurrently with Study II. In the pre-implementation period, intermittent monitoring was applied with a Pinard stethoscope (March through June 2016, *n*=1,640), whereas in the post-implementation period, strap-on automatic Moyo was applied (July to mid-December 2016, *n*=2,442). The primary outcome was detection of abnormal baseline FHR. Secondary outcomes included frequency of assessment of FHR, partograph documentation, time intervals, intrauterine resuscitations and perinatal outcomes.

Results: In Study I, the Hand-held Doppler was found to be superior to the Pinard stethoscope (6.0% vs 3.9%, *p*=0.008) in the detection of abnormal baseline FHR during labour. Overall, perinatal outcomes did not differ between the two arms. However, post-hoc analysis showed that, for new-borns with abnormal FHR whose mothers had given birth vaginally, the composite adverse outcomes (neonatal unit admissions and perinatal deaths) were less prevalent in the Doppler arm (7 of 43 births, 16.3%) than in the Pinard arm (10 of 23 births, 43.5%), *p*=0.021.

Study II, building on the results of Study I, showed that the Moyo was superior to the Doppler (13.3% vs 9.8%) (*p*=0.002) in the detection of baseline FHR abnormalities. The results for the time from admission to detection of abnormal FHR and from last FHR to birth were shorter in the Moyo arm than in the Doppler. However, the time from detection of abnormal FHR to birth was approximately 31% longer in the Moyo

compared to the Doppler. Caesarean section rates were higher with the Moyo (19%) arm compared to the Doppler (13%) (p=0.031). Overall, perinatal outcomes did not differ between the two arms.

In Study III, the Moyo was found to be superior to the Pinard (8.0% vs 1.6%) (p<0.0001) in the detection of baseline FHR abnormalities. Time from admission to birth and from last FHR to birth was shorter in the Moyo arm than the Pinard. The quality of intrapartum care provision improved significantly post-implementation in the Moyo arm. These included partograph use/documentation (98% vs 54%), and frequency of FHR monitoring (every 60 min vs 150 min). Other improvements included intrauterine resuscitations, and vacuum extraction of 5.8% vs 2.2% post- versus pre-implementation, respectively.

Conclusions: This PhD project shows that the Hand-held Doppler was superior to the Pinard in the detection of abnormal baseline FHR. Further, it showed that implementation of strap-on automatic FHR assessment with the Moyo led to earlier and more frequent detection of abnormal FHR at the referral hospitals. This implementation was associated with improved quality of intrapartum care and partograph use. Moreover, the time from detection of abnormal FHR to birth was longer in the Moyo groups. Implementation of studies coupled with timely obstetric responses and powered to detect differences in perinatal outcomes are recommend.

Publications included

This thesis is based on the following research articles, which will be referred to throughout the text by Roman numerals:

Paper I:

Kamala BA, Kidanto H, Wangwe P, Dalen I, Mduma E, Perlman J, Ersdal HL. **Intrapartum foetal heart rate monitoring using a handheld Doppler versus Pinard stethoscope: a randomized controlled study in Dar es Salaam**. Int J Women's Health. Dove Press; 2018; Volume 10: 341–348. doi:10.2147/IJWH.S160675

Paper II:

Kamala B, Kidanto H, Dalen I, Ngarina M, Abeid M, Perlman J, Ersdal HL. **Effectiveness of a Novel Continuous Doppler (Moyo) Versus Intermittent Doppler in Intrapartum Detection of Abnormal Foetal Heart Rate: A Randomised Controlled Study in Tanzania**. Int J Environ Res Public Health. Multidisciplinary Digital Publishing Institute; 2019;16: 315. doi:10.3390/ijerph16030315

Paper III:

Kamala BA, Ersdal HL, Dalen I, Abeid MS, Ngarina MM, Perlman JM, Kidanto H. **Implementation of a novel continuous foetal Doppler (Moyo) improves quality of intrapartum foetal heart rate monitoring in a resource-limited tertiary hospital in Tanzania: An observational study**. PLoS One. Public Library of Science; 2018;13: e0205698. doi: 10.1371/journal.pone.0205698

Contents

1 Introduction

1.1 Background

Childbirth is regarded as a normal physiological, social and cultural process. However, it is prone to complications, which may lead to the demise of the foetus and the death of the new-born. An adequate supply of oxygen during labour and birth is crucial for foetal viability and the prevention of vital organ injury. Any interruption along the oxygen pathway (Figure 1) results in progressive deterioration of foetal oxygen, leading to a reduced amount of oxygen in foetal blood (hypoxemia) and tissue (hypoxia). Hypoxia leads to metabolic acidosis, lactic acid accumulation and redistribution of blood to vital organs (acidaemia) and, consequently, low umbilical artery pH and base deficit.

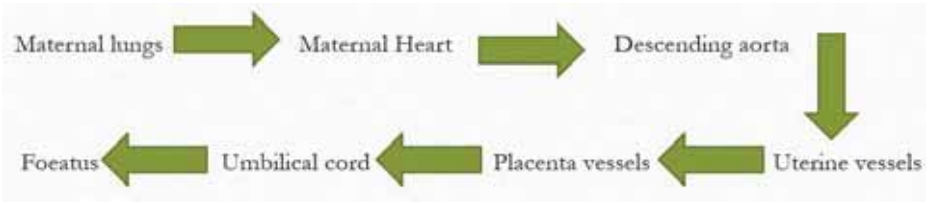

Figure 1: Oxygen transferred from the maternal circulation to the foetus through maternal and foetal blood

Hypoxia leads to reduced cardiac output and the foetus responds with different qualitative and quantitative patterns of foetal heart rates (FHR). These patterns include baseline FHR abnormalities (tachycardia, bradycardia), variability, decelerations and accelerations. Furthermore, hypoxia leads to ischaemic cerebral injury, resulting in short- and long-term adverse perinatal outcomes.[1,2] Short-term adverse perinatal outcomes include fresh stillbirth (FSB), birth asphyxia, low Apgar score, intensive care admissions and early neonatal death. Long-term adverse outcomes include the development of cerebral palsy, as well as neuro-cognitive and behavioural disabilities.[3–5] Thus, FHR monitoring during labour (intrapartum) may provide crucial information on the adequacy of foetal oxygenation and, if indicated, may lead to prompt lifesaving

intervention/s to prevent brain injury.[6,7] In low-resource settings, the risk of adverse events related to reduced oxygen delivery to tissues is high, largely due to inadequate labour monitoring.[8,9] Placing a focus on providing quality care during labour and at the time of birth, timely identification and protecting the foetus from hypoxia with subsequent ischemia, may save the lives of many new-borns.[5,10]

1.1.1 Global burden of under-5, neonatal mortality and stillbirths

Globally, a total of 5.4 million occurred in 2017. The highest risk of death is during the first month of life amounting to 17 deaths per 1,000 live births. These neonatal deaths translated to 46% (2.5 million in 2017) of the under-5 deaths; an increase from 40% in 2000.[2,11,12] One million (equivalent to 38%) of these 2.5 million neonatal deaths occurred within 24 hours of birth (termed early neonatal deaths). Moreover, 25% of deaths are intrapartum-related (asphyxia), with the other main causes related to prematurity and infections (Figure 2). In 2017, intrapartum-related events caused nearly 11% of under-5 mortality.[8,9,11]

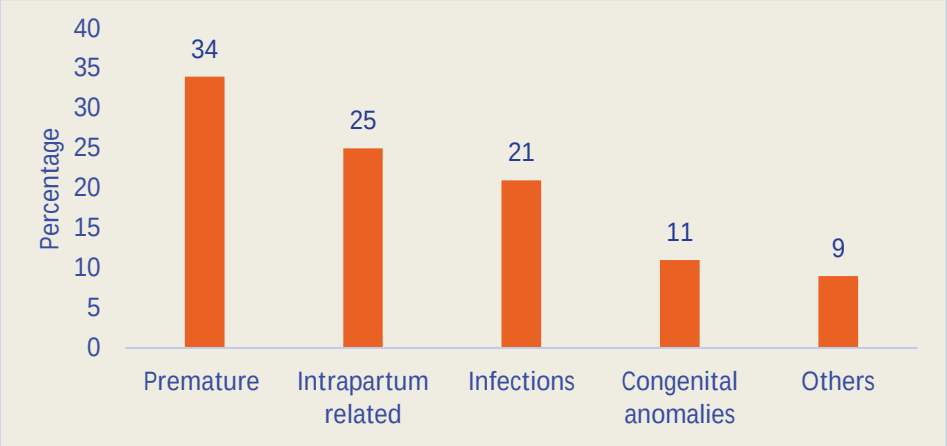

Figure 2: Causes of neonatal deaths (Source: WHO - Maternal and Child Epidemiology Estimation; Methods and data sources for child cause of deaths, 2017)

The progress observed in the reduction of mortality is uneven by age. It has declined by 60% among infants aged 1–5 years, 50% among 1–11 month-olds and by 40% among neonates over the past two decades.[12] The disparity in the decline has been attributed to a global shift to perform interventions in the post-neonatal period with less emphasis on the neonatal period.[13] With no accelerated interventions in place, 28 million neonates will die between 2018 and 2030; more than a quarter of them due to asphyxia.[14]

In 2017, almost 2.6 million stillbirths occurred, with FSB accounting for 40% (1.1 million) of the total number.[15,16] The majority of FSB are intrapartum-related stillbirths. The burden of these FSB figures may be higher than reported, as nearly half of the world's new-born babies have no birth certificate, and the majority of neonatal deaths and almost all stillbirths are not documented.[9,11] Overall, a total of 5.1 million stillbirths and neonatal deaths occur every year, of which 33% (1.7 million) are estimated to be intrapartum-related.

1.1.2 Perinatal mortality epidemiology

In 2017, Sub-Saharan Africa and South Asia had the highest neonatal mortality rate, both at 27 deaths per 1,000 live births, which is 9 times higher than in high-income countries (HIC). These two regions account for nearly 80% of global new-born deaths. Intrapartum-related neonatal mortality rates were 25 times higher in the LIC.[8] However, these estimates are higher than documented, as there is lack of registry data on these vital statistics.[11] The leading causes of neonatal deaths in sub-Saharan Africa and South Asia in a population-based survey were asphyxia (40% and 34%), infections (35% and 37%) and prematurity (19% and 24%), respectively.[17] These causes of deaths have all declined markedly in HIC, primarily because of improved quality of obstetric care compared to LIC. There is a need for improved intrapartum management and continuum of care through the postnatal period in LIC.

Moreover, globally, the proportion of women giving birth with a skilled birth attendant increased to 73%, but only half of the births in sub-Saharan Africa are covered by skilled birth attendants, showing striking disparities in quality of care provision around labour and birth.[12,14] The burden of stillbirths in sub-Saharan Africa and South Asia is estimated at 17 and 35 per 1,000 live births, respectively.[17] These FSB rates are 50-fold higher in LIC compared to HIC.[10]

1.1.3 Global strategies to reduce perinatal mortality

In the Sustainable Development Goals (SGD) era, the discourse has shifted from health for development, to development being a necessary component of health improvement. Target 3.2 of the SDG3 calls for the end of preventable deaths of new-borns with a target mortality rate below 12 per 1,000 live births by 2030.[18] Most countries have already achieved this target, but mostly in HIC. Accelerated efforts are needed to allow the remaining countries, predominantly LIC, to achieve this target and, as a consequence, save the lives of children.[12,18–20]

Although FSB is an important marker of quality of intrapartum care, the measurement of the global burden of disease, as contained in the SDGs, only counts deaths that occur after a live birth. Moreover, analyses of development aid have shown that stillbirth studies and interventions were rarely funded. [5,21]

In 2016, the WHO responded by launching a perinatal mortality audit to identify specific stillborn causes and improve the quality of perinatal care.[22] Also, the Every New-born Action Plan (ENAP), developed by WHO/UNICEF, addresses the importance of the accountability of stillbirths in supporting the United Nations' *Every Woman Every Child* movement.[5,23] ENAP supports countries in reaching the target of no more than 12 new-born deaths per 1,000 live births, and less than 12 stillbirths per 1,000 births, by 2030.[5,21]

Although most high- and middle-income countries have achieved the ENAP target, more than 56 LICs, mostly in Africa, have double the burden, necessitating accelerated efforts. ENAP, UNICEF and the WHO have endorsed interventions during labour, birth and immediately after birth as they have proven to save the lives of many new-borns. A 5-year network on improving the quality of care and to prevent maternal, new-born and child health deaths was launched in 2017 targeting a 50% reduction in these deaths.[24]

1.1.4 Global research priorities on perinatal mortality

While new-born survival has gained rapid attention in recent years, the corresponding actions are still inadequate.[25] The WHO, ENAP, Disease Control Priorities and the World Bank recommend research and testing implementation studies that focus on the time of labour and birth with essential monitoring tools, including FHR monitoring devices and admission ultrasound.[5,26–29] The Every New-born Study group recommended innovative and context-specific implementation research around the intrapartum period to reduce perinatal mortality.[30] Quality improvement research in relation to the reduction of intrapartum stillbirths, neonatal mortality and disability was also recommended by experts.[31] The development and testing of simple, innovative, user-friendly, robust, low-cost FHR monitors in labour is a priority, calling for research on quality of intrapartum care to reduce perinatal deaths.[1,11,13]

1.2 Intrapartum FHR monitoring

FHR monitoring is widely used for foetal surveillance. However, there exists an incongruity among scientists about its use to predict foetal well-being. Most abnormal FHR tracings by electronic monitors have high sensitivity but low specificity to adverse foetal outcomes.[32] The intrinsic positive predictive value (PPV) of abnormal FHR tracing, i.e., the probability of a positive test resulting into an adverse outcome, is very low.[33] This is largely due to the large number of false-positive results.

Some studies reported the low sensitivity of 27% for foetal academia and 5-min Apgar score and PPV as low as 2% for most adverse new-born outcomes.[34–37] Studies using FIGO criteria reported sensitivity of up to 95% and PPV as low as 5% for different FHR abnormalities.[38]

However, despite these low specificity and PPV results, other studies have documented that detected FHR abnormalities had a more than 2-fold odds of being associated with foetal and new-born morbidity and mortality. [32,35] Specifically, detected tachycardia had a 1.8-fold odds of neonatal admission.[37] Moreover, these studies have shown high negative predictive values (NPV) at more than 90%.

Despite low PPV, baseline FHR monitoring during labour remains the mainstay midwifery aspect, being central providing quality intrapartum care in most LIC. Numerous studies show that intrapartum abnormal FHR detection is associated with adverse perinatal outcomes.[32,37] FSB and early neonatal deaths (markers of preventable deaths during labour), low Apgar scores, seizures, encephalopathy, and respiratory failure are some of the short-term adverse outcomes. Many presumably healthy foetuses may die unnoticed due to inadequate FHR monitoring. This underpins the importance of adequate FHR monitoring during labour.

In order to improve the quality of labour management and perinatal outcomes, the WHO developed a partograph.[39] This resource is basically a graphic representation of the progress of labour events and foetal status plotted against time. Its use is one of the important components of quality of care provision during labor.[40] FHR monitoring should be combined with partograph documentation to increase the regularity of observations, identify early warning signs, and effect timely decision making.[26,39] The use of a partograph during labour is fundamental to improving the quality of intrapartum care and subsequent perinatal outcomes in LIC.[41] If FHR and partograph use is implemented properly, this may result in a significant reduction of perinatal deaths and the associated long-term morbidities.[9]

Unfortunately, in sub-Saharan Africa there is a substantial gap in quality, whereby less than half of births have appropriate partograph documentation.[42–44] This is mainly due to competing priorities, such as a lack of appropriate and effective monitoring devices, and a chronic shortage of staff.[45] For example, in a tertiary hospital in Zanzibar, the ratio of skilled birth attendants to labouring women was 1:6. Further, the period of time from the last FHR documentation in the partograph to diagnosis of stillbirth or a live birth was more than 200 minutes.[45] Other studies in Tanzania reported limited access to FHR monitoring tools, lack of skills and lack of the use of the partograph as hindrances towards achieving standard intrapartum care.[46–48]

Because more emphasis is now being placed on giving birth at health-care facilities in Tanzania, more women are more aware of the benefits of being assisted by experienced birth attendants. However, this has led to an increase in the workload at referral hospitals in low-resource areas, including Tanzania, many of which are underequipped and understaffed. Thus, the promotion of facility-based births should also address the need to improve quality of care, including an increase in human resources, and training and equipping them with effective tools to assess labour progress. This will provide an opportunity for them to perform different intrapartum resuscitation interventions, such as the administration of intravenous fluids and to stop uterotonics when foetal jeopardy is identified. Intrapartum interventions may lead to improved maternal circulation, increased foetus oxygenation and the reduction of asphyxia-related adverse outcomes.[17,49]

In LIC, FHR monitoring is conducted mostly by intermittent assessment with either hand-held Doppler or Pinard stethoscope.[7,50] However, FHR monitoring is rarely conducted according to current international guidelines (Table 1).[45,51–57] The reasons for this inadequacy include ineffective FHR monitoring equipment, a shortage of human resources, and a lack of locally adapted guidelines. Most of the international guidelines on FHR monitoring are compatible with HIC, where

monitoring is conducted by electronic foetal monitors. However, this practice has been documented to have resulted in unnecessary interventions, including increased caesarean section rates.[58,59] Morover, these guidelines recommend a 1:1 midwife-to-woman ratio, which is not feasible in LIC.[60,61] Even those guidelines that have been developed for global use have not been adapted to respond to local needs. Most of the recommended techniques are feasible in HIC, and few studies have been completed in LIC.[9]

Table 1: Consensus international guidelines on intrapartum foetal monitoring using intermittent auscultation for low risk pregnancies* (From Housseine et al., 2018)[60]

Guideline	Year	assessment Frequency first stage	Frequency of auscultation second stage	Timing	Duration	Recommended device
NICE, UK[51]	2017	At least every 15 min	Every 5 min	After contraction	At least 60 s	Pinard Stethoscope or Doppler Ultrasound
FIGO	2015	15 min	Every 5 min	During and at least 30s after contraction	At least 60 s	Pinard Stethoscope or Doppler Ultrasound
RANZCOG, Australia/New Zealand	2014	Every 15–30 min	Every 5 min	Towards the end of and after each contraction	30–60 s	Not mentioned
ACNM, USA	2010	Every 15–30 mins	Every 5 min	After contraction	30–60 s	Doppler Ultrasound
ACOG, USA	2009	At least every 30 min	At least every 15 min	Not stated	Not stated	Doppler Ultrasound
SOGC, Canada	2018	15–30 min	5 min	After contraction	30–60 s	Not mentioned
RCOG, UK	2001	At least every 15 min	At least every 5 min	After contraction	At least 60 s	Pinard Stethoscope or Doppler Ultrasound
WHO IMPAC,	2015	Every 30 min	Every 5 min	After contraction	At least 60 s	Pinard Stethoscope or Doppler Ultrasound

**All guidelines recommend the use of continuous EFM except WHO IMPAC which did not give recommendation for high risk pregnancies.*

1.2.1 History of FHR monitoring methods

Foetal heart auscultation was given little attention until it was discussed for the first time by Mayor and Kergaradec in 1818, when they needed to assess whether the foetus was alive or dead.[62] Its popularity was later accelerated by Kennedy's publication about obstetric auscultation in 1833. In the early 1800s, Laënnec rolled a sheet of paper into a tube and listened through the device, which was later replicated in wood for foetal heart auscultation; a method that has continued to be used to date.[45] The following sections describes the various different developments in FHR monitoring tools.

The Pinard stethoscope was developed by a French physician, Dr A. Pinard, in the 1880s, and was in wide use by the 1950s.[62] It is the most common instrument, using Laënnec's technique of sound amplification, transmitting it from the foetal heart to the examiner's ear. It is currently used in mostly in LIC to intermittently detect abnormal FHR and to facilitate obstetric intervention. However, there is a need for a significant degree of skills and experience to use it accurately. One must count heartbeats while watching a clock and perform multiple calculations to obtain accurate records. Auscultation with this foetal stethoscope has been reported to be uncomfortable for both the patient and the midwife. The DeLee stethoscope is an alternative to the Pinard stethoscope but using the same technology (Photo 1).

Photo 1: Pinard and DeLee stethoscope foetal heart rate monitors (copyright-free internet images)

The Handheld Doppler was developed in the 1960s using a technology developed by Austrian physicist, Christian Doppler.[61,62] It is an electronic device used for intermittent auscultation and relies on a single-crystal doppler effect. The Doppler uses ultrasound-detected movements of foetal cardiac structures and subjects them to signal modification. Handheld Doppler devices are simple to use and cause less maternal discomfort than the Pinard foetal stethoscope. The readings can be objectively recorded but the device requires electricity or batteries.

Another type of Doppler is called the Freeplay wind-up handheld foetal Doppler. It has rechargeable batteries and can also be hand-cranked, providing rapid recharging with only a minute of winding, and can be used for to up to 10 minutes. Its readings are objective, and the device (Photo 2) is well accepted by mothers and health care providers in LIC.[63,64]

Photo 2: hand-held Doppler (Source: Muhimbili National Hospital Labour Ward)

Continuous electronic foetal heart rate monitoring was introduced into hospitals in the 1970s using electronic foetal monitoring (EFM) by Cardiotocography (CTG) for continuous monitoring. The device records the FHR parameters, including variabilities, decelerations, accelerations, tachycardia and bradycardia as well as the uterine contractions in labour. It has two transducers placed on the mother's abdomen to detect FHR and uterine muscle activity.[45] Records may be captured externally via an

ultrasound transducer attached to the mother's abdomen, or internally, via a foetal scalp electrode placed directly on the baby's head.[65] It needs a continuous supply of electricity, specific storage environment, and continuous staff training for accurate interpretation. Readings are printed on paper and are sometimes stored on a computer for later reference.

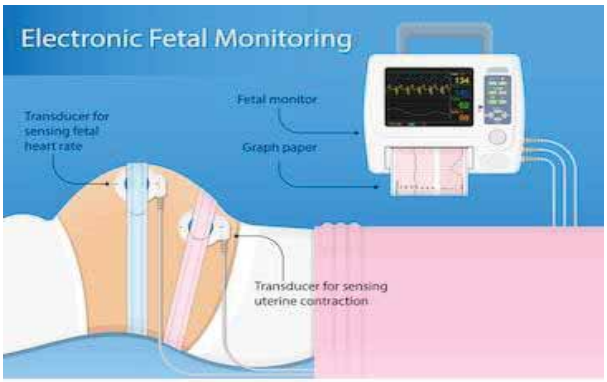

Photo 3: Electronic Foetal heart rate monitor (Cardiotocograph) (Source: copyright-free internet image)

1.2.2 Safer Births project and the development of an automatic strap-on continuous FHR monitoring device termed Moyo

Safer Births is a research, development and implementation project designed to improve foetal heart rate monitoring, new-born resuscitation and perinatal outcomes worldwide. The project was aimed at developing innovative products and training materials to better equip and train healthcare workers and at establishing new knowledge related to labour and births in LIC. It is a collaborative project involving various Norwegian and Tanzanian institutions. Safer Births implementation activities were conducted in conjunction with the Helping Babies Breathe program in Tanzania.

As one of the strategies to improve FHR monitoring to facilitate awareness of foetal distress and to inform decision-making, an automatic strap-on FHR monitor called Moyo was developed. This device was designed to facilitate early identification of foetuses at risk of asphyxia (Photo 4).

As part of the Safer Births project, a randomized controlled study, carried out in rural settings in Tanzania, revealed that the use of Moyo increased the identification of baseline abnormal FHR and subsequent intrauterine resuscitations.[66] Further, qualitative studies on the preferences and acceptability of the strap-on Moyo device among mothers and clinical staff have been conducted. The findings of these studies show that preference and acceptance was high compared to other devices. Also, the use of Moyo was reported to positively affect the women's birth experience, whereby an audio-visual monitor reassured them of the wellbeing of the foetus.

Photo 4: Part 1: Moyo sensor strapped onto the mother's abdomen for prolonged monitoring. Lightweight and portable, it allows the mother to move around freely. Part 2: Metal pads to detect maternal heart rate (Photo reprinted with permission from Laerdal Global Health)

In 2008, Wyatt recommended a number of necessary features for developing appropriate technology for use in low resource settings.[67] Table 2 summarizes a comparison of different FHR monitoring devices by these recommended parameters.

Table 2: comparison of different FHR monitoring methods available by different parameters.

Parameter	Pinard stethoscope	Hand-held Doppler	Wind-up Hand-held Doppler	CTG	Moyo
	Pinard stethoscope				
Availability for LIC	Available	Available	Available	Limited availability	Available in some countries
Cost	Inexpensive	Relatively inexpensive	Relatively inexpensive	Expensive	Relatively inexpensive
Power and consumables	Not needed	Continuous supply of replacement batteries	Built-in rechargeable batterie, can be hand cranked	Continuous power supply	Built-in rechargeable battery from multiple mains of electricity
Use	Intermittent	Intermittent	Intermittent	Continuous	Both intermittent and continuous
Maternal FHR comparison	No	No	No		Yes
FHR display	No	Yes	Yes	Yes	Yes
FHR records	No	No	No	Yes continuous	Yes, for 30 min
Acceptability by mothers	Low	High	High	Low due to limited mobility	High
Acceptability by clinical staff	Low	High	High	Low	High
Operation in harsh environment	Yes	Yes	Yes	No	Yes
Mode of operation	Skilled listening and arithmetic	Simple to use with minimal training	Simple to use with minimal training	Skilled use and interpretation needed	Simple to use with minimal training
Life span	>5 years	5 Years	5 Years		5 years
Availability for LIC	Available	Available	Available	Not available	Available in some countries
Cost US$)	~3–5	~200	~200	Expensive	~198
Mobility of the women	Allows mobility	Allows mobility	Allows mobility	Does not Allow mobility	Allows mobility

1.2.3 Current FHR monitoring practices

The main methods for intrapartum FHR in LIC are intermittent monitoring using mostly the Pinard and, to a lesser extent, the hand-held Doppler. However, a research gap exists in the effectiveness of these FHR assessment techniques in these settings, including Tanzania. In sub-Saharan Africa, two documented randomized studies had investigated FHR devices; specifically, the intermittent Doppler and the Pinard method, by 2016. One study in Uganda showed increased FHR detection in the Doppler compared to the Pinard arm, however, with no difference in perinatal outcomes.[7] The second study, conducted in Harare, showed that abnormalities in foetal heart rate were detected more often by the Doppler than with the Pinard method. This resulted in less hypoxic ischemic encephalopathy, seizures and deaths.[68] Recently, two additional studies have been conducted in rural settings in Tanzania as part of the Safer Births program. The first study, which compared the Pinard and hand-held Doppler, showed no difference in abnormal FHR detection and subsequent perinatal outcomes.[69] The second study compared the Moyo with the Pinard method and showed that the use of Moyo increased FHR detection and intrapartum resuscitations compared to the Pinard with similar perinatal outcomes.[66]

1.2.4 FHR monitoring techniques in HIC

Most of the RCTs and systematic reviews in the use of FHR monitoring techniques have been conducted in HIC.[58,65] A systematic review of 12 trials compared continuous monitoring with CTG versus intermittent monitoring with the Doppler or Pinard. In the intermittent monitoring arms of the studies, women received one-to-one care. The findings showed that there was no difference in the numbers of intrapartum-related deaths between the groups, but there was a reduction in incidence of neonatal seizure.[58,70] A cohort study conducted in the US showed that continuous CTG was associated with lower intrapartum-related deaths and less rates of low Apgar score incidence at 5 minutes.[71,72] However,

in both reports, continuous monitoring was associated with significantly more births by caesarean section and by instrumental vaginal births with no differences in new-born morbidity and mortality.

A recent systematic review analysis of 36 studies, six from LIC, found improved outcomes with the use of partograph during labour. Using a CTG increased the odds of caesarean section by approximately 30% with no benefits on perinatal outcomes observed.[41] The review recommended the use of intermittent FHR monitoring combined with partograph a feasible technique to improve new-born outcome. Implementation studies on these methods were also recommended.

The effectiveness of a novel strap-on automatic Moyo monitoring device has not been evaluated in an urban setting. Moreover, there is no evidence to date on the implementation of FHR monitoring in relation to partograph use, nor on the quality of health care provision during labour. Because there is an uncertainty regarding the appropriate FHR device to use during labour and its relationship to adverse outcomes, there is a need to identify the most effective and scalable FHR technique.

1.3 Tanzania-Setting and Context

1.3.1 The country and the people

Tanzania (Figure 3) is situated in Eastern Africa within the African Great Lakes region, occupying an area of 947,300 km² (land: 885,800 km^2, water: 61,500 km^2). Important landmarks of Tanzania include Mount Kilimanjaro, Africa's highest mountain in north-eastern Tanzania, the Ngorongoro crater, the Serengeti National Park, and many lakes, including Lake Victoria. Administratively, Tanzania has a total of 31 regions; 26 in Tanzania Mainland, and 5 in the Zanzibar islets.[73]

Tanzania has a population of 55 million, with an average annual growth rate of 2.8%. Tanzania has the largest population in East Africa, and almost a third of the population is urban. Tanzania's youthful population – about two-thirds of the population is aged under 25 – is growing rapidly

because of the high total fertility rate of 4.8 children per woman.[74] The economy depends on agriculture, providing 85% of exports, and employs 65% of the work force. Over 28% of the population live below the Basic Needs Poverty Line ($1.90 per day) and 10% below the Food Poverty Line ($0.50 per day). Table 3 illustrates selected economic and heath indicators.

Figure 3: Map showing Tanzania and Dar es Salaam (Source: free internet image)

Table 3: selected economic and health indicators (Source: 2012 Census survey, Demographic Health Survey 2010 and 2015, Tanzania in Figures 2016)

Indicator	**2015/2016 estimates**
Population growth rate	2.75%
Crude birth rate (births/1,000 population)	35.6
Crude death rate (deaths/1,000 population)	7.6
Infant mortality rate (deaths/1,000 live births)	39.9
Total fertility rate: (children born/woman)	4.77
Life expectancy at birth: total population (years)	62.6
Male (years)	61.2
Female (years)	64.1
Contraceptive prevalence rate (currently married women, mCPR)	38.40%
Health expenditures: percentage of GDP (2014	5.60%
Physicians density: physicians/100,000 population (2012)	3
Unemployment rate:	10.30%
Population below poverty line: $1.90 a day (2015)	22.80%

GDP - per capita (PPP):	$3,300

1.3.2 Tanzanian health system

Tanzania has a hierarchical health structure running parallel with an administrative hierarchy. Primary health care facilities, including dispensaries, are at the bottom, with health centres at ward level, district hospitals at district level, regional referral hospital at regional level, zonal hospitals, and one national hospital. Due to the inaccessibility of facilities offering maternal and new-born care, some communities have established maternity waiting homes located near health facilities to facilitate access.

Dispensaries conduct normal births. These facilities are usually equipped with few beds for medical treatment or observation before referral. Women first treated in dispensaries are referred to the health centres that admit patients. In recent years, some of the health centres have been upgraded to hospitals to cater for the high demand for advanced care. District hospitals act as referral facilities for health centres. At these hospitals, specialized care is provided, depending on the available specialist. Referrals from districts are made to the regional referral hospitals, which provide more advanced care. However, in Dar es Salam, the main commercial city, three district hospitals (Temeke, Amana and Mwananyamala) have been upgraded to regional referral hospitals due to an increased specialized care demand. Zonal hospitals are positioned at the highest hierarchical level, and are staffed with specialized doctors, super-specialists and specialized equipment and care. Muhimbili National Hospital occupies the highest level of all facilities and receives referrals from multiple referral hospitals. A total of 7,685 (70% public and 30% private) health facilities were established in Tanzania by 2017. Under Public Private Partnership (PPP), some private hospitals have signed service agreements with the government to provide health services as designated hospitals. These include the exemption of pregnant women and under-5 children from out-of-pocket payments.

Tanzania is among one of the sub-Saharan African countries of those that record a serious shortage (54%) of Human Resources for Health (HRH); a key element for the delivery of quality health care.[75] Efforts to mitigate the shortage include the expansion of training institutions, increased enrolment, transformation to a competence-based curriculum and task sharing among care providers.

1.3.3 National health policies and programs

With the health system conforming to a pyramid structure, from the community at the lowest level to the Muhimbili Hospital at national level, the coordination and management of health-care functions are shared by two ministries. The first is the Ministry of Health Community Development Gender Elderly and Child (MOHCDGEC), which is responsible for the formulation of policies and technical guidelines and overseeing service delivery from the regional referral hospitals and consultant hospitals. The second is the President's Office-Regional Administration and Local government (PO-RALG) Directorate of Health, Social Welfare & Nutrition Services (DHSWNS), which implements the policies, standards and strategic plan, and oversees the district hospitals, health centres, dispensaries and various community-based services.

The Reproductive and Child Health Section (RCHS), under MOHCDGEC, is responsible for the preparation and review of policies, guidelines, and manuals for maternal and child health. The Section also coordinates activities and programs with other ministries and organizations dealing with RCH issues and conducts a review of standards of quality maternal and childcare.

Some health policies that target the improvement of perinatal care include the health payment exemption policy, cost sharing and health insurance. Pregnant women and children under the age of 5 are among those exempted from paying health insurance. Cost share covers include all Tanzanians, whereby the government have subsidized medical care

costs. Contributing to the National Health Insurance fund is mandatory for all government employees and is optional for those employed in the private sector, as well as for groups and individuals.

MOHCDGEC has programs and frameworks for the provision, monitoring and evaluation of RCH services. However, program implementation is largely under-budgeted and the fund disbursement mechanisms to the districts are poor.[76,77] In 2007, the Primary Healthcare Service Delivery Program (PHSDP 2007–2017) was established, aimed at accelerating the provision of primary health care. Activities included strengthening health systems, financing, medicine provision, equipment and supplies.[78] This led to only partial success, as the maternal mortality rate (MMR) and the perinatal mortality rate increased between 2010 and 2015 due to substandard care during labour and births.[79] As a part of the improvement of the quality of care, Direct Health Facility Financing (DHFF) was introduced. Also, some health facilities are linked to Results-Based Financing (RBF) and the Community Health Fund, giving them some degree of financial autonomy.[80]

1.3.4 Current strategies for new-born care

Progress towards the prevention of neonatal deaths has been slower compared to improvements in the overall under-5 mortality rate (Figure 4). The decline was recorded as being reduced from 40 to 25 deaths per 1,000 live births for neonatal deaths from 1999 to 2016. The neonatal contribution to under-5 mortality rates increased from 27% to 37% during the same period.[81–83]

To improve perinatal health with a specific focus on perinatal mortality, a cross-cutting strategy was formulated. This was the National Road Map Strategic Plan to Improve RMNCAH: The One Plan II (2016–2020), which was built on the Health Sector Strategic Plan IV (HSSP 2015–2020). One of the aims of the RMNCAH is to reduce perinatal mortality by 20% by 2020.

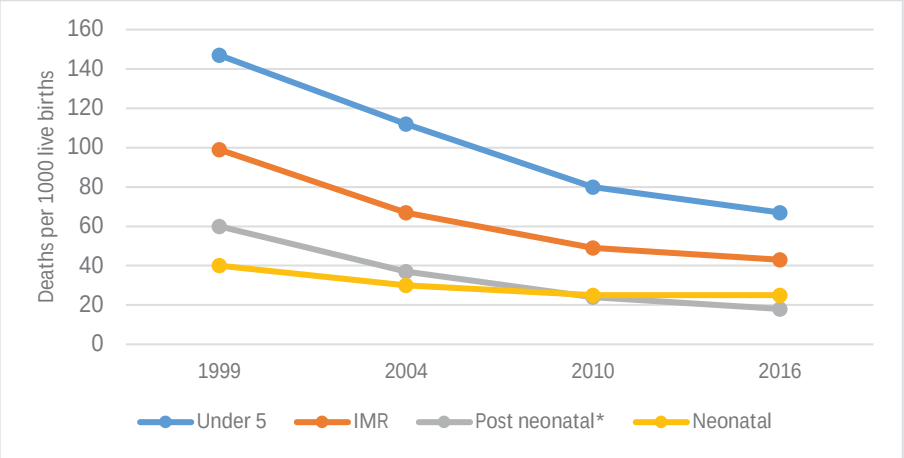

Figure 4: Trends in early childhood mortality (Source: DHS-1999, 2004, 2010, 2016)
**Computed as the difference between the neonatal and infant mortality rates*
IMR=Infant mortality rate

Care during childbirth, Emergency Obstetric and New-born Care (EmONC) guidelines form the major elements of the strategy. EmONC is a set of evidence-based packages of interventions and services that serve to identify obstetric and new-born complications and to make timely and appropriate management decisions for improving the quality of care. The basic components of EmONC (BEmONC) are supposed to be provided at all health facilities. At hospital level, comprehensive (CEmONC) services are provided. Some of the health centres have been upgraded to provide CEmONC services. However, according to an assessment of EmONC in 2015, only 13% of dispensaries, 28% of all health centres and 62% of hospitals were capable of performing all functions.[79,84] This shows that there is still inadequate quality of care provision during labour and birth.

1.4 Conceptual framework

Modified WHO vision 2015 framework for quality of care in labour
The World Health Organization (WHO) defines quality of care as 'the extent to which health care services provided to individuals and patient

populations improve desired health outcomes. In order to achieve this, health care needs to be safe, effective, timely, efficient, equitable, and people-centred."[85] Quality of care in most of the health facilities in LIC is complex and needs multidisciplinary interplay. Post-2015, the WHO envisioned a world where all pregnant women and new-borns would obtain access to quality care around the perinatal period, in line with the WHO global ENAP and the Ending Preventable Maternal Mortality (EPMM) agenda.[5,14]

The WHO framework was used in this thesis to conceptualize quality of care for maternal and new-born health. Important components of the framework, including its policies, strategies and guidelines (Figure 5), have been identified.

There has been an increased number of births occurring at tertiary facilities due to the available expertise and facilities for operative births compared to those available at lower facility levels. This compromises the quality of care provision due to inadequate levels of human resources, lack of physical infrastructure, and supplies not matching demand. Hence, the importance of the health system is recognised in the improvement of the skills of the workforce, the availability of the medical products, and the provision of continuous medical education, finance, leadership and governance, which will cascade down to the quality of care provision.[86]

In order to provide quality care during labour, Tanzania needs to have competent, skilled, midwives who are equipped with effective tools. This should be coupled with readily available and accessible elements of infrastructure, such as adequate operating theatres. Also, skilled providers should be supplied with locally developed or adapted guidelines and EmONC services.

In the provision of care (Figure 5), a safe, effective and efficient intrapartum FHR monitoring device, forms a critical element of improved and safe care. When FHR monitoring with appropriate tools is

combined with appropriate partograph use, this should provide an actionable information system to assist in the review and audit of the labour.[26,39]

A secondary element is a need for effective communication about the labour progress with the mother, as well as promoting the woman's dignity and respect. All these elements should lead to improved quality of intrapartum care, which forms the causal pathways that lead towards better perinatal outcomes, as shown in the framework.

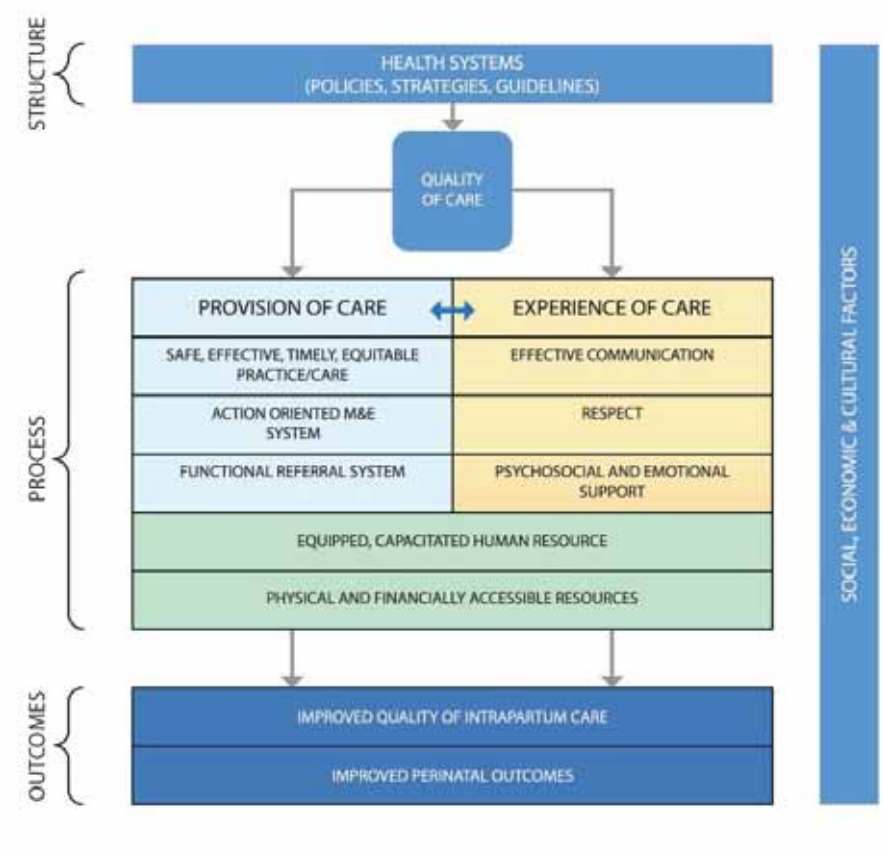

Figure 5: Quality of care framework to improve perinatal outcomes (Modified from the WHO Vision 2015)

1.5 Summary

The rates of stillbirths and neonatal deaths are high in Tanzania and significantly contribute to the burden of disease. There are geographical and income disparities associated with this burden, with the highest rates being found in sub-Saharan Africa (including Tanzania). Moreover, there is an increased volume of mothers giving births at health facilities, which, when coupled with a shortage of skilled birth attendants and inappropriate tools to monitor labour, increases the risk of adverse perinatal outcomes, including FSB and early neonatal deaths. Several international guidelines and documents, including those developed by the WHO and UNICEF, recommend interventions focusing on the improvement of quality of care around labour and births, because they provide a triple return on investment; i.e., the wellbeing of the mother, foetus and new-born.[5,11,57,87] Intrapartum FHR monitoring and partograph use in labour are considered important quality strategies that may facilitate improvement in the provision of care during labour and birth.

However, in LIC (including Tanzania), where most births occur, there are uncertainties about the kinds of devices that are effective in FHR monitoring during labour. It is hypothesized that studies evaluating effective FHR monitoring devices, and their subsequent implementation, will improve the quality of care, and, by proxy, improve perinatal outcomes. This thesis responds by contributing to a better understanding of effective FHR monitoring devices during labour. Further, it assesses the implementation strategies for FHR monitoring in relation to partograph use, and intrapartum-related interventions where appropriate.

2 Aims of the PhD project

The overall aim of this PhD project was to compare the effectiveness of different FHR monitoring devices and the associated improvement in quality of intrapartum care at two urban referral hospitals in Dar es Salaam, Tanzania.

2.1 The specific aims of the studies were:

1. To compare the effectiveness of intermittent monitoring with a hand-held Doppler versus the Pinard stethoscope in the detection of baseline abnormal FHR in labour (Study I).
2. To compare the effectiveness of continuous monitoring with the strap-on automatic Moyo versus intermittent monitoring with the hand-held Doppler in the detection of baseline abnormal FHR in labour (Study II).
3. To describe time intervals for different events in labour, mode of giving births and perinatal outcomes for the different FHR monitoring methods (all studies).
4. To assess the quality of midwifery practices related to FHR monitoring (including partograph documentation) pre-implementation using the Pinard stethoscope compared to post-implementation of the automatic strap-on Moyo (Study III).

2.2 Research questions

In urban referral hospitals in Tanzania:

1. Does intrapartum intermittent FHR assessment with a hand-held Doppler differ in detection of baseline abnormal FHR compared to a Pinard stethoscope among low-risk parturient women? (Study I)
2. Does intrapartum FHR assessment with a strap-on automatic Moyo differ in the detection of baseline abnormal FHR compared

to intermittent assessment with hand-held Doppler among parturient women? (Study II)

3. Which FHR monitoring method is associated with earlier detection of baseline abnormal FHR? (All studies)
4. Does the implementation of strap-on automatic Moyo compared to intermittent assessment with Pinard stethoscope affect partograph documentation and the quality of midwifery practices in labour? (Study III)

2.3 Hypotheses:

1. Intermittent FHR assessment with hand-held Doppler will detect more baseline abnormal FHR compared to Pinard stethoscope among parturient women (Study I).
2. FHR assessment with strap-on automatic Moyo will detect more baseline abnormal FHR compared to intermittent assessment with hand-held Doppler among parturient women (Study II).
3. FHR assessment with strap-on automatic Moyo will detect baseline FHR abnormalities earlier compared to intermittent assessment with hand-held Doppler and Pinard stethoscope among parturient women (Studies II & III)
4. FHR assessment with strap-on automatic Moyo will improve quality of intrapartum care (including the use of partograph) as compared to intermittent assessment with Pinard stethoscope (Study III).

3 Methods and participants

3.1 Study settings

All three studies were conducted in Dar es Salaam; the major commercial city and former capital of Tanzania, located on the Eastern coast and facing the Indian Ocean. It has total area of 1393 km^2 with five municipalities. In 2019, the projected population of the city is approximately 6.3 million and it has the highest growth rate of any region in the country (5.6% year). Roughly 35% of the Dar es Salaam population comprises children under the age of 14.[74]

3.1.1 Muhimbili National Hospital

Studies I and II were conducted at Muhimbili, a teaching hospital and the largest consultant hospital in Tanzania, situated in Ilala municipality. About 10,000 births are facilitated annually, corresponding to about 35 births per day. The hospital serves as a tertiary referral hospital for the whole country. It deals with many complicated obstetric cases with more than 50% of them by caesarean section (the highest rate in the country). The high rate of caesarean sections is due to increased referral of complicated cases from the lower-level facilities, maternal requests and inappropriate indications. By 2016, approximately 7% of births were stillborn and 2% died within 24 hours.[88] Births are conducted by nurse-midwives and doctors, assisted by medical and midwifery students.

The labour ward at Muhmbili has 20 birthing beds (Figure 6). There are approximately 25 nurse midwives, which is far below the WHO benchmark for the supply of a minimum of 20 skilled birth attendants and 60 beds per 3,600 births per year, respectively.[89] The ward is managed by 5 nurse-midwives and 2 nursing assistants in each shift of 12 hours. The doctors-on-call team comprises 1 consultant, 1 obstetrician, 2 obstetric residents, and 1 intern doctor on 24-hour call. There is an obstetric operating theatre located in a separate building adjacent to the maternity block equipped with two operating beds.

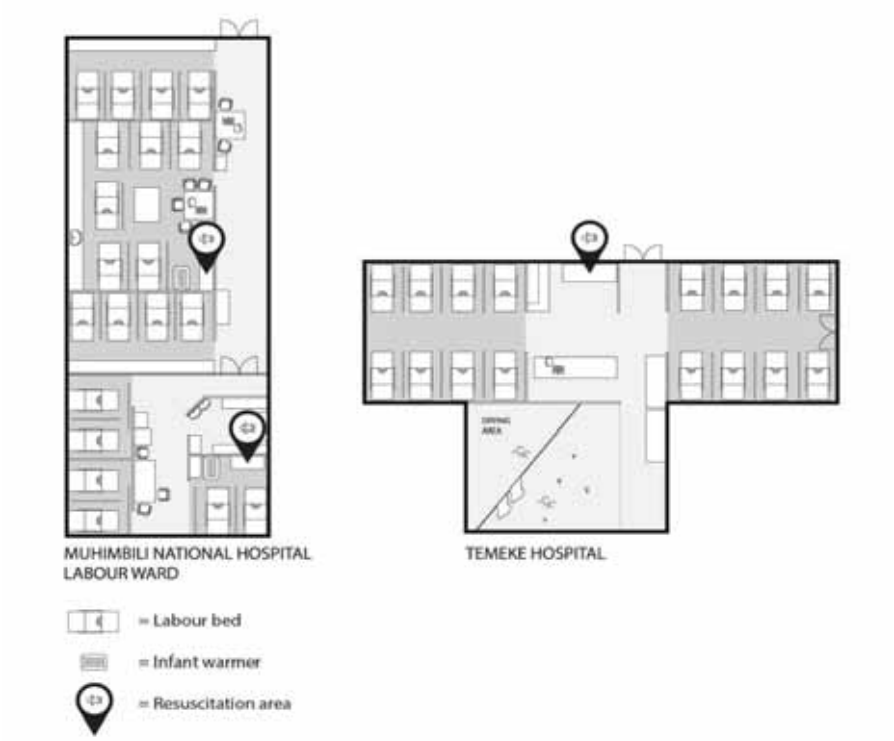

Figure 6: Schematic drawing of the labour ward at Muhimbili and Temeke (Illustration by Darja and Karl-Otto)

On admission, a nurse-midwife screens all women for vital signs registration, initial FHR assessment, and vaginal examination before they enter the labour ward. A brief obstetric history and vital signs are taken, and the required information is entered in the labour ward register. In cases of uncertainties, the midwives and on-call doctor review the partograph and make collective decisions. After a normal vaginal birth, mothers and babies are observed in the hospital for up to 24 hours, whereas caesarean births entail 48 to 72 hours of observation. Babies in need of medical attention are admitted to the neonatal unit.[90,91]

3.1.2 Temeke Regional Referral Hospital

Study III was conducted at Temeke Regional Referral Hospital, located within the Temeke municipality. The municipality is the industrial district of the city and has the largest concentration of low-income residents in Tanzania at about 2 million people. It has about 135 health facilities that refer complicated cases to Temeke Hospital for advanced care.

The hospital has about 30–50 births per day (more than 15,000 per year). Its labour room (Figure 6) has 18 beds (far below the WHO benchmark) and a general operating theatre in a separate building is used for obstetric and other surgical cases. The obstetrics unit has two qualified obstetricians, 12 general doctors, 25 nurse-midwives, five medical attendants and a varying number of rotating intern medical doctors and nurses who perform assist births. Nurses have three shifts per day with an average of three nurses and one medical attendant per shift. Doctors have two shifts per day with one medical doctor and two interns during the day and night shifts, respectively. Some emergency cases are referred to Muhimbili.

3.2 Study design

This thesis comprised three interlinked quantitative studies (Table 4). A variety of quantitative study designs were used to achieve the overall aims stated above. The two RCTs (Studies I and II) were a sequential design and were carried out at Muhimbili, and one pre/post observational study (Study III) was conducted at Temeke (Table 4). Study I was conducted from 1st April 2013 to 30th September 2015. Study II was conducted from 1st March 2016 to 30th September 2017. Study II built on the results of Study I and used the most effective device to compare this with the novel strap-on automatic Moyo. Study III was conducted from 7th March 2016 to 15th December 2016, concurrent with Study II. The study methods are summarized in Table 5.

Table 4: Timelines of three PhD studies at Muhimbili and Temeke

	2013				2014				2015				2016				2017			
Quarter of the year	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Study I																				
Study II																				
Study III																				

Table 5: Summary of research design, methods and participants for three studies

	Study I	Study II	Study III
Study design	Randomized controlled study (Intermittent Doppler vs intermittent Pinard stethoscope)	Randomized controlled study (Continuous Moyo vs Intermittent Doppler)	Pre and post implementation study (Continuous Moyo vs Intermittent Doppler)
Sample size	Doppler (1,421) vs Pinard (1,423)	Moyo (1,479) vs Doppler (1494)	Post/Moyo (2,442) vs pre/Pinard (1640)
Study focus	Effectiveness in detection	Effectiveness in detection and timeliness	Improvement in midwifery practices and quality of care
Recruitment period	April 2013 to September 2015	March 2016 to September 2017	Pre: March to June 2016 Post: July-December 2016
Study setting	Muhimbili National Hospital	Muhimbili National Hospital	Temeke Regional Referral Hospital
Participants	Pregnant singleton women in true labour with normal baseline FHR on admission	Pregnant singleton women in true labour with normal baseline FHR on admission	Pregnant singleton women in true labour with normal baseline FHR on admission
Data Collection method	Structured case report form (CRF)	Structured case report form (CRF)	Structured case report form (CRF)
Data analysis methods	$\chi 2$ and Fisher's exact test Mann–Whitney test, Independent samples t-test, Binary logistic regression	$\chi 2$ and Fisher's exact test Mann–Whitney test, Independent samples t-tests, Binary and multinomial logistic regression, Linear regression (with a natural log-transformation)	$\chi 2$ and Fisher's exact test, Mann–Whitney test, Independent samples t-test Binary and multinomial logistic regression

3.2.1 Randomized controlled studies (Studies I and II)

Studies I and II were randomized controlled trials using a superior, parallel, open label design and conducted at Muhimbili Hospital. In both studies, the randomization sequence was computer-generated by an independent statistician. Details of the allocated group were given to the study coordinator, who supervised data clerks to write unique identifiers on cards and put them in sequentially numbered opaque sealed envelopes (SNOSE). The allocation sequence was concealed from investigators, participants and clinical staff implementing and assessing outcomes. However, due to the nature of the interventions (medical devices), it was not possible to blind the participants and clinical staff. Errors were minimized to 5% significance level, and probability to detect existing effect (power) was set at 80% for two-sided comparison of proportions. A minimum of 10% more women were included to account for potentially missing data in order to keep the sample large enough to detect meaningful difference.

3.2.2 Pre- and post-interventional study (Study III)

The third study (Study III) was conducted at Temeke in a pre- (3 months using intermittent Pinard) and post- (4.5 months using continuous Moyo) intervention design. Records at Temeke showed that abnormal FHR was detected in approximately 2.0% of all low-risk births using Pinard. An increase in the detection rate of 5% was the smallest change that we considered to clinically meaningful. Assuming an increase in detection rate of at least 5% with the strap-on Moyo monitor, we planned the study to include a minimum of 890 (total 1,780) women pre- and post-implementation, which would give a 90% power effect with an alpha level of 0.05 (two-sided comparison to detect such a change). This sample size was assumed to be reached within a study period of 4 months in total (2 months pre- and 2 months post-implementation). However, due to delays in implementation and to account for missing data, the study period was extended to a total of 7.5 months (3 months before and 4.5 months after).

3.3 Participants

The inclusion and exclusion criteria are presented in Table 6. Study I included term low-risk pregnant women in labour. Studies II and III included women with gestation age (GA) above 28 weeks as they were considered viable with current National guidelines.

Table 6: Inclusion and exclusion criteria for participants in three studies

Inclusion criteria	GA >28* complete weeks
	Cervical dilatation >3cm**
	Normal FHR on admission
	Singleton
	Written consent obtained
Exclusion criteria	Elective Caesarean section
	Severely sick client, e.g., eclampsia, pre-eclampsia
	Multiple pregnancy

Study I; GA >37 weeks, ** Study I; cervical dilatation >3cm and <7cm

3.4 Training of relevant clinical staff

In Study I, before the start of the implementation of the intervention, all labour ward staff (midwives and doctors) at both hospitals were trained for a full day on FHR management protocols. On-the-job short and frequent refresher training sessions were conducted intermittently to increase protocol adherence and accommodate incoming staff who did not receive the initial training. Training included theoretical information about FHR monitoring during labour, the management of an abnormal FHR and partograph documentation. The criteria for FHR monitoring were emphasized and included monitoring and recording of FHR this every 30 minutes in the first stage of labour, and every 5–15 minutes in the second stage, as per the WHO guidelines and other international guidelines.[45] For intermittent assessment (i.e., using Pinard and Doppler), midwives were trained to assess the FHR during the last 10 minutes of every half hour, particularly before, during, and immediately after a contraction. Any FHR abnormalities were to be reported to the doctor on call for consideration and potential actions.

In Studies II and III, in addition to the training described above, training sessions using a Moyo standard operating procedures were provided (Photo 5). The labour ward staff were also told that abnormal FHR detections should be reported to the doctor on call, who then acted according to hospital protocols.

Photo 5: Drs Muzdalifat, Matilda, Sisters Amina and Anna (Part 1 at Muhimbili) and Drs Muzidalifat and Kamala (Part 2 at Temeke) training midwives and doctors on intrapartum FHR monitoring and standard operating procedures for different methods (Photo taken by Benjamin Kamala and Gilbert Kilonzo, permission to use the photo was obtained from trained participants)

3.5 Training of research assistants

For all studies, research nurses were trained for one additional day on the research protocol and data collection methods (Photo 6). This ensured the accuracy and completeness of the data recorded on the paper-based case report form (CRF) (see Appendices 1 and 2 for entries relating to the three studies, respectively). Data were collected from mothers' antenatal cards, partograph, obstetric register, and, when needed, from routine neonatal morbidity and mortality records in the neonatal unit.

Photo 6: Dr Kamala Training research nurses on data collection process using care report form at Temeke (Photo taken by Gilbert Kilonzo, permission to use the photo was obtained from research nurses)

3.6 Study procedures

In all studies (Studies I, II & III), for intermittent auscultation, women were monitored using the standard protocol with a either a Pinard stethoscope or hand-held Doppler (Power-free Education Technology). The midwives then continued with their routine activities and periodically revisited the women to check and record FHR readings in the partograph and to perform other management as indicated.

For Studies II and III, women monitored with continuous Moyo received information on how the device was to be used by the enrolling midwife. Important information was provided to women randomized to the Moyo arm for its proper use. Moyo, equipped with a rechargeable battery, has a 9-crystal Doppler ultrasound sensor, which facilitates the rapid identification of FHR. It can be used continuously (strapped-on) or intermittently. The detection area is increased, necessitating less palpation. It has a 30-minute histogram display of the FHR (in continuous mode) and an audio-visual alarm if abnormal FHR is

detected. Monitor readings are coded with colours. A green reading indicates normal FHR. Yellow is a warning indicator for FHR outside the normal range (Figure 7). A question mark meant that no FHR is detected or that the sensor is displaced. A red reading with an alarm indicates when the records are outside the range for more than three minutes or when no FHR is detected, which may be an indicator of foetal death or a displaced sensor. The mothers would call the labour ward staff when there were abnormalities in the readings that had not been spotted by the attendant. A set of dry electrodes assist in the differentiation of maternal heart rate from FHR. All the above-mentioned features are meant to facilitate interventions and promote greater control of the management of multiple expectant women by the birth attendant.

For those mothers who consented. Moyo was strapped on for continuous FHR monitoring. The midwife continued with her routine activities, but periodically revisited the women to check and record the FHR reading or when an alarm sounded from the Moyo. The Moyo remained strapped on until the end of the second stage of labour, or immediately prior to the start of a caesarean section.

Figure 7: Moyo monitor with different colour codes for different FHR readings (Source: Laerdal Global Health)

3.7 Data collection and management

Data collection for the three studies was conducted by trained research nurses. CRFs were cross-checked by investigators for quality and completeness before entry. CRFs with queries were returned to the research nurse for verification and correction before data entry. A data entry template was generated in EpiData by the investigators and a statistician. Verified data were double entered by trained data clerks. Then, data were transferred to SPSS for analysis (IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.). Patient information was recorded using confidential codes for each woman and was kept in a secure place.

3.8 Measures/Variables

Table 7 summarises the primary, secondary and background variables and values for the different studies included in this thesis. Details of each variable is appended (Appendix 1 and 2)

Table 7: Primary, secondary and background variables registered and analysed for the three studies

Variable	Values/units of measure	Study I	Study II	Study III
Primary outcome				
FHR during labour	Normal, Abnormal	√	√	√
Secondary outcomes				
FHR documentation in labour	Yes, No			√
Frequency of FHR documentation	<30min, 30–60 min, 60–120 min, >120 min			√
Mode of birth	Normal (SVD), Assisted breech, caesarean section, Vacuum extraction	√	√	√
Indications for caesarean section	Obstructed labour, Abnormal FHR, Prolonged labour, Others		√	√
Received resuscitation	Stimulation, suction, ventilation		√	√
Apgar score at 5 minutes	Low (<7), Normal (≥7)	√	√	√
Birth outcomes	Normal, Admitted to neonatal unit, Fresh stillbirths	√	√	√
Intrauterine resuscitation	Stop oxytocin, change mother's position, Give IV fluids, Give Oxygen		√	√
Neonatal outcomes 24-hours	Normal, still admitted to neonatal unit, early neonatal death	√	√	√
Time from Admission to birth	Minutes		√	√
Time from Admission to Abnormal FHR detection	Minutes		√	√
Time from Last FHR to birth	Minutes	√	√	√
Time Between FHR assessment	Minutes			√
Time from abnormal FHR to birth	Minutes		√	√
Duration of stages of labour	Minutes	√	√	√
Baseline characteristics				
Age (years)	<20, 20–35, >35			
Birth weight	Low (<2500gm), normal (≥2500gm)	√	√	√
GA (weeks)	<37, 37–42, >42	√	√	√
Cervical dilatation on admission	Centimetres		√	√
Parity	1, 2–4, >4		√	√
Education	No formal education, primary, secondary, above secondary		√	√
Presentation	Cephalic, breech		√	√
Source of admission	Home, inpatient, Referrals	√	√	√
HCW assisting birth	Doctor, nurse midwife		√	√
Marital status	Married, Single, cohabiting		√	√
Antenatal visits	None, 1–3, >3		√	√
Maternal infection	Yes, No	√		
ANC problem	Yes, no	√	√	√
Health care worker attending birth	Doctor, nurse-midwife, nurse attendant, intern nurse, intern doctor		√	√
Obstetric complications	Yes, No		√	√

3.8.1 Primary outcomes

An abnormal baseline FHR was used as the primary outcome in all three studies. There is no global consensus on the range of normal baseline FHR. Some guidelines recommend a normal baseline range between 100-180 beats/min.[51,60] FIGO recommends a normal baseline FHR from 110-160 beats/min, thus abnormal FHR is considered to be <110 or >160 beats/min.[45] In this thesis, we used the range as stated in the national guidelines, which is defined as normal (120 to160 beats/min throughout labour and birth) or abnormal (absent, <120 or >160 beats/min). The classification of an abnormal FHR was reached after at least three abnormal assessments at different abdominal sites with the Pinard Stethoscope or the Handheld Doppler for intermittent assessment. For Moyo, a persisting abnormal FHR lasting for at least 3 minutes was classified as abnormal.

3.8.2 Secondary outcomes

In Study I, secondary outcomes included mode of birth (vaginal birth, caesarean section, assisted breech, and vacuum extraction), time intervals (admission to birth, detection of abnormal FHR to birth), perinatal outcomes, including Apgar scores at 5 minutes (abnormal was defined as an Apgar score <7) a surrogate measure of birth asphyxia,[4,92] bag mask ventilation, admission to neonatal unit for treatment, FSB, and death within 24 hours postpartum. Mode of birth was dichotomized into two categories (i.e., vaginal, including vacuum extraction, and caesarean section) due to there being relatively fewer cases in the vacuum extraction category. FSB was defined as an Apgar score of zero at both 1 and 5 minutes, with intact skin and suspected death during labour/birth. A composite perinatal outcome measure included FSB, admission to the neonatal area, and death within 24 hours.

In Study II, secondary outcomes included the Apgar score at 1 and 5 minutes; mode of birth, perinatal outcome at birth, and composite perinatal outcomes at birth and 24h, as defined in Study I above. Time

intervals included admission to abnormal FHR detection, admission to birth, abnormal FHR to birth, and last FHR to birth. After detection of abnormal FHR, the recorded intrauterine resuscitation procedures included discontinuing oxytocin, changing maternal position and administering intravenous fluids. Additionally, in Study III, partograph use was recorded, including frequency of documentation and intervals between FHR monitoring.

3.8.3 Background variables

Background variables for all studies included age of the mother (<20, 20–35, and >35 years), education level (no formal education, primary, secondary and tertiary), marital status (married/cohabiting and single), ANC visits (<4, and ≥4) and parity (1, 2–4,>4). GA (in complete weeks) was based on first trimester ultrasound (if available) or self-report of the last normal menstrual period. Preterm was defined as a GA <37 weeks; term pregnancy was defined as ≥37 and <42 weeks; and post-term as a GA >42 weeks. Antenatal maternal complications were recorded from Antenatal Cards or if the mother had any history of infection during her pregnancy. Birth weight in grams was recorded immediately after birth using a calibrated scale in the labour ward and was dichotomized as low birth weight if <2,500 g and normal if ≥2,500g.

3.9 Statistical analysis

In Studies I, II and III, descriptive statistics were presented as means (standard deviation, SD) or medians (inter quartile range, IQR) for continuous variables and as counts and proportions for categorical variables. Proportions were compared by Pearson chi-square tests. Odds ratios (OR) with 95% confidence intervals (CI) were calculated as estimates of the effect measure for categorical variables. Adjusted OR (AOR) values, using both logistic and multinomial regression, were estimated to account for imbalances in baseline characteristics and for an increase in subject-specific precision. The Shapiro–Wilk test was used to test for normality of continuous variables. Symmetrically distributed

continuous variables were compared by *t*-test, and the Mann-Whitney *U* test was used for skewed data. A *p*-value of <5% was considered statistically significant.

In Study II, in addition to above analyses, when comparing skewed time variables, we used linear regression analysis with a natural log-transformed outcome. Log-transformation was completed to improve model fit.[93] Due to this transformation, this effect is reported as relative change in median time in percentages.[94] In Studies I and II, CONSORT reporting guidelines were used to report the findings of these studies to provide transparency and reliable evidence on the effect of the interventions. STROBE was used as the reporting guideline for Study III.

3.10 Ethical considerations

3.10.1 Patient and public involvement

The need for the development of user-friendly FHR monitoring was initially evaluated at Haydom, a rural-based hospital in Northern Tanzania, and at Muhimbili Hospital. The Moyo was then designed and developed, in collaboration with clinical staff at these hospitals, at Laerdal Medical and Stavanger University Hospital in Norway. This design of Moyo was in response to the needs of the clinical staff and expectant mothers in these resource-limited settings to improve the quality of care during labour. In addition, focus was placed on the increased use of the partograph during labour and birth, with the ultimate goal of reducing FSB and END. Patients were informed of the design, advantages and disadvantage of their participation being recruited as participants Appendix 3.

3.10.2 Ethical clearance

All studies were conducted in accordance with the Declaration of Helsinki.[95] For Study I, Ethical clearance to conduct and publish the study was granted by the Publication and Ethical Committee of the

MUHAS (Ref: MU/DRP/AEC/Vol.XVIII/105). The protocols for Studies II and III were approved by both the National Institute of Medical Research in Tanzania (NIMR/HQ/R.8c/Vol. I/388, Appendix 4) and the Regional Committee for Medical and Health Research Ethics, Western Norway (REK Vest). Approvals to publish the studies were sought from NIMR (Study II: NIMR/HQ/P.12 VOL. XXIV/15, Study III: NIMR/HQ/P.12 VOL. XXV/57). All participants gave their written informed consent for inclusion before they participated in any of the studies. For parturient women who were in severe pain, randomization was conducted and differed consent to use the data was later sought, after birth and when the mother was in a more comfortable situation. Local permission to conduct each study was sought from the Muhimbili Hospital Directorate of Research and Consultancy and the Temeke Municipal Council. The protocols for Studies I and II were registered at ClinicalTrials.gov Identifier: NCT01869582 and NCT02790554, respectively.

3.10.3 Data and safety monitoring committee

The randomized studies were monitored by an independent data monitoring committee comprising one statistician and one paediatrician and aimed at protecting participant exposure to unreasonable risks and to determine whether the trial should be stopped before the scheduled completion date. Discontinuation was planned in case of imbalances in serious adverse effects (FSB and END). Blinded data analysis was conducted mid-way through the trial and the committee recommended the continuation of the study based on the results of this analysis.

4 Summary of results

This thesis aimed at comparing the effectiveness of FHR monitoring methods and associated improvement in quality of intrapartum care. The main findings of these three studies are summarized in this section and detailed results can be found in the individual papers, as appended.

4.1 Study I

In total, 2,844 eligible women were assigned to FHR monitoring with either Pinard (*n*=1,423) or Doppler (*n*=1,421) at Muhimbili. Abnormal FHRs were more often detected in the Doppler (6.0%) versus the Pinard (3.9%) arm (AOR = 1.59, 95% CI: 1.13–2.26). Secondary outcomes (Apgar score < 7, delivery of bag mask ventilation, mode of birth, perinatal admissions and deaths, and time intervals between events) revealed no significant differences (Table 8).

Table 8: Comparison of labour and perinatal outcomes in the Doppler versus Pinard arms among low-risk parturient women at MNH

Primary/secondary outcomes	Unadjusted OR	*p*-value	AOR*	*p*-value
Abnormality of FHR	1.56 (1.12–2.21)	0.012	1.59 (1.13–2.26)	0.008
Mode of birth: Caesarean section	0.98 (0.79–1.23)	0.89	0.96 (0.77–1.21)	0.76
Apgar 5 minutes <7	1.31 (0.76–2.26)	0.40	1.38 (0.79–2.24)	0.25
Bag Mask ventilation attempted	1.19 (0.80–1.57)	0.51	1.18 (0.84–1.65)	0.35
Admissions to neonatal unit at birth	1.36 (0.82–2.25)	0.24	1.42 (0.86–2.33)	0.17
Fresh stillbirths	0.63 (0.20–1.92)	0.41	0.67 (0.22–2.07)	0.49
Still admitted at 24 hours	1.22 (0.65–2.28)	0.63	1.25 (0.66–2.34)	0.49
Perinatal deaths (FSB + deaths within 24 hours)	0.59 (0.22–1.65)	0.32	0.62 (0.26–1.73)	0.36
Composite outcomes (Perinatal deaths and admissions)	0.99 (0.59–1.69)	0.98	0.73 (0.34–1.47)	0.35

*Logistic and multinomial regression analysis adjusted for maternal infection and sources of admission.
Abbreviations: AOR, adjusted odds ratio; FHR, foetal heart rate; FSB, fresh stillbirth

4.2 Study II

In total, 2,973 eligible women were assigned to FHR monitoring with either Moyo (*n*=1,479) or Doppler (*n* = 1,494) at Muhimbili. Abnormal FHRs were more often detected in the Moyo arm (13.3%) versus the Doppler (9.8%) arm (adjusted odds ratio = 1.46, 95% CI: 1.16–1.76) (*p*=0.002), as shown in Table 9. There were higher rates of caesarean section in the Moyo arm as compared to the Doppler arm; i.e., 18.9% versus 12.9%, respectively (*p*=0.03). Overall, perinatal outcomes did not differ between the two arms (Table 9).

Table 9: Comparison of labour and perinatal outcomes between strap-on Moyo versus intermittent Doppler

Primary/secondary outcomes	Unadjusted OR (95% CI)	*P*-value	AOR (95% CI)	*P*-Value
FHR during labour				
Abnormal	1.41 (1.12–1.77)	0.003	1.46 (1.16–1.76)	0.002
Mode of childbirth				
Caesarean section	1.58 (1.29–1.93)	0.001	1.26 (1.01–1.53)	0.031
Apgar score at 1st minute				
Abnormal (<7)	0.79 (0.61–1.03)	0.082	0.92 (0.69–1.22)	0.56
Apgar score at 5th minute				
Abnormal (<7)	0.83 (0.55–1.25)	0.38	0.95 (0.69–1.63)	0.80
Birth outcomes				
Admitted for treatment	0.73 (0.56–0.94)	0.017	0.88 (0.69–1.17)	0.39
FSB	0.98 (0.39–2.48)	0.97	1.43 (0.55–1.19)	0.46
Admitted + FSB	0.74 (0.58–0.96)	0.021	0.91 (0.69–1.19)	0.50
24–hours outcome				
Still admitted for treatment	0.75 (0.57–0.98)	0.036	0.93 (0.69–1.24)	0.52
FSB+END	1.09 (0.46–2.57)	0.85	1.59 (0.65–3.90)	0.35
Admitted + FSB + END	0.77 (0.59–1.00)	0.051	0.97 (0.72–1.26)	0.71

Table 10 shows that time from admission to birth was comparable between study arms (*p*=0.40). Time interval from admission to abnormal FHR detection was 14% sooner in the Moyo arm as compared to the Doppler arm. Time from last FHR measurement to birth was significantly shorter in the Moyo arm by 12% compared to the Doppler arm, which showed an increased frequency of FHR monitoring. Among births with abnormal FHR, time from detection to birth was 36% longer in the Moyo arm as compared to the Doppler arm. Time from detection

to birth was significantly longer in those giving birth by caesarean section (nearly 2 hours) compared to vaginal birth.

Table 10: Comparison of time intervals between intermittent Doppler and strap-on automatic Moyo

Time intervals	Unadjusted effect size (%)	*P*-value	Adjusted effect size (%)	*P*-value
Admission to abnormal FHR Detection	1 (-17–22)	0.96	-14 (-29–4)	0.12
Admission to birth	15 (8–20)	<0.001	-2 (-7–31)	0.40
Last FHR to birth	-8 (-16–1)	0.082	-12 (-19–4)	0.006
Abnormal FHR to birth (All births)	52 (22–90)	0.001	36 (9–70)	0.007
Abnormal FHR to birth (vaginal birth)	52 (19–95)	0.001	36 (5–77)	0.018
Abnormal FHR to birth (caesarean section)	8 (-21–48)	0.50	8 (-21–48)	0.68

4.3 Study III

A total of 4,082 eligible women were provided with FHR intermittent monitoring with Pinard (*n*=1,640) in the pre-intervention and with strap-on Moyo (*n*=2,442) in the post-implementation. Abnormal FHRs were more often detected post-implementation with Moyo (8.0%) versus pre-implementation with Pinard (1.6%) (AOR = 6.9, 95% CI: 3.9–12.2) (p<0.001) (Table 11). Higher rates of caesarean section and vacuum birth were recorded post-implementation with Moyo as compared to pre-implementation with Pinard (5.4 vs 2.6% and 5.8 vs 2.2%, respectively) (p<0.001).

Table 11: Unadjusted and adjusted comparison of FHR documentation practices and outcomes post vs pre-implementation of strap-on automatic Moyo

Variable	Unadjusted OR (Moyo vs Pinard)	*p*-value	Adjusted OR (Moyo vs Pinard)**	*p*-value
Intrapartum FHR monitoring				
Yes	38.5 (28.57–50.0)	<0.001	45.5 (34.4–62.5)	<0.001
FHR during labour*				
Abnormal	5.44 (3.14–9.41)	<0.001	6.9 (3.9–12.2)	<0.001
Mode of birth				
Caesarean Section	2.23 (1.57–3.16)	<0.001	5.8 (3.3–10.0)	<0.001
Vacuum	2.84 (1.96–4.12)	<0.001	3.85 (2.5–5.8)	<0.001
Received resuscitation	0.57 (0.48–0.68)	<0.001	0.63 (0.52–0.75)	<0.001
Stimulation	0.74 (0.61–0.89)	0.001	0.86 (0.71–1.06)	0.14
Suction	0.95 (0.78–1.14)	0.57	0.99 (0.81–1.22)	0.96
Ventilation attempted	1.95 (1.37–2.78)	<0.001	2.28 (1.57–3.30)	<0.001
Low Apgar score at 5 minutes (<7)	1.58 (0.95–2.64)	0.19	1.58 (0.95–2.64)	0.19
Birth outcomes				
Admitted to neonatal unit	1.55 (1.09–2.19)	0.014	1.71 (1.18–2.47)	0.005
Fresh Stillbirths	0.78 (0.28–2.15)	0.63	0.90 (0.30–2.63)	0.85
Neonatal outcomes 24-hours				
Admitted to neonatal unit	1.87 (1.19–2.91)	0.006	2.11 (1.33–3.38)	0.002
END	0.95 (0.30–3.01)	0.94	0.99 (0.29–3.30)	0.97
(FSB+END)	0.98 (0.43–2.17)	0.96	0.73 (0.31–1.72)	0.47

*Only those who were monitored are included in the denominator, **Adjusted for baseline imbalances; SVD= Spontaneous vaginal birth, FSB= Fresh Stillbirths, END=Early neonatal deaths, AOR = Adjusted Odds Ratio

An increased proportion of women received intrauterine resuscitation post-implementation in the Moyo group versus the Pinard group. Specifically, oxytocin was discontinued in 2.4% of women as compared to 0.4%; changing position and initiating IV fluids increased to 5.5% from 0.1%, and to 6.5% from 0.5%, respectively, post versus pre-implementation. Figure 8 shows that, during the post-implementation period, 2% of the women had the FHR undocumented in the partograph compared to the pre-implementation period, which was 46%. The frequency of the FHR monitoring/documentation in the partographs was higher post-implementation.

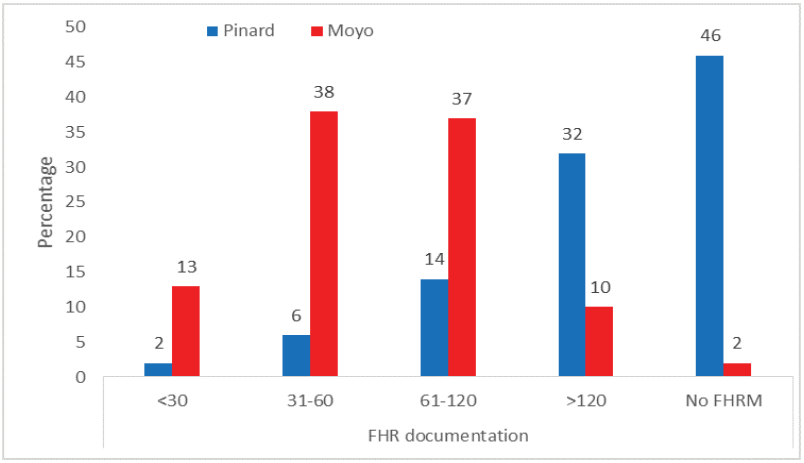

Figure 8: Frequency of foetal heart rate monitoring and documentation pre-implementation (Pinard) vs post-implementation of the Moyo

Table 12 shows that the median time interval from admission to birth was 13 min shorter post-implementation (p=0.002), the median time interval from the last FHR assessment to birth was 45 versus 60 minutes (p<0.001), and the median time interval between FHR documentation in the partograph was every 60 versus every 150 minutes (p<0.001), post- versus pre-implementation, respectively.

Table 12: Observed time intervals during labour and comparison pre versus post-implementation periods

	Pre-implementation Pinard	**Post-implementation Moyo**	***p*-value**
Admission to birth	**(*n*=1640)**	**(*n*=2442)**	
	225 (130, 387)	212 (117, 355)	0.002
Admission to Abnormal FHR detection	*n*=14	*n*=191	
	230 (120, 630)	138 (65, 302)	0.184
Last FHR to birth	*n*=890	*n*=2389	
	60 (30, 100)	45 (21, 85)	<0.001
Between FHR monitoring	*n*=890	*n*=890	
	150 (86, 299)	60 (41, 86)	<0.001
Abnormal FHR to birth	*n*=14	*n*=191	
	28 (19, 57)	43 (23, 80)	0.255

Data is presented as median (IQR)

5 General discussion of results

This thesis found that FHR monitoring using the strap-on automatic Moyo monitor was superior to using a Hand-held Doppler (Study II), which was in turn superior to using a Pinard stethoscope in the detection of baseline FHR abnormalities in labour (Study I). The strap-on Moyo monitor detected abnormalities significantly earlier as compared to the Doppler and the Pinard methods of FHR monitoring. Time from detection of abnormal FHR to birth was found to be longer in the strap-on Moyo arm compared to the Doppler and Pinard monitoring methods (Studies II and III). Midwifery practices improved significantly after the implementation of the strap-on Moyo device. These practices included improved frequency of FHR assessments, partograph use/documentation in labour, and intrauterine resuscitation (changing of mother's position, stopping oxytocin and administration of intravenous fluids). Also, the use of vacuum birth and caesarean section increased in both Studies II and III. The use of continuous Moyo was not associated with any statistically significant difference in overall perinatal outcomes, because the studies were not powered to do so.

5.1 Abnormal FHR detection

These findings on baseline FHR abnormalities are comparable to prior studies in LIC, where the Doppler technologies detected more FHR abnormalities.[7,68] There are several reasons for an increase in the detection of abnormal FHR using the Moyo and Doppler monitors compared to the Pinard. The Moyo and Doppler devices use Doppler technology, which is more sensitive and provides digital sound and readings, which do not require much skill to interpret and can easily be confirmed by peers. The reading is displayed within a short period of time and involves less targeting for the foetal heart, unlike the Pinard, which requires the attendant to perform a mental arithmetic calculation while listening and while watching the clock. Further, the Pinard is

difficult to use in certain labouring and birthing positions and requires a complete minute of counting to calculate FHR.[45] Additionally, due to the subjective nature of the Pinard stethoscope readings, it is difficult to use in a noisy labour ward. Midwives may feel unsure about its reliability and hence are less likely to use it compared to the two electronic devices.[67,96] In prior studies, mothers further reported that the two techniques were more comfortable compared to the Pinard stethoscope.[7,64]

However, acid-base tests were not available to confirm of foetal hypoxia. Furthermore, studies in this thesis included a narrow range of normal baseline FHR (120–160 beats/min) as compared to other studies and international guidelines. These may have resulted in high false positive rates due to high sensitivity and the low PPV, as documented previously.[29,36–38] These FHR positivity rates need to be carefully interpreted and supplemented with adjunct tests, such acid-base tests and intrapartum ultrasound coupled with appropriate clinical judgement, to make appropriate decisions.

This thesis also found that continuous Moyo monitoring detected abnormal FHR more frequently than did the intermittent Doppler monitoring technique (Study II). The reasons may be due to increased sensitivity and continuous strap-on monitoring of the Moyo device, which is equipped with a 9-crystal sensor as compared to the single-crystal sensor in the Doppler. Additionally, Moyo has an increased detection area, and is equipped with an audio-visual alarm, where abnormal FHR is detected, and a 30-minute histogram review of the tracing. Furthermore, on admission, mothers were instructed on how the Moyo was being used and were told to call the midwives or any clinical staff when the colour changed on the monitor readings and/or if there was an alarm. Moreover, mothers continuously heard the foetal heart sounds, providing reassurance of their babies' viability. Given the interactive nature of the midwife-mother relationship, the monitor may

have influenced the increased detection of abnormal FHR which could have been missed otherwise.[97]

The observed difference in FHR detection using the hand-held Doppler between Study I (6.0%) and Study II (9.8%) can be explained by two main reasons. First, in Study I, we included only term parturient women (>36 weeks), who have less risk of having distressed foetuses, as compared to Study II, which included parturient women from 28 weeks. Secondly, due to time differences in conducting the studies, there may be changes in the risk for the population of women who attended Muhimbili compared to a prior population. For example, historical data showed a relative increase in caesarean section rates from about 30% in 2013 to more than 50% in 2016, showing a significant change in population dynamics of the women who were attended at Muhimbili.

5.2 Quality of care improvement

There had been an improvement in the level of skilled birth attendance, which resulted in an increase in the number of facility-based births; to almost 63% in Tanzania in 2015[81] and 73% globally by 2017.[15] However, this demand has not been matched by a parallel improvement in the quality of care provision. Tanzania reported a 54% shortage of health care workers in 2015.[75] A significant number of deaths may thus be attributed to inadequate care provision during labour.[5,11,17,98]

An ENAP report documented that the use of partograph is a marker of quality improvement measures in labour. This tool, developed and recommended by the WHO, has been evaluated in different countries and it has been shown that, if used properly, it is a prerequisite for significant improvement in intrapartum care, thus resulting in the reduction of maternal and foetal deaths and early neonatal morbidity and mortality.[1,39,42,99–102] Unfortunately, its use in LIC is low, due to the absence of user-friendly intrapartum FHR monitoring devices where the most frequently used device is the Pinard stethoscope. The finding of

low FHR monitoring documentation (54%) in the pre-implementation period of Study III is consistent with previous studies conducted in Sub-Saharan Africa and South Asia.[42,43,81,103] Another study, carried out in a tertiary facility in Zanzibar, found that 80% of FSB have no documented FHR, partly due to a shortage of human resources and a lack of appropriate devices to assess labour.[100] Health care workers with demanding workloads are more likely to miss important changes in the foetal condition without access to an appropriate assessment device.[45,67]

The improvements shown in the quality of intrapartum FHR monitoring, i.e., partograph documentation, increased FHR monitoring frequencies and increased intrapartum resuscitation, in Study III are probably due to the recognised user-friendly features of the Moyo device. These features enable the midwife to attend several patients concurrently, with minimal interruption to their routine duties, which is one major benefit of this device when responding to increased numbers of facility birth.[15,81] Communication forms an important component of the experience of care in the WHO quality of care framework (Figure 5). The use of the Moyo device improves effective communication between the midwife and expectant mothers and reassures and empowers the mother.[97]

As documented in the quality of care framework (Figure 5), this improved quality of intrapartum care provision is integral to the causal pathway towards a reduction of adverse perinatal outcomes. If coupled with continuum of care, i.e., locally developed guidelines and equipped birth attendants, and timely response to operative births and resuscitation of new-born, improved quality of care provision may improve the outcomes.[26,49,104]

Despite improved rates, the documentation of FHR monitoring frequencies of <30 min and <60 min were still low (13% and 51%, respectively) with continuous monitoring as compared to the available recommended guidelines (Table 1).[45,51,105] This relatively low frequency of documentation indicates that other factors in the continuum of care

contribute to this suboptimal documentation. As documented earlier, the use of this WHO partograph should be coupled with simple, timely and realistic management guidelines to meet the demand and achieve the desired effect. For example, in the newly developed locally-tailored document for intrapartum care, the PartoMa guidelines, developed in a tertiary facility in Zanzibar, documentation of FHR every 30 minutes is recommended, but less than every 60 minutes was accepted.[10,106] The implementation of these tailored guidelines has resulted in improved perinatal outcomes.[10]

In addition, the midwife was able to respond to the abnormal FHR by implementing intrauterine resuscitation attempts more frequently in an effort to reduce intrapartum hypoxia, preventing vital organ demage.[1,2,107] These resuscitation methods included changing the mother's position, stopping oxytocin, and giving intravenous fluids interventions, which increases body perfusion. Furthermore, in Study III, we observed more than double an increase in the number of vacuum extractions. Vacuum births are immediate measures made in response to persistently abnormal FHR with full cervical dilatation. Given the fact that the infrastructure for performing caesarean sections may not be readily available in all settings, properly conducted vacuum extraction may improve perinatal outcomes.

These cumulative findings indicate that monitoring with the strap-on automatic Moyo, a device developed and tailored to respond to local needs in LIC, significantly improved midwifery standards and the quality of care provided during the intrapartum period, as recommended by local and international guidelines. The device was developed with multiple consultative meetings with clinical staff and patients in the low-resource setting, responding to local needs on FHR monitoring. This improved quality of intrapartum care is the proxy indication towards improved perinatal outcomes, as described in the conceptual framework and the WHO quality of care guidelines (Figure 5).[26]

5.3 Time intervals

In both Studies II and III, it was observed that the Moyo detected abnormal FHR earlier than did the Doppler and Pinard. An ability to detect earlier FHR abnormalities earlier is a good intrinsic property in a screening tool as it provides chances of improving outcomes, through associated timely response.[33] Moreover, the time intervals from detection of abnormal FHR to birth were found to be longer in the continuous Moyo arm than in the Doppler and Pinard arms. As observed in Study III, there was increased intrauterine resuscitation in response to FHR abnormalities, which may have resulted in longer time to birth in the Moyo groups.

However, the median time to caesarean section was too long (>2 hours in both arms of Study II). These delays to birth among the caesarean section group may have potentiated more instances of foetal compromise and hence adverse perinatal outcomes. Timely caesarean sections are needed if improvements in perinatal morbidity and mortality are expected. For example, a study conducted in Zanzibar revealed that an hour's delay led to a 20% increased odds of FSB.[100] These delays in timely response may be due to multiple factors. Firstly, both health facilities are tertiary referral level with a high volume of clients and are understaffed (midwife–patient ratio averaging more than 1:5). The ability to respond to every decided caesarean section may have been highly compromised. Secondly, caesarean sections were not always readily available due to high demand, leading to queuing for this intervention or a lack of skills in conducting instrumental vaginal births. These might have led to delayed time from detection to birth.

5.4 Perinatal outcomes

In all three studies, despite the increased detection of an abnormal FHR, there were no statistically significant differences in overall perinatal outcomes (i.e., Apgar score, FSB, END, neonatal admission). There are several potential reasons for this lack of difference.

Firstly, the studies were performed among relatively low-risk pregnant women, who have a lower chance of having distressed babies, and hence fewer adverse perinatal outcomes. In order to detect such small proportion differences, a very large sample would have been needed,[65,72,108,109] and the studies were not powered to do so.

Secondly, while an abnormal FHR was detected earlier using continuous rather than intermittent monitoring, the time to birth was longer in the Moyo arm. While it is possible that after the detection of FHR abnormalities resuscitation was instituted, leading to continuation of normal labour, the delay could also be due to overwhelmed staff. Such a delay may lead to lack of improvements in perinatal outcomes that could have resulted from early detection. Recent studies conducted as part of the Safer Births project in rural Tanzania documented that adverse perinatal outcomes were associated with delayed birth of babies with detected FHR abnormalities.[110,111] Timely birth of these babies may have improved perinatal outcomes in the continuous Moyo groups. Remarkably, in the studies in this thesis, the median time from abnormal FHR detection to birth by caesarean section was much higher (almost 2 hours) than recommended (30 min).[112] Potential reasons for this delay may relate to the fact that some of the women scheduled for caesarean section were held back due to other more urgent caesarean section cases. Additionally, the labour ward and obstetric theatre are situated in different buildings at both hospitals, hence increasing the time lag from decision to incision. It is believed that, if the early detection was coupled with timely responses, this would have resulted in the statistically significant differences that were found in the perinatal outcomes in Studies II and III.[59,72]

5.5 Caesarean section rates

In Studies II and III, the Moyo arm had higher rates (18%) compared to the Doppler (13%) arm, results that are consistent with previous studies on continuous FHR monitoring.[108] These studies, conducted in HIC,

showed that continuous electronic foetal monitoring was associated with higher detection of abnormal FHR and more operative births. Most tests with high sensitivity have shown to have low PPV, which may lead to unnecessary interventions, such as caesarean sections.[32,34] In HIC, misinterpretation of the CTGs readings and the use of CTG as a predictive rather than a screening tool for caesarean section and cerebral palsy-related litigation issues, were reported as the reasons for increased the number of unnecessary caesarean sections.[58,70,71] The same reasons may have caused increased rates of caesarean section seen in the continuous monitoring groups in these studies. Adverse events during labour are multifactorial and should not entirely rely on FHR rather than on the general status of the mother and foetus. Moreover, intrapartum interventions such caesarean section and resuscitation need to be rational and executed in a timely manner to avoid adverse perinatal events.[71] For example, large cohort studies in the Netherlands and the United States reported better perinatal outcomes in the use of continuous FHR monitoring, showing that the use of continuous monitoring coupled with rational and timely operative birth may not be entirely detrimental.[72,113] Moreover, in this study, clinicians and midwives may not have undertaken timely and appropriate interventions once the decision was made to perform a caesarean section.[114]

6 Discussion of the methods

In the philosophy of science, knowing the causes of things helps us to understand how things in the world work and how we can make use of this knowledge to improve social systems to change the world in which we live.[115] Although there have been multiple debates across the world on causation as to whether science should rely on the existence of causal routes, it remains important in the knowledge produced in both the social and natural sciences that we describe the relationship between events and to make inferences based on a convincing body of evidence.

In this thesis we employed a probabilistic and interventionism account of a difference-making view of causation philosophy.[116] In a probabilistic account of causal inference, the probability of an event occurring or not occurring is higher in the presence of the cause than when it is absent.[117] On the other hand, the interventionism/manipulation theory suggests the cause happens before the event/outcome and hence there is mostly some time lag between the two, as is the case in experimental studies.[115,117,118]

Our experimental (randomized and pre and post) study designs were based on these two theories of causal relationships. Both designs aimed at ascertaining the causal relationship between the interventions (FHR monitoring) and several outcomes (quality of care provision and perinatal outcomes). The strengths and limitations of these methodologies are discussed in the coming sections.

6.1 Study design and internal validity

This thesis employed a prospective study design, which is the preferred and best design for establishing relationships between the outcome of interest and exposure variables. In this model, the investigators observe the developments of the outcome as per the exposure of interest and hence establishing associations between different factors in relation to

time.[33] In this thesis, a variety of designs were used to achieve the overall aims stated above.

Randomized controlled trials (RCT) are among the most credible (gold standard) and sit at the top of the hierarchy of study designs in terms of quality of evidence with respect to their ability to establish causal associations between an intervention and an outcome.[119,120] RCTs provide evidence with unbiased comparison between groups.[121–123] Randomization ensures that all other potential confounders are allocated randomly between the study arms and differences that will be observed occur by chance rather than by bias. The detection rates of FHR abnormalities between either of the two study arms would be similarly equal if the FHR monitoring devices were switched between the arms. The advantages of using RCT include the elimination of selection bias.[119,124]

Conversely, accurate estimation of the effect measured in RCT methodology relies on measurements that have very little error. There are two types of potential errors; namely, systematic, and random errors. Systematic errors can occur because of errors in the data collection equipment or in the study design. An estimate that has little systematic errors, i.e., less biases, is described as being 'valid', whereas that with few random errors is termed as 'precise'.[125,126] The validity of inferences concluded as they refer to members of the target population is named 'internal validity', whereas that pertaining to external population is termed as 'external validity' or 'generalizability'.[124]

Biases that result from errors in the design and conduct of studies lead to a reduction in internal validity of certain studies and can lead to the underestimation or overestimation of the true intervention effect (effect size). In the following sections, different sources of biases are discussed. Also presented is how these were overcome in this thesis to increase the reliability of the results presented here.

6.1.1 Selection bias

Selection bias refers to systematic error in which there exists differences between the baseline characteristics of the groups that are being compared. In order to prevent selection bias in allocating interventions to participants, the random sequence generation and concealment rules were employed

If random sequence generation is perfectly implemented, prognostic factors will be balanced evenly across the intervention groups on average. Some systematic reviews in studies that have had inadequate sequence generation have resulted in exaggerated estimated measures of intervention.[127] In Studies I and II, the two comparison groups were computer generated using simple randomization with an equal allocation ratio by an independent statistician to ensure equal distribution of the potential risks.

To counter the knowledge of the next sequence, efforts were made to conceal the allocation of the sequence to avoid systemic enrolment into a certain treatment group. Analyses of studies with poor allocation concealment found an increase of 18–40% beneficial effect of intervention as compared to studies with proper concealment.[123,128]

In Studies I and II, details of the allocated group were given to the study coordinator, who used sequentially numbered opaque sealed envelopes. The allocation sequence was concealed from the clinical staff who enrolled participants and assessed the outcomes. Envelopes were opened only after the enrolled participants completed. It is believed that this reduced the effect of the perceived effectiveness of certain FHR monitoring devices among some clinical staff.[123]

6.1.2 Masking, performance and detection bias

Masking refers to making either participants and/or implementors unaware of the interventions in which participants are allocated. In double masking, both participants and implementors are masked. A lack of masking may systematically affect performance and how outcomes

are determined (detection bias), leading to the exaggeration of the intervention by up to 9%.[128] This lack of masking increases the chances of the Hawthorne effect occurring, i.e., the participants are more likely to perform to the investigator's expectations if their allocation is not masked.[93] However, a double-masking strategy was not possible in these two RCTs, and there may have been systematic preference of devices, leading to biased assessments. However, the effect may have been minimal, as the Hawthorn effect is more prevalent in studies with subjective outcomes and fewer participants, contrary to the studies in this thesis, which had hard outcomes and large sample.[129]

6.1.3 Attrition bias

Sometimes referred to as incomplete outcome measure is attrition bias; a systematic difference between randomized groups in withdrawals or drop-out from a study. Dropouts may have certain characteristics, leading to systematic differences. In our studies, all women who consented and were randomized were followed until birth and the babies were followed either until discharge or until 24 hours maximum with no loss to follow-up, reducing the incidence of attrition biases.

6.1.4 Selective outcome reporting

Statistically non-significant results are more likely to be selectively withheld from publication with the purpose of concealing an ineffective intervention. In this thesis, the studies were registered at ClinicalTrials.gov with a full description of their primary and secondary outcomes prior to commencement. All outcomes, including non-significant results, were reported in published papers.

6.1.5 Baseline imbalance and confounder

Baseline imbalance in background characteristics strongly related to outcome measures can cause bias in the intervention effect estimate. This can occur by chance and should be taken into consideration. In Study II, significant imbalances were found in baseline factors that confounded secondary outcomes. GA, which influences perinatal outcomes and

cervical dilatation with an effect on time intervals, was imbalanced at baseline despite efforts to sequence their generation and concealment. To mitigate the confounding effect of these variables, multivariate regression was conducted for perinatal outcomes. However, potential rest-confounding factors, either not reported or unknown, may have affected the interventional outcomes. In this study, we used a simple randomization scheme, which may have caused imbalances in treatment groups within confounding factors and which may lead to type 1 error, i.e., false positive rates. However, we believe that the sample size was large enough to counterpoise this potential bias.[120]

6.2 Biases in a pre- and post-implementation study (Study III)

Pre- and post-intervention studies, a type of quasi-experimental study, are studies that aim to evaluate interventions but that do not use randomization. The main weakness of a quasi-experimental design is a lack of randomization, which may affect the internal validity of the research findings.

This study design was chosen for two main reasons. Firstly, as documented earlier, when an intervention is to be introduced in a clinical setting with multiple outcomes to be observed, a pre- and post-intervention (quasi-experimental designs) is the preferred design.[130] In this study, multiple quality-of-care-related outcomes were being investigated. Due to these multiple outcomes, this was the preferred design. Secondly, previous studies, including Study I in this thesis, have documented an increased effectiveness of FHR abnormalities detection using Doppler technology.[7,50] The Moyo device uses Doppler technology with increased sensors, and it was therefore believed that its implementation would be beneficial in terms of quality of FHR monitoring and, consequently, perinatal outcomes.

However, a pre- post-implementation design is threatened by several factors that may affect its internal validity.[131] First, difficulties may be encountered in controlling for important confounding variables due to lack of randomization. Secondly, the observed effects may be related to natural changes that the midwives experience with the passage of time, i.e., their maturation. Thirdly, there may be other events happening concurrently with an intervention which may affect the outcomes, leading into false conclusions. Fourthly, there may be some interactions with other concurrent interventions, and lastly, cyclical seasonal trends may threaten the attribution of an observed outcome to an intervention.[131–133]

To increase the internal validity of the findings, most of the potential confounders were identified and controlled for in the multivariate regression models. Secondly, the time from pre- and post-intervention was too short for maturation to have made many significant changes in the quality of care provision. Thirdly, to the best of our knowledge there was no concurrent intervention, events or systemic changes that might have improved these midwifery practices, and an identical complement of staff was available during both time periods. Fourthly, the follow-up time was short; up to 24 hours post-birth, hence the number of participants lost to follow-up bias was minimized. Moreover, the Hawthorne effect may have little influence on the differences in quality of care observed as, in both time periods, clinical staff were aware of the study that was going on and the sample size was too large for this effect to influence the findings.

6.3 Statistical analysis

Before the commencement of these studies, we performed sample-size calculations using estimate measures from previous studies (Studies I and II) and hospital records (Study III).

Intention to treat (ITT) analyses were used. This is the recommended analysis as it is accepted as the least biased method of estimating the interventional effects of experimental studies investigating causality.[134] For births with normal outcomes who were discharged before 24 hours, the last observation was carried forward and an imputation approach was assumed.[135] However, ITT may be limited by the fact that, where more participants do not receive the allocated interventions, a dilution of treatment effect can occur.

6.4 External validity

External validity or generalizability refers to how the results are applicable to or inferred by the general population. In our studies we had clearly defined inclusion and exclusion criteria. We included singleton pregnant women, with GA above 28 weeks admitted with normal FHR in an active phase of labour. Because both Muhimbili and Temeke are referral hospitals, a significant number of women were excluded in this study as they mostly arrived in either the second stage of labour, with abnormal FHR, multiple pregnancies or had elective caesarean sections. Hence the average intervention effects on primary outcomes (FHR abnormalities) and secondary outcomes, such as perinatal morbidity and mortality, caesarean section rates are more likely to be differ (underestimated) compared to the general population of parturient women.[124] These strict inclusion criteria posed low external validity. However, it is anticipated that the rates of detection of abnormal FHR would be proportionally increased, as found in these studies.

6.5 Ethical Issues

Both biomedical and social science research, when performed with human participants, are bound to ethical principles. The Declaration of Helsinki, decreed in 1964, emphasized the principles of autonomy, beneficence, non-maleficence and justice and has since been amended several times.[95] These principles are aimed at safeguarding the interest

of the research participants and the community at large. Research should be conducted in the way that the study participants, and the communities and environments in which they are based, are safeguarded against serious adverse events.[136] These considerations have been carefully attended to for each of the studies presented in this thesis, and have followed each of the basic ethical principles discussed below.

6.5.1 The consent processes

The concept of informed consent originated from the Nuremberg Trials, parts of which were held to try Nazi doctors for their participation in crimes against humanity in the 1940s. The concept was expanded by the World Medial Association and first mandated in 1964 under the Declaration of Helsinki.[137] A person should be made aware of all possible benefits and any potential harm which may result from their participation in the research and they must be free from coercive pressures or harms, especially those amongst the vulnerable population.[95]

In this PhD research project, the participants' consent form was designed to include the necessary components and information in Kiswahili language for easy comprehension (Appendix 3). The participants were informed that their refusal to participate would not deny them being provided standard care in the management of their treatment. They were also informed that they had the right to withdraw from participation

However, there were some issues which raised ethical dilemmas. Firstly, some labouring women might have been in such severe pain that, on admission, the consent process may not have been conducted in an effective, free and comfortable manner. To deal with this ethical issue, we requested amendments to the protocol to include a "differed consent" process from the institutional review boards; both in Tanzania and Norway. In this amendment, an eligible labouring woman who was not able to provide consent at the time of admission was randomized per protocol. The consent was then sought after she had given birth to the

baby and was in a comfortable state and then able to better understand the study objectives and intention of the results.

Secondly, nurse-midwives working in the labour ward screened and recruited the mothers in the study and took them through the consent process. Labouring women may have been afraid to refuse to consent due to a perceived authoritative power possessed by the nurses, which may be perceived as provision of inappropriate care. To address this issue, we conducted training with the research nurses to emphasize the importance of adhering to ethical principles for ensuring free and informed consent.

6.5.2 Vulnerable population, consent process and child protection

A vulnerable population includes people who lack an ability to make personal life choices, decisions to maintain independence and self-determine necessitating requirement of potential safeguard against real or potential harms for the protection of their welfare and rights.[138] They include pregnant women, foetuses, children, mentally disabled persons and the poor.

According to Tanzanian law, a child is anyone aged below 18 complete years, but females can be married at as young as 14 years. Within this contradiction we assumed the positioning of an emancipated minor concept. An “emancipated” minor signifies that the individual has assumed most adult responsibilities before reaching the adult age (usually 18). Those participants who were aged under 18 years were assigned the designation of emancipated minor in our studies, as they were already pregnant (a role assumed but adults) and/or either married, taking care of children and holding other roles assumed to have the ability to make an informed decision.

6.5.3 Responsibility for avoiding harm

It has been earlier documented by consequentialism theorists that research activities should provide good outcomes only. However, current debates recommend weighting the types of risks and damages versus the

positive values of research as these may be just as appropriate and satisfactory as the whole.

In this project involving foetal wellbeing monitoring, mothers and their expected babies may be subjected to serious harm, such as the distress of the foetus, the death of the new-born and/or babies born with various degrees of impairments due to inadequate monitoring. To control for these adverse serious events, an independent data monitoring committee was established, comprising a paediatrician and statisticians. Their roles were to conduct analysis and perform a midway evaluation.

6.5.4 Norms, value and integrity of research

Scientific dishonesty is defined as actions or omissions that lead to false or distorted research results or that give misleading information related to specific research findings.[137,139] For scientific integrity in this thesis, the protocols were registered on the ClinicalTrial.gov database. Data were analysed and interpreted by multiple investigators. All authors had a role in making sure that they critically reviewed the results objectively and were in consensus with the results, their interpretation, and the related conclusions and recommendations. Further, the research funding received for this project was independent. Before accepting the funding, it was clarified that the funders had no role in the study design, data collection, analysis, or the decision to publish the manuscript.

7 Conclusions:

This PhD project contributes to the scientific body of evidence on effective FHR monitoring devices during labour in referral hospitals in a low-resource setting. The continuous monitoring Moyo device was found to be the most effective in the detection of abnormal FHR, followed by the handheld Doppler, when both were compared to the Pinard stethoscope. The use of continuous monitoring should help birth attendants to recognise distressed foetuses complementing their midwifery skills. Adjunct tests, such as acid-base tests may facilitate decision making, however such tests are rarely available in LICs.

Moreover, the longer time from abnormal FHR detection to birth in the continuous Moyo arms may have been due to concurrent intrapartum resuscitation or due to overwhelmed clinical staff and inadequate infrastructure for timely interventions. Overall perinatal outcomes did not differ; likely because of relatively low power to detect small differences.

The findings in this PhD project suggest that implementation of a continuous FHR monitoring contributed to better partograph documentation. It further improved the quality of intrapartum care (timely detection and frequent resuscitation). Continuous FHR monitoring using an appropriate device in LICs may be considered in the continuum of care provision in tertiary hospitals, as the shortfall in human resources continues to be an addressed.

7.1 Recommendations

7.1.1 Health system

- Trained skilled birth attendants need to be provided with appropriate working tools, and facilities be staffed with those who possess the necessary skills to provide quality improvement services.
- Low level health facilities should be strengthened so that women are attended at those settings and to relieve the tertiary facilities of the high volume of births. Services that need to be strengthened include operating theatres, blood transfusion services, emergency drugs, and resuscitation equipment, so that complications can be managed locally.
- The development of appropriate technologies suitable for LIC need to be participatory responding to the local needs of the clinical staff and patients. This will increase the acceptability and usefulness of such innovations.

7.1.2 Institutional/Hospital level

- Appropriate FHR Monitoring devices need to be made available in the labour ward so that surveillance of FHR can be structured and recorded appropriately in the partograph, quality of care can be improved, and intrapartum-related morbidity and mortality can be reduced.
- Adjunct tests, such as admission and intrapartum ultrasound and blood gas tests, need to be made available at tertiary hospitals to complement screening tests.
- There should be locally adopted guidelines developed by participatory and consultative meetings with clinical staff on the appropriate management of any identified intrapartum abnormalities.
- Continuous medical education must be provided to existing and incoming clinical staff in low doses and at high frequency so that skills can be propagated successfully.

- Also, an emphasis needs to be placed on providing training to labour ward clinical staff (doctors and midwives) on instrumental birth such as the use of vacuum. Caesarean section should be conducted only when optimally indicated and not substituted for vacuum births.
- The hospital administration needs to endeavour to increase and retain staff who are already working in the labour ward. A high turn-over of staff was evident during the studies included in this thesis, which proved to be a huge challenge as well as revealing a need to provide frequent training sessions for new members of staff.
- Labour wards and obstetric theatres should be strategically situated to facilitate the transfer of parturient women for caesarean section. This will facilitate timely responses when caesarean sections are necessary and will reduce the decision-to-incision time lag.

7.2 Future studies

- Large multicentre studies powered to detect differences in perinatal outcomes are recommended.
- Conducting systematic review and meta-analysis of similar studies may generate findings with enough power.
- The findings of improved quality of care provision are obtained from one health facility; whether the conclusions can be generalized needs further study. Conducting further implementation research with similar methods but in different settings to determine the effectiveness of the implementation and to increase external validity of the findings is recommended.
- Qualitative studies at tertiary facilities to assess barriers to facilitating timely interventions by the clinical staff, including low usage of instrumental births, are recommended.

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Appendices

Appendix 1 – Case Report Form Muhimbili (Study I and II)

1	Study Station	☐1 MNH ☐2 HLH
2	Mother Hospital ID (HLH) or Case note number (MNH)	☐☐☐☐☐☐☐☐☐☐
3	Delivery Number (MNH)	☐☐☐☐☐☐☐☐☐☐
4	Mother's age (in complete years)	☐☐Years
5	Gravida	☐☐
6	Parity	☐☐ (number of children) ☐☐Born alive ☐☐Born dead
7	Marital status	☐1Married ☐2 Single ☐ 3Cohabiting ☐4 Others (Specify)_____
8	Maternal education	☐ No formal education ☐ 2 Primary education ☐3 Secondary education ☐ 4 College and above
9	Antenatal care attendance	☐1 YES No. of visits _____ ☐ 2 NO
10	Antenatal problem (PIH, Anaemia, PROM, Infection, etc)	☐1 YES ☐ 2 NO
11	Source of admission	☐1 Referral: _____ ☐2 Home 3☐ Maternity home (waiting area) ☐☐:☐☐ Hours since start of labour
12	**During admission to labour ward (>3 cm)**	**Date:** ☐☐☐☐☐☐ **(ddmmyy) Time** ☐☐:☐☐
13	Cervical dilatation (on admission)	☐☐ CM ☐99 Not measured
14	Number of Foetus (e.g. 1, 2, 3, 4…..)	☐ number of foetuses
15	Gestational age	☐1 Term ☐2 Pre-term ☐☐ WEEKS
16	Foetal Heart Rate (FHR) on admission	☐1 Normal (120-160 BPM) Rate: ☐☐☐ **BPM** ☐2 Abnormal; ☐☐☐ **BPM** ☐3 Not detectable ☐9 Not measured
17	Presentation	☐1Cephalic ☐2 Breech ☐ 3 Others (specify)_____
	SCREENING Not Eligible if (for FHR)	Abnormal or undetected FHR at admission, Unable/refused to give differed consent, came in second stage (full dilatation), multiplies (twins and more)
18	RANDOMISATION	☐ 1 Pinard ☐ 2 Doppler ☐3 Moyo; number of Moyo (device) ☐☐☐☐
	Labour/delivery information (Take all the records and this section should be filled after delivery)	
19	Maternal fever	☐1 YES ☐2 NO
20	Maternal Infection (>1 is possible) ☐1 Reproductive tract ☐2 UTI ☐3 malaria ☐4 HIV ☐5 Others; mention - _____	 ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO

21	Equipment checked	☐1 YES ☐2 NO ☐3 NA (MNH)
22	Delivery kit present	☐1 YES ☐2 NO ☐3 NA (MNH)
23	Resuscitation kit present	☐1 YES ☐2 NO ☐3 NA (MNH)
24	Bag mask present	☐1YES ☐2 NO ☐3 NA (MNH)
25	**Foetal heart rate (Every 30 minutes in 1. Stage and every 15 minutes in 2. Stage)**	☐**1 Normal (120-160 BPM) (Skip to Q28)** ☐**2 Abnormal: Rate:** ☐☐☐ **BPM Time** ☐☐**:** ☐☐ ☐**3 Not detectable** ☐**9 Not measured**
26	Those in Doppler with abnormal FHR, was it confirmed by Moyo?	☐1 Yes ; If yes what rate ☐☐☐BPM ☐ 2 No
27	If abnormal FHR, What was done? ☐1 Stop oxytocin ☐2 change mother's position ☐3 IV fluid given ☐4 Oxygen given ☐5 Others (Specify).....	 ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO
28	Duration of labour	
	1st. stage 2nd. stage 3rd. stage	☐☐:☐☐ hrs:min ☐☐:☐☐ hrs:min ☐☐:☐☐ hrs:min
29	Last FHR measurement before delivery	☐☐☐BPM; Time ☐☐:☐☐
30	Amniotic Fluid colour	☐1 Clear ☐2 Slight Meconium ☐3 Thick Meconium ☐ 4 Blood stained
31	Labour complications • Obstructed labor • Uterine rupture • Pre-Eclampsia • Eclampsia • Cord Prolapse • Bleeding/Placenta Praevia • Shoulder dystocia	 ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO
32	Mode of delivery *(If 1,3,4 or 5 skip to HCW attending delivery)*	☐1 VD (SVD) ☐2 C/S ☐3 VD (ABD) ☐4 VD (Vacuum) ☐5 Others; mention __
33	Date of delivery	☐☐☐☐ ☐☐ YEAR
34	Time of delivery	☐☐ ☐☐ (24 HOURS)
35	Category of CS	☐1 Emergency CS ☐2 Elective CS
36	If CS; what indication	☐ 1 Obstructed labour ☐ 2 Fetal distress ☐ 3 Previous CS ☐ 4 Malpresentation ☐ 5 Others; mention_____
37	HCW attending the delivery	☐1 Midwife ☐2 Ward attendant ☐5 Doctor ☐3 Student ☐4 Clinical officer ☐6 None

	Neonatal information	
38	Birth weight	☐☐☐☐GRAM
39	Sex of new-born	☐1 MALE ☐2 FEMALE ☐3 Ambiguous
40	Apgar score (range 0-10)	☐☐ 1 MIN ☐☐ 5 MIN

41	RESUSCITATION ATTEMPTED	☐1 YES; Fill in this section☐2 NO; *go to next section*
42	Use of Newborn Resuscitation Monitor (NRM)	☐1 YES ☐2 NO ☐3 NA If Yes; name of monitor _____ If No; mention reason _____
43	Who took care of the Newborn	☐1 Midwife ☐2 Obstetrician ☐3 Clinical Officer ☐4 Paediatrician 5☐ Other MD ☐6 AMO ☐7 Others ____
44	Stimulation Suction Bag mask ventilation Device used for bag mask ventilation	☐1 YES ☐2 NO ☐1 YES; by use of Penguin ☐3 YES; not Penguin ☐2 NO ☐1 YES ☐2 NO ☐1 Upright bag ☐2 Standard bag ☐4 Upright bag with PEEP
45	Did the attending HCW/midwife call for help to resuscitate? Who provided resuscitation	☐ 1 YES ☐ 2 NO ☐1 Midwife ☐2 Operating Nurse ☐3 Clinical Officer ☐4 Doctor ☐5 Other; _____ ☐6 AMO
46	Last HBB full course attended?	☐☐MONTH ☐☐ YEAR ☐ 2 Never Attended ☐ 3. Not Sure ☐☐ 4 On job training
47	Ever practiced with NeoNatalie in past 7 days?	☐1 YES ☐2 NO

48	NEONATAL OUTCOME within 30 min	☐1 NORMAL ☐2 Admitted neonatal unit for treatment (36 in MNH) ☐3 Death ☐4 Stillbirth (fresh) ☐5 Stillbirth (macerated) ☐ 6 Admitted to Neonatal unit for observation *(If 3,4, or 5 skip neonatal outcome)*
49	Neonatal outcome at 24 hours postpartum /at discharge _____ hours postpartum	☐1 NORMAL ☐2 Still in neonatal unit ☐3 Death ☐6 Seizures
50	Neonatal outcome of admitted baby at _____ days (max 7 days)	☐1 NORMAL ☐2 Still in neonatal unit ☐3 Death ☐6 Seizures
	For premature (GA <35 weeks)	
51	Antenatal Dexamethasone	☐1 YES ☐2 NO ☐3 NA
52	Number of dosages	☐ ☐ Enter the actual number
53	Maternal antibiotics	☐1 YES ☐2 NO
54	Neonatal antibiotics (Amp/Genta)	☐1 YES ☐2 NO
55	Initial temperature	☐☐ ☐ Place the value in degrees of centigrade

56	**Maternal outcome (Complications)** • PPH	☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO

	• Perineal tear (>/=3rd degree) • Cervical tear • Retained placenta • Others specify ---------- Status at discharge	☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO ☐1Alive ☐ 2 Near miss ☐3 Dead

Appendix 2- Case Report Form (Temeke Study III)

SN	MOTHERS HOSPITAL ID	☐☐☐☐☐☐☐☐
1	Delivery Number	☐☐☐☐☐☐☐☐
2	Gravida	☐☐
3	Parity	☐☐ (number of children) ☐☐Born alive ☐☐Born dead
4	Number of foetuses	☐ number of foetuses
5	Source of admission	☐1 Referral ☐2 Home ☐3 Inpatient ☐ 4 others (Specify) _____
6	Mother's age (in complete years)	☐☐ in complete years
7	Marital status	☐1Married ☐ 2 Single ☐ 3 Cohabiting ☐4 Others (Specify)_____
8	Maternal education	☐1 No formal education ☐ 2 Primary education ☐3 Secondary education ☐ 4 College and above
9	Antenatal care attendance	☐1 YES: _____ ☐2 NO
10	Pregnancy complication	☐1 YES: Specify) _____ ☐2 NO
11	**ON ADMISSION to Labour ward >/=3cm**	Date: ☐☐☐☐☐☐ (DD/MM/YY); TIME ☐☐ : ☐☐ hr/min
12	Gestational age	☐☐ WEEKS
13	Foetal heart rate	☐1 Normal (120-160) ☐☐☐ BPM ☐2 Abnormal ☐☐☐ BPM ☐3 Not detectable ☐9 Not measured
14	Cervical dilatation (on admission)	☐☐ CM
15	Presentation	☐1Cephalic ☐2 Breech ☐ 3 Others (specify)_____
16	Device used to monitor FHR	☐ 1 Pinard ☐ 2 Doppler ☐3 Moyo; # of Moyo (device) ☐☐☐
	LABOUR AND DELIVERY	
17	Maternal fever	☐1 YES ☐2 NO
18	Maternal Infection (more than 1 is possible) • Reproductive tract • UTI • Malaria • HIV • Others; mention - _____	☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO
19	**Foetal heart rate (Every 30 minutes in 1. Stage and every 15 minutes in 2. Stage)**	**☐1 Normal (120-160) ☐2 Abnormal: ☐☐☐ BPM; TIME ☐☐:☐☐ hr/min ☐3 Not detectable ☐9 Not measured**

20	Those in Pinard with abnormal FHR, was it confirmed by Moyo?	☐1 Yes ; If yes what rate ☐☐☐BPM ☐ 2 No
21	Device mostly used for taking FHR	☐1Pinard ☐2 Handheld Doppler ☐3 None ☐4 Moyo
22	If abnormal FHR, what was done? ☐1 Stop oxytocin ☐2 change mother's position ☐3 IV fluid given ☐4 Oxygen given ☐5 Others (Specify).....	☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO
23	Duration of labour: 1st. stage 2nd. stage 3rd. stage	☐☐:☐☐ hrs:min ☐☐:☐☐ hrs:min ☐☐:☐☐ hrs:min
24	Labour complications • Obstructed labor • Uterine rupture • Pre-Eclampsia • Eclampsia • Cord Prolapse • Bleeding/Placenta Praevia • Shoulder dystocia • Others (specify)_____	☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO
25	Last foetal heart rate before delivery How many times was FHR taken in labor	☐☐ ☐ BPM TIME ☐☐:☐☐ hr/min ☐9 Not measured ☐☐ (Enter the number)
26	Mode of delivery	☐1 VD (SVD) ☐2 C/S ☐3 VD (ABD) ☐4 VD (Vacuum) ☐5 Others; mention _____ ☐ 6 Referred; Date: ☐☐☐☐☐☐; Time☐☐:☐☐ hr/min
27	Referral	☐1 Muhimbili ☐2 Other: Specify_____
28	Date and time of birth	Date ☐☐ ☐☐ ☐☐ Time ☐☐ : ☐☐ hr/min
29	If CS; what indication	☐ 1 Obstructed labour ☐ 2 Foetal distress ☐ 3 Previous CS ☐ 4 Malpresentation ☐ 5 Others; mention_____
30	HCW attending the delivery	☐1 Midwife ☐2 Ward attendant ☐5 Doctor ☐3 Student ☐4 Clinical officer ☐6 None
	NEWBORN INFORMATION	
31	Birth weight	☐☐☐☐ GRAM
32	Sex of newborn	☐1 MALE ☐2 FEMALE

33	Apgar score (range 0-10)	☐☐ 1 MIN ☐☐ 5 MIN
34	RESUSCITATION ATTEMPTED Stimulation Suction Bag mask ventilation	☐1 YES; Fill in this section ☐2 NO; *go to next section* ☐1 YES ☐2 NO ☐1 YES; ☐2 NO ☐1 YES ☐2 NO
35	NEONATAL OUTCOME within 30 min	☐1 NORMAL ☐2 referred neonatal unit ☐ 6 KMC ward ☐3 Death ☐4 Stillbirth (fresh) ☐5 Stillbirth (macerated)
36	Neonatal outcome at 24 hours postpartum /at discharge _____ hours postpartum	☐1 normal ☐2 Still KMC ☐5 Still in neonatal unit ☐3 Death ☐ 4 Referred ☐6 Seizures
37	Neonatal outcome of admitted baby at _____ days (max 7 days)	☐1 NORMAL ☐2 Still in KMC ☐5 Still in neonatal unit ☐3 Death ☐ 4Referred ☐6 Seizures

38	**Maternal outcome (Complications)** • PPH • Perineal tear (>/=3rd degree) • Cervical tear • Retained placenta • Others specify ---------- Status at discharge	☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO ☐ 1 YES ☐ 0 NO ☐1Alive ☐ 2 Near miss ☐3 Dead

Appendix 3-Consent Forms

RIDHAA YA KUTUMIA TAARIFA KWA AJILI YA UTAFITI WA UZAZI SALAMA (SAFERBIRTH)

Mimi ninaitwa ..... ni muuguzi/mkunga katika hospitali ya Taifa ya Muhimbili.

Wakati wa uchungu tutatumia kifaa kimojawapo kati ya tulivyonavyo kwa ajili ya kupima na kufuatilia mapigo ya moyo ya mtoto wako. Vifaa hivi vimeruhusiwa kutumika na vyote vinatoa majibu yanayotuwezesha kujua mtoto wako anaendeleaje tumboni. Lakini hatuna hakika kipi ni bora zaidi ya kingine. Hivyo tunahitaji kujua ili tuweze kusaidia kugundua mapema watoto wenye shida na kuweza kuokoa watoto wengi zaidi. Tunaomba ruhusa yako kutumia taarifa zako za wakati wa uchungu na kujifungua na za mtoto wako kwa ajili ya utafiti. Hatutakuhoji wala kuchukua taarifa Zaidi. Jina lako halitaonekana popote katika taarifa za kiutafiti. Una haki ya kukataa au kukubali kutoa ruhusa ya taarifa zako kutumika kwa ajili ya utafiti.

Je unaruhusu taarifa zako kutumika kwa ajili ya utafiti?

a. Ndiyo (Endelea na Utafiti) sahihi ya mgonjwa/dole gumba……

b. Hapana (sitisha) sahihi ya mgonjwa/dole gumba……..

c. Sahihi ya muuguzi……
….

d. Tarehe …….

Ahsante kwa muda wako na kwa uamuzi wako.

CONSENT FORM -English Version

SAFER BIRTH RESEARCH PROJECT

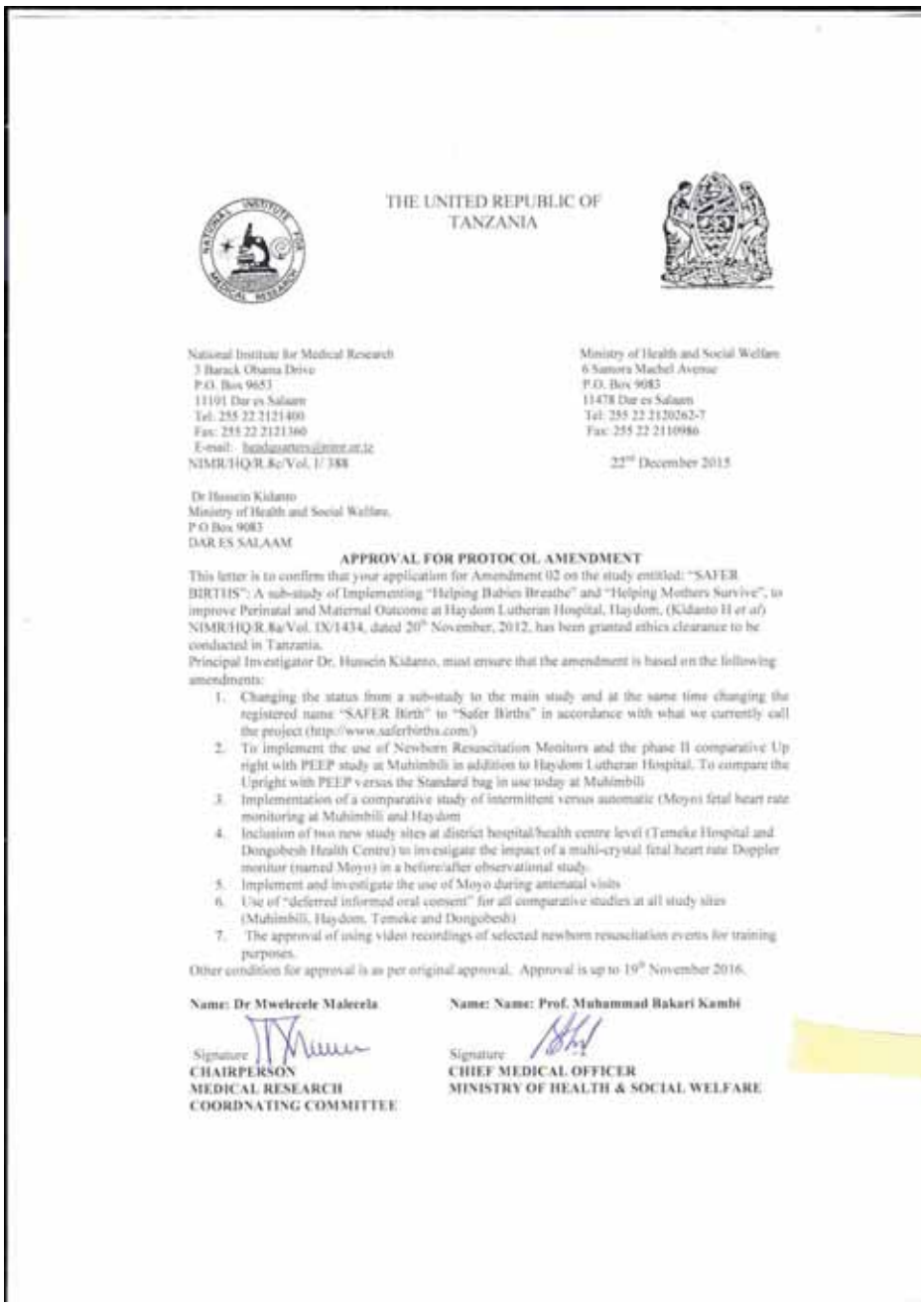
My name is ……. I am a midwife at this hospital (Muhimbili National Hospital).

Together with my colleagues we are conducting research on fetal heart rate monitoring during labor. In the labor process we are going to use either of the two devices to monitor the heart rate of your expected baby. These fetal heart rate monitoring devices a have been approved and certified by responsible authorities. These devices help us understand the wellbeing of your expected baby. We are unsure which device is more effective in detecting abnormal fetal heart rates.We want to know which one is more effective in identifying babies with problems so that we can save their lives. We re requesting for your consent to use the information gathered from the labor process for research purposes. We will not take any other information from apart from what is written in your partogram. You name will not appear anywhere in our records. We will use unique identification numbers only. You have the right to accept or reject to participate in this research. Your decision to rejection or to accept participation will not in any way affect the line of your management. You will be managed according to the hospital protocol.
Do you allow us to you the information collected to be used for research purpose?

e. Yes (Continue with research)
Signature/Fingerprint……
f. No (stop)
g. Midwife signature……
….
h. Date …….

Thank you for your time

Appendix 4- Ethical clearance certificate



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NIMR/HQ/R.8c/Vol. I/ 388

22nd December 2015

Dr Hussein Kidanto
Ministry of Health and Social Welfare,
P O Box 9083
DAR ES SALAAM

APPROVAL FOR PROTOCOL AMENDMENT

This letter is to confirm that your application for Amendment 02 on the study entitled: "SAFER BIRTHS": A sub-study of Implementing "Helping Babies Breathe" and "Helping Mothers Survive", to improve Perinatal and Maternal Outcome at Haydom Lutheran Hospital, Haydom, (Kidanto H *et al*) NIMR/HQ/R.8a/Vol. IX/1434, dated 20th November, 2012, has been granted ethics clearance to be conducted in Tanzania.

Principal Investigator Dr. Hussein Kidanto, must ensure that the amendment is based on the following amendments:

1. Changing the status from a sub-study to the main study and at the same time changing the registered name "SAFER Birth" to "Safer Births" in accordance with what we currently call the project (http://www.saferbirths.com/)
2. To implement the use of Newborn Resuscitation Monitors and the phase II comparative Up right with PEEP study at Muhimbili in addition to Haydom Lutheran Hospital. To compare the Upright with PEEP versus the Standard bag in use today at Muhimbili
3. Implementation of a comparative study of intermittent versus automatic (Moyo) fetal heart rate monitoring at Muhimbili and Haydom
4. Inclusion of two new study sites at district hospital/health centre level (Temeke Hospital and Dongobesh Health Centre) to investigate the impact of a multi-crystal fetal heart rate Doppler monitor (named Moyo) in a before/after observational study.
5. Implement and investigate the use of Moyo during antenatal visits
6. Use of "deferred informed oral consent" for all comparative studies at all study sites (Muhimbili, Haydom, Temeke and Dongobesh)
7. The approval of using video recordings of selected newborn resuscitation events for training purposes.

Other condition for approval is as per original approval. Approval is up to 19th November 2016.

Name: Dr Mwelecele Malecela
Signature
CHAIRPERSON
MEDICAL RESEARCH
COORDNATING COMMITTEE

Name: Name: Prof. Muhammad Bakari Kambi
Signature
CHIEF MEDICAL OFFICER
MINISTRY OF HEALTH & SOCIAL WELFARE

Paper I

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ORIGINAL RESEARCH

Intrapartum fetal heart rate monitoring using a handheld Doppler versus Pinard stethoscope: a randomized controlled study in Dar es Salaam

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Background: Fetal stethoscopes are mainly used for intermittent monitoring of fetal heart rate (FHR) during labor in low-income countries, where perinatal mortality is still high. Handheld Dopplers are rarely available and are dependent on batteries or electricity. The objective was to compare the Pinard stethoscope versus a new wind-up handheld Doppler in the detection of abnormal FHR.

Materials and methods: We conducted a randomized controlled study at Muhimbili National Hospital, Tanzania, from April 2013 to September 2015. Women with gestational age ≥37 weeks, cephalic presentation, normal FHR on admission, and cervical dilatation <7 cm were included. Primary outcome was abnormal FHR detection (<120 or >160 beats/min). Secondary endpoints were time to delivery, mode of delivery, and perinatal outcomes. χ^2, Fisher's exact test, Mann–Whitney test, and logistic regression were conducted. Unadjusted and adjusted odds ratios were calculated with respective 95% confidence interval.

Results: In total, 2,844 eligible women were assigned to FHR monitoring with Pinard (n=1,423) or Doppler (n=1,421). Abnormal FHRs were more often detected in the Doppler (6.0%) versus the Pinard (3.9%) arm (adjusted odds ratio =1.59, 95% confidence interval: 1.13–2.26, p=0.008). Median (interquartile range) time from abnormal FHR detection to delivery was comparable between Doppler and Pinard, ie, 80 (60,161) and 89 (52,165) minutes, respectively, as was the incidence of cesarean delivery (12.0% versus 12.2%). The incidence of adverse perinatal outcomes (fresh stillbirths, 24-hour neonatal admissions, and deaths) was similar overall; however, among newborns with abnormal FHR delivered vaginally, adverse outcomes were less incident in Doppler (7 of 43 births, 16.3%) than in the Pinard arm (10 of 23 births, 43.5%), p=0.021.

Conclusion: Intermittent FHR monitoring using Doppler was associated with an increased detection of abnormal FHR compared to Pinard in a low-risk population. Time intervals from abnormal FHR detection to delivery were longer than recommended in both arms. Perinatal outcomes were better among vaginally delivered newborns with detected abnormal FHR in the Doppler arm.

Keywords: fetal heart rate, perinatal outcomes, Pinard stethoscope, Doppler

Introduction

Childbirth is regarded as a normal physiological process; however, in low-income countries (LIC) there is an increased risk of mortality for both the mother and her newborn.[1] More than 99% of all newborn deaths occur in LIC, with important causes including lack of skilled personnel, essential technology, and supplies, including medicines.[2] Annually, 1.02 million fresh stillbirths (FSB) occur,[1,3,4] and intrapartum-related neonatal deaths account for almost 40% of 2.6 million neonatal deaths.[5]

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Intrapartum interruption of placental blood flow to the fetus has both short-term and long-term adverse consequences. Short-term outcomes include stillbirth, low Apgar score, need for resuscitations, neonatal intensive care unit admissions, and early neonatal deaths.[6] Long-term outcomes include cognitive and behavioral disabilities – affecting perhaps as much as one million children each year.[7,8] A focus on high coverage of good quality care during birth, including timely identification and rescue of the fetus from intrapartum hypoxia,[9] will save the lives of many newborns.[10] Effective fetal heart rate (FHR) monitoring tools for early detection of FHR abnormalities should facilitate appropriate obstetrical interventions, and hence contribute to the reduction of FSB and early deaths.[11]

Auscultation with the fetal stethoscope may be uncomfortable to the patient and midwives,[6,12] but it is often the only method of fetal monitoring available in many units in LIC.[6] Handheld Doppler devices are simple to use and relatively cheap, compared to electronic fetal monitors, and cause less maternal discomfort than the Pinard fetal stethoscope.[13] On the other hand, they require electricity or batteries.[2] The Freeplay wind-up handheld fetal Doppler has rechargeable batteries and can also be hand-cranked to provide rapid recharging with 1 minute of winding, providing 10 minutes of use. Its readings are reliable, and the device is well accepted by mothers and health care providers in LIC.[14,15]

A recent Cochrane Systematic review reported on a paucity of studies (trials) comparing intermittent auscultation of fetal heart rate in labor for fetal well-being using the methods described in this manuscript which are frequently used in low-income settings.[16] Only 2 studies were identified in the subject area, and several important outcomes were not reported, indicating presence of uncertainties regarding the use of intermittent auscultation of FHR in labor. The review recommended more randomized trials in low-income settings comparing different monitoring tools and timing for intermittent auscultation.

The aim of this study was to compare the effectiveness of 2 devices for intermittent FHR monitoring during labor, ie, the Pinard fetal stethoscope (Pinard) versus the FreePlay wind-up handheld Doppler (Doppler) (Power-free Education and Technology, Cape Town, South Africa) regarding their ability to detect FHR abnormalities. Secondary outcomes were time intervals from abnormal FHR detection to delivery, mode of delivery, and perinatal outcomes (FSBs, 24-hour neonatal admissions, and deaths).

Materials and methods

Design

This is a prospective nonblinded randomized controlled study comparing Pinard and Doppler for intermittent FHR monitoring. Women were randomly allocated to one of the 2 study arms by choosing Sequentially Numbered Opaque Sealed Envelopes scheme.

Study setting

This study was conducted at Muhimbili National Hospital (MNH) in Dar es Salaam from April 2013 to September 2015. MNH is a teaching hospital for the Muhimbili University of Health and Allied Sciences and is the largest consultant hospital in the United Republic of Tanzania. It is situated in Dar es Salaam, which has a population of nearly 5 million and an annual population growth rate of 4.3%.[17] About 10,000 deliveries are conducted annually, corresponding to about 35 deliveries per day. The hospital serves as a tertiary referral hospital of the city and the neighboring regions. It deals with many complicated obstetric cases, 50% of these ending in cesarean section (the highest in the country). The high rate of cesarean sections is due to increased referral of complicated cases from the lower-level facilities and suboptimal indications.[18,19] Deliveries are conducted by nurse-midwives and doctors, assisted by medical and midwifery students from the university.

Study population

This study involved low-risk pregnancies that met the following eligibility criteria: gestation age ≥37 weeks, cephalic presentation, normal FHR on admission, and cervical dilatation ≤7 cm. Exclusion criteria included women presenting with placental abruption, ruptured uterus, elective cesarean section, and multiple pregnancies. In addition, women admitted without FHR measure, or severely ill patients who could not give consent, were excluded from the study, but were managed according to the hospital protocol.

Training and FHR monitoring

Before start of the study, a 1-day workshop was conducted to train midwives and the doctors on all aspects of the research protocol as well as the detection and interpretation of FHR abnormalities, using both devices. They were trained to follow the World Health Organization guideline of monitoring FHR every 30 minutes during the first stage, and every 5–15 minutes during the second stage of labor. Midwives were trained to listen to the FHR during the last 10 minutes of every half hour, particularly before, during,

and immediately after a contraction. Any FHR abnormalities were to be reported to the doctor on call for consideration and potential actions.

Data collection and management

Data were collected using a structured data collection form. Gestation age (GA) was based on first trimester ultrasound (if available) and self-report of the last normal menstrual period. Preterm was defined as a GA <37 weeks; term pregnancy was defined as ≥37 and <42 weeks; and post-term as a GA >42 weeks. Maternal infection was recorded from Antenatal Cards or if the mother had any history of infection during her pregnancy. Birth weight in grams was recorded immediately after delivery using a calibrated scale in the labor ward and was dichotomized as low birth weight if <2,500 g and normal if >2,500 g.[20] FSB was defined as an Apgar score of zero at both 1 and 5 minutes with intact skin and suspected death during labor/delivery. Antepartum death/macerated stillbirth was defined as an Apgar score of zero at both 1 and 5 minutes with desquamated skin and suspected death before start of labor. Adverse perinatal outcomes, such as FSB, 24-hour, and admissions to neonatal unit for treatment were used as markers of suboptimal intrapartum care. A composite perinatal outcome measure included FSB, admissions, and deaths within 24 hours.

Data were double-entered in Epidata (EpiData Association, Odense, Denmark) by 2 independent data clerks. Random, periodical cross-checks were conducted on the entered data. If there were any discrepancies between the 2 entered databases, the data clerks rechecked the original data together and corrected where necessary.

Outcomes

The primary outcome measure was the detection of an abnormal baseline FHR. FHR was defined as normal if it was between 120 and 160 beats/min, and abnormal if <120 or >160 beats/min. Secondary outcomes included mode of delivery, time intervals during labor to delivery, newborn characteristics (ie, Apgar scores at 5 minutes and attempted bag mask ventilation), and perinatal outcome (ie, FSB and admission to neonatal unit, or death within 24 hours postpartum).

Sample size calculation and statistics

Data from another study in rural Tanzania revealed an abnormal FHR detection rate of 2.7% among low-risk deliveries using fetal stethoscopes.[11] We postulated that the use of Doppler as opposed to the Pinard would detect a minimum of 5% abnormal FHR. To detect the differences at a significance level of 0.05 with 80% power, 1,176 women were needed in each arm, giving a total sample of 2,352 using Openepi software.[21] We included 2,844 women, 20% more than the calculated sample, to compensate for potentially missing data.

Analysis was performed with Statistical Package for Social Sciences (SPSS) 23 (IBM Corporation, Armonk, NY, USA). χ^2 and Fisher's exact tests were used to compare proportions between groups, whereas Mann–Whitney tests and Independent sample *t*-tests were used to compare groups with respect to continuous variables. Furthermore, we report adjusted odds ratios from logistic regression analysis with 95% confidence intervals. A *p*-value of <5% was considered statistically significant.

Ethical considerations

All women provided written informed consent to participate in and allow for publication of data before enrollment. They were informed about the study and those found to have an abnormal FHR would be managed according to hospital protocols. The trial was registered on the ClinicalTrial.gov website with identifier number NCT01869582. Ethical clearance to conduct and publish the study was given by the Publication and Ethical Committee of the Muhimbili University of Health and Allied Sciences (reference number: MU/DRP/AEC/Vol.XVIII/105).

Results

During the study period, 20,848 women delivered at MNH, and 3,317 were eligible for recruitment (Figure 1). Of these, 2,844 (86%) consented to participate and were randomized to either the Pinard arm (n=1,423) or Doppler arm (n=1,421).

Table 1 compares antenatal characteristics between the two groups. Maternal infections were significantly more common in the Doppler group (p=0.027). There were more referred patients/inpatients in the Pinard group as compared to the Doppler group. Other parameters, such as GA, antenatal problems, and birth weight, were similar between groups (Table 1).

A comparison of primary and secondary outcomes in the two arms is presented in Table 2. Adjusted odds ratios are presented for all the variables after controlling for imbalances in the maternal variables (Table 1). There was a significantly higher proportion of FHR abnormalities detected in the Doppler (6.0%) compared to the Pinard (3.9%) group

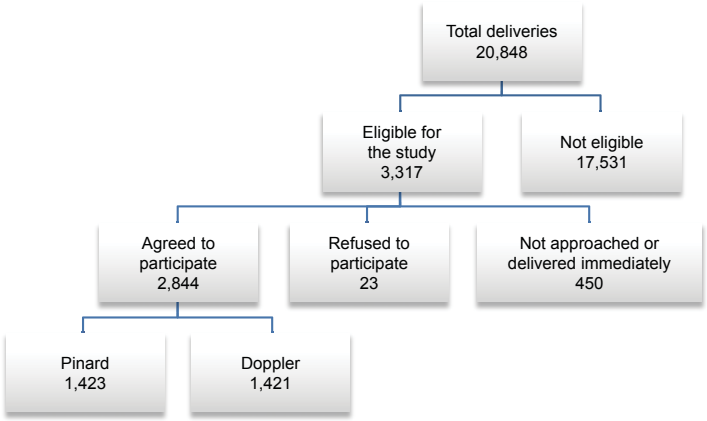

Figure 1 Trial profile.

(adjusted odds ratio =1.59, p=0.008). Overall, there were no significant differences in any of the secondary outcomes (Apgar score <7, delivery of bag mask ventilation, mode of delivery, perinatal admissions, and deaths).

The mean (±SD) duration of first stage of labor was similar in both groups (ie, nearly 11 hours 30 minutes ±2 hours 40 minutes, p=0.83). The mean duration of second stage was slightly longer in the Doppler (34±14 minutes) compared to the Pinard (32±14 minutes) group (t-test, p=0.039). The median (interquartile range) time intervals from detection of an abnormal FHR to delivery were almost comparable, ie, 80 (60, 161) minutes in the Doppler group, and 89 (52, 165) minutes in the Pinard group (Mann–Whitney test, p=0.88) for all modes of deliveries.

Figure 2 shows that, overall, 142 (5.0%) cases of abnormal FHR were detected in this study. Among the 16 perinatal deaths, 8 (50%) were noted to have an abnormal FHR pattern. One perinatal death was recorded among newborns delivered by cesarean section. Subgroup analysis of the composite perinatal outcomes (ie, FSB and 24-hour deaths and admissions to a neonatal area) revealed that newborns with abnormal FHR delivered vaginally had a more unfavorable outcome in the Pinard group (10 of 23; 43.5%) compared to the Doppler group (7 of 43; 16.3%) (Fisher's exact test, p=0.021). There was no time difference in this subgroup analysis between the study arms (p=0.305).

Discussion

We found a higher likelihood of detecting abnormal FHR by intermittent monitoring using the Doppler technique as opposed to the Pinard. However, overall, perinatal outcomes were similar, although subgroup analysis revealed that newborns with abnormal FHR delivered vaginally had better perinatal outcomes in the Doppler compared to the Pinard group. The time intervals from detection of an abnormal FHR to delivery were long in both groups.

Our findings on FHR abnormalities are comparable to prior studies completed in Kampala and Harare, where the Doppler detected more FHR abnormalities than the Pinard fetal stethoscope.[22,23] The Kampala study reported that despite a higher detection of FHR abnormalities with the Doppler technique, no improvement in perinatal outcome was seen,

Table 1 Comparison of maternal characteristics in the Pinard and Doppler groups among low-risk parturient women at MNH

Antenatal characteristics	Pinard n=1,423 (%)	Doppler n=1,421 (%)	Total (%) n=2,844 (%)	p-value*
Maternal infection	28 (2.0)	48 (3.3)	76 (2.7)	0.027
Low birth weight	65 (4.6)	62 (4.3)	127 (4.4)	0.790
GA ≥42 weeks	6 (0.4)	8 (0.6)	14 (0.5)	0.790
Antenatal problem	128 (9.0)	111 (7.7)	239 (8.4)	0.250
Referred patient/inpatient	205 (14.4)	158 (11.0)	363 (12.7)	0.008

Note: *χ^2 tests.
Abbreviations: GA, gestational age; MNH, Muhimbili National Hospital.

Table 2 Frequencies of abnormal FHR detections, newborn characteristics, and perinatal outcomes in the Pinard and Doppler arms among low-risk parturient women at MNH

Primary/secondary outcomes	Pinard n=1,423 (%)	Doppler n=1,421 (%)	Unadjusted OR	*p*-value*	AOR**	*p*-value*
Abnormality of FHR	56 (3.9)	86 (6.0)	1.56 (1.12–2.21)	0.012	1.59 (1.13–2.26)	0.008
Mode of delivery: cesarean section	174 (12.2)	172 (12.0)	0.98 (0.79–1.23)	0.89	0.96 (0.77–1.21)	0.76
Apgar 5 minutes <7	23 (1.6)	30 (2.1)	1.31 (0.76–2.26)	0.40	1.38 (0.79–2.24)	0.25
Bag mask ventilation attempted	68 (4.8)	76 (5.3)	1.19 (0.80–1.57)	0.51	1.18 (0.84–1.65)	0.35
Admissions to neonatal unit at birth	28 (2.0)	38 (2.7)	1.36 (0.82–2.25)	0.24	1.42 (0.86–2.33)	0.17
Fresh stillbirths	8 (0.6)	5 (0.3)	0.63 (0.20–1.92)	0.41	0.67 (0.22–2.07)	0.49
Still admitted at 24 hours	18 (1.3)	22 (1.5)	1.22 (0.65–2.28)	0.63	1.25 (0.66–2.34)	0.49
Perinatal deaths (FSB + deaths within 24 hours)	10 (0.7)	6 (0.4)	0.59 (0.22–1.65)	0.32	0.62 (0.26–1.73)	0.36
Composite outcomes (perinatal deaths and admissions)	28 (2.0)	28 (2.0)	0.99 (0.59–1.69)	0.98	0.73 (0.34–1.47)	0.35

Notes: Data are presented as n (%) and AOR. *Wald test. χ^2 test. **Multiple logistic regression analysis adjusted for maternal infection and sources of admission.
Abbreviations: AOR, adjusted odds ratio; FHR, fetal heart rate; FSB, fresh stillbirth; MNH, Muhimbili National Hospital.

which is similar to our overall finding. A suggested reason for this relates to several contextual constraints in low-resource settings leading to lack of timely interventions to deliver the baby.[9] These constraints include, among others, a delay in decision-making due to a high patient to staff ratio in the labor ward, and often multiple simultaneous patients waiting for an emergency cesarean section.[18,22] A longer than recommended decision-to-delivery time interval may in part explain the lack of difference in perinatal outcomes between the groups in the present study. One would have anticipated that the higher detection rate of abnormal FHR by Doppler would lead to a timelier intervention such as a cesarean section. However, the frequency of a cesarean section was unaffected, and we speculate that the striking imbalance between available health resources (staff, access to theater) and large volume of patients likely play a crucial role.[24,25] Therefore, in order to effectively manage critical cases and improve perinatal outcomes, improved FHR monitoring techniques coupled with better staffing, as well as improved equipment and theater facilities, ie, an overall increased capacity and improved systems, are necessary in order to affect perinatal outcomes.

A subgroup analysis of those newborns with a detected abnormal FHR, delivered vaginally, revealed improved composite perinatal outcomes in the Doppler compared to the Pinard group. These findings are similar to those found in the Harare study,[21] which involved dedicated research midwives, and where improved perinatal outcomes were reported in the Doppler arm. These findings may also indicate that midwives can detect FHR abnormalities more frequently and earlier when using the Doppler technique compared to a fetal stethoscope, thereby recognizing signs of intrapartum hypoxia more often and at an earlier stage.

There might be several reasons for more and/or earlier detection of abnormal FHR in the Doppler group. The Doppler technique provides digital sound and readings, which do not require much skill to interpret and can easily be confirmed by peers, as opposed to the Pinard, which requires a complete minute of counting.[15] Additionally, midwives may feel unsure about the reliability of the Pinard assessments.[18] A qualitative study (in-depth interviews and focus group discussions) performed among labor ward staff at MNH reports that the Doppler was the preferred device for improving FHR monitoring.[26]

Limitations

This study was not powered to detect overall differences in perinatal outcomes. A study involving an appropriate sample size, perhaps in a more high-risk population and coupled with timely obstetric intervention, might be able to show differences in overall perinatal outcomes. Second, the documented fear of blame from peers and hospital management at MNH, as suggested in the qualitative study previously conducted in the same hospital,[26] might have led to a defensive practice with overreporting of abnormal FHR. Third, in this study, we have not been able to perform other tests, such as fetal scalp pH levels, to confirm possible fetal hypoxic state. Fourth, the study involved 2 different medical devices in measuring FHR, and it was not possible to blind the patients and providers.

Conclusion and recommendation

Monitoring of FHR using a wind-up Doppler was associated with an increased detection of abnormal FHR. Overall perinatal outcomes were comparable between groups, but there were better perinatal outcomes for newborns with detected abnormal FHR delivered vaginally in the Doppler

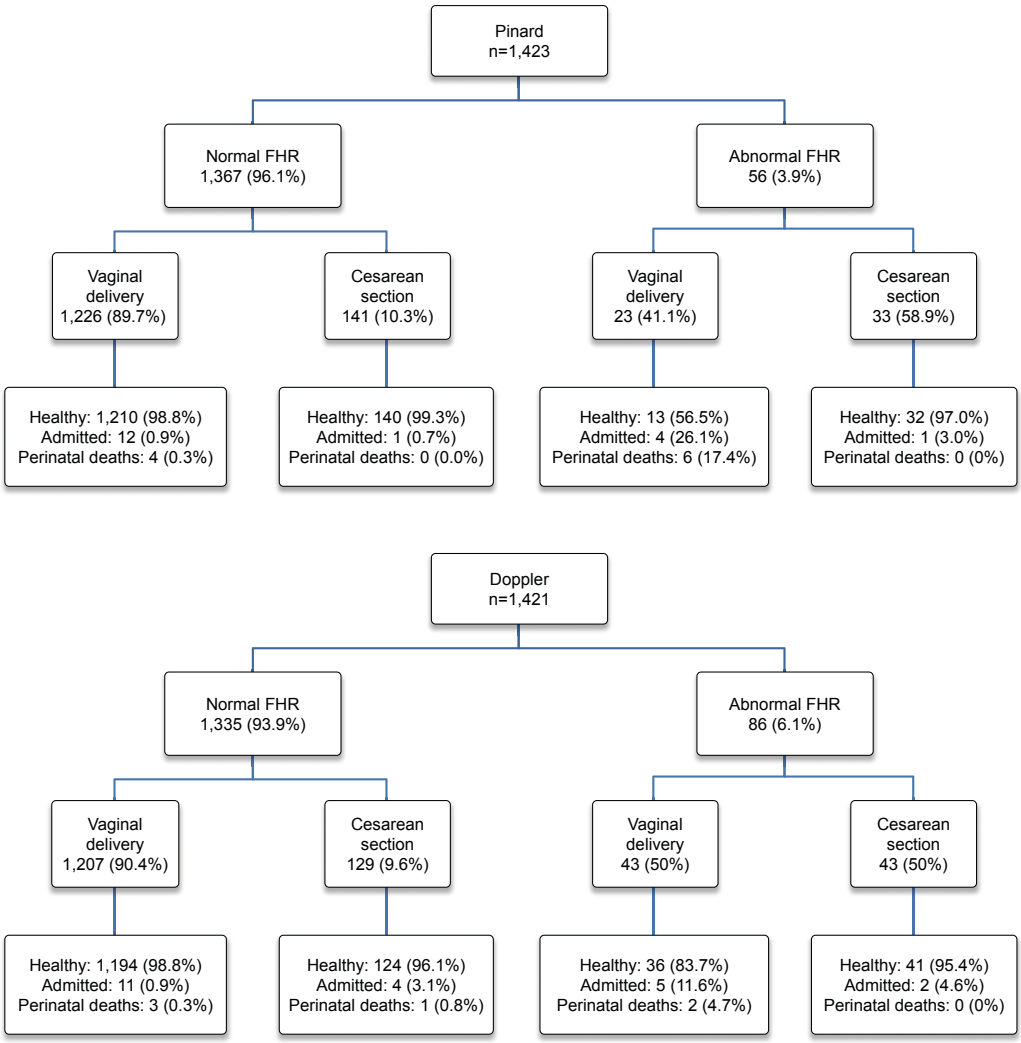

Figure 2 Flow diagrams of FHR detections, mode of delivery, and perinatal outcomes in both arms, Pinard and Doppler.
Abbreviation: FHR, fetal heart rate.

group. A study powered for perinatal outcomes, coupled with timely interventions, may be able to demonstrate differences in overall perinatal outcome.

Data sharing statement

Data can be made available to editors and/or reviewers upon request from Research, Teaching and Consultancy Unit of Muhimbili National Hospital (address: PO Box 65000, Dar es Salaam, Tanzania; phone: +255 22 215 1599; fax: +255 22 215 0534; email: info@mnh.or.tz)

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Author contributions

BAK conducted the initial statistical data analysis and prepared all sections of the first draft and compiled the final manuscript. HLK conceived and designed the study and supervised the training of research midwives and the data collection process. He was also involved in data analysis and the interpretation of the results. PJW and ERM participated in the design of the study and the review of the manuscript. ID reviewed the statistical analysis and the final draft of the manuscript. HLE and JMP were involved in design of the study, interpretation of data, and critically reviewed the manuscript. All authors contributed toward data analysis, drafting and critically revising the paper and agree to be accountable for all aspects of the work. All authors agreed on the final submitted manuscript.

Disclosure

BAK received unconditional funding for studies from Laerdal Foundation. The other authors report no conflicts of interest in this work.

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Paper II

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Article

Effectiveness of a Novel Continuous Doppler (Moyo) Versus Intermittent Doppler in Intrapartum Detection of Abnormal Foetal Heart Rate: A Randomised Controlled Study in Tanzania

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Abstract: *Background*: Intrapartum foetal heart rate (FHR) monitoring is crucial for identification of hypoxic foetuses and subsequent interventions. We compared continuous monitoring using a novel nine-crystal FHR monitor (Moyo) versus intermittent single crystal Doppler (Doppler) for the detection of abnormal FHR. *Methods*: An unmasked randomised controlled study was conducted in a tertiary hospital in Tanzania (ClinicalTrials.gov Identifier: NCT02790554). A total of 2973 low-risk singleton pregnant women in the first stage of labour admitted with normal FHR were randomised to either Moyo (n = 1479) or Doppler (1494) arms. The primary outcome was the proportion of abnormal FHR detection. Secondary outcomes were time intervals in labour, delivery mode, Apgar scores, and perinatal outcomes. *Results*: Moyo detected abnormal FHR more often (13.3%) compared to Doppler (9.8%) (p = 0.002). Time intervals from admission to detection of abnormal FHR were 15% shorter in Moyo (p = 0.12) and from the detection of abnormal FHR to delivery was 36% longer in Moyo (p = 0.007) compared to the Doppler arm. Time from last FHR to delivery was 12% shorter with Moyo (p = 0.006) compared to Doppler. Caesarean section rates were higher with the Moyo device compared to Doppler (p = 0.001). Low Apgar scores (<7) at the 1st and 5th min were comparable between groups (p = 0.555 and p = 0.800). Perinatal outcomes (fresh stillbirths and 24-h neonatal deaths) were comparable at delivery (p = 0.497) and 24-h post-delivery (p = 0.345). *Conclusions*: Abnormal FHR detection rates were higher with Moyo compared to Doppler. Moyo detected abnormal FHR earlier than Doppler, but time from detection to delivery was longer. Studies powered to detect differences in perinatal outcomes with timely responses are recommended.

Keywords: foetal heart rate; Moyo; Doppler; perinatal outcomes

1. Introduction

The intrapartum period poses a great risk for both baby and mother. Globally, 2.6 million neonates die annually during the neonatal period, accounting for approximately 46% of all under-five deaths [1]. Approximately 36% of these neonates die on the first day [1,2], and 25% are intrapartum related [1,3].

Moreover, 40% of 2.6 million stillbirths are intrapartum related and termed fresh stillbirths (FSB) [4]. Most of these perinatal deaths occur in low income countries (LIC) where effective emergency obstetric care provision is low [3].

Prolonged intrapartum foetal hypoxia, invariably because of interruption of placental blood flow, may result in a FSB or a severely asphyxiated neonate [5,6]. Following delivery, such neonates may die, or survive with variable degrees of hypoxic-ischemic brain injury, leading to long-term neurocognitive and behavioural impairment [7,8].

Intrapartum foetal heart rate (FHR) monitoring is an important strategy in providing a more targeted and appropriate management of foetal well-being [9]. Intermittent assessment with either a hand-held Doppler or Pinard Stethoscope is the main method of intrapartum FHR monitoring in LIC [10,11]. However, studies document that intrapartum FHR monitoring is not conducted according to current international guidelines [12–14], due to a shortage of human resource and appropriate monitoring equipment [12,15], leading to perinatal morbidity and mortality [16].

Our previous studies using a novel continuous Doppler (Moyo) showed that accurate FHR monitoring enhanced early detection of the at-risk foetus [17,18]. The Moyo device has features that may facilitate early identification of foetuses at risk of intra-partum hypoxia and improve the quality of midwifery practices [17]. Continuous intrapartum FHR monitoring with cardiotocograph (CTG) coupled with timely interventions, such as caesarean sections in high income countries, has been associated with improved perinatal outcomes [9]. There is a paucity of studies on FHR monitoring in LIC, where most births occur, posing a critical need to implement and test new monitoring strategies in these settings [19]. An ideal device for LIC settings should be low-cost, simple to operate, possible to operate on a range of power sources, and without a need for continuous power supply, which the Moyo device represents [20].

We hypothesized that continuous intrapartum monitoring with Moyo as compared to intermittent Doppler assessment would lead to more timely and frequent detection of FHR abnormalities. The objective of the study was to compare the effectiveness of continuous monitoring (Moyo-intervention) versus intermittent hand-held (Doppler-standard of care) in the intrapartum detection of abnormal FHR.

2. Materials and Methods

2.1. Study Design

We conducted a parallel-arms, unmasked randomised controlled study from March 2016 to September 2017 at Muhimbili National Hospital (MNH) in Dar es Salaam, Tanzania.

2.2. Study Settings

MNH is the national referral hospital and a teaching hospital for Muhimbili University. The hospital provides both basic and comprehensive emergency obstetric care and has approximately 10,000 annual deliveries; 50% by Caesarean section (CS) [10]. The labour ward at MNH has 20 delivery beds and approximately 25 nurse midwives. The ward is managed by 5 nurse-midwives and 2 nursing assistants in each shift of 12 h. The doctors-on-call team comprises 1 consultant, 1 obstetrician, 2 obstetric residents, and 1 intern doctor on 24-h call. There are two obstetric operating theatres in a separate building adjacent to the maternity block.

On admission, a nurse midwife screens all women for vital signs registration, initial FHR assessment, and vaginal examination before entering the labour ward. A brief history and vital signs are taken and required information entered in the labour ward register. The on-call doctor reviews the partograph and undertakes the initial and subsequent obstetric examination until delivery. After a normal vaginal delivery, mothers and babies are observed in the hospital for 6–10 h. Babies with respiratory distress and others in need of medical attention are admitted to the neonatal unit. Management protocols for mothers and babies in this setting have been described previously [21].

2.3. Study Participants

The study participants included mothers in labour with an estimated gestational age above 28 weeks and with ≥3 cm cervical dilatation. Exclusions included scheduled elective CS, multiple pregnancies, cases with abnormal or undetectable FHR on admission, admission in the second stage with full cervical dilation, precipitous delivery, and critically ill patients with no measurements of FHR.

2.4. Patient and Public Involvement

The need for development of the Moyo device started at Haydom, a rural based hospital in Northern Tanzania, and MNH responding to increased intrapartum related perinatal morbidity and mortality [5,6,22]. The device was developed in collaboration with clinical staff at these hospitals, Laerdal Medical, and Stavanger University Hospital in Norway. It was in response to the needs of the clinical staff and mothers in these resource limited settings to reduce FSB and END (early neonatal deaths). Patients were told of the design of the study before being recruited to participate. Qualitative studies on preferences and acceptability of the continuous FHR monitoring with the Moyo device among mothers and clinical staff have been conducted in these settings. Positive responses on this device compared to the traditional Pinard stethoscope and Doppler were obtained and documented in our previous studies [23,24].

2.5. Randomisation, Concealment, and Masking

A randomisation sequence was computer-generated by an independent statistician. Details of the allocated group were given to the study coordinator, who supervised data clerks to write on cards and put them in sequentially numbered opaque sealed envelopes and sealed them. The allocation sequence was concealed from investigators and nurses enrolling participants and assessing outcomes. Envelopes were prepared and stored in a locked cabinet. Consecutively numbered envelopes were opened only after the enrolled participants completed assessments. The women and enrolling nurses were unaware of the allocation group until after eligible women were informed about the study and a written consent was obtained. Women, nurses, and doctors were unmasked.

2.6. Training

Pre-study trainings using a Moyo training package focusing on standard operating procedures for Moyo and international FHR monitoring standards were conducted in January and February 2016 by study investigators. All labour ward staff were trained for a full day on these FHR management protocols before starting the study. Continuous on-job refresher trainings were conducted (every two months) to increase protocol adherence and accommodate incoming staff who did not receive the initial training. Training included theoretical information about FHR monitoring during labour and management of an abnormal FHR. Criteria for FHR monitoring were established and included monitoring recording every 30 min in the first stage of labour, and every 5–15 min in the second stage [12–14]. The labour ward staff were also told that abnormal FHR detections should be reported to the doctor on call, who should act according to hospital protocols. Research nurses (at least 2 per shift) were trained for one additional day on research protocol and data collection to ensure accuracy and completeness of the data in the paper-based case report form (CRF). Data were collected from mothers' antenatal cards, partograph, obstetric register, and, when needed, from routine neonatal morbidity and mortality records in the neonatal unit.

2.7. The Intervention (The Moyo Device)

Moyo (Figures 1 and 2) (Moyo, Laerdal Global Health, Stavanger, Norway) is a novel strap-on FHR monitor equipped with a rechargeable battery, containing a nine-crystal Doppler ultrasound sensor, which facilitates the rapid identification of FHR within 5 s. Additional features of the Moyo device have been described in our previous studies [17,18,23].

Women randomised to the Moyo arm received information on how the device was to be used by the enrolling midwife before the device was strapped on. The midwife continued with her routine activities, but periodically revisited the women to check and record the FHR reading or in case of an abnormal FHR alarm from Moyo [23]. Moyo continued to be strapped on until the end of the second stage or immediately prior to the start of a CS.

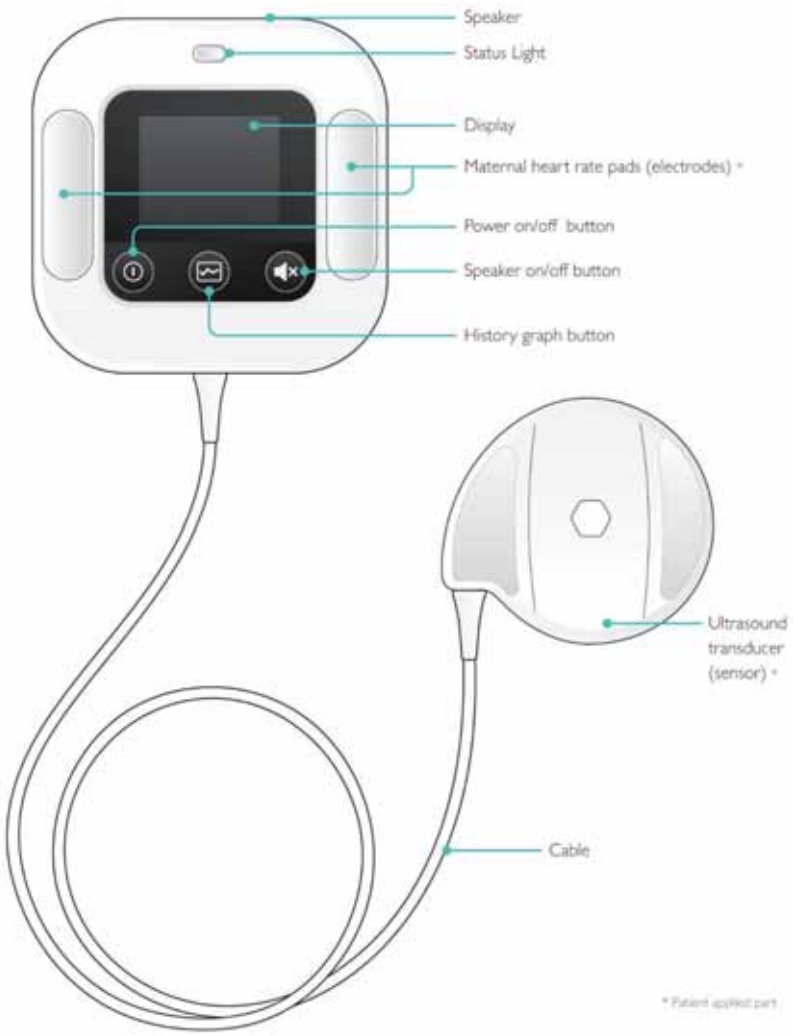

Figure 1. Moyo—the novel continuous FHR (foetal heart rate) monitor (Laerdal Global Health). * patient applied part.

Figure 2. The Moyo FHR monitor with a 30-minutes historical display (Laerdal Global Health).

2.8. Control (Hand-Held Doppler)

In the control arm, women were monitored intermittently with the standard protocol of FHR monitoring every 30 min in the first stage and 5–15 min in the second stage using a hand-held Doppler (Power-free Education Technology, Pet.og.za, Cape Town, South Africa). Doppler detects FHR and provides a steady state number per min on a display, as well as an audible sound of the FHR [11]. It permits the midwife to locate the FHR while allowing others, including the mother, to hear the FHR. The midwife would continue with her routine activities and periodically revisit the women to check and record FHR readings in the partograph and perform other management as indicated.

2.9. Outcomes

The primary outcome measure was FHR defined as normal (120 to160 beats/min throughout labour and delivery) or abnormal (absent, <120 or >160 beats/min lasting for at least two min) in the continuous Moyo despite repositioning of the Moyo sensor, and with three abnormal assessments at different sites in the intermittent Doppler arm.

Secondary outcomes included the Apgar score at one and five minutes (abnormal was defined as an Apgar score <7); mode of delivery (vaginal delivery, CS, assisted breech, and vacuum extraction); perinatal outcome at birth (i.e., normal, admission to the neonatal unit, or FSB), outcome at 24-h (i.e., normal, still admitted to the neonatal unit, or END); and composite perinatal outcomes at birth and 24-h (normal, admission in neonatal unit, FSB, and END). Apgar score <7 at five minutes was used as a surrogate measure of birth asphyxia [25]. Mode of delivery was dichotomized into two categories (i.e., vaginal, including vacuum delivery, and CS) due to relatively fewer cases in the vacuum delivery category. Time intervals included admission to abnormal FHR detection, admission to delivery, from abnormal FHR detection to delivery, and last FHR assessment to delivery. After detection of abnormal FHR, recorded intrauterine resuscitation included discontinuing oxytocin, changing maternal position, administering intravenous fluids, and provision of oxygen.

2.10. Trial Monitoring and Stopping Rules

The trial was monitored by an independent data monitoring committee comprising one statistician and one paediatrician aimed at protecting participant exposure to unreasonable risks. Discontinuation was planned in case of imbalances in serious adverse effects (FSB and END). Blinded data analysis was conducted mid-way through the trial and the committee recommended continuation of the study.

2.11. Sample Size Estimation

Historical data showed that when using the hand-held Doppler, abnormal FHR was detected in 4.5% of low-risk deliveries. We postulated that continuous assessment of FHR using Moyo would detect a minimum of 7% of abnormal FHR. To detect these differences at a significance level of 0.05 with 80% power, a minimum of 1350 cases would be needed in each arm. An additional 10% was added to the sample size to allow for missing data. The final sample size was 2970.

2.12. Data Management

Data collection was conducted by trained research nurses (at least 2 per shift) filling the CRF. CRFs was cross-checked by the investigators for quality and completeness before entry. All CRFs with queries were returned to the research nurse for verification and correction before data entry. A data entry template was generated in Epi Data by investigators and statistician. All verified data were double-entered by trained data clerks. Then, data was transferred to SPSS for analysis (IBM SPSS Statistics for Windows, Version 23.0, IBM Corp, Armonk, NY, US). Patient information were recorded using confidential codes and kept in a secured place.

2.13. Statistical Analysis

Descriptive statistics were expressed as means (standard deviation, SD) or medians (inter quartile range, IQR) for continuous variables and as counts and proportions for categorical variables. Proportions were compared by a Pearson chi-square test. Odds ratios (OR) with respective 95% confidence intervals were calculated as estimates of the effect for categorical variables. Adjusted OR (AOR) using both logistics and multinomial regressions were estimated to account for imbalances in baseline characteristics and for an increase in subject-specific precision. Symmetrically distributed continuous variables were compared by *t*-test, and the Mann-Whitney U was used for skewed data. To adjust for baseline imbalances when comparing skewed time variables, we used linear regression analysis with a natural log-transformed outcome to calculate beta-coefficients. Due to this transformation, we used beta coefficients to estimate the effect size (ES), i.e., relative change in median time in percentages as documented before [26]. A p-value < 0.05 was considered significant.

2.14. Ethical Clearance

The study was registered at ClinicalTrials.gov Identifier: NCT02790554. All subjects gave their written informed consent for inclusion before they participated in the study. The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by both the National Institute of Medical Research in Tanzania (NIMR/HQ/R.8a/Vol. IX/1434) and the Regional Committee for Medical and Health Research Ethics, Western Norway (REK Vest). Local permission was sought from MNH Directorate of Research and Consultancy. Permission to publish was granted by NIMR (NIMR/HQ/P.12 VOL. XXV/57).

3. Results

From March 2016 to September 2017, a total of 3547 admitted women were eligible. Of these, 438 were not randomised due to precipitous labour and 136 did not consent to participate in the study. In total, 2973 women were enrolled, 1479 assigned to Moyo and 1494 to Doppler as shown in the study profile (Figure 3).

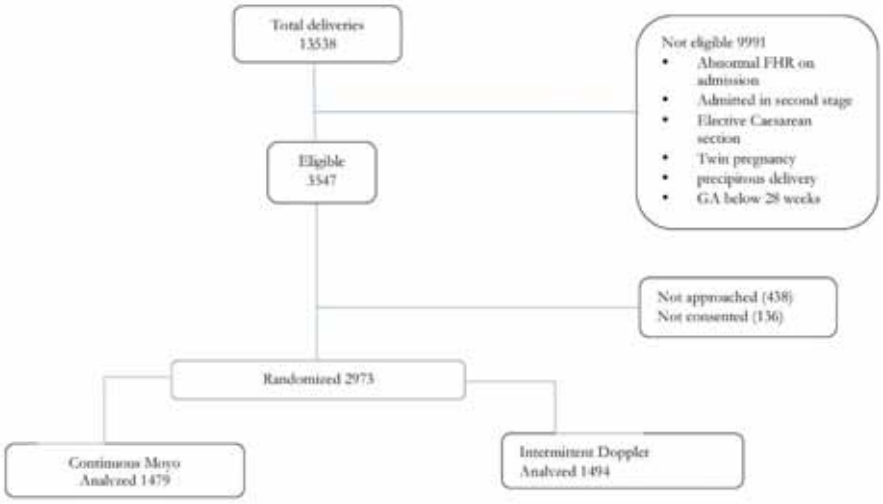

Figure 3. Trial profile.

3.1. Maternal, Antenatal, and Perinatal Characteristics

Maternal, antenatal, and perinatal characteristics of the study subjects are shown in Table 1. Maternal mean age was comparable between study arms. The Moyo arm had a lower proportion of preterm deliveries compared to Doppler (12% vs. 17%, $p \leq 0.001$). Women in the Moyo arm were admitted earlier in labour with a mean cervical dilatation of 4.4 ± 1.5 cm compared to 5.0 ± 1.7 cm in the Doppler arm, $p \leq 0.001$.

Table 1. Baseline demographic, clinical, and perinatal characteristics of randomized low risk pregnant women in labour.

Variables	Intermittent Doppler (n = 1494)	Continuous Moyo (n = 1479)
Age (years)		
Mean (SD)	28.3 (5.6)	27.8 (5.3)
<20	84 (5.6)	66 (4.5)
20–35	1223 (81.9)	1260 (85.2)
>35	187 (12.5)	153 (10.3)
Education		
No/Primary	557 (37.3)	424 (28.7)
Secondary	375 (25.1)	366 (24.7)
College/University	562 (37.6)	689 (46.6)
Marital status		
Married/Cohabiting	1370 (91.7)	1384 (93.6)
Single	124 (8.3)	95 (6.4)
Antenatal care visits		
<4	466 (31.2)	402 (27.2)
≥4	1028 (68.8)	1077 (72.8)
Parity		
Median (IQR)	2 (1, 3)	2 (1, 3)
Prime	576 (38.6)	697 (54.8)
2–4	805 (53.9)	709 (47.9)
>4	113 (7.6)	73 (4.9)

Table 1. *Cont.*

Variables	Intermittent Doppler (*n* = 1494)	Continuous Moyo (*n* = 1479)
Gestational age (weeks)		
Mean (SD)	37.8 (2.9)	38.1 (2.5)
<37(Preterm)	251 (16.8)	174 (11.8)
≥37(Term)	1243 (83.2)	1305 (88.2)
Birth weight (grams)		
Mean (SD)	2979 (649)	3073 (611)
<2500	273 (18.3)	193 (13.0)
2500–3500	944 (632)	987 (66.7)
>3500	277 (18.5)	299 (20.2)
Cervical dilation on admission (cm)		
Mean (SD)	5.0 (1.7)	4.4 (1.5)
Antenatal problem		
No	1104 (73.9)	1159 (78.4)
Yes	390 (26.1)	320 (21.6)
Obstetric complication		
No	1389 (93.0)	1344 (90.9)
Yes	105 (7.0)	135 (9.1)
Source of admission		
Referred/admitted	623 (41.7)	529 (35.8)
Home	871 (58.3)	950 (64.2)

Data shown as *n* (%) unless otherwise stated. SD: Standard deviation, IQR: Interquartile range.

3.2. Primary and Secondary Labour and Perinatal Outcomes

Primary and secondary outcomes were adjusted for baseline variables separately. The difference of proportions of preterm births between the two study arms showed a significant influence in the effect measures estimates on most of the perinatal outcomes. Other baseline demographic and clinical characteristics were added in the logistic regression model to increase the precision of subject-specific effect measure estimates (Table 2). There were significantly higher numbers of FHR abnormalities detected in the Moyo versus Doppler arms, i.e., 13.3% versus 9.8%, respectively (AOR = 1.46; 95% CI: 1.16–1.76, $p = 0.002$). There were higher rates of CS in the Moyo as compared to the Doppler arm, i.e., 18.9% versus 12.9%, respectively (AOR = 1.26; 95% CI: 1.01–1.53, $p = 0.03$). AOR of low Apgar scores at one and five minutes did not differ between study arms. AOR of admission to neonatal unit for treatment, FSB, and composite adverse perinatal outcome at delivery were comparable in both study arms after adjustment for gestational age. Similarly, the AOR of admissions to the neonatal unit for treatment, FSB, END, and composite adverse perinatal outcomes at 24-h were not significantly different after adjustment for baseline imbalances.

3.3. Comparison of Time Intervals between Continuous Moyo and Intermittent Doppler

Table 3 shows comparisons of linear regression models with natural-log-transformation of skewed time variables between the two study arms. We adjusted for mean admission cervical dilatation since it differed significantly between the two study arms (Table 1). Time from admission to delivery was comparable between study arms ($p = 0.39$). Time interval from admission to abnormal FHR detection was on average 14% shorter in the Moyo as compared to the Doppler arm ($p = 0.124$). Time from last FHR measurement to delivery was on average 12% significantly shorter in the Moyo arm compared to the Doppler arm ($p = 0.006$). Among deliveries with abnormal FHR, the time from detection to delivery was on average 36% significantly longer in Moyo compared to the Doppler arm ($p = 0.007$). Subgroup analysis showed that this difference between the time from detection of abnormal FHR to delivery was 36% significantly longer among vaginal deliveries ($p = 0.018$) and 8% longer among CS deliveries ($p = 0.680$) in Moyo compared to the Doppler arm.

Table 2. Comparison of labour and perinatal outcomes between intermittent Doppler and continuous Moyo.

Labour and Perinatal Outcomes	Intermittent Doppler (*n* = 1494)	Continuous Moyo (*n* = 1479)	Unadjusted OR * (95% CI)	*p*-Value	AOR (95% CI) **	*p*-Value
FHR during labour						
Normal	1347 (90.2)	1282 (88.4)				
Abnormal	147 (9.8)	197 (13.3)	1.41 (1.12–1.77)	0.003	1.46 (1.16–1.76)	0.002
Mode of delivery						
Vaginal	1302 (87.1)	1200 (81.1)				
CS	192 (12.9)	279 (18.9)	1.58 (1.29–1.93)	0.001	1.26 (1.01–1.53)	0.031
Apgar score at 1st minute						
Normal (≥7)	1361 (91.1)	1373 (92.8)				
Abnormal (<7)	133 (8.9)	106 (7.2)	0.79 (0.61–1.03)	0.082	0.92 (0.69–1.22)	0.555
Apgar score at 5th minute						
Normal (≥7)	1442 (96.2)	1436 (97.1)				
Abnormal (<7)	52 (3.5)	43 (2.9)	0.83 (0.55–1.25)	0.375	0.95 (0.69–1.63)	0.800
Delivery outcomes						
Normal	1338 (89.6)	1361 (92.0)				
Admitted for treatment	147 (9.8)	109 (7.4)	0.73 (0.56–0.94)	0.017	0.88 (0.69–1.17)	0.387
FSB	9 (0.6)	9 (0.6)	0.98 (0.39–2.48)	0.971	1.43 (0.55–1.19)	0.464
Admitted + FSB	156 (10.4)	118 (8.0)	0.74 (0.58–0.96)	0.021	0.91 (0.69–1.19)	0.497
24-h outcome						
Normal	1352 (90.5)	1368 (92.5)				
Still admitted for treatment	132 (8.8)	100 (6.8)	0.75 (0.57–0.98)	0.036	0.93 (0.69–1.24)	0.523
FSB + END	10 (0.7)	11 (0.7)	1.09 (0.46–2.57)	0.849	1.59 (0.65–3.90)	0.345
Admitted + FSB + END	142 (9.5)	111 (7.5)	0.77 (0.59–1.00)	0.051	0.97 (0.72–1.26)	0.706

* Odds ratio for abnormality/poor outcome for Moyo vs. Doppler ** Adjusted for baseline characteristics imbalances. Data shown as *n* (%) unless otherwise stated. OR: Odds ratio, CI: confidence intervals, FHR: Foetal Heart Rate, CS: Caesarean Section, END: Early neonatal deaths; FSB: fresh stillbirths.

Table 3. Comparison of time intervals (in minutes) between intermittent Doppler and continuous Moyo.

Time Intervals	Intermittent Doppler (Median (IQR))	Continuous Moyo (Median (IQR))	Unadjusted β-Coefficient (95% CI)	Unadjusted Effect Size (%)	*p*-Value	Adjusted β-Coefficient (95% CI) *	Adjusted Effect Size (%)	*p*-Value
Admission to abnormal FHR Detection (minute)	*n* = 147 197 (108, 330)	*n* = 197 192 (110, 330)	0.00 (−0.19–0.20)	1 (−17–22)	0.962	−0.15 (−0.34–0.04)	−14 (−29–4)	0.124
Admission to delivery	*n* = 1494 240 (150, 390)	*n* = 1479 288 (171, 288)	0.14 (0.08–0.19)	15 (8–20)	<0.001	−0.02 (−0.07–0.27)	−2 (−7–31)	0.399
Last FHR to delivery	*n* = 1494 15 (9, 30)	*n* = 1479 13 (6, 30)	−0.08 (−0.17–0.01)	−8 (−16–1)	0.082	−0.13 (−0.21–0.04)	−12 (−19–4)	0.006
Abnormal FHR to delivery (All deliveries)	*n* = 147 40 (25, 98)	*n* = 197 73 (40, 130)	0.42 (0.20–0.64)	52 (22–90)	0.001	0.31 (0.09–0.53)	36 (9–70)	0.007
Abnormal FHR to delivery (VD)	*n* = 114 30 (20, 52)	*n* = 133 54 (30, 94)	0.42 (0.17–0.67)	52 (19–95)	0.001	0.31 (0.05–0.57)	36 (5–77)	0.018
Abnormal FHR to delivery (CS)	*n* = 33 110 (89, 162)	*n* = 64 122 (78, 141)	0.08 (−0.23–0.39)	8 (−21–48)	0.496	0.08 (−0.24–0.39)	8 (−21–48)	0.680

* Adjusted for cervical dilatation (by linear regression of natural-log-transformed time intervals); IQR: interquartile range, CI: Confidence Intervals; FHR: foetal heart rate; VD: vaginal delivery, CS: Caesarean Section; All time intervals are in minutes.

3.4. Indications for CS and Intrauterine Resuscitation

Table 4 shows the indications for CS in relation to FHR detection in the two groups. Overall, there was no difference in the proportion of FHR abnormalities in the Moyo compared to Doppler arms (22.9% vs. 17.2%, respectively, $p = 0.129$). There were no differences in FHR abnormalities for the different indications except for obstructed labour group, where FHR abnormalities were detected more often in the Moyo versus the Doppler group (17.3 vs. 7.7%, respectively, $p = 0.052$).

Table 4. Comparison of indications for Caesarean section (CS) by foetal heart rate (FHR) abnormalities between Doppler and Moyo.

Indication for CS	Intermittent Doppler $n = 192$		Continuous Moyo $n = 279$		p-Value
	Normal FHR $n = 159$ (82.8)	Abnormal FHR $n = 33$ (17.2)	Normal FHR $n = 215$ (77.1)	Abnormal FHR $n = 64$ (22.9)	
Obstructed labour	72 (92.3)	6 (7.7)	100 (82.6)	21 (17.3)	0.052
Persistently abnormal FHR	0 (0)	21 (100)	0 (0)	39 (100)	NA
Prolonged labour	53 (100)	0 (0)	85 (98.8)	1 (1.2)	NA
Others	34 (85.0)	6 (15.0)	30 (90.9)	3 (9.1)	0.584

Data is shown as n (%), NA: Not applicable because one of the cells contains a zero value.

Overall, 85.3% of all foetuses with an abnormal FHR detected received at least one intrauterine resuscitation (87.0% vs. 84.0% for Moyo vs. Doppler, respectively, $p = 0.281$). These interventions included discontinuing oxytocin (38.8% vs. 30.6%, $p = 0.117$), changing maternal position (57.5% vs. 45.5%, $p = 0.859$), and administering intravenous fluids (77.7% vs. 82.9%, $p = 0.234$) for the Moyo versus the Doppler arms, respectively.

3.5. Abnormal Foetal Heart Rate Detection, Mode of Delivery, and 24-Hour Perinatal Outcomes in the Continuous Moyo Versus Intermittent Doppler Arms

Figure 4 shows subgroup comparisons of abnormal FHR detection, mode of delivery, and perinatal outcomes between the two arms. Of the 21 perinatal deaths that occurred within 24 h (i.e., 10 FSB and 11 END), 16 were associated with an abnormal FHR detection, equally proportioned in both arms. In cases with abnormal FHR detection, nearly equal proportions of deaths occurred with vaginal deliveries (5.3% vs. 4.4%, $p = 0.749$) in both arms, whereas it was lower in the Moyo compared to the Doppler arm (i.e., 1.6% vs. 9.1%, $p = 0.077$) in CS deliveries, respectively. With a normal FHR, in CS deliveries, there were no deaths in the Moyo arm while there were two deaths in the Doppler arm. For vaginal deliveries, two of the three deaths in the Moyo arm were due to congenital malformation and one due to foetal distress.

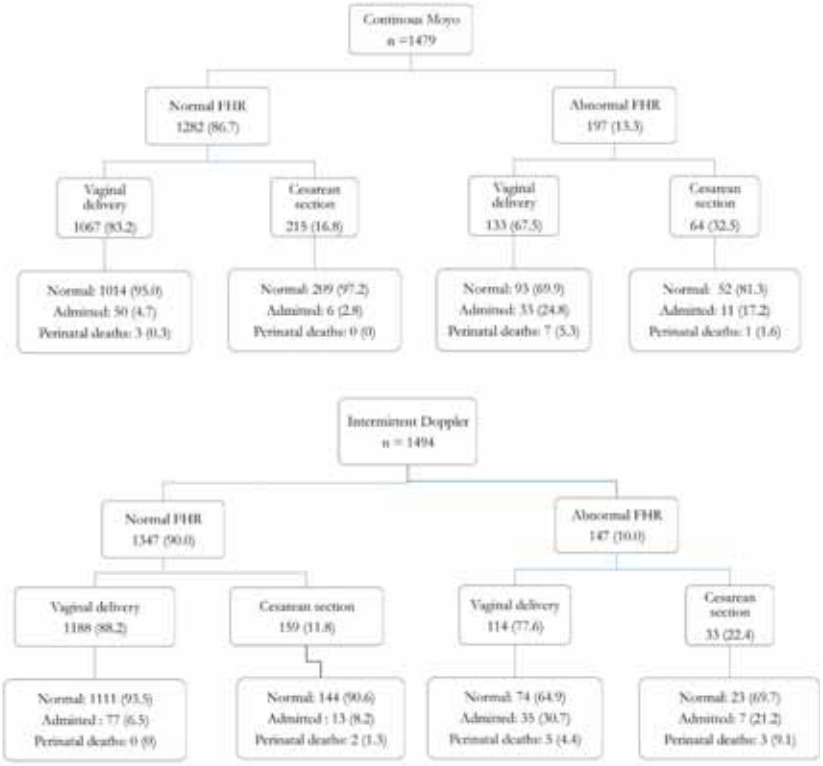

Figure 4. Flow diagrams of foetal heart rate (FHR) detections, mode of delivery, and perinatal outcomes in continuous Moyo and intermittent Doppler.

4. Discussion

This is the first randomised controlled study comparing a robust continuous FHR monitoring device (Moyo), developed for LIC settings to intermittent monitoring (Doppler) in an urban resource limited hospital. Use of the Moyo device identified 46% more foetuses with an abnormal FHR compared to Doppler assessments. An abnormal FHR was detected earlier when using the Moyo as compared to Doppler, however, the time from detection to delivery was longer in the Moyo arm. The CS rates were 26% higher in Moyo compared to Doppler although the difference was due to primary causes rather than an abnormal FHR. There were no differences in perinatal outcomes between the two groups after adjustment for baseline imbalances.

The findings from this study are similar to a recent study by our group comparing the Moyo device with a Pinard fetoscope in a rural setting in Tanzania [18]. Thus, there was an increased detection of abnormal FHR and intrauterine resuscitation in the Moyo arm, however, no differences were noted in perinatal outcomes [18]. One potential explanation for the increased and earlier detection of abnormal FHR when using Moyo is likely due to the increased sensitivity and continuous monitoring of the device. Thus, Moyo has an increased detection area, can detect FHR within 5 s, and has a 9-crystal sensor as compared to the single-crystal sensor in the Doppler machine. In addition, the Moyo is equipped with an automatic alarm which beeps in case of sustained abnormal FHR (>3 min), enabling the midwife to record the abnormalities, which are likely missed by intermittent auscultation [17]. Furthermore, the device provides 30-min FHR recording for review, enabling midwives to monitor labour progress accurately, as we recently documented [17]. In addition, we have recently published

qualitative assessment among mothers randomised to continuous monitoring with Moyo versus intermittent Doppler assessment, and reported that Moyo was the preferred device [23]. This was due to an interactive maternal-midwife component of Moyo, related to the fact that mothers could continuously hear the foetal heart sounds. This provided reassurance of their babies' viability [23].

Despite the increased detection of an abnormal FHR, there were no significant differences in perinatal outcomes (Figure 4). There are several potential reasons for this finding. Firstly, the study was performed among relatively low-risk labouring women, who are less likely to have distressed babies, and hence fewer adverse perinatal outcomes. As noted previously, a very large sample would have been needed to detect such small differences in proportions [9,27–29], and the study was not powered to do so. Secondly, while an abnormal FHR was detected earlier using continuous rather than intermittent monitoring, there was a significant overall delay to delivery in both the Moyo and Doppler arms, i.e., 73 min vs. 40 min, respectively, potentially leading to more foetal compromise. Recent studies in rural Tanzania have documented adverse perinatal outcomes associated with delayed delivery of babies with detected FHR abnormalities [5,6]. Timely delivery of these babies may have improved perinatal outcomes in both groups. Notably, in this study, the median time from abnormal FHR detection to delivery by CS was as high as 112 and 100 min in the Moyo and Doppler arms, respectively. The recommended time from decision to Caesarean delivery of the distressed baby is less than 30 min as per current international guidelines [30,31]. Potential reasons for this delay may relate to the fact that some of the women scheduled for CS were held back due to other more urgent CS cases [32]. The overall CS rate at MNH is above 50%, and most of these are done on an emergency basis [32]. Additionally, the labour ward and obstetric theatre are situated in two different buildings, hence increasing the time lag from decision to actual CS (Table 3) [21]. Importantly, evidence from high income countries indicates that the use of advanced FHR monitors coupled with timely CS for foetal distress is associated with reduced neonatal hypoxia, seizures, and perinatal deaths [7,27,28].

The higher rates of CS in the Moyo (26%) compared to the Doppler arm is consistent with previous studies and systematic reviews [7,9,28,33]. However, in this study, the higher CS rates were due to primary obstetric causes (such as obstructed labour) rather than the abnormal FHR (Table 4). Furthermore, previous studies have reported that clinicians and midwives may not undertake timely and appropriate interventions once a decision to perform a CS is taken, leading to the foetus being compromised [33,34]. This could have been a challenge in our study as well (with the obstetric theatre located in a different building), especially in the Moyo arm, with higher rates of CS.

Limitations

In this resource limited setting, the technology to conduct scalp foetal blood gas sampling, and thus, the ability to identify co-existent hypoxia/acidosis, was not available to support the significance of the FHR abnormalities. Moreover, there was an imbalance in the distribution of preterm infants and cervical dilatation on admission between the two randomisation arms; however, these were adjusted for in the regression analysis. Thirdly, due to the nature of the intervention (medical device), it was not possible to blind the health care workers who implemented and assessed the outcomes. In this study, we used simple randomization instead of a randomised block design with different block sizes, which would have minimized any unmasked bias. Fourth, some women were not randomized in this study due to precipitous labour and few were missed due to concurrent multiple admission, which may have made the findings less generalizable. Moreover, this study was designed to detect an abnormal <120 or >160 beats/min or absent FHR. Thus, the degree or persistence of bradycardia or the degree of the FHR variability were not recorded, which may have influenced the outcome. Finally, the study involved low-risk pregnancies with fewer adverse perinatal outcomes than would have been expected in the overall population.

5. Conclusions

An abnormal FHR was detected more frequently and earlier when using continuous monitoring with Moyo as compared to intermittent assessments using Doppler. There were no differences in adverse perinatal outcomes; the latter was likely related to the small sample size, a delayed response to delivery, and the low-risk nature of the study population. Studies designed and powered to detect differences in perinatal outcomes among high risk foetuses with timely obstetric responses are recommended [28].

Author Contributions: B.K. participated in the designing of the study, training, overall data curation, formal analysis and original draft preparation. H.K. participated in conceptualization, design, methodology, supervised data collection, review and editing and critically reviewed the manuscript. M.A. and M.N. participated in the methodology, training of midwives, supervision and review of the manuscript. I.D. reviewed the statistical analysis and the final draft of the manuscript. J.P. was involved in the design of the study and critically reviewed the manuscript. H.E. was involved in design of the study, interpretation of data, and critically reviewed the manuscript. All authors agreed on authorship and the final submitted manuscript.

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Data Availability: Raw data is available only on request. One can contact the Head of Research, teaching and Consultancy unit of Muhimbili National Hospital: Address, P.O. Box 65000. City, Dar es Salaam. Phone, +25-5222151599. Fax, +25-5222150534. Email: info@mnh.or.tz. No additional data available.

Conflicts of Interest: The authors have no conflicts of interest.

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Paper III

PLOS ONE

RESEARCH ARTICLE

Implementation of a novel continuous fetal Doppler (Moyo) improves quality of intrapartum fetal heart rate monitoring in a resource-limited tertiary hospital in Tanzania: An observational study

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Data Availability Statement: Data are available only upon request, due to ethical restrictions on sharing the dataset because it contains potentially identifying participant information. One can contact the Directorate of Research Temeke Municipal Council: Address, PO Box 46343, Dar es Salaam, Tanzania. Phone, +255 22 2928132. Email: temeke@tmc.go.tz on data request.

Abstract

Background

Intrapartum Fetal Heart Rate (FHR) monitoring is crucial for the early detection of abnormal FHR, facilitating timely obstetric interventions and thus the potential reduction of adverse perinatal outcomes. We explored midwifery practices of intrapartum FHR monitoring pre and post implementation of a novel continuous automatic Doppler device (the Moyo).

Methodology

A pre/post observational study among low-risk pregnancies at a tertiary hospital was conducted from March to December 2016. In the pre-implementation period, intermittent monitoring was conducted with a Pinard stethoscope (March to June 2016, n = 1640 women). In the post-implementation period, Moyo was used for continuous FHR monitoring (July-December 2016, n = 2442 women). The primary outcome was detection of abnormal FHR defined as absent, FHR<120or FHR>160bpm. The secondary outcomes were rates of assessment/documentation of FHR, obstetric time intervals and intrauterine resuscitations. Chi-square test, Fishers exact test, t-test and Mann-Whitney U test were used in bivariate analysis whereas binary and multinomial logistic regression were used for multivariate.

Results

Moyo use was associated with greater detection of abnormal FHR (8.0%) compared with Pinard (1.6%) (p<0.001). There were higher rates of non-assessment/documentation of FHR pre- (45.7%) compared to post-implementation (2.2%) (p<0.001). At pre-

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implementation, 8% of deliveries had FHR documented as often as $\leq$ 60 minutes, compared to 51% post-implementation (p<0.001). Implementation of continuous FHR monitoring was associated with a shorter time interval from the last FHR assessment to delivery i.e. median (IQR) of 60 (30,100) to 45 (21,85) minutes (p<0.001); and shorter time interval between each FHR assessment i.e. from 150 (86,299) minutes to 60 (41,86) minutes (p<0.001). Caesarean section rates increased from 2.6 to 5.4%, and vacuum deliveries from 2.2 to 5.8% (both p<0.001). Perinatal outcomes i.e. fresh stillbirths and early neonatal deaths were similar between time periods. The study was limited by both lack of randomization and involvement of low-risk pregnant women with fewer adverse perinatal outcomes than would be expected in a high-risk population.

Conclusion

Implementation of the Moyo device, which continuously measures FHR, was associated with improved quality in FHR monitoring practices and the detection of abnormal FHR. These improvements led to more frequent and timely obstetric responses. Follow-up studies in a high-risk population focused on a more targeted description of the FHR abnormalities and the impact of intrauterine resuscitation is a critical next step in determining the effect on reducing perinatal mortality.

Introduction

Worldwide 40% of 1.2 million stillbirths are intrapartum-related, i.e., termed fresh stillbirths (FSB) [1]. Some of these deaths are sometimes misclassified as early neonatal deaths (END) [2]. The identification and potential prevention of these FSB has not been addressed in the Sustainable Development Goals (SDG) [3,4]. About 2.6 million babies die annually during the neonatal period, of whom approximately 36% die on the first day, and 73% during the first week of life [5,6]. These neonatal deaths account for approximately 46% of all under-five deaths [6], an increase from the approximately 40% noted in 2000 [7,8] due to decline in mortality in other ages. Nearly a quarter of these neonatal deaths are intrapartum-related and occur mostly in low-resource settings [6,9–11].

Fetal heart rate (FHR) monitoring is crucial for the early screening and identification of existing or impending asphyxia. Studies show that an abnormal FHR detected during labor is associated with intrapartum fetal hypoxia, which may lead to an FSB, END or a live-born infant with variable degrees of hypoxic-ischemic brain injury [2,9,12–15]. Hence, early detection of a hypoxic state is a first step in potentially preventing these important problems. It is estimated that approximately 3 million deaths related to FSB and END could potentially be prevented by equipping and training health workers with tools, i.e., enhanced FHR monitoring capability to enhance the quality of care around the time of birth [12].

Indeed, improved FHR monitoring, coupled with the use of partogram documentation, has the potential to reduce intrapartum-related perinatal deaths [15–17]. Several reports show that appropriate documentation is completed in less than half of all deliveries [16–18], due to competing priorities and shortages of staff [19]. For example, in a tertiary hospital in Zanzibar, the ratio of birth attendant to laboring women was 1:6 [10], far less than the recommended 1:1 ratio for high-risk deliveries [20,21].

Auscultation with a fetal stethoscope, and occasionally with a fetal Doppler, are often the only method of fetal monitoring available in many low-resource settings [22,23]. In high-resource countries, cardiotocograph (CTG) is used, but complexities including high cost and need to continuous electricity supply limit use in low-resource settings [24]. Wyatt et al. theorized that the ideal device for these settings should be affordable and simple to operate [24].

The recent development of a novel strap-on FHR monitor, called Moyo, has facilitated a more rapid identification of the FHR and may be a breakthrough in identifying fetuses at high-risk of intrapartum hypoxia-ischemia. Although the reliability of the device is difficult to ascertain, it is noteworthy that in a recent qualitative assessment among mothers in Tanzania, it was noted that Moyo was the preferred device to use. This likely reflects the maternal-midwife interactive nature of the device, as well as the ability of the mother to hear fetal heart sounds providing "reassurance" of her fetus wellbeing [25].

We hypothesized that continuous FHR monitoring device will facilitate detection of abnormal FHR and timely interventions. The primary objective of the present study was to compare continuous FHR monitoring during labor using the Moyo device with prior intermittent FHR monitoring using a Pinard stethoscope for the detection of FHR abnormalities defined as absent, FHR<120 or FHR>160bpm in a resource-constrained tertiary hospital. Secondary outcomes were subsequent obstetric interventions, partogram documentation, frequency of newborn resuscitations, and the effect on perinatal outcomes.

Methods

Study design

A pre/post observational analytical study among low-risk pregnancies was conducted from March through December 2016 at Temeke Regional Referral Hospital in Dar es Salaam. In the pre-intervention period of 3 months (March to June), Pinard stethoscopes were used intermittently, and in the post-intervention period of 5 months (July to December), Moyo devices were used for continuous monitoring of FHR during labor.

The intervention

The Moyo (Laerdal Global Health, Stavanger, Norway) device is a novel strap-on FHR monitor equipped with a battery, containing a nine-crystal Doppler ultrasound sensor which facilitates the rapid identification of FHR (Fig 1). It can be used in either continuous or intermittent mode. The detection area reaches about 15 cm in radius, which makes palpation and aiming for heart beats less critical. Using a set of dry electrodes, maternal heart rate can be differentiated from FHR. The Moyo displays a 30-minute historical graph of FHR, as well as an audio-visual alarm which alerts the midwife every time there is an abnormal FHR or undetected FHR lasting for more than three minutes and continued alarming until something was done to correct the abnormality. We collected data on an intervention by the midwife following the initial Moyo alarm but not on subsequent alerts. A training flowchart is also provided to facilitate decision-making and timely responses.

Study setting

This study was conducted at Temeke, a referral hospital located in Dar Es Salaam, Tanzania. Temeke municipality has a population of about 2 million people [26]. The municipality has about 135 health facilities referring complicated cases to Temeke for advanced care. The hospital has about 30–60 deliveries per day (more than 12 000 per year). Its labor room has 18 beds and a general operating theatre is used for obstetric and other surgical cases. The obstetrics

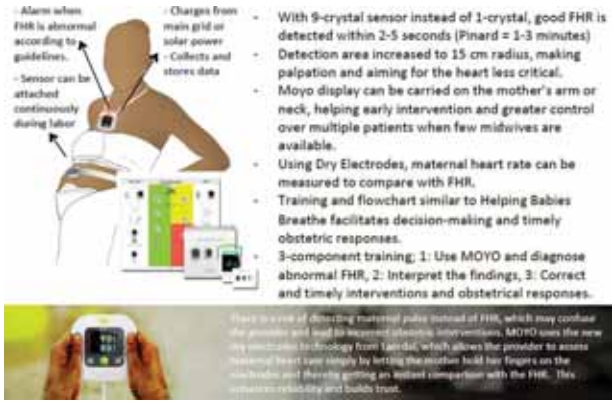

Fig 1. Moyo–The new continuous fetal heart rate monitor (Laerdal Global Health). FHR abnormalities defined as absent, FHR<120 or FHR>160bpm).

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unit has two qualified obstetricians, 12 general doctors, 25 nurse-midwives, five medical attendants and a varying number of rotating intern medical doctors and nurses who perform deliveries. Nurses have three shifts per day with an average of three nurses and one medical attendant per shift. Doctors have two shifts with one medical doctor and two interns during the day and night shifts, respectively. Some emergency cases are referred to Muhimbili National Hospital.

Training

Study training, focusing on the standard operating procedures for using the Moyo, was conducted in February 2016. The study investigators (MAS, MMN, BAK) trained midwives (n = 25) and doctors (n = 12) from the labor ward for one day. For both study periods i.e. pre- and post-implementation, training included FHR monitoring during labor (normal FHR range, i.e., 120 to 160 bpm) and the management of an abnormal FHR defined as absent, FHR<120 or FHR>160bpm). The criteria for monitoring were established and included the monitoring and documentation of the FHR every 30 minutes in the first stage of labor, every 15 minutes in the second stage, and immediately after every contraction, as per WHO and other international guidelines [27,28]. Refresher training sessions were conducted monthly to accommodate incoming healthcare workers. Research nurses (2 per shift) were trained separately on the research protocol and data collection to ensure the accuracy and completeness of the data. They observed deliveries in the labor room and followed admissions into neonatal units in shifts.

Study procedures

During the pre-implementation period, upon admission of the eligible women in the labor ward, a written consent was sought. FHR was to be monitored intermittently by auscultation using a Pinard stethoscope every 30 minutes in the first stage of labor, every 15 minutes in the second stage, and immediately after every contraction. A midwife auscultated the FHR for a complete minute with the Pinard stethoscope. Only baseline FHR was recorded in this study.

The Pinard is unable to delineate either decelerations or accelerations. FHR was recorded as abnormal if the FHR was absent or FHR<120 or FHR>160bpm.

During the implementation period, eligible woman admitted to the labor ward was given initial information about the Moyo by the nurse midwife. For those who consented, a Moyo was strapped on for continuous FHR monitoring. The midwife would then continue with her routine activities but also periodically (every 30 minutes) revisit the woman to check and record FHR reading from the Moyo monitor, or when the alarm for abnormal FHR was activated. Similarly, FHR was recorded as abnormal if there was absent heart rate or FHR<120 or FHR>160bpm from the Moyo monitor. The Moyo device was strapped on to the mother until the end of the second stage of labor or just before the commencement of a caesarean section. During both periods, the midwives were supposed to document the FHR in the partogram.

Research nurses recorded the frequency of the partogram and FHR documentation, the intrapartum management of different events (stopping oxytocin, giving intravenous fluids, changing mother's position) and perinatal outcomes on the data collection form.

Study population

The study population included every low-risk woman admitted in labor. Exclusions included those scheduled for elective cesarean section, twin pregnancies, women with abnormal FHR on admission i.e. absent; FHR<120 or FHR>160bpm, critically ill patients or with no measurements of FHR on admission, and admission in the second stage of labor coupled with full cervical dilatation.

Sample size

At Temeke, historical data showed that, when using available fetal auscultation, i.e., a Pinard stethoscope, abnormal FHR was detected in approximately 2.0% of all low-risk deliveries. Assuming an increase in detection rate to at least 5% with the Moyo device, we planned the study to include a minimum of 890 (total 1780) cases pre- and post-implementation, which would give us 90% power with alpha level of 0.05. This sample size was assumed to be reached within a study period of totally 4 months (2 months pre- and 2 months post-implementation), however, due to delays in implementation and to account for missing data, the study period was extended to totally 7.5 months.

Data collection

Data were collected using a data collection form, containing background characteristics which included maternal age (categorized as < 20, 20–35 and > 35 years), education level (primary, secondary and post-secondary training), marital status (married or single), antenatal care (ANC) attendance (none, 1–3 and > 3 visits), parity (nulliparous, 1–3 and > 3 deliveries), and gestational age (GA, in weeks) which was later dichotomized into preterm and term; all of these variables were extracted from the women's ANC cards on admission. The recorded labor and delivery variables included source of admission (home, referral or inpatient), presentation of the baby (cephalic or breach), and mode of delivery (normal vaginal, vacuum delivery and caesarean section). Intrauterine resuscitation performed after the detection of abnormal FHR were recorded, and included change of maternal position, discontinuing oxytocin, giving intravenous fluids and oxygen administration. Time intervals included labor ward admission to delivery, last FHR to delivery, and intervals between FHR monitoring.

Outcome measures

Outcome measures included abnormal FHR detection i.e. absent, FHR<120 or FHR> 160bpm, mode of delivery, Apgar score at 5 minutes (low if the score was < 7), resuscitation (stimulation, suction and ventilation), FSB, admissions to neonatal unit, END at 24 hours, and composite perinatal mortality (FSB and END).

Data management and analysis

The collected data were crosschecked for accuracy and completeness by the investigators before entry. Trained data clerks conducted double-entry of the verified data. Data consistency was checked, and mismatched cases were retrieved and corrected accordingly before analysis. Data analysis was conducted using SPSS (IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp).

Mean (SD), median (IQR) and proportion were used for descriptive statistics of background variables and outcomes. Pearson's Chi-square and Fisher's exact tests were used to test for proportion differences. *T*-test and Mann-Whitney *U* test were used to compare group mean and median respectively. Binary and multinomial logistic regression analyses were used to compare outcome variables pre- and post-implementation of the Moyo. We present unadjusted and adjusted odds ratio (AOR) with 95% confidence intervals (95%CI). STROBE was used as reporting guideline of this study.

Ethical clearance

This study was part of the Safer Births project, certified by both the National Institute of Medical Research in Tanzania (NIMR/HQ/R.8a/Vol. IX/1434) and the Regional Committee for Medical and Health Research Ethics, Western Norway (REK Vest). Permission to publish was granted by NIMR (NIMR/HQ/P.12 VOL. XXIV/15). Local permission was sought from Temeke Municipal Council. In the labor ward, participants were informed about the study and provided written consent if they agreed to participate. Routine clinical performance and patient information was recorded using confidential codes and these were kept in a safe and secure place by the investigators. Research staff were trained on maintaining confidentiality and signed a confidentiality agreement.

Results

During the study period, 7777 deliveries were recorded at the hospital (Fig 2), 3053 pre- and 4724 post-implementations of Moyo. Pre-implementation 1781 women were eligible and 1640 (92%) consented to participate. Post-implementation 2673 women were eligible and 2442 consented to participate (91.3%). Main reasons for exclusion included an abnormal FHR on admission, mothers scheduled for elective caesarean section, and those who presented with full cervical dilatation on admission.

The maternal and obstetric characteristics of the women included in both study periods are shown in Table 1. There were more primigravid mothers, more married women, mothers with a higher educational level, infants of a higher gestational age, and less premature infants (all $p<0.001$) post- versus pre-implementation.

Fig 3 shows the frequency of FHR monitoring pre- and post-implementation of the Moyo. During the post-implementation period, 2389/2442 (98%) of the women had the FHR monitored and documented in the partogram compared with the pre-implementation period, which was 890/1640 (54%) of the women ($p<0.001$). Overall, the frequency of the FHR monitoring was higher in post-implementation compared to pre-implementation ($p<0.001$). Post-

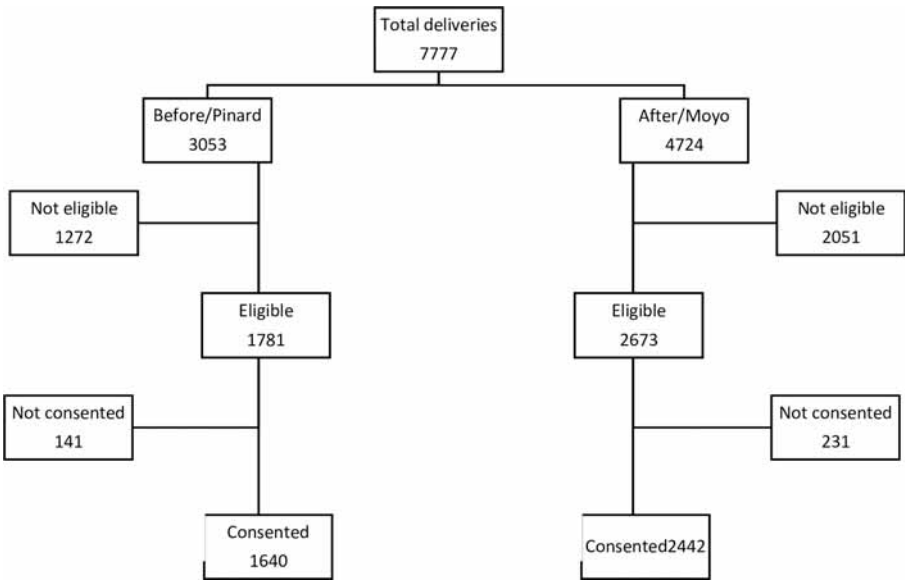

Fig 2. Flow chart of the study population.

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implementation, 13% of the women were documented every < 30 minutes compared to 2% pre-implementation. Approximately 38% of the mothers had their FHR documented every 30–60 minutes in the post-implementation period compared to 6% pre-implementation. Furthermore, post-implementation, 37% and 10% of the mothers had FHR documented every 61–120 and >120 minutes compared to 14% and 32% pre-implementation, respectively (all $p<0.001$).

An increased proportion of women received intrauterine resuscitation (i.e., change of mother's position, stopping oxytocin, starting IV fluids and oxygen administration) post-implementation. Specifically, oxytocin was discontinued in 2.4% as compared to 0.42%; changing position and initiating IV fluids increased to 5.5% from 0.06% and to 6.5% from 0.5%, respectively (all $p<0.001$).

Table 2 shows the proportions, unadjusted and adjusted comparisons of different labor, delivery and perinatal outcomes between the two time-periods. Women had 45 times higher odds of having the FHR monitored and documented post-implementation (AOR 45; 95% CI 34.4–62.5) ($p< 0.001$). An abnormal FHR detection had almost 7 times higher odds of being detected post-implementation (AOR 6.90, 95%CI 3.89–12.24). A caesarean delivery was 5.7 times and a vacuum extraction 3.8 times higher odds post- versus pre-implementation (both $p< 0.001$). Overall, infants had higher odds of receiving any form of resuscitation post-implementation ($p < 0.001$). More specifically, a lower proportion of babies were stimulated post- versus pre-implementation (11.3% vs 14.8%, $p = 0.001$), whereas a higher proportion received bag mask ventilation post- compared to pre-implementation (5.0% vs 2.6%, $p<0.001$). More babies were admitted to a neonatal area following birth and at 24-hours post-delivery during the post- compared to pre-implementation period ($p = 0.001$). Perinatal mortality did not differ between the two time periods.

Table 1. Baseline maternal and obstetric characteristics of women admitted in the labor ward at temeke hospital pre- and post-implementation of a continuous automatic Doppler (Moyo) from March to December 2016.

Maternal/Obstetrics characteristics		Pre-implementation; Pinard (N = 1640)	Post-implementation; Moyo (N = 2442)
Age (years)	(Mean ± SD)	25.7±6.1	25.4±6.0
	<20	267 (16.3)	394 (16.1)
	20–35	1234 (75.2)	1859 (76.1)
	>35	134 (8.5)	189 (7.7)
Parity	Primigravida	622 (37.9)	1104 (46.9)
	2–4	877 (53.5)	1145 (46.9)
	Grand multiparity	141 (8.6)	193 (7.9)
Source of admission	Home	1050 (64.0)	2025 (82.9)
	Inpatient/Referrals	590 (36.0)	417 (17.1)
Marital status	Married	1243 (75.8)	2074 (84.9)
	Single/cohabiting	397 (24.8)	368 (15.1)
Antenatal visits	None	37 (2.3)	37 (1.5)
	1–3	652 (39.8)	941 (38.5)
	>3	951 (58.0)	1464 (60.0)
Education	Primary	1131 (69.0)	1908 (78.1)
	Secondary and above	509 (31.0)	534 (21.9)
Gestation age (weeks)	(Mean ± SD)	38.4±2.0	38.9±1.7
	Preterm	45 (2.7)	39 (1.6)
	Term	1595 (97.3)	2403 (98.4)
Cervical dilatation (cm)	(Mean ± SD)	6.3±1.5	6.2±1.5
Presentation	Cephalic	1630 (99.4)	2413 (98.8)
	Breech	10 (0.6)	29 (1.2)
*HCW attending delivery	Doctor	86 (5.2)	135 (5.5)
	Nurse/midwife	1554 (94.8)	2307(94.5)

*HCW: Healthcare worker

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There were more caesarean sections (5.4%) post- compared to pre-implementation (2.6%) (p <0.001). The primary indications for caesarean section were: fetal distress, 48% vs 35%; obstructed labour, 9% vs 14%; prolonged labor, 23% vs 40%; and previous CS, 12% vs 9%, in post- versus pre-implementation periods, respectively ($p = 0.349$).

Table 3 shows the median (IQR) time intervals comparing those who had at least one FHR assessed and documented post- versus pre-implementation of the Moyo. The median time interval from admission to delivery was 212 compared to 225 minutes ($p = 0.002$), the median time interval from the last FHR assessment to delivery was 45 versus 60 minutes ($p<0.001$), and the median time interval between FHR documentation in the partogram was every 60 versus every 150 minutes ($p<0.001$), post- versus pre-implementation, respectively. There was no significant difference in time interval from either admission to detection of abnormal FHR or from abnormal FHR detection to delivery.

Discussion

The findings in this study demonstrate that implementation of continuous FHR monitoring using a novel Moyo device, was associated with a 6.90-fold increased detection of abnormal FHR i.e. absent, FHR<120 or FHR>160bpm, markedly improved intrapartum FHR

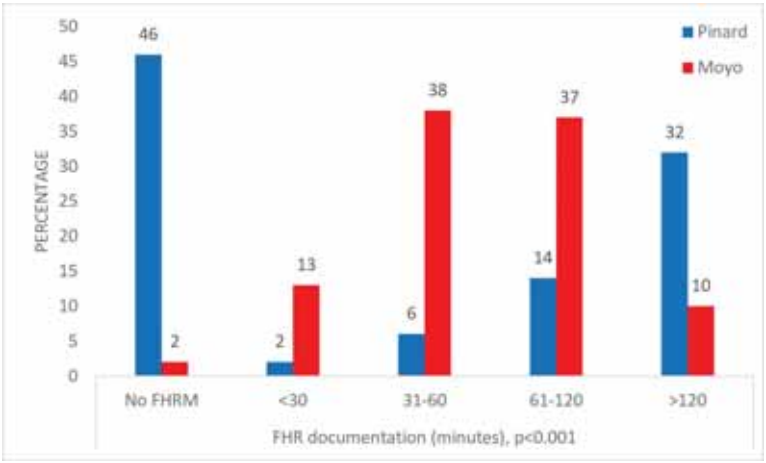

Fig 3. Frequency of Fetal Heart Rate monitoring and documentation post-implementation vs pre-implementation of the Moyo.

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monitoring practices, enhanced documentation on the partogram, a reduced time interval from the last FHR assessment to delivery and was coupled with more intrauterine resuscitations. A cesarean section was 5.7-fold higher odds, and a vacuum extraction delivery 3.8-fold higher odds post-implementation. Overall, the need for resuscitation interventions was less post-implementation, however, more babies received bag mask ventilation during the latter period. There were no differences in FSB and END, but there were more admissions to the neonatal unit following delivery and at 24-hours during the post-implementation period.

Adherence to standard clinical practice of FHR monitoring, especially in low income countries, has been persistently inadequate, which likely has contributed to the unchanged rates of FSB and END over time. In order to facilitate FHR monitoring as well as partograph documentation in accordance with international guidelines, strategies have focused on augmenting human resources, pre- and in-service continued training, as well as enhancing supportive supervision [29]. Further studies have addressed poor midwives attitudes, as well as lack of confidence and skills, as additional important factors contributing to suboptimal FHR monitoring [29–31]. Using the Moyo device, the ability of the midwife to identify an abnormal FHR was improved in two ways. First, by visually documenting the details of abnormal FHR in real-time, via the 30-minutes histogram review of the tracing. Second, via activation of an alarm, if the FHR abnormality was of a three-minutes duration. This latter feature allowed the midwife to monitor several mothers simultaneously, which is a major benefit of this device. This translated into improved FHR monitoring practices including timely responses, such as reduced time to the detection of an abnormal FHR following admission, shorter times from the last FHR measurement to delivery as well as shorter overall duration of labor. This is consistent with previous studies showing that improved fetal surveillance was associated with reduction of labor time [32]. In addition, the midwife was then able to respond to the abnormal FHR, by implementing intrauterine resuscitation attempts more frequently, in efforts to reduce intrapartum hypoxia/ischemia as documented earlier [33]. These cumulative findings indicate that by providing continuous FHR monitoring, coupled with an audible alarm system, a significant

Table 2. Proportions, unadjusted and adjusted comparison of FHR documentation practices and outcomes post vs. pre-implementation of strap-on automatic Doppler (Moyo).

Variable	Values	Pre-implementation; Pinard (N = 1640)	Post-implementation; Moyo (N = 2442)	Unadjusted OR (Moyo vs. Pinard)	p-value	Adjusted OR (Pinard vs. Moyo)**	p-value
FHR monitoring during labor	Yes	890 (54.3)	2389 (97.8)	38.46 (28.57–50.0)	<0.001	45.45 (34.4–62.5)	<0.001
	No	750 (45.7)	53 (2.2)	1		1	
FHR during labor*	Normal	876 (98.4)	2198 (92.0)	1		1	
	Abnormal***	14 (1.6)	191 (8.0)	5.44 (3.14–9.41)	<0.001	6.90 (3.89–12.24)	<0.001
Mode of delivery	Normal (SVD)	1561 (95.2)	2167 (88.7)	1		1	
	Caesarean Section	43 (2.6)	133 (5.4)	2.23 (1.57–3.16)	<0.001	5.79 (3.34–10.01)	<0.001
	Vacuum	36 (2.2)	142 (5.8)	2.84 (1.96–4.12)	<0.001	3.851 (2.54–5.83)	<0.001
Received resuscitation	Yes	321 (19.6)	297 (12.2)	0.57 (0.48–0.68)	<0.001	0.63 (0.52–0.75)	<0.001
Stimulation	Yes	242 (14.8)	276 (11.3)	0.74 (0.61–0.89)	0.001	0.86 (0.71–1.06)	0.14
Suction	Yes	210 (12.8)	298 (12.2)	0.95 (0.78–1.14)	0.57	0.99 (0.81–1.22)	0.96
Ventilation attempted	Yes	43 (2.6)	122 (5.0)	1.95 (1.37–2.78)	<0.001	2.28 (1.57–3.30)	<0.001
Apgar score at 5 minutes	<7	25 (1.5)	51 (2.10)	1.58 (0.95–2.64)	0.19	1.58 (0.95–2.64)	0.07
Birth outcomes	Normal	1586 (96.8)	2327 (95.3)	1		1	
	Admitted to neonatal unit	47 (2.9)	107 (4.4)	1.55 (1.09–2.19)	0.014	1.71 (1.18–2.47)	0.005
	Fresh Stillbirths	7 (0.42)	8 (0.33)	0.78 (0.28–2.15)	0.630	0.90 (0.30–2.63)	0.85
Neonatal outcomes 24-hours	Normal	1603 (98.0)	2353 (96.7)	1		1	
	Admitted to neonatal unit	27 (1.7)	74 (3.0)	1.87 (1.19–2.91)	0.006	2.11 (1.33–3.38)	0.002
	END	5 (0.3)	7 (0.3)	0.95 (0.30–3.01)	0.940	0.99 0.29–3.30)	0.97
	Perinatal deaths (FSB +END)	12 (0.7)	15 (0.6)	0.98 (0.43–2.17)	0.958	0.73 (0.31–1.72)	0.47

SVD = Spontaneous vaginal delivery, FSB = Fresh Stillbirths, END = Early neonatal deaths, AOR = Adjusted Odds Ratio

*Only those who were monitored are included in the denominator

**Adjusted for baseline imbalances

*** absent, FHR<120 or FHR>160bpm

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improvement in midwifery standards and quality of care delivered during the intrapartum period, in accordance with international guidelines, is possible [27,28].

The finding of low FHR monitoring documentation (54%) in the pre-implementation period is consistent with previous studies in Nepal, Ethiopia, and Ghana, where the rates were as low as 20%, 30% and 55%, respectively [18,30,34]. In these countries, the most frequently used device was the Pinard stethoscope. Health care workers with demanding workloads are highly likely to miss important changes in fetal condition with intermittent FHR monitoring [24,35]. The improvements shown in FHR monitoring, and adherence to the partogram in this study, are likely due to the user-friendly features of the Moyo device, which enables the midwife to attend to several patients concurrently, with minimal interruption of routine duties. Despite improved rates, the documentation of FHR monitoring frequencies of < 30 min were still low (13%) with continuous monitoring as compared to the available guidelines [36]. This low frequency of documentation was also reported when using intermittent auscultation FHR monitoring in the high-resource setting (48%) where the midwife-to-patient ratio was nearly 1:1, indicating that other factors may be contributing to this suboptimal documentation [29].

Table 3. Comparison of different median time intervals pre- and post-implementation of the Moyo at Temeke*.

Time intervals (q1, q3)	*Pre-implementation Pinard*	*Post-implementation Moyo*	*P-value**
Admission to delivery	**(*n* = 1640)**	**(*n* = 2442)**	
	225 (130, 387)	212 (117, 355)	0.002
Admission to Abnormal FHR** detection	*n* = 14	*n* = 191	
	230 (120, 630)	138 (65, 302)	0.184
Last FHR assessment/ documentation to delivery	*n* = 890	*n* = 2389	
	60 (30, 100)	45 (21, 85)	<0.001
Between FHR assessment/ documentation	*n* = 890	*n* = 890	
	150 (86, 299)	60 (41, 86)	<0.001
Abnormal FHR to delivery	*n* = 14	*n* = 191	
	28 (19, 57)	43 (23, 80)	0.255

q1 25th percentile and q3 75th percentile

*Mann-Whitney U test, FHR = Fetal Heart Rate

**absent, FHR<120or FHR>160bpm

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In this study, we noted an increased rate of caesarean section deliveries from 2.6 to 5.4%, presumably in response to the abnormal FHR. This rate is similar with a worldwide population-based ecological study (2012) that reported an overall caesarean rate of 5.2% in low income countries [37]. The World Health Organization (WHO) suggests that a rate of between 10 and 15% at a population level, may reflect optimal intrapartum care, provided decisions are based on balancing the risks and benefits of this intervention [38,39].

It is noteworthy that while the overall need for resuscitation decreased post continuous monitoring, the number of babies receiving bag mask ventilation increased. This incongruous finding may be due to several interrelated factors. First, the higher incidence of an abnormal FHR may have reflected an intrapartum hypoxia/ischemia state, with resultant respiratory depression upon delivery. Second, the caesarean deliveries were invariably performed under general anesthesia and depending on the duration between initiation of anesthesia and delivery, this may have resulted in the initial respiratory depression, particularly in the setting of an abnormal FHR. There were no differences in FSB and END likely reflecting a low occurrence of these morbidities in this low-risk population. An explanation for the increased number of admissions post-implementation to a newborn area is not entirely clear. However, more mothers underwent caesarean section, invariably under general anesthesia post-implementation. In this setting, mothers are usually separated from their newborns for 24 hours after the caesarean section. In addition, some of these neonates were admitted for observation following bag mask ventilation, and/or were waiting for their mothers to recover from surgery.

Limitations

There were several limitations. First, this was a pre- and post-implementation study design, hence there was no randomization. However, we consider the time difference between the pre- and post-implementation period of too short a duration for factors other than the intervention to cause the improvements. Furthermore, there were no observed systemic changes that might have led to improved FHR monitoring. Second, although imbalances in baseline characteristics were observed, these were adjusted in the regression analysis to remove potential confounding effects and improve the precision of the effect measures estimates. Third, the study involved only low-risk pregnancies with fewer adverse perinatal outcomes than would

have been expected in the overall population. Fourth, some health workers might have failed to complete the partogram, even if FHR measurements were taken, leading to a misclassification as being non-documented. Fifth, only baseline FHR abnormalities i.e. absent, FHR<120bpm or FHR>160bpm were recorded while early, late decelerations or rapid accelerations were not addressed in this study. Unfortunately, the time from alert to response was not collected in this study. Moreover, we did not collect data on when there was an alert without a response. This important question will be included in future prospective studies in the high-risk population.

Conclusion

Implementation of the Moyo device, which continuously measures FHR, was associated with improvement in the quality of FHR monitoring practices, and the detection of abnormal FHR (absent; FHR<120bpm or FHR>160bpm) in the resource-constrained setting. These improvements led to more frequent and timely obstetric responses. Follow-up studies in the high-risk population, focused on a more targeted description of the FHR abnormality, including the duration, recurrence, and the relation to uterine contractions, as well as the impact of intrauterine resuscitation on the FHR abnormalities, is a critical next step in determining the impact on reducing perinatal mortality.

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