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Comparative Analysis of Life Curve Mobile Application: an Easier Alternative to Existing Traditional Paper Partograph

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Research question
Is Life Curve Mobile Application superior to existing traditional Paper Partograph?
Hypothesis
The Life Curve Mobile Application is not superior to existing traditional Paper Partograph.
Alternate Hypothesis:
The Life Curve Mobile Application is Superior to existing traditional Paper Partograph.
Objectives

- To determine the effectiveness of Life Curve Mobile Application compared to existing traditional Paper Partograph.
- To compare the user friendliness of Life Curve Mobile Application and existing traditional Paper Partograph.

I. Background

Approximately 303,000 maternal deaths occurred globally in 2015, of which 99% occurred in the developing countries[1]. On an average 239 women die per 100,000 live births every year in developing countries[2]. Majority portion of this maternal death are seen in Sub-Saharan Africa and Southern Asia[1.] Thus Maternal mortality ratio continues to be the major index of the widening discrepancy in the level of care and the outcome of reproductive health between the advanced and developing countries[3]. From 1990 to 2015 Bangladesh has achieved 69.1 percent reduction in maternal mortality ratio but failed to achieve Millennium Development Goal of 75% reduction and in 2015 there were about 176 maternal deaths per 100000 live births[2]. Causes of maternal mortality include postpartum hemorrhage, eclampsia, obstructed labor, and sepsis. Among those obstructed labor accounts for 8% of maternal deaths[5]. The reported incidence of obstructed labor expected to reach 20% in developing countries though other causes are also significant[6]. Obstructed labor may also lead to atonic postpartum hemorrhage, maternal exhaustion and dehydration, uterine rupture and obstetric fistulas[7,8] eventually leading to maternal mortality. For these reasons WHO recommended paper Partograph to monitor the labor and early identification of impending complication.

Paper Partograph:

The Partograph as a graphic assessment is recommended for routine monitoring of the 1st stage of labour to help the birth attendants identify any slow progression of labour[9] and thus prevents prolonged labour and its complications[10]. Formerly called the Friedman's curve, the partograph was designed by Friedman in 1954 following a study on a large number of parturients in USA[11]. Requiring only a printed sheet to chart what should be routine care, the partograph would seem to be an appropriate technology in low- and middle-income countries (LMICs) with a clear place in maternity care.

Problem Description of Use of Paper Partograph:

Though Paper Partograph is an effective tool but, however, it is often reported as substantially underused[12]. To overcome the under-utilization since the inception of partograph, several types of partograph have been developed in various countries to suit local needs[13]. But still use of partograph is not increasing satisfactorily[14.] Despite more than 50 years of training and investments in the partograph in a low-resource setting, due to low rate of implementation and provider competencies it can be said that the paper partograph has failed practically to reach the potential of its original design i.e to provide an inexpensive and simple "early warning system"[15] for identifying complications during childbirth.[11]

According to Cochrane collaboration review the limited use of the partograph probably results more from the contextual challenges of fragile health systems than from deficiencies in the tool itself[16]. Moreover, besides the lack of preprinted partograph in the health institutions, poor knowledge and attitude towards partograph were identified as barriers of using partograph during labour[17-19].

The WHO prospective trial in South East Asia suggested that proper use of paper partograph reduced prolonged labour and promoted more appropriate obstetric assessment and intervention. Although, a Cochrane review of trials in variable resourced settings found insufficient evidence to either support or discourage its use[16]. Some gaps remain in the evidence base, and the assumption of universal relevance in a diversity of contexts and for a diversity of women is still debated[20.]

Differences between the available versions of partograph could be confusing[21], and their completion required intensive training. Difficulties tended to arise when birth attendants' graphing skills were less developed than their obstetric knowledge[22-23]. Identifying the latent phase of labour was a particular area of confusion[21,24] and it is possible that the simplified version of the partograph may be more likely to be completed[25]. The requirement for a certain level of literacy[26], and for translation into local languages[27] were potential barriers to uptake. Finally, you cannot use a partograph if you do not have it: procurement and supply chains are often problematic in LMICs, and limited availability was reported[28-30]

Bangladesh Scenario:

Several major challenges are identified for underutilization of Partograph in Bangladesh. Overburdened health systems in Bangladesh are often unable to supply the administrative and organizational support needed for proper and consistent use of the partograph. Shortage of trained personnel[31] who are competent in labor management and inadequate referral systems for women in labor who experience complications are more evident in low resource countries. Moreover, the tool itself may present difficulties for health care providers as they lack the underlying knowledge and skills that is required for proper monitoring of the patient, drawing of the partograph with the findings and ultimately manual interpretation of data.

Problem Analysis & Justification of New Tools:

To get the beneficial effects of paper partograph it should be used correctly and consistently. Trainers and supervisors must recognize that, while the partograph appears to be simple, it assumes a foundation of knowledge and skills in assessment of labor, gathering of data, presentation and interpretation of data are also essential[31]. Every facility that serves laboring women must have clearly articulated protocols of care that is synchronized with the partograph. Hence considering the pros & cons of the present paper partograph a concept of much easier, efficient and cost effective alternative becomes a point of concern. Mobile computing devices are increasingly being used by health care professionals and soon will become ubiquitous in clinical environments[32]. Many medical applications for smartphones have been developed and widely used by health professionals and patients. The use of smartphones is getting more attention in healthcare day by day[33]. Considering these barriers at hand we aimed to develop a tool to monitor stages of labour which will be easier to use and available at hand. So, we took this opportunity to program an innovative mobile application which is an easier, efficient and cost effective tool for monitoring labour.

Details of Life Curve Mobile Application (LCMA):

Life Curve Mobile Application is a user friendly android mobile application by which any health professional including midwives & nurses can monitor the labour very easily and efficiently.

It has five functional segments:

Details of the women in Labour: The settings interface makes it possible to enter particulars of mother comprising name of the mother, her age, contact number, previous obstetric history (if any), significant history of allergy, identification number, date of admission, time of admission along with the name & contact number of the concerned Physician or distance monitor.

Details of the labour: Includes all essential parameters of labour monitoring: Fetal & Maternal heart rate, Blood pressure, Temperature, Cervical dilatation, Fetal head descent & Number of uterine contraction in 10 minutes.

***Analysis of the Values*:** When health care providers input the value of labour monitoring parameters this application will analyze the values by an algorithmic method and visualize a color pictogram (Fetus within a Mother's womb) depicting current state of both mother and baby according to the values. This pictogram demonstrates the condition of mother and baby by three colors: Red, Yellow and Green. Here Red indicates 'critical', Yellow means 'close observation necessary' and Green stands for 'safe condition'. For example: considering that rest of the parameters are within normal limits when maternal blood pressure is about 180/90mm Hg and fetal heart rate is 120/min, it will visualize the picture of mother by red color with a green color baby(Figure 1). Insertion of values of cervical dilation every 4 hours and rest of the values in half hour intervals will generate an automated graph like the existing paper Partograph. Using this graph the attending

health care provider will be able note if the parturient mother has crossed the alert line or action line and will be able take necessary action according to standard protocol. Also, the software interface will show a warning yellow indicator (beeping text with yellow highlight) when patients condition crosses alert line and a red indicator (beeping text with red highlight) when patients condition crosses action line along with sending a message to the respective health care provider.

***Alarm System*:** Instantaneous generation and transfer of text message to concerned physicians or distance monitor when any parameter is out of range ensures the accountability and alertness of the physician as well as opens scope for distance monitoring. Beeping alarm system also alert the attending nurse and peers of the mother**.**

Storage of Data: All the values entered in the application are recorded with network provided time. There is no chance of deletion of the values, messages or pictograms minimizing the need of retrograde use of the application. Moreover, outcome of the labor can be stored in the application by touching 'Stop Notify' option. An outcome interface will be shown to the user where following information can be recorded: normal delivery, instrumental delivery, caesarian section (along with indications like non progress of labor, obstructed labor, deep transverse arrest, cephalo-pelvic disproportion or CPD, failed instrumental delivery, foetal distress or other causes), distant referral of mother, still birth, APGAR score of foetus, NICU referral of foetus, maternal complications (like post partum hemorrhage, ruptured uterus, obstetric fistula or others) and other information. These stored information will provide a scope for research regarding outcome of labour or others, which is an additional benefit of the application.

II. Methodology of the study

Study design

A Randomized Controlled Trial (RCT) is proposed. This study design is selected because LCMA is a new tool which needs to compare with simplified version of paper Partograph version 2000 by WHO to prove its efficacy and usability. Randomized controlled trials ensure maximum strength to compare the outcome variable thereby representing the strongest design with the greatest likelihood of providing clear and accurate assessment.

Study sites

This study [Randomized Controlled Trial (1:1)] will be conducted in six tertiary care health facilities in Bangladesh. Inclusion criteria for health facilities are: a minimum of 1,000 deliveries per year, the major health care facility in its region, and not a primary health care unit. Institution should have all kind of expertise to manage all kind of complications including caesarean section, augmentation of labour, assisted vaginal delivery and good intrapartum care practices (e.g. intermittent fetal monitoring, respectful maternity care, good midwifery care).

Time frame:

The study should be conducted from January 2017 to December 2017, after having clearance from Institutional ethical review committee for 1 year duration.

Sample size calculation:

The sample size was calculated using the formula $N=(Z\alpha+Z\beta)2 \times 2p(1-p)\div d\ 2$,taking the level of significance as 5%, $Z\alpha=1.96$ and power of the test as 80%, $Z\beta=0.84$. $p=0.113$. A sample size of 65 in each group was calculated.

In order to achieve the main objective of this study, in each study site 65 control and 65 case mother would be selected and a total 780 of women in early labour will be included.

Inclusion Criteria: All women admitted for vaginal birth with-

- Single live fetuses
- Women are in the first stage of labour (both in latent phase or early active phase)
- Women undergoing induction of labour
- Those with spontaneous labour onset presenting at cervical dilatation of ≤6 cm
- vertex gestations
- Those willing to participate.

Women will be considered for inclusion whether or not they primarily receive antenatal care and plan to deliver at the participating hospital.

Exclusion criteria:
Women will be excluded from the study having any of the following characteristics-

- False labour
- Multiple pregnancy
- Gestational age less than 34 weeks (i.e. 33 weeks and 7 days)
- Advanced first stage of labour (≥7 cm cervical dilatation)
- Absence of an identifiable fetal heart sound at hospital admission (presumed intra-uterine fetal death)
- Elective C-section
- Indication for emergency C-Section or laparotomy on admission
- Pre-labour C-section
- Attempted induction of labour but no labour achieved
- Non-emancipated minors without a guardian
- Women who are not capable of giving consent due to labour distress or any health problem(such as obstetric emergencies (e.g. eclampsia) or
- Women having diagnosed Mental disorder.
- Short statured women (<140cm.)
- Antepartum haemorrhage
- Severe preeclampsia / eclampsia
- Malpresentations and
- Anaemia (haemoglobin <10g)

Participant recruitment
Assessment of study eligibility and recruitment of participants will be carried out by trained research Physician, who will approach women for consent for participation in the study at hospital admission except when they meet any of the exclusion criteria listed above.

Outcome Variable:
Following outcome variable will be considered for comparison in both simplified Partograph and LCMA:

1. Labor crossing the alert line in Paper Partograph and alert line in automatically generated graph of LCMA (or showing the yellow text indicator).
2. Labor crossing the action line in Paper Partograph and action line in automatically generated graph of LCMA (or showing the red text indicator).
3. Augmentation of labor.
4. Outcome of labour like :

- Rate of cesarean section,
- Perinatal outcome
- Admission to NICU
- Apgar score less than 7 at 5minutes after birth.
- Intra partum related perinatal death (Fresh still birth)

5. Management of maternal complication like-

- Rate of caesarian section
- Instrumental delivery

6. User friendliness of LCMA in comparison to simplified Partograph.
7. Difficulty in using Partograph and LCMA.

Admission Procedure: In each participating health facility, trained research nurses will screen all women admitted for vaginal birth using the screening form. Once the eligibility of the women to participate in this study is determined, the research Physician will invite the potential participant to join the study and seek her individual consent using the individual consent form.

Data collection Procedures: Data will be gathered continuously for a period of 6 months at each facility. At each facility, research assistants will be trained to perform data collection and distributed to ensure coverage of typical hospital shifts. They are responsible to extract information regarding demographic characteristics and information relevant to women in a preformed form.
Research nurses will ensure that data extraction covers the three process levels of intrapartum care that are relevant to the study objectives i.e. hospital admission, labour and childbirth process, and postnatal period/hospital discharge).

Research physician will examine the patient and check all the parameters and input the data in LCMA as well as plot the Partograph.

A hospital coordinator will facilitate and oversee the data collection process and training of local research staff, conduct training of existing hospital staff on adequate documentation of labour events, and transfer completed data collection forms to the Principle Investigator.

After end of the study hospital coordinator would provide a separate questionnaire where research physicians will score the Partograph and Life Curve for each of the following categories: timeliness, teachability, overall usefulness, informing the consultant, interpretation and overall rating.

Data collection will start at hospital admission and end in the event of maternal death, transfer or hospital discharge.

Follow-up procedures

Data will be collected during hospital stay only which will start at hospital admission and will end in the event of maternal death, transfer or hospital discharge. No follow-up will take place after discharge of the patients.

Criteria for discontinuation of a participant

Women who had initially given consent and later decline to continue participation will be discontinued from the study.

Conduct of the studies: (Figure 1)

Principle investigator visit to monitor the study progress and communicate with local investigator as well as Hospital coordinator to monitor the trail progress.

Data management:

Data entry done in four level.

Level one: By research Assistant (Demographic profile etc. which was mentioned above)

Level two: By research Nurse (Hospital admission, primary screening etc which was mentioned above)

Level three: By research physician (Main outcome variables)

Level four: By research assistant (Entry of cumulative data in SPSS)

All investigator will check the recruitment, loss to follow up, completeness of data for main outcome variable and they report all the relevant documents to Principle investigator.

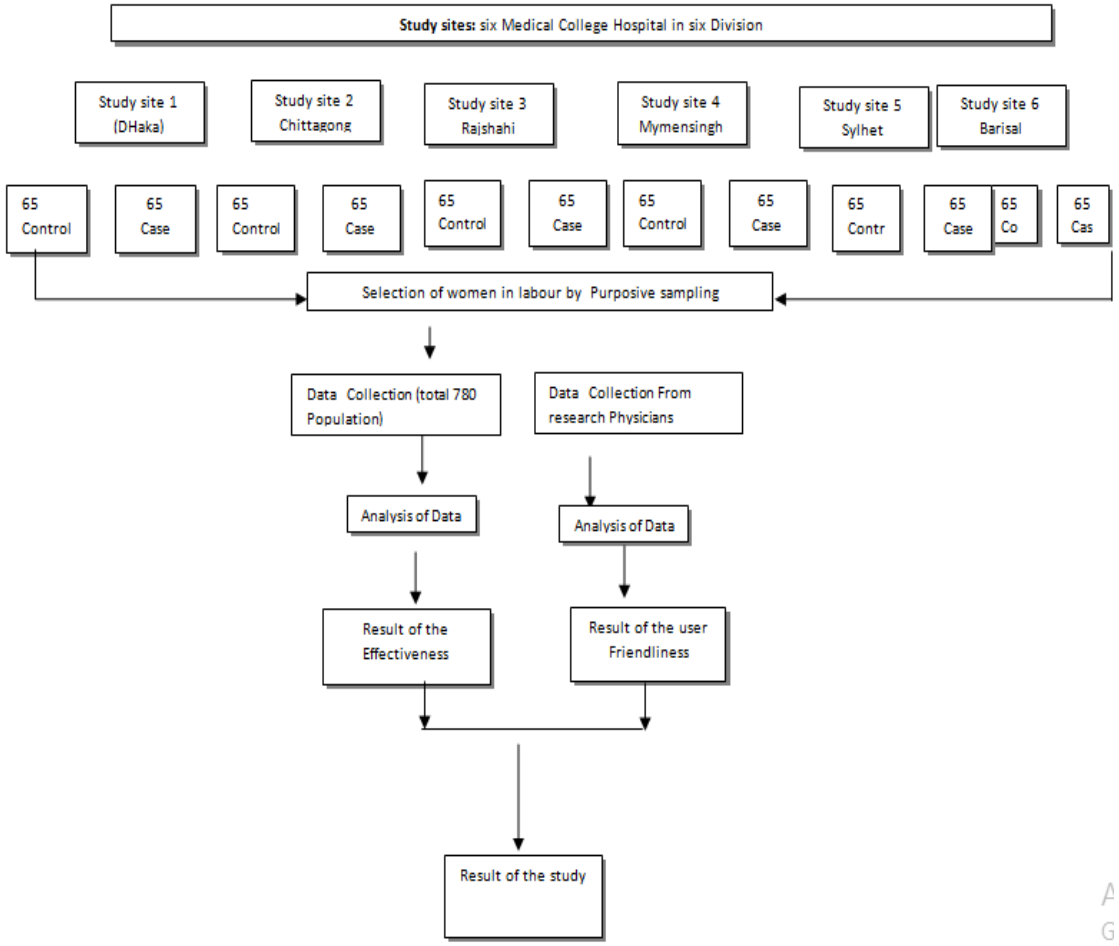
Procedure of Data Analysis:

Analysis will be done using Chi-square test in SPSS v.23 where p value less than 0.05 will be considered significant and the mean (±SD) user friendliness score will be calculated for both the tools. If any difficulty is faced, it will be mentioned in a separate sheet and solved by principle investigator in coordination with statistical analysis team.

III. Conclusion

Rapid advances in mobile technologies and applications as well as users creating a new opportunities for the integration of mobile applications into existing Health services to support and alleviate existing barriers to achieve universal health coverage. Inspite of usefulnees of Paper partograph,"Life Curve Mobile Application" made a new horizon of health system to integrate mobile technology into Health system to protect the right of mothers, ensures more and effective care especially in low resource settings.

Figure 1: Road Map of the RCT



Declaration

List of abbreviation

LCMA-Life Curve Mobile Application
LMICs - Low- and middle-income countries
MPH- Master of Public Health
RCT – Randomized Control Trial
USA – United States of America
WHO - World Health Organization

Ethics and Consent Statement: Not applicable.

Consent for Publication: Not Applicable.

Competing interests:

The authors declare that they have no competing interests.

Authors contributions:

MJH, SHT conceive the Concept and Design of Life Curve Mobile Application and this software were developed by SHT and MJH. Conception and design of this article were made by MJH and SMYA. MJH wrote the first draft of the manuscript. SMYA, ZA, FSB and ASK were performed major experiments and took part in the analysis and result validation of this software. ASK and MJH corrected the first draft of the manuscript. All authors read and approved the final manuscript

Availability of Data and Materials

As this is the first innovation and this data are not used by any other sources and not shared for any other purpose.

- Project name: Life Curve Mobile Application
- Operating system(s): e.g. Android
- Programming language: e.g. Java

- Other requirements: e.g. Java 1.3.1 or higher
- License: Not Published yet
- Any restrictions to use by non-academics: No

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