Abstract

For birthing attendants, who are working in primary and secondary health centers in developing countries, there is an inadequate usage of World Health Organization's (WHO) partograph, a paper tool used to track labor progression. Uterine contraction data is one of the most important partograph parameters needed to diagnose labor complications such as prolonged and obstructed labor. The current WHO standard recommends midwives monitor contractions by palpating the patient's abdomen for ten minutes and counting the frequency and duration of the contractions. However, the high patient to midwife ratio limits the time midwives can spend properly measuring contractions, leading to contractions being ignored or inaccurately monitored 88% of the time. Without uterine contraction information, common complications often go undiagnosed resulting in 90,000 maternal deaths annually.

To help birthing attendants complete the partograph and monitor labor progression, we have developed TocoTrack, which is a novel uterine contraction monitor designed for developing countries. When strapped on, the device measures the frequency and duration of contractions and outputs the data in partograph form to an LCD display, which midwives can copy over to their paper partograph. The monitor actively provides feedback to the midwife using LED's to alert them of problems, such as low battery and poor placement of the monitor. Through automation of the monitoring process, TocoTrack will enable more midwives to properly track the progression of labor and make accurate diagnoses on complications, having a widespread impact on maternal and newborn health.

Clinical Problem

Clinical Background and Need

Every day, approximately 800 women die from preventable pregnancy and childbirth issues [1]. 99% of all maternal deaths occur in developing countries, mostly in sub-Saharan Africa and South Asia. The WHO calculated that maternal mortality rates are 15 times higher in developing countries than in developed countries. The maternal mortality ratio in developing countries in 2013 is 230 per 100,000 versus 16 per 100,000 in developed countries, with a few developing countries reaching 1,000 per 100,000 [2]. Newborn mortality is close to 3 million annually and an additional 2.6 million babies are stillbirths [3, 4].

In developing nations, over 71 million pregnancies occur with the assistance of midwives in birthing clinics that lack the most basic medical equipment. Midwives, with minimal medical training, attend to these patients in overcrowded labor wards, where the average midwife to mother ratio is 1:4. Financial limitations further prevent these local practices from buying medical equipment considered standard in the United States, as well as prevent them from acquiring the resources to train midwives on how to use the equipment. In developing nations, mothers rarely receive the degree of care needed during labor and delivery, leading to roughly 1000 deaths every day due to pregnancy related complications [5]. 80% of these deaths are preventable through better monitoring of labor progression [5]. While levels of antenatal care have increased in many parts of the world during the past decade, only 46% of women in low-income countries benefit from skilled care during childbirth and just over a third of all pregnant women have the recommended 4 antenatal care visits [6].

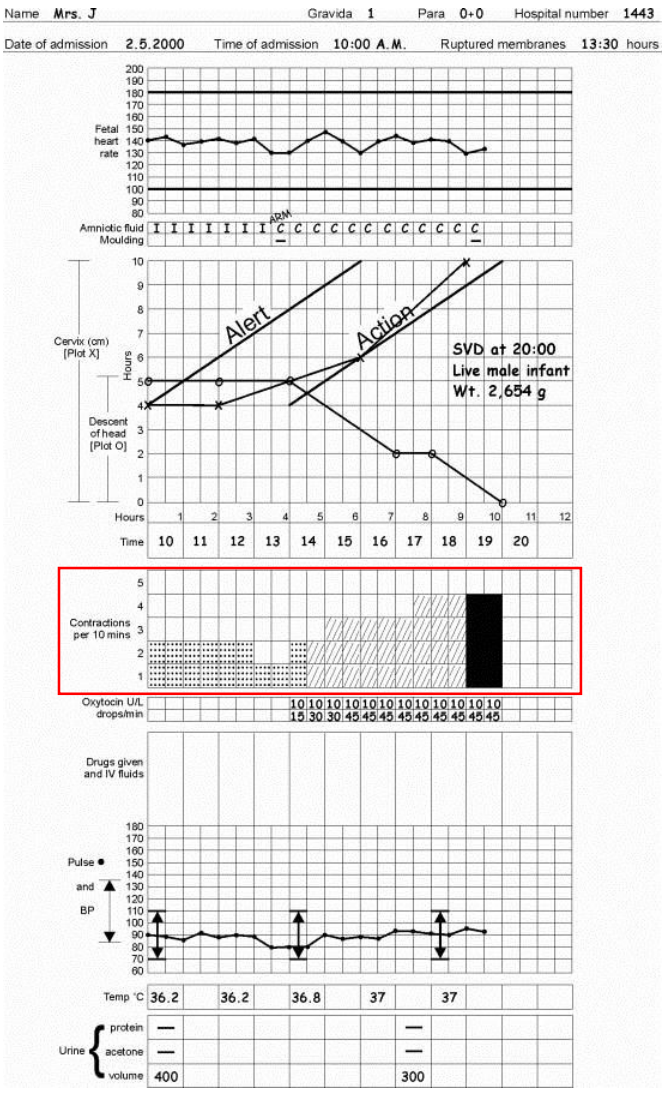

Figure 1: Shown is the WHO recommended partograph, where the red box represents contraction data.

Currently, one of the tools to monitor progression of labor and diagnose possible complications is the WHO partograph (Figure 1), which is a tool that allows midwives to record 14 labor parameters. The protocol requires that midwives return to each patient every half hour to record the progression of these parameters. Midwives are trained to interpret the trends recorded on the partograph in order to make general clinical decisions and follow up with the appropriate action. One of the most important parameters needed to identify complications is uterine contractions [2, 7]. However, uterine contractions are not properly monitored 88.6% of the time due to the lengthy process of monitoring by hand [8]. Under the current standard, midwives have to feel for contractions by placing their hands on the mother's abdomen for 10 minutes and then filling out the contraction frequency and duration data on the partograph. Because there are a limited number of midwives, they cannot dedicate 10 minutes to just one parameter and so this procedure is frequently skipped. This negligence of contraction data contributes to the misdiagnosis of the two most common labor complications, obstructed and prolonged labor, which contributes to over 40% of maternal deaths and 25% of child deaths [2].

Importance of Uterine Contraction Monitoring

Although uterine contraction patterns are rarely monitored, they are clinically necessary to accurately differentiate between several common pregnancy complications, such as prolonged labor and obstructed labor [2]. Prolonged labor is characterized by regular painful contractions with cervical dilation more than 4 cm and lasting longer than 12 hours. Obstructed labor means that the fetus is not descending through the pelvis, but contraction progression is strong [9]. During this time, contraction strength has stagnated and is failing to generate sufficient force. With proper diagnosis, midwives can then perform needed clinical interventions, such as (1) delivering oxytocin to augment labor if the mother is struggling with prolonged labor (2) recommending caesarean sections for obstructed labor.

While a midwife may be able to determine that there is unsatisfactory progress of labor based on parameters such as cervical dilation and fetal heart rate, contraction patterns are important in making a distinction between the underlying problems and recommending the best course of

action for the labor. According to the WHO, complications going undetected or misdiagnosed leads to higher mortality rates and increased incidence of other complications or conditions such as sepsis, postpartum hemorrhage, ruptured uterus, infections, fistula, etc.

Design

Design Specifications and Challenges:

In order to optimize our solution design, we have talked with numerous end-users including certified nurse midwives in our target setting, obstetrics and gynecologists, and accomplished global health experts. These experts advised us on how to design our device to best meet the clinical need and have been providing us with useful feedback to optimize and improve our prototypes. From conversations with these end-users, we determined the primary user needs and some of the most important challenges that our target setting would present.

Primary User Needs:

1. To create an automated device or method that can detect uterine contraction frequency and duration patterns for birthing attendants in a crowded labor ward
2. To output data consistent with the partograph requirements in an easily interpretable form for birthing attendants in the developing world
3. To reduce the time a birthing attendant needs for contraction monitoring
4. To allow accurate contraction monitoring to enable improved clinical decisions and proper diagnosis of possible labor complications

Important Challenges:

1. Most midwives in clinics were only trained to fill out and understand the partograph.
2. The labor wards are overcrowded with a high mother to midwife ratio of 4:1.
3. Most rural clinics have few resources to buy expensive or complicated devices, or to train nurses and midwives to use and incorporate these complex technologies.
4. There are frequent periods of time without electricity, which limits the use of technologies that require constant electricity.
5. There are limited financial resources and access to other peripheral technologies such as smartphones or tablets.

Our Prototype and Its Innovation:

With these considerations in mind, we designed TocoTrack, which is an affordable, easy to use, and comfortable uterine contraction monitor that analyzes and outputs contraction data in a partograph-compatible form. Instead of measuring contractions continuously by hand, the midwife can strap the device onto the patient's abdomen and allow it to collect data for ten minutes after calibration. After the ten minutes, the device will analyze and output the contraction data in a partograph-compatible form so that midwives can return and easily copy

Figure 2: Image of our current prototype

the partograph boxes onto their physical partograph. This allows a midwife to complete all WHO partograph parameters and comply with WHO's standard of monitoring contractions for each woman every 30 minutes. By automating this process, midwives will save substantial time and have uterine contraction information readily available in a form they understand, allowing them to diagnose labor complications and take the proper clinical intervention.

In our current prototype shown in figure 2, the device utilizes the LCD screen to output the partograph boxes and utilizes LED lights to provide operator feedback. Firstly, a blue LED lights up when there is low-battery and needs to be charged. Moreover, the device notifies the midwife when it is reading contraction data by lighting a green LED light. Lastly, the device turns on a red LED light in order to indicate any problem establishing a baseline reading. The device is also lightweight and portable, weighing less than 150 grams and requiring only a USB cord to recharge. On a full charge, TocoTrack can run for over 48 hours. Finally, TocoTrack is completely self-contained as all of the processing is done internally and the output is displayed on the device itself.

Once the device is strapped on, it utilizes a strain gauge mechanism to detect uterine contractions. The strain gauges, which are variable resistors that change their resistance in response to strain, are adhered onto both top and bottom faces of the leaf spring. They are incorporated into a Wheatstone bridge circuit along with two low-tolerance resistors, which allows for greater sensitivity as well as detection of both contraction and relaxation.

Unlike other low cost uterine contraction monitors, TocoTrack automates the analysis for the midwife. Midwives are not trained to read the complicated waveform produced by other monitors. TocoTrack instead analyses the information for midwives, and outputs in the information as a completed partograph. TocoTrack starts by first filtering out noise due to factors like breathing and patient movement. When looking for signs of a contraction, the device first finds peaks within the data. The code then looks at the slope of the points and finds the position before the peak where the upward slope begins and the position after the peak where the downward slope terminates. These two positions represent, respectively, the point at which the contraction started and ended. The code then can easily find the time passed between these two points in order to get the duration of the contraction. If a peak is too sharp, or does not have sufficient duration, the peak is considered noise and a partograph box will not be outputted for it. If no contractions are detected during the monitoring period, then the partograph boxes will be left blank on the output for that 30-minute section.

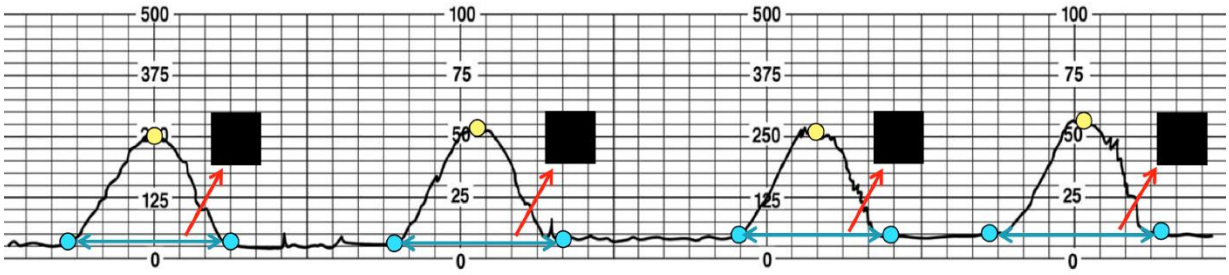

Figure 3: An example of how the algorithm analyzes contraction data

As seen in the digitized tocograph above in Figure 3, our algorithm identified the four peaks (as shown in yellow) and calculated the duration of each by find the starting and ending point of the contraction (as show in blue) and subtracting the two numbers. The output displayed 4 fully shaded partograph boxes, which correctly corresponds to the results determined by clinicians.

Evidence of Working Prototype:

Preliminary Testing

We have tested the probe on inflation and deflation of a ball to confirm the bi-directionality of the probe that responds to both compression and relaxation. We have also strapped the device on team member's bicep and abdomen to test whether or not the device senses the change of firmness of a muscle and the range of the sensitivity. In order to test the algorithm that filters out noise and determines frequency and duration of contractions, we ran digitized raw tocograph data from contraction strips through the algorithm and the outputted partograph boxes matched the actual data correctly 95% of the time. Additionally, the device's battery life of 48 hours under constant use was tested and confirmed.

Patient Testing

Starting April 20th, we performed a preliminary IRB-approved study at The Johns Hopkins Hospital to test the accuracy of our device in comparison to the clinical uterine contraction monitor, also known as a tocodynamometer. In order to do this, both our device and a standard tocodynamometer were used simultaneously on a patient. All patients tested were over 35 weeks of gestation and under a BMI of 40. After gaining consent, both monitors were strapped onto the patients and the women were monitored for a period between ten and twenty minutes. During that time, we asked the women for feedback on our device. After collecting the data, we took photocopies of the tocodynamometer output and compared them to our digital tracing.

Thus far, we have tested the device on a total of 10 patients. All the subjects stated that our device was as comfortable as the tocodynamometer used in standard of care in the U.S., and that the device was not intimidating. Out of the 10 pregnant women, 2 patients were experiencing contractions. For these patients, our monitor correctly and timely identified when a contraction started, and outputted the correct partograph box corresponding to the duration of the contraction. For the other 8 patients, who were not experiencing contractions, our monitor correctly identified the reading as normal breathing, movement, and noise, with no contractions present and, therefore, no partograph box output. As can be seen in Figure 4, our device detects the changes in firmness at the abdominal level on the expectant mother in a similar fashion as the current standard of care at the Johns Hopkins University (the tocograph strip). The slight differences can be attributed to the difference in placement of the monitor along the abdomen. Nevertheless, the correct uterine contraction analysis was performed and the proper partograph boxes were outputted.

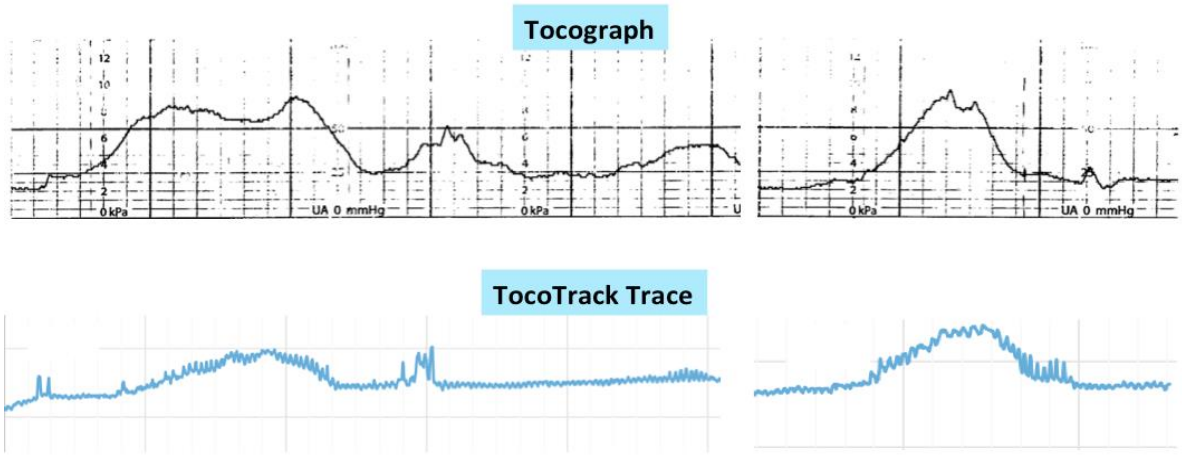

Figure 4: Comparison between the standard of care tocograph and the contraction waveform produced by TocoTrack

Tanzania Feedback

In mid-April, we sent our device to three clinics in Tanzania as a pilot for their midwives. Along with the device, we also sent a short video that showed exactly how to use the device. The head nurse midwife administered a survey on our behalf in which midwives provided feedback on the device. Of the twenty midwives surveyed, all of them confirmed the need for a uterine contraction monitor and expressed the problem that needed to be addressed as the process of monitoring by hand. The certified nurse midwife who administered the study summarized the overall feedback from the twenty midwives with the following statement: “The midwife feedback on the device was extremely positive. They think assessment of contractions every 30 minutes is one of the hardest things they have to do and that the process of feeling for contractions by hand is not always reliable. So, they think that our device will be very helpful. The midwives believe that the device is fairly light and that patients would have no objections to it being used. They think it would save them a lot of time and let them monitor more patients more effectively.”

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