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Overcoming Challenges of in Person Prenatal Care: A Pilot Study on the Usability and Acceptability of a Remote Monitoring Device for Pregnant Women in India

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Aim: Pregnancies considered high-risk, such as those with gestational diabetes (GDM), require continuous monitoring and special attention to properly manage maternal and fetal parameters. Personalized care is crucial for all pregnant women, particularly those residing in disadvantaged communities, to improve maternal and fetal outcomes. This study evaluated the feasibility and acceptability of the CareMother Fetosense digital, portable device for monitoring non-stress

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test/cardiotocography (NST/CTG) results remotely, with the aim of reaching the quality care to the last mile.

Methodology: Six hospitals in Karnataka were included in this pilot study, and nine doctors were conveniently selected to participate. The doctors were provided with CareMother Fetosense devices to distribute among pregnant women, depending on their individual risk factors and observations. GDM patients in their last trimester (in the last 4-6 weeks of their pregnancy) were instructed to learn to use the device, download the app, and send the report. Total 305 pregnant women were surveyed using a close-ended questionnaire that covered questions about their characteristics, the outcomes of the fetal NST, and the women's perceptions of using the device. A descriptive analysis of the survey data was performed using STATA version 15.1.

Results: The majority of the women were primigravida or first-time pregnant (54%), and the remaining 46% were multigravida. A major fraction of the NST results were reactive (89%), indicating that the fetal heart rate responded appropriately to fetal movements during the test. The majority of women diagnosed with GDM reported reactive results (n=37 out of 41). Overall, the women reported finding the usage of the Fetosense device simple, easy, and comfortable, with 99% of them having no issues.

Conclusion: This device records fetal heartbeat and uterine contractions and sends real-time alerts to clinicians, allowing for efficient remote monitoring from anywhere. The findings of this study provided a sense of reassurance to pregnant women, and it eliminated the need for repeated visits and unnecessary anxiety. Such advanced healthcare solutions utilizing remote monitoring techniques have the potential to offer substantial cost-saving benefits, alleviate the burden for these women, and increase accessibility to healthcare services.

Keywords: Gestational diabetes mellitus; fetal heart rate; non-stress test (NST); telemonitoring; caremother fetosense.

1. INTRODUCTION

Annually, more than 200 million pregnancies are reported globally [1]. The prevalence of high-risk pregnancies is increasing, primarily due to advanced maternal age at conception, unhealthy lifestyles, overweight and obesity, and concurrent comorbidities [2,3]. The proper management of maternal and fetal parameters, which can significantly affect the outcome of pregnancy, such as preterm rupture of membranes (PROM), fetal growth restriction (FGR), preeclampsia (PE), and gestational diabetes mellitus (GDM), requires continuous monitoring and special attention [4].

Gestational diabetes mellitus (GDM) is one of the most common pregnancy-related complications. Women with GDM require careful monitoring of fetal growth, particularly in the last 8-10 weeks of pregnancy, and any decrease in fetal movements should be promptly reported. Healthcare facilities typically employ cardiotocography (CTG) or non-stress tests (NSTs) to assess fetal heart rate (FHR) and rhythm in response to movements and contractions. The NST is usually done from the 32nd week of gestation until delivery to continuously monitor the fetal heart rate and assess the overall fetal well-being. The aforementioned test serves the purpose of ascertaining whether the fetus is susceptible to intrauterine death or neonatal complications, frequently associated with high-risk pregnancies or suspected fetal hypoxemia. The NST result is considered reactive, if the fetal heart rate accelerates or increases, with fetal movement. A borderline or non-reactive report may require a repeat testing or an immediate action to ensure maternal and fetal well-being. The frequency of testing varies, ranging from weekly to every other day, depending on the presence of high-risk conditions [5].

However, frequent hospital visits during pregnancy can be challenging for many women and may result in increased anxiety and fear. The added stress of pregnancy and clinical visits, as well as the associated clinical expenses and travel time, may negatively impact family life [6,7]. Furthermore, hospitals are frequently overburdened and inadequately staffed, which often leads to significant patient volumes, resulting in prolonged wait times for patients. These challenges are compounded for women living in remote areas, where access to medical care is limited due to a shortage of doctors, skilled healthcare workers, and medical infrastructure. Women in severely affected rural areas may have to travel for several hours or even days to receive specialized medical

attention. Personalized care is essential for all pregnant women to improve maternal and fetal outcomes [8,9].

Recent advancements in the health system have led to the development of e-health, a technology-enabled approach that enhances and personalizes healthcare services through the internet and related technologies. E-health has been incorporated into pregnancy care, with the development of telemonitoring systems that track maternal and fetal parameters [10,11]. The CareMother Fetosense NST/CTG digital, portable device is a recent development that can be used by pregnant women at home. This device records fetal heartbeat and sends real-time alerts to clinicians, allowing for efficient remote monitoring from anywhere [12]. This pilot study aims to assess the usability and acceptability of the CareMother Fetosense digital, portable device among pregnant women for monitoring non-stress test/cardiotocography (NST/CTG) results remotely in Karnataka, India.

2. METHODS

2.1 Study Setting and Participants

For this pilot study, six hospitals located in small towns of Karnataka state were included, and nine doctors were conveniently selected to participate. The doctors were provided with CareMother Fetosense devices, and underwent digital skill transfer training conducted by Bengaluru-based ARTIST (Asian Research and Training Institute for skill Transfer) to ensure their proficiency in the usage of the device, and subsequently, the doctors were expected to teach their patients how to use the device as well.

They were asked to select the antenatal patients in the “high risk” category presenting at their respective antenatal clinics, based on the need to monitor the fetal well being at a greater frequency. They were asked to ensure the use the new device for “care at home” for these patients who consented to use this device, with a view of minimising the scheduled visit to the clinic .The largest group belonged to Gestational Diabetes diagnosed as per standard FIGO recommended guidelines. This group was selected for analysis since in this condition, the fetal surveillance is largely by fetal movements and NST rather than less liquor and poor .growth. The chance of late silent fetal demise is also significant and known with the fluctuating glycemic levels.The overall data from others were primarily used to define the ease of use, reassurance and alleying the anxiety and cost reductions in totality.

2.2 Data Collection and Analysis

The GDM patients in their last trimester (in the last 4-6 weeks of their pregnancy) were given the device to learn how to use it, download the app, and send the report. They were instructed to report weekly and return the equipment at the time of delivery. The average frequency of reporting was twice weekly, which entailed taking six to eight readings (or six to eight graphs) maximum for a period of four weeks if the reported results were reactive. However, if a woman reported borderline or non-reactive results for two consecutive tests, she was advised to report to the healthcare facility immediately, and appropriate actions were taken.

During the four month period of June 2022 to September 2022, a total of 305 pregnant women who were registered with these doctors were surveyed using a close-ended, short questionnaire that covered questions about their characteristics, including their age, gestation week, risk factors, and indications. Additionally, the survey covered questions about the outcomes of the fetal non-stress test (NST) and the women's perceptions of using the device.

A descriptive analysis of the survey data was performed using STATA version 15.1. Continuous variables, such as age, were expressed as mean and standard deviation, while categorical variables were expressed as numbers and percentages.

3. RESULTS

The results describe the characteristics of the study sample, as well as the outcomes of the fetal non-stress test (NST) and women's perceptions of using the device (Fig. 1).

The average age of the mothers in the sample was 28.2 years, with a relatively narrow range of 19-41 years. More than half of the women were primigravida or first-time pregnant, and the remaining 46% were multigravida. The average gestational age at which the findings were reported was 36.3 weeks, with a relatively small standard deviation of 1.9 weeks.

The majority of the NST results were reactive, with 89% of reports falling into this category. This

indicates that the fetal heart rate responded appropriately to the fetal movements during the test. A small percentage of reports were borderline (4%) or non-reactive (7%), which may suggest a need for further evaluation or monitoring of fetal well-being.

Of all the women surveyed, 13.4% (n=41 out of 305) were diagnosed with Gestational Diabetes Mellitus (GDM). The majority of reports within this sub-group, specifically 90%, demonstrated reactive results (n=37 out of 41). Among these, in 22 cases, the Fetal Heart Rate (FHR) was reactive despite the presence of GDM and decreased fetal movement or other associated indications (Fig. 2).

Overall, the women reported finding the usage of the device simple, easy, and comfortable, with 99% of them having no issues. Only a small percentage of women (1%) found it somewhat difficult to use. This subgroup consisted of primigravida women, between the ages of 29 and 30 years, with routine indications and no reported risk factors.

These results provide important information about the characteristics of the study sample and the outcomes of the fetal non-stress test, as well as women's perceptions of using the device. However, it is important to note that these findings are specific to this particular study and may not be generalizable to other populations or settings.

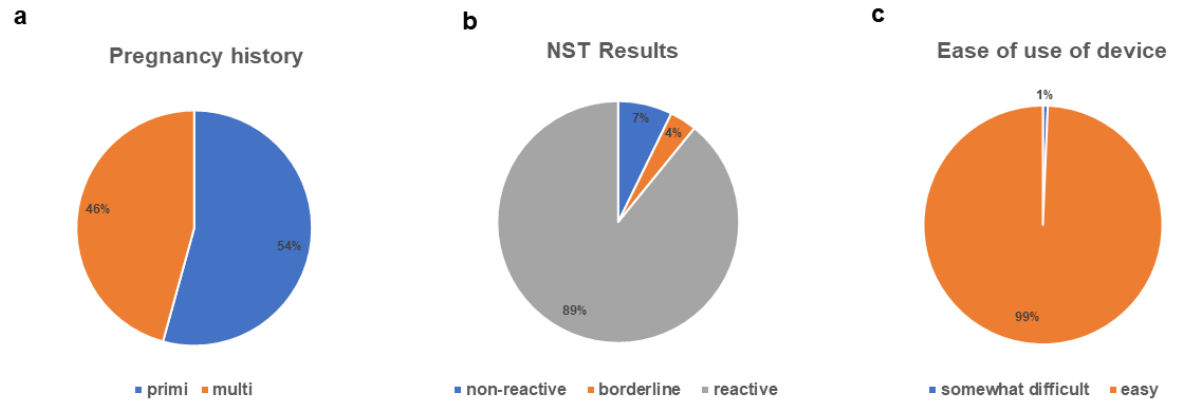

Fig. 1. The characteristics of the study sample (a), the outcomes of the fetal Non-Stress Test (NST) (b) and women's perceptions of using the Fetosense device (c) as shown in proportions

GDM (indications)	Reactive	Borderline	Non reactive
Total, n=41	n=37	n=2	n=2
Routine (no additional indication), n=16	n=15	n=1	n=0
GDM, less fetal movement, n=6	n=5	n=1	n=0
GDM with data on other additional indications, n=19 (High sugar= 8, High BP=4, IUGR= 2, Leaking liquor=1, Less Liquor=2, precious pregnancy=1, pain abdomen=1)	n=17	n=0	n=2

Fig. 2. NST results of pregnant women with GDM as captured by Fetosense device

4. DISCUSSION

Complications during pregnancy can elicit feelings of anxiety and fear, particularly when an extended stay in the hospital is required. For instance, in cases of Gestational Diabetes Mellitus (GDM), a pregnant woman may need to attend regular clinical visits to monitor fetal heart rate. This can result in increased clinical expenses, travel time, and disrupted family life, particularly for women from disadvantaged communities [4,7,13].

Fortunately, advanced healthcare solutions utilizing remote monitoring techniques can alleviate the burden for these women and increase accessibility to healthcare services. These innovative digital technologies are being integrated into the healthcare sector, providing healthcare providers and recipients with cutting-edge health solutions that enhance personalized healthcare and outcomes [10,11,14]. The present study aims to evaluate the feasibility and acceptability of the CareMother Fetosense digital, portable device for monitoring non-stress test/cardiotocography (NST/CTG) results remotely. This interactive smartphone-based NST/CTG machine enables on-site testing via wireless probes and immediate notification of abnormal results [12].

Of all the participating women, 89% reported reactive results while 7% and 4% reported non-reactive and borderline results, respectively. Notably, all patients who reported reactive results (n=271) were spared from hospital visits, which would have otherwise been required twice weekly for testing. As the device enabled the convenience of testing from home, only a small number of patients with non-reactive results were asked to come for further evaluation. Patients with borderline results were advised to repeat the test and only visit the hospital if borderline or non-reactive results were obtained again. In the sub-group of women with Gestational Diabetes Mellitus (GDM), the majority of reports were observed to be reactive. This finding provided a sense of reassurance to pregnant women, and it eliminated the need for repeated visits and unnecessary anxiety. Overall, nearly all women (99%) found the use of the device to be simple, convenient, and comfortable. These results indicate that the CareMother Fetosense device could offer a promising solution to improve the accessibility of NST/CTG monitoring for pregnant women. The ease of use and alleying the anxiety, both to the care givers and the family with remote monitoring devices outlined by this pilot study, sets the path for future largescale implementation The inference from this pilot study is primarily the vision to action – possibility of such point of care devices being used at scale in the near future in low middle income countries.

Several prior studies have also documented the experiences and perceptions of female participants regarding home-based telemonitoring of pregnancies in comparison to conventional in-clinic maternal and fetal monitoring. These prior studies have indicated that telemedicine holds the potential to offer significant psychological advantages during pregnancy [4,10,15,16]. Specifically, the use of telemonitoring in the provision of antenatal care has been demonstrated to enhance women's perception of quality of care, particularly in cases of high-risk pregnancies. This positive influence on the quality of care has been found to have a beneficial impact on the quality of life of pregnant women, and to effectively reduce the deleterious consequences of antenatal anxiety on both maternal and fetal health [4,17].

Moreover, the extensive and unprecedented use of telemedicine in response to the COVID-19 pandemic had significant and enduring implications for the delivery of healthcare services. It has enabled patients to receive healthcare services at home, while simultaneously reducing contact between patients and healthcare providers [18,19]. Usability and acceptability of a Remote Monitoring Device for Pregnant Women is yet another huge opportunity.

5. CONCLUSION

The appeal of telemonitoring lies in its usability, and potential to enhance access to care, communication, and outcomes while minimizing the need for clinic visits and travel time..These transformations are expected to significantly reduce costs and workloads, an essential consideration given the continuous rise in healthcare expenses. Therefore, digital and portable devices such as CareMother Fetosense has the potential to offer substantial cost-saving benefits [20–22] and reach quality care to the last mile.

CONSENT AND ETHICAL APPROVAL

Written consent for participation was requested after explaining that participation in the study is entirely voluntary, and confidentiality and

anonymity will be strictly maintained. Ethical approval for this pilot study was taken from the Institutional Ethics Committee (IEC).

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COMPETING INTERESTS

Authors have declared that they have no known competing financial interests or non-financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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