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CLINICAL ARTICLE

Obstetrics

Integrating technologies to provide comprehensive remote fetal surveillance: A prospective pilot study

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Abstract

Objective: To determine the feasibility of extending remote maternal-fetal care to include fetus well-being.

Methods: The authors performed a prospective pilot study investigating low-risk pregnant participants who were recruited at the time of their first full-term in-person visit and scheduled for a follow-up telemedicine visit. Using novel self-operated fetal monitoring and ultrasound devices, fetal heart monitoring and amniotic fluid volume measurements were obtained to complete a modified biophysical profile (mBPP). Total visit length was measured for both the in-person first visit and the subsequent telemedicine encounter. A patient satisfaction survey form was obtained.

Results: Ten women between 40+1 and 40+6 weeks of gestation participated in telemedicine encounters. Nine women (90%) were able to complete remote mBPP assessment. For one participant, fetal assessment was not completed due to technically inconclusive fetal monitoring. Another participant was referred for additional assessment in the delivery room. Satisfactory amniotic fluid volume measurements were achieved in 100% of participants. The telemedicine encounter was significantly shorter (93.1 ± 33.1 min) than the in-person visit (247.2 ± 104.7 min; $P < 0.001$). We observed high patient satisfaction.

Conclusion: Remote fetal well-being assessment is feasible and time-saving and results in high patient satisfaction. This novel paradigm of comprehensive remote maternal and fetal assessment is associated with important clinical, socioeconomic, and logistics advantages.

KEYWORDS
biophysical profile, fetal monitoring, fetal ultrasound telemedicine, pregnancy, remote health care, telehealth

1 | INTRODUCTION

There is a significant worldwide trend towards remote care, reinforced by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic.[1–4] Previous studies have shown that telemedicine may reduce travel time and cost.[5–10] In the context of pregnancy, remote care provides an opportunity for pregnant women to replace lengthy and repeated visits in the clinic or hospital with virtual encounters in a location of their choice, be it workplace or home. In addition, pregnant women may be at an increased risk for morbidity due to coronavirus disease 2019 (COVID-19) infection according to several studies and may benefit even more from comprehensive remote care assessment during the pandemic.[11–13] Despite the increasing demand, remote maternal-fetal care has been generally limited to maternal rather than fetal assessment.

Comprehensive maternal-fetal assessment of pregnant women consists of medical history, vital signs, ultrasound (US) assessment of the fetus, and fetal heart rate tracing. Until recently, remote care for pregnant women was limited to the maternal aspects, while fetal well-being assessment required in-person visits. Recent technologic advances provide an opportunity for remote fetal US as well as remote fetal monitoring. Seminal studies established feasibility and utility of each technology independently and set the stage for a paradigm shift towards remote maternal-fetal assessment.[14–20] However, the combination of the fetal nonstress test heart monitoring and US amniotic fluid evaluation scored by the modified biophysical profile (mBPP) achieve a better detection rate for fetal acidemia than either of the technologies apart.[21–26]

In most centers, maternal-fetal surveillance requires that the patients physically arrive at the unit and spend up to several hours waiting between tests. In some countries, due to geographic distribution and scarcity of medical centers, women seeking routine follow-up must overcome significant logistic hurdles in addition to the costs of transportation, parking, and time loss. Lengthy visits and long hours of waiting often cause patient dissatisfaction. Furthermore, such medical units have substantial costs due to maintenance, manpower, equipment, and facilities. Therefore, utilizing technology may allow patients to receive proper medical attention without having to physically arrive at a specific crowded unit for lengthy periods of time.

In the current study, we sought to assess the feasibility of a novel, remote, comprehensive fetal well-being assessment by combining remote fetal monitoring with remote fetal US to achieve the mBPP in the context of women presenting for full-term pregnancy surveillance.[27,28] In addition, we sought to analyze the virtual session's effect on patient satisfaction and visit duration.

2 | MATERIALS AND METHODS

This was a prospective pilot study including full-term low-risk pregnant participants carrying singleton appropriate for gestational age fetuses. It was conducted in a single tertiary university–affiliated medical center between July 14 and December 17, 2021. The study design and protocol were reviewed and approved by the institutional review board at the Sheba Medical Center (SMC-7937-20).

Inclusion criteria included: (a) singleton pregnancy; (b) maternal age between 18 and 45 years; (c) gestational age between 39 + 0 and 40 + 6 at time of telemedicine encounter; (d) estimated fetal weight up to 2 weeks prior to recruitment between the 10th and 90th percentiles; (e) amniotic fluid deepest vertical pocket between 2 cm and 8 cm, or amniotic fluid index between 80 mm and 240 mm; (f) reassuring fetal monitoring; and (g) biophysical profile score 10 of 10.

Exclusion criteria included: (1) one of the following pregnancy complications: diabetes (gestational or pregestational), hypertensive disorders of pregnancy, hypercoagulability (acquired or hereditary), major maternal underlying disease (acute or chronic), or intrahepatic cholestasis of pregnancy; (2) complications in previous pregnancies including fetal death, hypertensive disorders of pregnancy, intrauterine growth restriction, placental abruption, or fetal asphyxia; (3) previous cesarean delivery or other uterine corpus incisions; (4) major fetal anomalies; (5) contraindication for vaginal delivery; (6) reduced fetal movements; (7) rupture of membranes; (8) vaginal bleeding greater than bloody show; (9) regular contractions; or (10) cervical conditions and maternal request which permit induction of labor.

Upon their first in-person visit, potentially eligible participants underwent a thorough medical evaluation including medical history, physical examination, vital signs, urine dipstick, biophysical profile, amniotic fluid volume assessment, fetal weight estimation if indicated (i.e., no weight estimate within 2 weeks), and fetal monitoring. Eligible patients were offered to participate in the study and those interested received a full explanation of the study design with written informed consent obtained. Participants were invited for a scheduled follow-up appointment 2 to 3 days after their initial evaluation.

The telemedicine encounter was conducted at our medical center for safety reasons as this was the first study assessing the use of comprehensive remote maternal-fetal assessment. The women were introduced into a private room and instructed in person by an obstetrician how to operate the remote fetal heart rate monitoring device (HeraBEAT) and how to use the remote US device (Pulsenmore Ltd., Omer, Israel) for amniotic fluid volume measurement. Both devices connect with smartphone applications, which allow real-time transmission of the data. The telemedicine control center was in a separate room within the medical center and kept real-time monitoring of the fetal monitoring and amniotic fluid volume measurement taken by the participant independently. We chose to use single deepest vertical pocket for amniotic fluid volume assessment as it is more practical in this setting and is associated with a lower false-positive rate for oligohydramnios.[29–31] Audio and visual communication was established for the evaluation. User experience was designed so that patients viewed on the smartphone screen the US image and fetal heart rate, providing ongoing feedback and reassurance. The patients were instructed that in case of nonreassuring or inconclusive findings, they would be referred to the adjacent obstetric unit for further evaluation.

Monitor and US results were documented. Total visit length was measured for the initial visit, including transportation to and from our medical center. For telemedicine encounters the visit length was measured as the total time between admission and discharge since it is the presumed time patients would have spent had they stayed at home for the remote care assessment. A patient satisfaction survey form was filled by the participants based on the Six Simple Questions (SSQ, Data S1) survey.[32,33] Statistical analysis was performed using IBM SPSS Statistics version 25 software (IBM, Armonk, NY, USA). Statistical significance was defined as $P<0.05$.

3 | RESULTS

Overall, 13 women were recruited. Of them, three entered spontaneous labor before the scheduled remote care visit. Ten women between 40+1 and 40+6 weeks of gestation eventually participated in a remote care visit (Table 1). Nine participants (90%) were able to complete comprehensive remote care and one participant was not able to complete the assessment due to technically inconclusive fetal monitoring. It is of note that among the nine women completing remote assessment, one was referred for additional assessment in the obstetric unit due to nonreactive fetal heart rate and lack of fetal body movements on US. Satisfactory amniotic fluid volume on US was obtained for all participants (Table 2).

The net length of the telemedicine encounter (93.1±33.1 min) was significantly shorter than the initial in-person visit (247.2±104.7 min) ($P<0.001$ paired t-test). Participants' satisfaction was high with perfect scores in three of the six questions and high scores in the remaining questions (Table 3). All participants indicated that they would prefer such surveillance in the future.

Average gestational age at delivery was 41+2 days (±2.5 days). Seven of the participants had spontaneous vaginal births, one delivered with assisted vacuum extraction, and two had cesarean deliveries due to nonreassuring fetal monitor during trial of labor. All participants gave birth to healthy newborns with normal Apgar scores of 9 and 10 after 1 and 5 min, respectively.

TABLE 1 Demographics.

	$n=10$
Age (years)	35 (±4.5)
Body mass index	28.7 (±4.5)
Gestational age (median)	
Initial visit	40+0 (±1.8)
Telemedicine encounter	40+3 (±1.8)
Delivery	41+2 (±3.5)
Mode of delivery:	
Spontaneous	7 (70)
Instrumental (vacuum extraction)	1 (10)
Cesarean delivery	2 (20)
Newborn birthweight (grams)	3470.1 (±215.8)

Note: Data are given as mean (±standard deviation) or number (percentage) unless otherwise indicated. Gestational age is given as weeks+days of gestation.

4 | DISCUSSION

Remote fetal well-being assessment is feasible by combining remote fetal US and monitoring technologies to establish an mBPP score. Furthermore, remote assessment can shorten visit length and is associated with high patient satisfaction.

Remote maternal well-being assessment is increasingly used with the advancement of digital telemedicine tools.[34–36] In contrast, fetal remote evaluation has not yet been established or widely adopted into clinical practice. Mhajna et al. found that remote fetal heart monitoring is achievable.[14] Hadar et al. added that hand-held self-operated US assessment is feasible.[20] Our novelty lies in the integration and application of these technologies to establish fetal well-being assessment based on the mBPP.

We were able to obtain the amniotic fluid single deepest vertical pocket in all participants and complete the fetal heart rate

TABLE 2 Follow-up visit results.

	$n=10$
Ultrasound assessment	
Satisfactory biophysical profile	9 (90)
Satisfactory deepest vertical pocket	10 (100)
Fetal heart rate monitoring	
Satisfactory nonstress test	8 (80)
Nonreactive	1 (10)
Technically inconclusive	1 (10)

Note: Data are given as number (percentage).

TABLE 3 Questionnaire results.

	Question number[a]					
	#1	#2	#3	#4	#5	#6
Participant 1	6	7	1	7	1	7
Participant 2	7	7	1	7	1	7
Participant 3	N/A	7	7[a]	7	1	7
Participant 4	6	7	1	7	1	7
Participant 5	7	7	1	7	1	7
Participant 6	7	7	1	7	1	7
Participant 7	6	7	1	6	1	7
Participant 8	6	7	1	7	1	7
Participant 9	7	7	1	7	1	7
Participant 10	7	7	1	7	1	7
Average score	6.6	7	1.6	6.9	1	7

Abbreviation: N/A, not available.

[a]Presumably a mistake: seven being the lowest grade for the question.

assessment in 90% of them. Among the participants with technically adequate assessment, one was converted to in-person assessment due to nonreactive fetal monitoring and absence of fetal movements during the US assessment. These findings highlight the importance of well-defined referral protocols in the case of nonreassuring fetal assessment. In our view, protocols should consist of several response levels ranging from repeating the remote assessment through ambulatory referral for in-person assessment and culminating in urgent referral to the labor and delivery ward.

As expected, the telemedicine assessment was significantly shorter than the initial in-person visits. Some of the time-saving is related to transportation and parking, as previously reported.[37–39] An additional contribution to time-saving was related to optimizing the waiting between sequential phases of the maternal-fetal assessment: vital signs measurement, urine dipstick collection, fetal monitoring, fetal US, and finally physician encounter. Not only are the intervals in remote care shorter but the patient convenience is much higher at home or at work.

The SSQ survey[32,33] demonstrated overall high satisfaction. All participants declared that they would prefer remote care over in-person visits. Although not captured by the SSQ survey, an interesting finding repeatedly expressed by the participants was their satisfaction with playing an active role in assessing their fetus.

The study was designed as a pilot study and is limited to the assessment of feasibility, potential time-saving, and patient satisfaction. In addition, we chose to conduct the telemedicine visits within our medical center for risk mitigation reasons. Therefore, our results may not reflect potential technological hurdles related to connectivity at home. On the other hand, this setting did not unlock the full potential of remote assessment in terms of time-saving and convenience.

The main limitation of this study is the small number of participants; We have proven the concept to be feasible but there is more to be done before it is implemented on a large scale. The main strengths of the study lie in the prospective design, the use of cutting-edge technologies, and the integration of technologies for complete remote fetal assessment.

Future studies may extend our findings to additional potential advantages of practicing maternal-fetal telemedicine. The first is keeping pregnant patients and health providers safe during times of pandemic or even during the flu season, as demonstrated during the COVID-19 pandemic.[40] Another increasingly important aspect is reducing health disparities for patients residing in rural areas distant from high-quality medical care.[37–39] Scaling and implementation of comprehensive remote care for pregnant women at home is associated with the costs and logistics of providing patients with personal blood pressure cuffs, remote US probes, and remote fetal monitoring probes. In addition, implementation is linked with costs beyond those required in the pilot setting such as dedicated personnel and ongoing information technology support. Those may be balanced by reducing costs of maintaining clinics and manpower, while providing a more efficient medical assessment for patients. In a wider view, replacing repeat travel and transportation of pregnant women to clinics with remote care may contribute to reduction in greenhouse gas emission.[5,41]

In conclusion, we demonstrated the feasibility of extending remote maternal care to include comprehensive remote fetal well-being consisting of fetal heart rate monitoring and US assessment. The proposed new clinical paradigm is associated with high patient satisfaction and time reduction. Further studies and an appropriate digital infrastructure are required for implementing the new paradigm on a large scale.

AUTHOR CONTRIBUTIONS

The manuscript was written by ON and AT. AF assisted with statistical analysis. BW, ES, and SMT critically revised the manuscript. All authors participated in the design and execution of the study. All authors read and approved the manuscript.

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HeraMed supplied fetal monitoring probes and technical support for their use without cost. PulseNmore supplied the US probes and technical support for their use without cost. Additional costs were incurred by Sheba Beyond and the Sheba Women's Health Innovation Center. Decisions regarding study design, results interpretation, and manuscript writing were made solely by the authors.

CONFLICT OF INTEREST STATEMENT

AT reports the following financial disclosures: primary medical inventor of a mechanical device for the prevention of preterm birth and holds minority shares in PregnanTech, a company commercializing the invention under the name “The Lioness”; cofounder and chief medical officer of Shela Ltd. developing Maternal-Fetal Precision Medicine; chief medical advisor and holds minority shares in Signalife Ltd., developing direct measurement of fetal pH in the labor and delivery ward; serves as consultant of Pollie Ltd., developing digital interventions for polycystic ovary syndrome.

DATA AVAILABILITY STATEMENT

Data available on request from the authors.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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