Received: 12 May 2024 | Revised: 17 November 2024 | Accepted: 2 January 2025

DOI: 10.1002/ijgo.16148

CLINICAL ARTICLE

Obstetrics

Hybrid remote and in-clinic maternal-fetal surveillance for women with gestational diabetes: A prospective pilot study

Michal Axelrod[1,2] | Hila Lahav Ezra[1,2] | Esther Galler[1,2,3] | Omer Nir[1,2] | Keren Ofir[1,2] | Galia Barkai[2,3] | Eyal Sivan[1,2] | Shali Mazaki-Tovi[1,2] | Abraham Tsur[1,2,3,4]

[1]The Josef Buchmann Gynecology and Maternity Center, Sheba Medical Center, Tel Hashomer, Israel

[2]The School of Medicine, Tel Aviv University, Tel Aviv, Israel

[3]Sheba Beyond Virtual Hospital, Sheba Medical Center, Tel Hashomer, Israel

[4]The Dina Recanati School of Medicine, Reichman University, Herzliya, Israel

Correspondence
Michal Axelrod, The Josef Buchmann Gynecology and Maternity Center, Sheba Medical Center, Derech Sheba 2, Ramat Gan, Israel.
Email: michalaxelrod2805@gmail.com

Abstract

Objective: This study explores a hybrid approach to maternal-fetal care for gestational diabetes (GD), integrating virtual visits seamlessly with in-clinic assessments. We assessed the feasibility, time efficiency, patient satisfaction, and clinical outcomes to facilitate wider adoption of maternal-fetal telemedicine.

Methods: We conducted a 4-week prospective study involving 20 women with GD at ≥32 weeks of pregnancy, alternating between remote and in-clinic weekly visits. Remote assessments began with women self-measuring vital signs and using a digital urine dipstick. The remote encounter started with a midwife performing anamnesis and remotely connecting women to the fetal nonstress test. A physician concluded the meeting with remote sonographic assessment of amniotic fluid maximal vertical pocket that together with the nonstress test provided the modified biophysical assessment as well as a video encounter and ongoing glycemic control assessment. We assessed the feasibility of remote visits, compared visit durations, evaluated women's satisfaction using the Telehealth Usability Questionnaire, examined glucose documentation adherence during hybrid care compared with the following period until birth, and assessed GD-related clinical outcomes.

Results: Remote visits had a success rate of 97.4% (38 of 39), with significantly shorter durations compared with in-clinic visits (median 59.0 min vs. 159.0 min, $P < 0.001$). Women expressed high satisfaction (6.6 of 7), and adherence with recording fasting glucose values during the study period was significantly higher than the following period until birth (92.2% vs. 61.8%, $P = 0.001$). Notably, none required induction of labor for glycemic control imbalance, and there were no cases of macrosomia, shoulder dystocia, or neonatal hypoglycemia.

Conclusion: The hybrid approach to maternal-fetal care for GD demonstrated feasibility, safety, time efficiency, improved patient satisfaction, and enhanced glycemic control adherence.

KEYWORDS
adherence, digital intervention, glycemic control, telemedicine, ultrasound

1 | INTRODUCTION

Maternal-fetal medicine has unique challenges in fully integrating remote care compared with other clinical disciplines such as internal medicine and psychiatry.[1] Therefore, current use is mainly limited to individual aspects of care such as remote surveillance of maternal blood pressure, ongoing glycemic control, and fetal monitoring episodes. Therefore, remote care remains the exception rather than the rule and is utilized only by a few early adopters.[2–4]

Seminal studies have established the feasibility of replacing each component of in-clinic visits with remote care digital technologies. Maternal evaluation entails monitoring vital signs,[5–8] conducting routine urine analysis,[9] ongoing glycemic control in the case of diabetes,[10–13] and physician-patient video communication.[14] Fetal evaluation involves essential procedures such as fetal monitoring and ultrasound examinations.[15–17] Moreover, we have previously demonstrated the feasibility of remote capture of the modified biophysical profile (mBPP) integrating remote fetal monitoring with remote ultrasound measurement of the deepest amniotic fluid pocket.[18]

However, achieving widespread adoption by mainstream providers (the early majority of pragmatists) requires establishing an evidence-based approach that includes a thorough and comprehensive assessment of both maternal and fetal aspects.[19,20] In addition, a hybrid approach providing some in-clinic visits can address the need for human face-to-face contact between providers and patients, as well as facilitate periodical assessments that cannot be performed remotely, such as sonographic fetal growth assessment. Optimally, home care may also improve patients' engagement and adherence with evidence-based protocols and even improve some clinical outcomes.[21–24]

Among the pregnant population, women with gestational diabetes (GD) constitute a compelling subset for studying maternal-fetal telemedicine implementation. The notable incidence of this condition (7–10%),[25,26] the need for close glucose level monitoring from diagnosis throughout pregnancy,[27] and frequent clinic visits that might culminate in up to twice-weekly maternal and fetal assessment starting at 32 weeks of gestation[28] makes this specific population optimal for investigating and implementing remote care system.

Therefore, we sought to determine the feasibility, time efficiency, satisfaction, adherence, and clinical outcomes of hybrid remote and in-clinic maternal-fetal surveillance for women with GD.

2 | METHODS

2.1 | Study population

We conducted a prospective clinical study following women with GD carrying a singleton pregnancy at or beyond 32 weeks of gestation. Participants were recruited at a single tertiary university-affiliated medical center between January 2022 and July 2022.

We selected 32 weeks of gestational age and beyond as the entry criterion for our study, based on recommendations in the literature advocating for the initiation of regular fetal monitoring for women with GD (class A2 GD [A2GD]) starting at this stage of pregnancy.[28] In addition, patients with class A1 GD (A1GD) were managed in the same way to ensure generalizability of the results. This approach aligns with our local practice and considers the limitations of the monitoring belt, which was validated for use starting at 32 weeks.

Inclusion criteria were: (1) maternal age between 18 and 50 years; (2) gestational age ≥32 + 0 at time of the study's first visit; (3) singleton gestation; (4) diagnosis of GD (A1GD/A2GD)[28]; (5) location within a 30-min drive from the medical center at the time of the remote assessment; (6) ability to understand English and Hebrew, required for reading the equipment instructions; and (7) enrollment in the medical center's app-based system for ongoing glucose and blood pressure surveillance.

Exclusion criteria were: (1) prepregnancy body mass index (BMI) ≥40 or ≤15 kg/m^2; (2) major maternal medical illness associated with increased risk for adverse pregnancy outcomes (e.g., pre-GD, systemic lupus erythematosus, chronic hypertensive disorder, cardiac disease, renal insufficiency); (3) need for in-clinic visits more than once every 2 weeks despite virtual care; (4) hospitalization during the study; (5) preterm labor (defined as regular painful contractions with cervical dilatation ≥2 cm), active vaginal bleeding, or ruptured amniotic membranes; (6) consistent reduction in fetal movement sensation; (7) fetal growth restriction, defined as an estimated fetal weight (EFW) <10th percentile; (8) known major fetal anomaly; and (9) known oligohydramnios, defined as an amniotic fluid index (AFI) <5 cm or maximal vertical pocket (MVP) <2 cm. Women who met one of the exclusion criteria after being recruited into the study were excluded from the study and moved to routine in-clinic follow-up or hospitalization as needed.

2.2 | Screening and recruitment

Women attending the antepartum high-risk pregnancy clinic were screened based on the above-described eligibility criteria. Potentially eligible women were provided with a comprehensive explanation of the study details and offered to participate. Those interested voluntarily signed an informed consent form, registered for the service application developed by our team on the Datos Ltd. platform, and were trained in operating the necessary equipment for remote visits. To ensure that participants could complete the study visits as outlined in the protocol, we capped enrollment at 35 weeks. This cutoff reduced the risk of missed visits due to spontaneous labor or the need for induction, which become more likely at later gestational ages.

All participants received a dedicated mobile device (Samsung Galaxy) equipped to support the various applications needed for the remote visits, as well as a cellular data plan, fetal monitor device (INVU by Nuvo), fetal ultrasound probe (PulseNmore Ltd), blood pressure cuff, and two digital home urine test kits (Healthy.io Ltd). Prior to the first remote visit, all participants were trained by a midwife (E.G.) using the remote ultrasound probe, the remote fetal belt,

the digital urine dipstick kit, and the digital GD app. The patients were required to complete a self-examination to the midwife's satisfaction as part of the training.

2.3 | Patient journey

The patient journey consisted of alternating in-clinic and remote weekly visits for a duration of 4 weeks (Figure 1a). After these 4 weeks we did not continue remote visits; however, participants were instructed to diligently continue recording their daily glucose measurements using the designated application provided by the service. From enrollment until labor, regardless of the completion of remote visits, patients who had insufficient documentation of glucose levels for more than 24 h received reminders via phone or message. Participants with uncontrolled glucose were instructed to start insulin or oral antidiabetic treatment or adjust the treatment dose as required.

During the in-clinic visits, routine comprehensive assessments were conducted, including vital signs monitoring, urine dipstick analysis, fetal monitoring, fetal ultrasound using the biophysical profile (BPP) methodology and EFW, and a physician-patient encounter (Figure 1b). The remote visits started with self-documenting of vital signs and glycemic control using the Datos Ltd. app, performing a urine test independently using a smartphone device and receiving immediate test results, facilitated through the Healthy.io test kit and platform. The remainder of the visit, including anamnesis, assessment of fetal heart rate (nonstress test [NST]) using the INVU device by Nuvo, and measurement of the MVP by ultrasound using the PulseNmore system to generate an mBPP, was conducted through virtual communication with the healthcare provider (partly by video through the Datos Ltd. platform; Figure 1b).

A midwife observed real-time assessment of fetal monitoring and a physician remotely assessed online fetal ultrasound, enabling prompt and accurate evaluation of the fetal condition and subsequent referral for further examination if deemed necessary. We did not monitor uterine activity as part of this study protocol. We informed participants that in case of technically insufficient or clinically nonreassuring maternal or fetal evaluation they may be called for additional in-clinic evaluation. For cases requiring additional evaluation of the fetal heart rate tracing, we defined three possible scenarios: (1) repeating the assessment at home; (2) self-transportation to the clinic for in-person evaluation; and (3) urgent referral via ambulance. Participants returned the study equipment during their fourth in-clinic visit.

2.4 | Outcomes

We defined the primary outcome as the feasibility of conducting a remote visit encompassing all its components as determined in

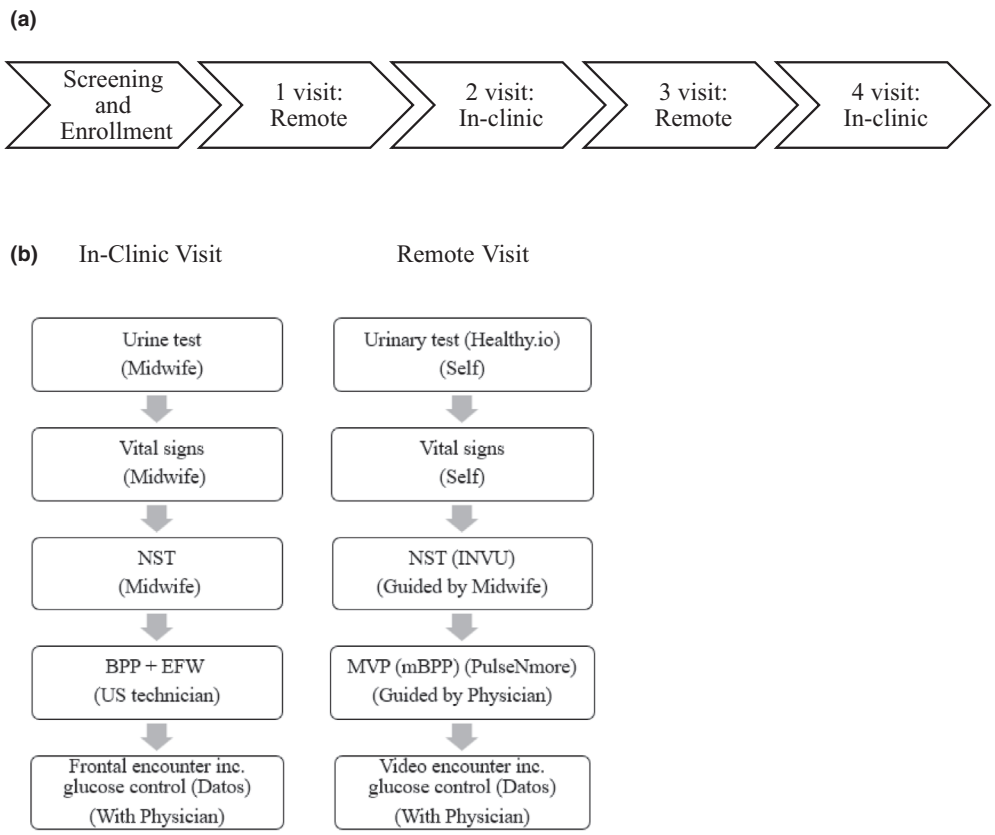

FIGURE 1 (a) Hybrid care protocol of weekly visits. (b) Visit components. BPP indicates biophysical profile; EFW, estimated fetal weight; mBPP, modified biophysical profile; MVP, maximal vertical pocket; NST, nonstress test.

real time by the maternal-fetal medicine clinic attending, in accordance with the established clinical standard of care (as described in Figure 1b). We measured the total duration of each remote visit from the initiation of fetal monitoring to the conclusion of the video call. We measured the duration of the in-clinic visits according to the door-to-door time. We assessed adherence to recording glucose values (regardless of their balance) in our application on the Datos Ltd. platform. The data were examined in the division for fasting measurements only and for all glucose measurements throughout the day including fasting and postprandial glucose measurements, during the hybrid care period and until delivery. We also assessed GD-related clinical outcomes (macrosomia – birth weight >4 kg, high-grade [3 or 4] perineal tears. shoulder dystocia, respiratory distress syndrome, hypoglycemia, and any neonatal complications).

2.5 | Patient questionnaires

The assessment of the telehealth intervention's usefulness, effectiveness, reliability, and patient satisfaction was conducted by independent filling of the Telehealth Usability Questionnaire (TUQ), Six Simple Questions (SSQ) survey, and Net Promotor Score (NPS) at the end of the fourth and final research visit (Appendices S1–S3).[29,30]

2.6 | Data collection and analysis

We collected demographic data, as well as birth and postpartum data from the electronic health records (EHRs). Visits were also documented in the EHR and data were captured from it. Data about vital signs and glucose monitoring were extracted from the Datos Ltd. system. Additional data were captured from the remote equipment used in the study (monitor and ultrasound). Deidentified data for study purposes were captured using REDCap software (Vanderbilt University).

The primary analysis involved mainly descriptive statistics to summarize the data. Categorical and ordinal variables are presented as the number of respondents (percentage) in each category. Quantitative variables were described using median and minimum–maximum due to the small sample size. A comparison of the duration of the visits (between remote visits and in-clinical visits) as well as a comparison of adherence with the documentation of glucose levels (during hybrid care and follow-up until delivery) were performed by univariate analysis using the paired Wilcoxon test due to the small sample size and the nonnormally distributed quantitative variables. These statistical approaches enabled the examination of relationships and differences within the data.

A two-sided P value <0.05 was considered statistically significant. Statistical analyses were performed using SPSS version 27 (IBM).

As previously mentioned, informed consent was collected from all participants. The study design and protocol were reviewed and approved by Sheba Medical Center institutional review board (trail reference number 8581-21-SMC).

3 | RESULTS

3.1 | Demographics

We enrolled 20 women with GD. The demographics of the women participating in the study are shown in Table 1. At enrollment, the median maternal age was 34.0 years (24.0–46.0 years) with a median BMI of 28.7 kg/m^2 (24.0–41.2 kg/m^2). Most participants were in their second pregnancy (median gravidity 2.0 [1–4]) and had a median gestational age of 33 + 0 weeks (32 + 0–35 + 0 weeks) at the first (remote) visit. Eleven (55.0%) women were initially diagnosed with A2GD and were treated with diabetes medications. The rest of the women (9 [45.0%]) were diagnosed with A1GD and achieved glycemic control by diet alone.

3.2 | Feasibility: completion of all remote visit components

Eighteen of 20 (90.0%) patients completed two full home visits. One participant withdrew consent after the first virtual visit. Another patient was referred for further in-clinic evaluation due to technical difficulties in completing the fetal monitoring. A defect was observed in the monitoring belt buckle used during that encounter and may have been the cause of the failure. Overall, 38 of 39 (97.4%) remote visits concluded in comprehensive maternal and fetal assessment including mBPP to the physician's satisfaction. In practice, except for the single referral to repeat monitoring at the clinic, all the components of the remote visit (urine test, vital signs, fetal monitoring, fetal ultrasound, glucose monitoring, and video encounter) were interpretable and fully completed. Furthermore, normal MVP and AFI measurements were recorded for all patients during remote and in-clinic visits, respectively. In addition, normal EFW measurements were documented for all in-clinic visits.

TABLE 1 Demographics and clinical characteristics of enrolled women.

Variable	(N = 20)
Age, years	34.0 (24.0–46.0)
BMI, kg/m^2	28.7 (24.0–41.2)
Gestational age at first visit, weeks	33 + 0 (32 + 0–35 + 0)
Gravidity	2.0 (1–4)
Nulliparity	8 (40.0)
GD type	
A1GD	9 (45.0)
A2GD	11 (55.0)
Current smoker	0 (0.0)
Hypothyroidism	3 (15.0)

Note: Data are presented as number (percentage) or median (minimum–maximum).

Abbreviations: A1GD, class A1 gestational diabetes; A2GD, class A2 gestational diabetes; BMI, body mass index; GD, gestational diabetes.

TABLE 2 Visits duration.

Visit type	Metric	First visit (min)	Second visit (min)	All visits (min)	*P* value
Remote visit	Total duration	66.0 (44.0–169.0)	55.0 (37.0–125.0)	59.0 (37.0–169.0)	**0.036 (first vs. second)**
	Ultrasound duration	5.0 (1.0–65.0)	5.0 (2.0–27.0)	5.0 (1.0–65.0)	0.659 (first vs. second)
	NST duration	26.0 (20.0–80.0)	25.0 (20.0–79.0)	25.0 (20.0–80.0)	0.794 (first vs. second)
In-clinic visit	Total duration	173.0 (136.0–268.0)	158.0 (124.0–247.0)	159.0 (124.0–268.0)	0.794 (first vs. second)
Comparison	Remote vs. in-clinic total visit duration				**<0.001**.

Note: Data are presented as median (minimum–maximum).

Abbreviation: NST, nonstress test.

TABLE 3 Adherence to glucose levels documentation.

Type of GD	Time of day	Hybrid care period	Post-hybrid care period	*P* value
A1GD	Fasting	88.21	66.04	0.050
	All day	74.99	59.41	0.028
A2GD	Fasting	95.84	58.00	0.018
	All day	84.62	44.38	0.005
Total	Fasting	92.23	61.81	0.001
	All day	80.06	51.50	<0.001

Note: All-day glucose documentation includes fasting and three postprandial readings per day. Data are percentages of recorded values relative to expected entries.

Abbreviations: A1GD, class A1 gestational diabetes; A2GD, class A2 gestational diabetes; GD, gestational diabetes.

TABLE 4 Delivery and neonatal outcomes.

Variable	(*N* = 19)
Labor induction	8 (42.1)
Mode of delivery	
Normal vaginal delivery	11 (57.9)
Operative vaginal delivery	1 (0.1)
Cesarean section	7 (36.8)
Gestational age delivery, weeks	39 + 0 (38 + 0–40 + 0)
Birth weight, g	3110.0 (2700.0–3830.0)
Macrosomia	0 (0.0)
Shoulder dystocia	0 (0.0)
Apgar at 1 min	9.0 (7.0–9.0)
Apgar at 5 min	10.0 (10.0–10.0)
NICU admission	0 (0.0)
Respiratory distress syndrome	0 (0.0)
Hypoglycemia	0 (0.0)
Neonatal complications	0 (0.0)

Note: Data are presented as number (percentage) or median (minimum–maximum).

Abbreviation: NICU, neonatal intensive care unit.

3.3 | Visits duration

Total remote visit length was significantly shorter (60.5 min [42.0–125.0 min]) compared with the in-clinic visit (170.0 min [140.0–209.0 min], $P < 0.001$). The second remote visit duration was significantly shorter than the first remote visit (55.0 min [37.0–125.0 min] vs. 66.0 min [44.0–169.0 min], $P = 0.036$). The median duration of ultrasound use was 5.0 min (1.0–65.0 min), while fetal monitoring was performed for a median time of 25.0 min (20.0–580.0 min) when the required minimum was defined as 20 minutes based on our department protocol (Table 2).

3.4 | Glucose monitoring adherence

As described in the Methods section, the study participants were asked to record glucose levels daily through a Datos application, both during the hybrid care period and afterwards until delivery. Adherence to recording fasting (92.23%) and all-day (fasting and postprandial; 80.06%) glucose values during the hybrid care period was high. Adherence decreased significantly both for fasting (61.81%) and all-day (fasting and postprandial; 51.50%) measurements in the period between the end of the hybrid care until birth ($P = 0.001$; Table 3). None of the participants required induction of labor for glycemic imbalance.

3.5 | Delivery and neonatal outcomes

Delivery and neonatal outcomes are presented in Table 4. Birth weight ranged from 2700 to 3830 g. There were no cases of macrosomia, high-grade perineal tears, shoulder dystocia, hypoglycemia of the newborn, or respiratory distress syndrome.

3.6 | Patient questionnaires

The TUQ indicated high usability of the telehealth system (6.6 of 7). Interestingly, the domain that received the lowest score was reliability (average 5.9 of 7), specifically question 17 ("The system gave error messages that clearly told me how to fix problem"), which scored an average of 5.2 of 7. Most of the women indicated that they would recommend the research equipment to friends and family, with the following NPS: INVU device (average 9.4 of 10), PulseNmore ultrasound (9.94 of 10), and Healthy.io kit (10 of 10). All women declared that they would choose the same type of care for their next pregnancy according to the six SSQ (Table S1).

3.7 | Adverse and safety events

No adverse events or safety incidents occurred during the use of the research equipment.

4 | DISCUSSION

4.1 | Principal findings

This prospective study, to our knowledge, is the first to demonstrate that comprehensive remote maternal-fetal care consisting of all aspects of the in-clinic visit, is feasible and time-efficient. Moreover, we demonstrated that the hybrid remote care approach is associated with improved patient satisfaction and better maternal adherence to glycemic control.

4.2 | Results in the context of what is known

To extend the findings of previous studies, our primary outcome was the feasibility of completing a comprehensive remote visit, covering all maternal and fetal components, in a manner comparable to an in-clinic visit and satisfactory to the physician.[1] The majority of the remote visits in our study achieved the study protocol's goals. In only one of the visits, a remote interpretable NST was not obtained. The participant's BMI was 40 (the upper limit of our BMI eligibility criteria) and she was at 32 weeks of gestation (the lower limit of our gestational age eligibility criteria). Two weeks later, at 34 weeks of gestation, an interpretable NST was obtained for the same participant. Hamm et al.[15] studied the same remote fetal monitoring device, allowing a higher BMI up to 50, and obtained an interpretable NST in 123 of 131 (93.95%) cases. However, they did not detail the association between BMI or gestational age with difficulty in obtaining remote NSTs or exploring other components of remote assessment.

The abbreviated duration of remote visits, when contrasted with in-clinic visits, aligns with anticipated time efficiency. This reduction is attributed to saving time on transport and parking as well as intervals between the various visit segments—onboarding, a nurse evaluation, NST, ultrasonography, and physician assessment. As we proceed from the pilot setting to the service setting, we expect waiting times between visit segments of the remote visits to increase. However, the interludes experienced during remote consultations offer a more optimal utilization of time, given that women can remain in their domestic or professional settings, rather than the confines of a clinical waiting area. It is noteworthy that the duration of the subsequent remote visit was markedly reduced compared with the initial visit, suggesting a learning curve not only for the staff but also for the participants.

Although normal MVP and AFI measurements were recorded for all visits in this study, questions remain regarding the role of MVP in evaluating polyhydramnios, which is more prevalent in the GD population. Some evidence suggests that the MVP method may overestimate polyhydramnios; however, further data are needed to confirm this finding.[31] We chose to use MVP measurement for remote visits in this protocol due to its relative ease for the physician in extracting MVP through the remote ultrasound performed by the patient. This choice is also supported by the lower associated risk compared with oligohydramnios[32] and the reassurance provided by additional weekly NSTs and biweekly AFI measurements.

During the 4-week study period, we observed strong adherence to glucose monitoring protocols. Interestingly, adherence significantly declined when patients transitioned back to exclusive in-clinic weekly assessments until birth, despite continued use of the same digital app for glycemic control and reminders issued after 24 h of insufficient glucose documentation. While the digital diabetes application can be used independently of the remote service, the heightened patient engagement during the hybrid care period may be attributed to the immediate feedback during remote visits and the empowerment derived from home care and active participation in the remote assessment process.

Furthermore, our study did not report any instances of labor induction due to glycemic imbalance, nor did we observe cases of macrosomia, shoulder dystocia, or neonatal hypoglycemia. However, it is important to approach these clinical findings with caution because of the limited cohort size, absence of a control group, and potential influence of eligibility criteria such as patient adherence and BMI restrictions up to 40.

The relationship between the effect of glucose level balance and clinical outcomes is a subject of debate in the literature. Our findings align with Kantorowska et al., who demonstrated that remote monitoring was superior to traditional methods for managing diabetes in pregnancy, resulting in improved maternal and neonatal outcomes.[11] Conversely, a recent meta-analysis showed no significant differences in balance and clinical outcomes.[33] However, it is crucial to note that most studies focusing on remote monitoring of glucose levels do not incorporate the comprehensive approach to remote monitoring utilized in our study, which may introduce bias into the results. Therefore, extensive randomized controlled trials are necessary to thoroughly investigate this matter.

Remote fetal monitoring was operated by a certified midwife. A physician conducted the rest of the visit, consisting of the remote

ultrasonographic assessment and video encounter. In practice, this can also be optimized by "working at the top of the license"—a certified midwife for fetal monitoring and the patient encounter, an ultrasound technician for completing the ultrasound, and OB/GYN or maternal-fetal medicine expert involvement only in complex cases.

The landmark HOTEL (Hospital Care versus Telemonitoring in High Risk Pregnancy) trial showed that telemonitoring for complicated pregnancies might be as safe as hospital admission. Notably, while not reaching statistical significance, there was one instance of fetal mortality in the telemonitoring group of the HOTEL study, compared with none in the hospital group.[21,22] Our approach integrates remote sonography, incorporating the mBPP. While the NST reflects the immediate fetal condition, amniotic fluid volume signifies long-term status. Miller et al., in a study of 56 617 antepartum tests, found that the false-negative rate of the mBPP was lower than that of NST alone compared favorably with the false-negative rates of the contraction stress test and the complete BPP, with a false-negative rate for fetal death within a week at 0.8 per 1000.[34] Therefore, our approach encompassing fetal ultrasonography in the remote visits offers a reliable and effective means of monitoring fetal well-being.

High satisfaction was demonstrated among the study participants, with a certain reservation in the domain of reliability that referred to the systems interface limitations. This emphasizes the importance of user training at onboarding, a user-friendly interface for all technologies, and online technical support for a seamless remote patient journey.[23]

4.3 | Clinical and research implications

Remote care will play an increasingly important role in maternal-fetal medicine if this model of care is further established and implemented.

In this pilot study, we selected a sample size of 20 participants, yielding 77 total encounters (39 remote and 38 in-clinic visits), to provide initial insights into the feasibility, efficiency, and patient satisfaction of a hybrid telemedicine model for GD care. The sample size was chosen to enable practical, yet meaningful, evaluation of the model within the constraints of a pilot setting, allowing us to identify preliminary trends and challenges that could inform larger, statistically powered studies in the future.

Future investigations may extend these findings to real-world evidence, explore economic considerations, and include randomized controlled trials to examine the clinical benefits of the improved adherence.

4.4 | Strengths and limitations

The strengths of the study are the prospective design, the comprehensive remote assessment leveraging an ensemble of cutting-edge digital technologies, and the linkage between individual remote visits and participants' adherence to an ongoing digital intervention. However, some limitations should be noted. The relatively small pilot sample size and the stringent eligibility criteria, implemented to ensure participant safety, may limit the generalizability of the findings. Furthermore, due to the prospective nature of the study, detailed information on participants' prior antenatal care, methods of glycemic control, and obstetric history was not collected, which may constrain the interpretation of specific outcomes.

5 | CONCLUSIONS

This pilot study suggests that a hybrid approach to maternal-fetal medicine, which integrates clinic visits with comprehensive virtual visits, may be feasible and safe. The findings indicate potential benefits in terms of time efficiency, patient satisfaction, and adherence to glycemic control, although further research with larger sample sizes, a more diverse cohort, and a control group is needed to fully assess the safety and efficacy of this approach.

AUTHOR CONTRIBUTIONS

The authors confirm contribution to the paper as follows: study conception and design: Axelrod M, Tsur A, Nir O, Barkai G, Sivan E, Mazaki-tovi S; data collection: Axelrod M, Lahav Ezra H, Galler E, Tsur A, Ofir K; analysis and interpretation of results: Axelrod M, Galler E, Tsur A; draft manuscript preparation: Axelrod M, Tsur A; All authors reviewed the results and approved the final version of the manuscript.

ACKNOWLEDGMENTS

The authors would like to acknowledge Hadar Amir for helping identify the relevant technologies for our clinical goals. In addition, the authors acknowledge the support of Sheba's Chief Digital Transformation Officer Beni Ben-Lulu as well as Sheba's information technology team: Shimi Ernst, Roy Panigel, and Levi Tsehmester.

FUNDING INFORMATION

Nuvo supplied fetal monitoring belts, digital blood pressure cuffs, cellular devices, and technical support for their use without cost. PulseNmore supplied the ultrasound probes and technical support for their use without cost. Healthy.io supplied urine test kits 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

A.T. reports the following financial disclosures that are not related to the current study: holds minority shares in PregnanTech as a primary medical inventor of a mechanical device for the prevention of preterm birth commercializing under the name "The Lioness"; co-founder and serves as chief medical officer of Shela Ltd. developing Maternal-Fetal Precision Medicine; serves as 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. In addition, A.T. reports receiving honoraria from GE healthcare for delivering an educational workshop during ISOUG World Congress in Seoul, South Korea, 2023. The other authors report no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

PREVIOUS PRESENTATION

Abstract poster presentation at the annual SMFM conference, 2023 San Francisco, California.

ORCID

Michal Axelrod https://orcid.org/0000-0001-8816-2562
Omer Nir https://orcid.org/0000-0003-0587-5802
Keren Ofir https://orcid.org/0000-0001-7534-0518
Galia Barkai https://orcid.org/0000-0002-0775-9015
Eyal Sivan https://orcid.org/0000-0002-1746-0025
Shali Mazaki-Tovi https://orcid.org/0000-0003-1603-3862
Abraham Tsur https://orcid.org/0000-0001-9092-4570

REFERENCES

1. Kane CK, Gillis K. The use of telemedicine by physicians: still the exception rather than the rule. *Health Aff*. 2018;37(12):1923-1930.
2. Ehsani JP, Doshi N, Daugherty JE, Goudarzi M. The use of telemedicine in obstetrics and gynecology. *Am J Obstet Gynecol*. 2010;202(2):97-101.
3. Riva JJ, Silver RM, Copenhaver MM. Telemedicine and maternal-fetal medicine: current applications and future directions. *Am J Obstet Gynecol*. 2015;213(3):301-307.
4. Fernandes BA, Alves B, Matosinhos AC, et al. The use and role of telemedicine in maternal fetal medicine around the world: an up-to-date. *Health Technol*. 2023;13(3):365-372.
5. Tucker KL, Mort S, Yu LM, et al. Effect of self-monitoring of blood pressure on diagnosis of hypertension during higher-risk pregnancy. *JAMA*. 2022;327(17):1656-1665.
6. Chappell LC, Tucker KL, Galai U, et al. Effect of self-monitoring of blood pressure on blood pressure control in pregnant individuals with chronic or gestational hypertension. *JAMA*. 2022;327(17):1666-1678.
7. Van Den Heuval JFM, Lieshout CV, Franx A, Frederix G, Bekker MN. SAFE@HOME: cost analysis of a new care pathway including a digital health platform for women at risk of preeclampsia. *Pregnancy Hypertens*. 2021;24:118-123.
8. Van Den Heuval JFM, Karoman SS, Solinge WW, Franx A, Lely T, Bekker MN. SAFE@HOME – feasibility study of a telemonitoring platform combining blood pressure and preeclampsia symptoms in pregnancy care. *Eur J Obstet Gynecol Reprod Biol*. 2022;20:30-36.
9. Tucker KL, Bowen L, Crawford C, et al. The feasibility and acceptability of self-testing for proteinuria during pregnancy: a mixed methods approach. *Pregnancy Hypertens*. 2018;12:161-168.
10. Laursen SH, Boel L, Udsen FW, et al. Effectiveness of telemedicine in managing diabetes in pregnancy: a systematic review and meta-analysis. *J Diabetes Sci Technol*. 2023;17(5):1364-1375.
11. Kantorowska A, Cohen K, Oberlander M, et al. Remote patient monitoring for management of diabetes mellitus in pregnancy is associated with improved maternal and neonatal outcomes. *Am J Obstet Gynecol*. 2023;228:726.e1-726.e11.
12. Bertini A, Garate B, Pardo F, et al. Impact of remote monitoring technologies for assisting women with gestational diabetes mellitus: a systematic review. *Front Bioeng Biotechnol*. 2022;10:819697.
13. Xie W, Dai P, Qin Y, Wu M, Yang B, Yu X. Effectiveness of telemedicine for pregnant women with gestational diabetes mellitus: an updated meta-analysis of 32 randomized controlled trials with trial sequential analysis. *BMC Pregnancy Childbirth*. 2020;20:198.
14. Balk E, Danilack V, Cao W, et al. Televisits compared with in-person visits for routine antenatal care. *Obstet Gynecol*. 2023;142(1):19-29.
15. Hamm RF, Shkolnik K, Keren N, et al. Utilization of a wireless monitoring device to perform nonstress tests in high-risk pregnancies from home. *Am J Obstet Gynecol*. 2023;229(23):463-464.
16. Mhajna M, Schwartz N, Levit-Rosen L, et al. Wireless, remote solution for home fetal and maternal heart rate monitoring. *Am J Obstet Gynecol MFM*. 2020;2:100101.
17. Toscano M, Marini TJ, Drennan K, et al. Testing telediagnostic obstetric ultrasound in Peru: a new horizon in expanding access to prenatal ultrasound. *BMC Pregnancy Childbirth*. 2021;21(1):328-340.
18. Nir O, Dvir G, Galler E, et al. Integrating technologies to provide comprehensive remote fetal surveillance: a prospective pilot study. *Int J Gynaecol Obstet*. 2023;164:662-667. doi:10.1002/ijgo.15018
19. Dorsey ER, Topol EJ. Telemedicine 2020 and the next decade. *Lancet*. 2020;395(10227):859.
20. Moore G. *Crossing the Chasm*. HarperCollins; 1991.
21. Bekker MN, Koster MPH, Keusters WR, et al. Home telemonitoring versus hospital care in complicated pregnancies in The Netherlands: a randomized, controlled non-inferiority trial (HoTeL). *Lancet Digit Health*. 2023;5:116-124.
22. Van Den Heuvel JFM, Ayubi S, Franx A, Bekker MN. Home-based monitoring and telemonitoring of complicated pregnancies: Nationwide cross-sectional survey of current practice in The Netherlands. *JMIR Mhealth Uhealth*. 2020;8:e18966.
23. DeNicola N, Grossman D, Marko K, Sonalkar S, Tobah YSB, Ganju N. Telehealth interventions to improve obstetrics and gynecologic health outcomes – a systematic review. *Obstet Gynecol*. 2020;135:371-382.
24. Ozturk GG, Akyildiz D, Karacam Z. The impact of telehealth application on pregnancy outcomes and costs in high-risk pregnancy: a systematic review and meta analysis. *J Telemed Telecare*. 2022;30:607-630. doi:10.1177/1357633X221087867
25. Zhou T, Du S, Sun D, et al. Prevalence and trends in gestational diabetes mellitus among women in the united stated, 2006-2017: a population-based study. *Front Endocrinol*. 2022;6:13.
26. Johns EC, Denison FC, Norman JE, Reynolds RM. Gestational diabetes mellitus: mechanisms, treatment, and complications. *Trends Endocrinol Metab*. 2018;29(11):743-754.
27. Scifres C, Feghali M, Althouse AD, Caritis S, Catov J. Adverse outcomes and potential targets for intervention in gestational diabetes and obesity. *Obstet Gynecol*. 2015;126(2):316-325.
28. ACOG Practice bulletin No. 190: gestational diabetes mellitus. *Obstet Gynecol*. 2018;131(2):49-64.
29. Harvey S, Rach D, Stainton MC, Jarrell J, Brant R. Evaluation of satisfaction with midwifery care. *Midwifery*. 2002;18:260-267.
30. Hajesmaeel-Gohari S, Bahaadinbeigy K. The most used questionnaires for evaluating telemedicine services. *BMC Med Inform Decis Mak*. 2021;21(1):36-46.
31. Lim KI, Butt K, Naud K, Smithies M. Amniotic fluid: technical update on physiology and measurement. *J Obstet Gynaecol Can*. 2017;39(1):52-58.
32. Crellin HB, Singh V. Sonography evaluation of amniotic fluid. *StatPearls [Internet]*. StatPearls Publishing; 2024.

33. Yue SW, Zhou J, Li L, et al. Effectiveness of remote monitoring for glycemic control on maternal-fetal outcomes in women with gestational diabetes mellitus: a meta-analysis. *Birth*. 2024;51(1):13-27.
34. Miller DA, Rabello YA, Paul RH. The modified biophysical profile: antepartum testing in the 1990s. *Am J Obstet Gynecol*. 1996;174(3):812-817.

SUPPORTING INFORMATION

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

How to cite this article: Axelrod M, Lahav Ezra H, Galler E, et al. Hybrid remote and in-clinic maternal-fetal surveillance for women with gestational diabetes: A prospective pilot study. *Int J Gynecol Obstet*. 2025;00:1-9. doi:10.1002/ijgo.16148