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Retrospective cohort of prenatal home ultrasound utilization and maternal-neonatal outcomes

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Abstract

Background Telehealth solutions, including ultrasound technology, are sought as a modality to enhance prenatal. We aimed to evaluate the utilization of a self-operated home ultrasound service in a real-world large cohort, comparing users vs. non-users. This service provides a handheld, app-connected ultrasound device for remote basic fetal monitoring, with its use determined at the discretion of the patient as a supplement - rather than a replacement - to standard prenatal care.

Methods Retrospective analysis comparing maternal and neonatal outcomes among users versus non-users of the home ultrasound service, between January 2020 and December 2022. Primary outcome measures were preterm delivery and a composite adverse neonatal outcome. Confounders were balanced between the groups using nearest neighbour matching with propensity scores. Multivariable analyses including the confounders were conducted in matched cohorts to obtain doubly robust estimates. A sensitivity analysis included those who began using the device before 22 gestational weeks and continued for more than 10 weeks. Safety was assessed by identifying any maternal, obstetrical, or neonatal complications plausibly linked to device use.

Results The study compared two cohorts; the exposed cohort of 4,460 pregnant women using Clalit's home ultrasound service (users), and the control (non-users) cohort of 102,707 pregnant women with an equal HMO insurance status. Users had higher socioeconomic scores, were more primiparous and had a higher incidence of chronic disease and pregnancy complications. Preterm birth rates and adverse neonatal outcomes did not differ between groups. Device utilization, both overall and stratified by actual utilization degree, was safe and not associated with any maternal, obstetrical or neonatal adverse pregnancy outcomes.

Conclusions A self-operated home ultrasound device, during the second and third trimester, is safe and not significantly associated with any pregnancy adverse event or neonatal complications.

Keywords Home, Mobile, Outcome, Pregnancy, Remote, Safety, Telehealth, Ultrasound

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Introduction

In past years, telehealth solutions have been adopted to minimize face-to-face visits [1]. Self-operated home ultrasound emerges as a potential tool to extend fetal monitoring beyond the clinic. These systems may improve access, patient engagement, and early detection of complications, particularly in settings with barriers to in-person care. However, their use also raises concerns - such as overuse, misinterpretation, or false reassurance. Despite increasing adoption, evidence regarding their clinical impact remains limited.

One such solution, for prenatal care, is the Pulsenmore ES system (Pulsenmore, Omer; Israel) (Fig. 1). It incorporates a handheld ultrasound smartphone cradle, with a user application, and a clinician dashboard, enabling parturients to use their smartphones for ultrasound self-scans. The device operates in two modes: app-guided mode, which offers asynchronous offline guidance by video-tutorials and healthcare professional interpretation, or clinician-guided mode, which provides real-time online teleconsultation with live ultrasound guidance and scanning, with a healthcare professional.

This self-operated ultrasound device provides basic fetal well-being supplemental information on heart activity, movements, and amniotic fluid volume estimation. It can be used for basic fetal evaluation [2, 3], high-risk pregnancy monitoring [4, 5] and anxiety reduction for women with a bad obstetric history [6].

Since March 2021, this technology was adopted by Clalit Health Services - Israel's largest health maintenance organization (HMO). In this context, we evaluated the use of a self-operated home ultrasound service offered to pregnant women as part of a large healthcare organization, and within the scope of this study, it was offered in the app-guided mode to pregnant women [7]. The service was designed to supplement - not replace - standard prenatal care, with formal clinical assessments such as non-stress test or ultrasound scans. It provided patients with an app-guided tool for remote fetal monitoring at their own discretion. The presumed benefits included increasing maternal reassurance between scheduled visits, enhancing patient engagement, and improving access to fetal monitoring in non-clinical settings, particularly when in-person care may be less accessible.

We aimed to examine the association of this home ultrasound service utilization during pregnancy with maternal and short-term neonatal outcomes in a real-world cohort.

Methods

Retrospective analysis of all pregnant women who received care under the Clalit HMO, comparing users versus non-users of the home ultrasound service.

Home ultrasound service

The service is available for pregnant women, beneficiaries of Clalit's high-tier insurance ("Mushlam"), from 14 + 0 weeks. The service was available to pregnant women across the entire geographic range of Clalit Health Services in Israel, without restriction to specific clinics or regions.

The service operates in the app-guided mode of the device, allowing expectant mothers to use it independently at their discretion. Each woman is allotted 150 scan minutes during her gestation, divided into 50 scans, each lasting three minutes, up to three scans per day. After watching a five-segment video tutorial within the application, the user can then scan herself, using the home ultrasound device (Fig. 2). The video tutorials are based on a standardized approach to ensure full fetal visualization [8].

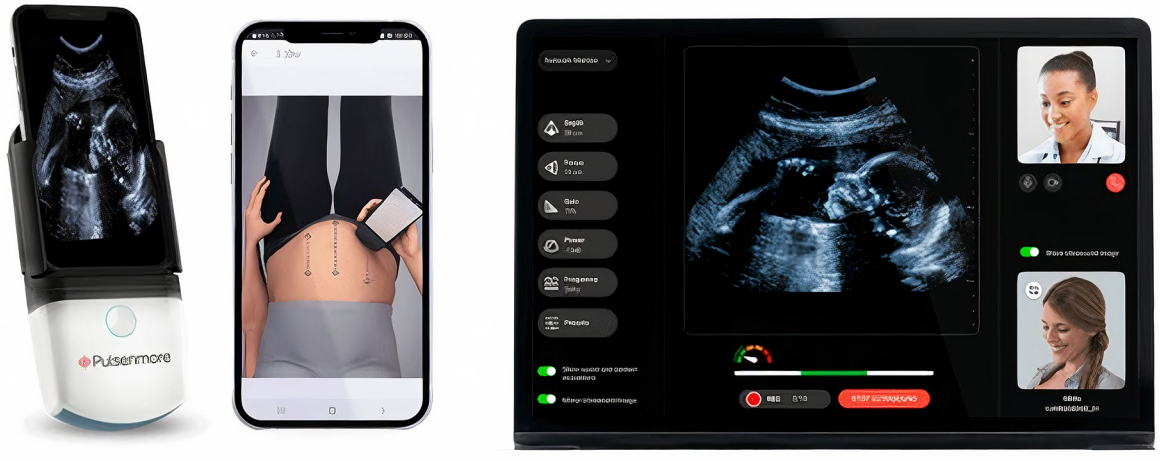

Fig. 1 The Pulsenmore ES system, with a handheld ultrasound transducer smartphone cradle, a user application and clinician's dashboard for either. app-guided or clinician-guided mode

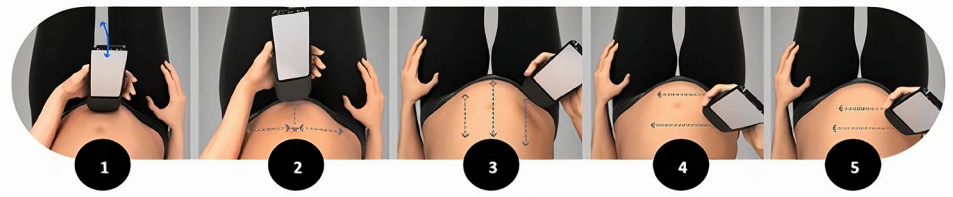

Fig. 2 The Pulsenmore ES System app-guided, 5-steps video tutorial. Step **1**: Tilt, scans the lower abdomen (15 s). Step **2**: Bottom to Top, scans the center, left and right abdomen (55 s). Step **3**: Bottom to Top, scans the right, center and left abdomen (55 s). Step **4**: Right to Left, scans above and below the naval (25 s). Step **5**: Right to Left, scans above and over the naval (30 s)

Completed scans are uploaded to a secure cloud, readily available for professional review via the clinician's dashboard. All uploaded scans were reviewed by a trained obstetrical sonographer - either an ultrasound technician or OBGYN physician. Feedback is provided to the user for three parameters: fetal cardiac activity, fetal movements, and amniotic fluid volume. Each scan is classified as: normal (all parameters satisfactory), abnormal (at least one parameter is abnormal, i.e. no heartbeat, no movements, or oligo- poly- hydramnios), or inadequate (at least one parameter cannot be technically evaluated).

Eligible users could begin self-scanning at their discretion following device acquisition and completion of an in-app instructional tutorial. There was no specific timing mandated for scan initiation. The device is intended for remote fetal monitoring as a supplement, not a replacement, for standard prenatal care and is used at user's discretion. Users are instructed not to draw conclusions or act independently based on the self-scans unless under direct medical supervision.

To support its safety, in concordance with the "as low as reasonably achievable" principle (ALARA), the device operates in 2–5 MHz wavelengths, with 2-Dimensional imaging (B-mode) and no Doppler. Acoustic output limits are 0.4 mechanical index and 0.03 thermal index, well below the 1.0 boundary.

Study population

Pregnant women with a singleton gestation, having Clalit's high-tier insurance ("Mushlam") between January 2020 and December 2022, who delivered at or after 22 + 0 weeks were stratified as users or non-users of the home-ultrasound service.

The decision to purchase the service and use the device was entirely patient-driven, without physician selection or referral. Both groups had possible access to the device, but the non-users opted not to acquire it. All participants received obstetrical care within the same healthcare system under standardized protocols, ensuring similar management approaches across groups.

Women were excluded based on data unreliability implausible values or missingness of gestational age at delivery, neonatal birthweight or first and last date of scan in the home-ultrasound users' subgroup.

Data collection

Deidentified maternal and neonatal data were extracted from Clalit's electronic medical records database and home ultrasound utilization data from Pulsenmore's dashboard.

The following parameters were collected - maternal age, socioeconomic score (in a scale of 1–10, as designated to each person in Israel according to education level, salary and place of residence), pre-pregnancy body mass index (BMI), preexisting chronic medical diagnosis, gravidity and parity, obstetrical complications during pregnancy, mode of delivery (vaginal, cesarean) and immediate fetal-neonatal outcomes (gestational age at delivery, gender, birthweight, 1- and 5- minute Apgar scores, umbilical cord pH).

Home ultrasound utilization included: date and gestational age of acquisition, date and gestational age of first and last self-scans, number of total scans and their results (normal, inadequate or abnormal; with details of which of the three parameters was abnormal or inadequate).

Outcome measures

The primary outcomes were preterm delivery (< 37 + 0 weeks) and a composite adverse neonatal outcome defined as any one of the following: stillbirth, 5-minute Apgar < 7, or umbilical arterial cord pH < 7.05. Preterm delivery rate was chosen as the primary outcome due to its significant impact on neonatal morbidity and healthcare resource utilization, as well as its potential sensitivity to enhanced monitoring.

Secondary outcomes included: neonatal birthweight in grams and percentile - calculated according to nationally accepted nomograms [9], small for gestational age (SGA) - defined as birthweight below the 10th percentile, placental abruption and delivery parameters (labor induction and mode of delivery).

Notably, detailed neonatal outcome data was only available for a partial subset of the cohort (19,046 of 106,674).

We also explored the overall safety of the device which was defined as the absence of device-related adverse events and/or unexpected clinical complications associated with its use.

Data quality assurance

Data inputs outside the technical limits for a specific variable were inspected for the overall quality of the input for that woman and were set to missing if deemed to be isolated and unrelated to the overall quality of the data entry for that woman.

Data entries were also checked for outliers by inspecting their overall distribution or cross referencing them against their biological correlates such as birthweight and gestational age. Extreme outliers (Z-score > 5) were set to missing.

The percentage of data entries modified during these procedures was less than 1% of all available data.

The missingness rate varied in the variables - for socioeconomic score and BMI, it was 12% and 14%, respectively and highest for the gravidity variable, 56%. For the smaller dataset, with detailed neonatal outcome information, the missingness rate was lower than 5%. The overall missingness rate in the data had no impact on the decision whether a variable should be imputed or not [10]. Imputation has been shown to be superior to reducing bias under various scenarios compared to doing a complete case analysis. The overall missingness pattern was visually inspected and the probability of missingness and their correlation with each other was inspected with a correlation matrix. The missingness pattern was non-monotone and the probability of missingness showed weak (0.2–0.4) or very weak correlation (0-0.2).

Based on these findings, we assumed that the missingness pattern observed in the data was "missing at random" and imputed them using multiple imputation by chained equations. Predictor matrix was built based on the correlation of all variables in the dataset, including the outcome variables. Imputation models were checked for convergence, plausibility of imputed values, model fit versus distributional discrepancy and correlation of marginal distributions of the observed data and imputed data.

Statistical analysis

Variables were presented as median and interquartile ranges for continuous scales and number, denominator, and percentage of the total for categorical scales unless otherwise specified. Confounders were balanced between the groups using nearest neighbour matching with propensity scores. The effectiveness of the matching was checked with density overlap of the confounders absolute standardized mean differences of confounders between the groups. Ultrasound users and non-users were matched 1:5 for preterm birth outcome analysis and 1:2 for composite neonatal adverse outcome analysis, to account for the overall size of available cohort for each outcome measure. Association estimates were obtained with logit-binomial and linear regression models. Multivariable analyses were also conducted in matched cohorts to obtain doubly robust estimates [11].

A sensitivity analysis was planned to include only those who started self-scanning prior to 22 weeks and utilized the device for more than 10 weeks to ascertain the effects of prolonged device utilization.

All analyses were conducted in R for Statistical Computing Software. p-value < 0.05 was considered statistically significant. p-values were two-tailed unless otherwise specified.

Determination of sample size

Sample size was determined by assuming an expected preterm delivery baseline event rate of 10% and allowing ± 2% change in the user's group with 90% power, Type I error probability of 0.05 (two-tailed), group allocation size 1:5 in the matched cohort (user vs. non-user), and Snell-R^2 of 0.05 for the multivariable binomial model. The estimation showed a total sample size requirement of 19,795 pregnancies for this analysis. For composite neonatal outcome analysis, we assumed a baseline event rate of 1.5% and allowing ± 1.5% change in the user's group with 90% power, Type I error probability of 0.05 (two-tailed), group allocation size 1:2 in the matched cohort (user vs. non-user, owing to smaller cohort size), and Snell-R^2 of 0.015 for the multivariable binomial model. The estimation showed a total sample size requirement of 4,544 pregnancies for this analysis.

Results

The study compared two cohorts: 4,460 users and a control cohort of 102,707 non-users, with equal insurance status. Following exclusion and missing data imputations 4,083 users and 102,591 non-users were included in the analysis (Fig. 3).

Non-users showed lower socioeconomic scores (median, 5.0 vs. 7.0, $p < 0.001$), higher gravidity (median: 2.0 vs. 1.0, $p < 0.001$), less asthma (4.5% vs. 7.2%, $P < 0.001$), inflammatory bowel disease (0.3% vs. 0.5%, $P = 0.007$) and chronic hypertension (0.5% vs. 0.9%, $P = 0.001$); as well as lower rates of gestational hypertension (0.3% vs. 0.6%, $P = 0.012$), preeclampsia (0.8 vs. 1.3%, $P = 0.003$), gestational diabetes (1.9% vs. 3.0%, $P < 0.001$), placenta previa (0.3% vs. 0.7%, $P < 0.001$) and oligohydramnios (1.7% vs. 2.7%, $P < 0.001$) - reflecting, the higher baseline risk nature of women who opted to utilize the service (Table 1).

Socioeconomic scores and pregnancy complications - hypertension and diabetes - showed density imbalance before matching (Supplementary Fig. 1). After propensity score matching (Supplementary Fig. 2), with exact matching on socioeconomic scores, propensity scores were evenly matched between the groups and covariate balance was achieved (Supplementary Fig. 3). After

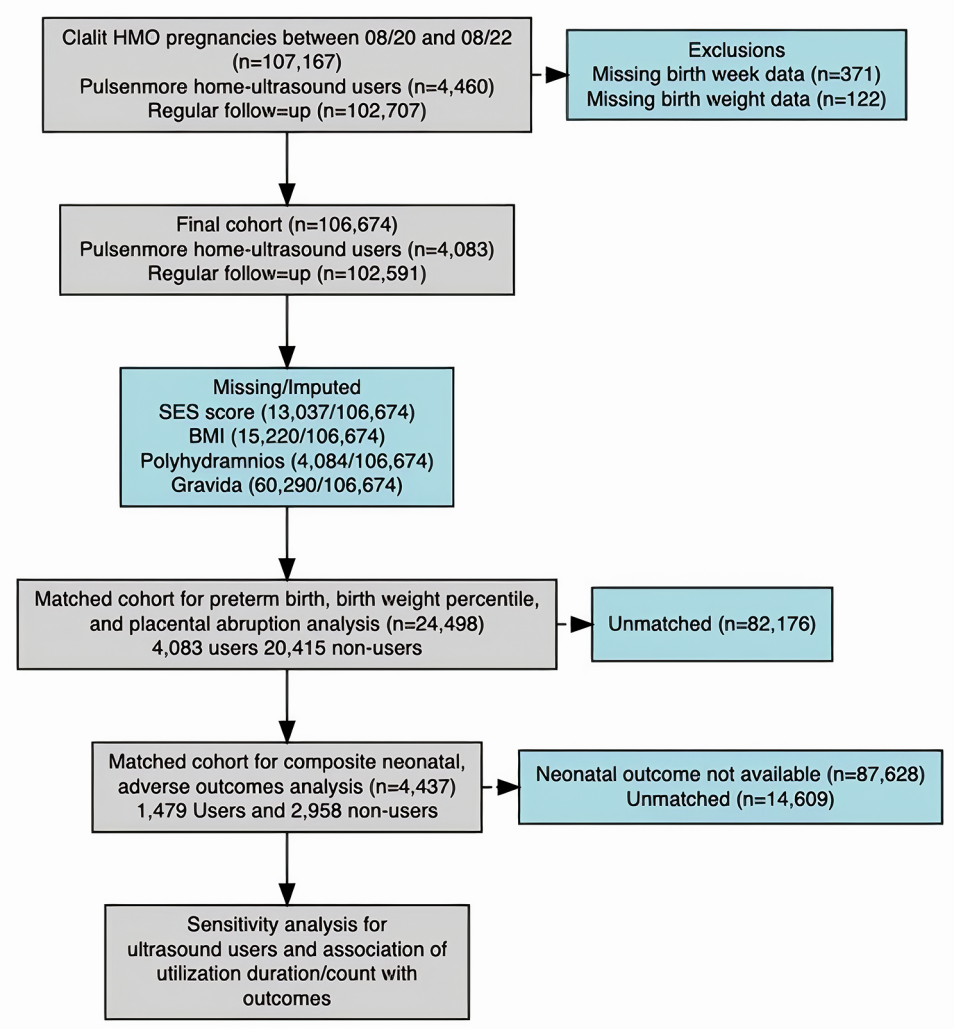

Fig. 3 Flow diagram of inclusion and exclusions and missing/imputed count HMO - Health Maintenance Organization; SES - Socioeconomic Score, BMI - Body Mass Index

matching, significant differences between the groups of the unmatched cohort, have dissipated, for the following variables: socioeconomic scores, gravida, asthma, inflammatory bowel disease, chronic hypertension, gestational hypertension, preeclampsia, gestational diabetes and placenta previa. Significant differences persisted through matching for oligohydramnios (1.8% vs. 2.7%, non-users vs. users $P<0.001$) as amniotic fluid abnormalities were not included in the propensity score models due to the possibility of oligohydramnios being on a causal pathway between exposure and outcomes (i.e., increased diagnosis rate due to home ultrasound utilization) which would classify it as a mediator variable and not confounder (Table 2).

In the matched cohort, preterm delivery rates were 6.7% in non-users and 7.2% in the users. Multivariable regression analysis. Adjusted for known risk factors, showed that maternal age (aOR: 1.04, 95% CI: 1.03–1.05, $P<0.001$), socioeconomic scores (aOR: 0.97, 95% CI: 0.94-1.00, $P=0.027$), BMI (OR: 0.99, 95% CI: 0.98-1.00, $P=0.036$), primigravity (aOR: 1.29, 95% CI: 1.17–1.44, $P<0.001$), preeclampsia (aOR: 4.62, 95% CI: 3.49–6.05, $P<0.001$) and placenta previa (aOR: 4.58, 95% CI: 3.10–6.61, $P<0.001$) had significant associations with prematurity. Home ultrasound use did not contribute independently to outcome variation and was not associated with preterm delivery in univariable (OR: 1.07, 95% CI: 0.94–1.22, $P=0.296$) or multivariable analyses (aOR: 1.07, 95% CI: 0.94–1.22, $P=0.307$) (Table 3).

Neonatal birthweight percentiles were not associated with home ultrasound use in univariable (coefficient: 0.69, 95% CI: -0.20-1.58, $P=0.131$) or multivariable models (coefficient: 0.62, 95% CI: -0.26-1.50, $P=0.168$).

Babies of women with higher BMI had significantly higher birthweight percentiles (coefficient: 0.74, 95% CI: 0.67–0.80, $P<0.001$) while babies born to primigravid

Table 1 Comparison of home-ultrasound users and non-users in the *whole* cohort

Variable	Non-Users *n* = 102,591	Users *n* = 4,083	*p*-Value
Maternal age, years	32.0 (28.0–36.0)	32.0 (29.0–36.0)	< 0.001
Socioeconomic score, 1–10	5.0 (4.0–7.0)	7.0 (5.0–8.0)	< 0.001
Body mass index, kg/m^2	23.9 (21.1–27.7)	23.5 (20.9 to 27.5)	< 0.001
Gravidity	2.0 (1.0–4.0)	1.0 (1.0 to 3.0)	< 0.001
Chronic diseases:			
Asthma	4665 (4.5)	293 (7.2)	< 0.001
Coagulation defects	120 (0.1)	3 (0.1)	0.570
Inflammatory Bowel Disease	279 (0.3)	21 (0.5)	0.007
Graves' disease	214 (0.2)	9 (0.2)	1.000
Hashimoto's thyroiditis	679 (0.7)	35 (0.9)	0.160
Systemic lupus erythematosus	39 (0.0)	3 (0.1)	0.473
Chronic hypertension	534 (0.5)	37 (0.9)	0.001
Pregnancy complications:			
Gestational hypertension	347 (0.3)	24 (0.6)	0.012
Preeclampsia	843 (0.8)	52 (1.3)	0.003
Gestational diabetes	1919 (1.9)	124 (3.0)	< 0.001
Placenta previa	274 (0.3)	28 (0.7)	< 0.001
Polyhydramnios	1297 (1.3)	38 (0.9)	0.071
Oligohydramnios	1722 (1.7)	111 (2.7)	< 0.001
Outcomes:			
Placental abruption	155 (0.2)	12 (0.3)	0.039
Gestational age at delivery, weeks	39.3 (38.6–40.3)	39.1 (38.3–40.0)	< 0.001
≤28 weeks	241 (0.2)	11 (0.3)	0.004
>28 & ≤32 weeks	663 (0.6)	31 (0.8)	
>32 & ≤36 weeks	5160 (5.0)	250 (6.1)	
36> & ≤42 weeks	96,412 (94.0)	3791 (92.8)	
>42 weeks	115 (0.1)	0 (0.0)	
Birthweight, grams	3250.0 (2950.0-3555.0)	3215.0 (2910.0-3500.0)	< 0.001
Birthweight, centiles	60.0 (37.0–79.0)	59.0 (37.0–79.0)	0.167

Variables presented as median (interquartile range) for continuous scales and number (percentage) for categorical scales

Table 2 Comparison of home-ultrasound users and non-users in the matched cohort

Variable	Non-Users *n* = 20,415	Users *n* = 4,083	*p*-Value
Maternal age, years	32.0 (29.0–36.0)	32.0 (29.0–36.0)	0.617
Socioeconomic score, 1–10	7.0 (5.0–8.0)	7.0 (5.0–8.0)	1.000
Body mass index, kg/m^2	23.4 (20.8–27.3)	23.5 (20.9–27.5)	0.399
Gravidity	1.0 (1.0–3.0)	1.0 (1.0–3.0)	0.706
Chronic diseases:			
Asthma	1437 (7.0)	293 (7.2)	0.780
Coagulation defects	16 (0.1)	3 (0.1)	1.000
Inflammatory bowel disease	106 (0.5)	21 (0.5)	1.000
Graves' disease	45 (0.2)	9 (0.2)	1.000
Hashimoto's thyroiditis	161 (0.8)	35 (0.9)	0.724
Systemic lupus erythematosus	14 (0.1)	3 (0.1)	1.000
Chronic hypertension	171 (0.8)	37 (0.9)	0.732
Pregnancy complications:			
Gestational hypertension	125 (0.6)	24 (0.6)	0.941
Preeclampsia	266 (1.3)	52 (1.3)	0.940
Gestational diabetes	602 (2.9)	124 (3.0)	0.800
Placenta previa	122 (0.6)	28 (0.7)	0.583
Polyhydramnios	231 (1.1)	38 (0.9)	0.297
Oligohydramnios	366 (1.8)	111 (2.7)	< 0.001
Outcomes:			
Placental abruption	41 (0.2)	12 (0.3)	0.325
Gestational age at delivery, weeks	39.3 (38.4–40.3)	39.1 (38.3–40.0)	< 0.001
≤28 weeks	48 (0.2)	11 (0.3)	0.248
>28 & ≤32 weeks	154 (0.8)	31 (0.8)	
>32 & ≤36 weeks	1166 (5.7)	250 (6.1)	
36> & ≤42 weeks	19,026 (93.2)	3791 (92.8)	
>42 weeks	21 (0.1)	0 (0.0)	
Neonatal birthweight, grams	3225.0 (2925.0-3525.0)	3215.0 (2910.0-3500.0)	0.081
Neonatal birthweight, centiles	59.0 (35.0–79.0)	59.0 (37.0–79.0)	0.150

Variables presented as median (interquartile range) for continuous scales and number (percentage) for categorical scales

women (coefficient: -3.55, 95% CI: -4.24-2.87, $P < 0.001$) and women with preeclampsia (coefficient: -6.57, 95% CI: -9.52 - -3.62, $P < 0.001$) had significantly lower birthweight percentiles in the multivariable analysis (Table 4).

The rate of placental abruption was similar in non-users and users (0.2% vs. 0.3%). Women with placenta previa (aOR: 21.9, 95% CI: 8.79–47.3, $P < 0.001$) and gestational diabetes (aOR: 4.33, 95% CI: 1.73–9.35, $P = 0.001$) had significantly higher odds of having a placental abruption (Table 5).

In the smaller sub-cohort, with detailed neonatal outcome data, there were again imbalances regarding confounders identified in the larger cohort, which was handled with the same propensity model. After matching, propensity scores were evenly matched, and covariate balance was achieved (Supplementary Fig. 4) in this sub-cohort as well (Supplementary Table 1).

Table 3 Logistic regression analysis for preterm birth in the propensity score matched cohort

Variables	Non-Users	Users	OR (95% CI, *p*)	aOR (95% CI, *p*)
Maternal age, years	32.4 (4.9)	33.2 (5.2)	1.03 (1.02–1.04, < 0.001)	1.04 (1.03–1.05, < 0.001)
Socioeconomic score, 1–10	6.5 (1.7)	6.5 (1.7)	0.99 (0.96–1.02, 0.553)	0.97 (0.94-1.00, 0.027)
Body Mass Index, kg/m^2	24.6 (5.2)	24.5 (5.3)	1.00 (0.99–1.01, 0.416)	0.99 (0.98-1.00, 0.036)
Gravidity:				
Multigravida	10,954 (93.7)	732 (6.3)	Reference	Reference
Primigravida	11,884 (92.8)	928 (7.2)	1.17 (1.06–1.29, 0.002)	1.29 (1.17–1.44, 0.001)
Gestational hypertension	135 (90.6)	14 (9.4)	1.43 (0.79–2.40, 0.204)	0.85 (0.45–1.47, 0.578)
Preeclampsia	242 (76.1)	76 (23.9)	4.48 (3.42–5.80, < 0.001)	4.62 (3.49–6.05, < 0.001)
Gestational diabetes	667 (91.9)	59 (8.1)	1.22 (0.92–1.59, 0.142)	1.04 (0.78–1.36, 0.794)
Placenta previa	112 (74.7)	38 (25.3)	4.75 (3.24–6.82, < 0.001)	4.58 (3.10–6.61, < 0.001)
Home-ultrasound, users	3791 (92.8)	292 (7.2)	1.07 (0.94–1.22, 0.296)	1.07 (0.94–1.22, 0.307)

OR: odds ratio, aOR: adjusted odds ratio, CI: confidence interval

Variables presented as mean (SD) for continuous scales and number (percentage) for categorical scales

Matching was performed using socioeconomic score, gravidity, chronic diseases (Asthma, lupus, chronic hypertension, Hashimoto's, Graves', coagulation defects,) and pregnancy complications (gestational hypertension, preeclampsia, gestational diabetes and placenta previa)

In the matched sub-cohort, the rate of severe composite adverse neonatal outcome was 1.4% in both non-users (41/2958) and users (21/1479) showing no significant association with home ultrasound use in univariable (OR: 1.02, 95% CI: 0.59–1.72, $P = 0.928$) or multivariable analyses (aOR: 1.01, 95% CI: 0.58–1.69, $P = 0.975$) (Supplementary Table 2). Women with preeclampsia (1.4% vs. 3.4%, $p = 0.224$) and placenta previa (1.4% vs. 3.8%, $p = 0.142$) had clinically meaningful increases in the composite neonatal adverse outcome, the differences did not reach statistical significance threshold.

The rate of cesarean deliveries (CD) in the user's group was slightly higher, albeit not statistically significant (26% vs. 23.4%, $P = 0.096$). The rate of labor induction in the user's group was slightly higher than in the non-user's group (35.3% vs. 29.7%, $P < 0.001$).

The median duration of device utilization was 13.6 weeks (6.4–19.6 weeks), and total scan count was 8 (IQR: 4.0–14.0) (Supplementary Fig. 5). Ultrasound device utilization differed substantially between users; 4061 (91.1%) women started using the device during the second trimester and 399 women (8.9%) started in the third trimester. The median number of scans was 8.0 (IQR: 4.0 to 15.0) in the group that started in the second trimester and 3.0 (IQR: 2.0 to 6.0) in the group that started in the third trimester (Supplementary Fig. 6).

Table 4 Linear regression analysis for birth weight percentile in the propensity score matched cohort

Variables	Coefficient (95% CI, *p*)	Adjusted coefficient (95% CI, *p*)
Maternal age, years	0.24 (0.17 to 0.31, < 0.001)	0.07 (-0.00 to 0.14, 0.053)
Socioeconomic score, 1–10	-0.16 (-0.35 to 0.04, 0.111)	0.00 (-0.20 to 0.21, 0.963)
Body mass index, kg/m^2	0.77 (0.71 to 0.83, < 0.001)	0.74 (0.67 to 0.80, < 0.001)
Gravidity:		
Multigravida	Reference	Reference
Primigravida	-4.63 (-5.29 to -3.96, < 0.001)	-3.55 (-4.24 to -2.87, < 0.001)
Gestational hypertension	-4.73 (-9.01 to -0.45, 0.030)	-5.15 (-9.43 to -0.86, 0.019)
Preeclampsia	-5.00 (-7.94 to -2.06, 0.001)	-6.57 (-9.52 to -3.62, < 0.001)
Gestational diabetes	2.17 (0.21 to 4.14, 0.030)	0.32 (-1.63 to 2.28, 0.746)
Placenta previa	3.94 (-0.33 to 8.21, 0.070)	3.16 (-1.05 to 7.37, 0.141)
Home-ultrasound, users	0.69 (-0.20 to 1.58, 0.131)	0.62 (-0.26 to 1.50, 0.168)

CI: confidence

Matching was performed using socioeconomic score, gravidity, chronic diseases (Asthma, lupus, chronic hypertension, Hashimoto's, Graves', coagulation defects,) and pregnancy complications (gestational hypertension, preeclampsia, gestational diabetes and placenta previa)

In a sensitivity analysis (Supplementary Table 3) we could not detect any statistically significant linear association between duration of device utilization (OR: 0.99, 95% CI: 0.97–1.01, $p = 0.448$) or total scan count (OR: 1.01, 95% CI: 0.99–1.03, $p = 0.145$) and delivery of an SGA baby. Similarly, no statistically significant linear association was detected between duration of device utilization (OR: 1.03, 0.96–1.11, $p = 0.483$) or total scan count (OR: 1.02, 0.97–1.07, $p = 0.301$) with the composite neonatal outcome.

Discussion

In this large-scale, retrospective real-world study, we aimed to examine the association between home ultrasound service utilization during pregnancy and adverse pregnancy outcomes. Our analysis compared a cohort of 4,460 pregnant women who used Pulsenmore's home ultrasound device with a cohort of 102,707 non-users.

Our key findings were: (1) Users have higher socioeconomic score, are more primiparous and have higher

Table 5 Logistic regression analysis for placental abruption in the propensity score matched cohort

Variables	Non-Users	Users	OR (95% CI, *p*)	aOR (95% CI, *p*)
Maternal age, years	32.5 (4.9)	33.5 (4.9)	1.05 (0.99–1.10, 0.108)	1.03 (0.97–1.09, $p=0.294$)
Socioeconomic score, 1–10	6.5 (1.7)	6.7 (1.8)	1.05 (0.89–1.23, 0.585)	1.04 (0.88–1.24, $p=0.612$)
Body mass index, kg/m^2	24.6 (5.2)	24.8 (5.4)	1.01 (0.96–1.06, 0.765)	0.99 (0.94–1.04, $p=0.728$)
Gravidity:				
Multigravida	11,658 (99.8)	28 (0.2)	Reference	Reference
Primigravida	12,787 (99.8)	25 (0.2)	0.81 (0.47–1.40, 0.455)	0.93 (0.53–1.64, $p=0.810$)
Gestational hypertension	149 (100.0)	0 (0.0)	NE	NE
Preeclampsia	316 (99.4)	2 (0.6)	2.99 (0.49–9.69, 0.129)	2.58 (0.41–8.76, $p=0.202$)
Gestational diabetes	719 (99.0)	7 (1.0)	5.02 (2.06–10.45, <0.001)	4.33 (1.73–9.35, $p=0.001$)
Placenta previa	143 (95.3)	7 (4.7)	25.86 (10.52–54.68, <0.001)	21.96 (8.79–47.37, $p<0.001$)
Home-ultrasound, Users	4071 (99.7)	12 (0.3)	1.46 (0.74–2.70, 0.245)	1.42 (0.71–2.64, $p=0.288$)

OR: odds ratio, aOR: adjusted odds ratio, CI: confidence interval, NE: not estimable

Variables presented as mean (SD) for continuous scales and number (percentage) for categorical scales

Matching was performed using socioeconomic score, gravidity, chronic diseases (Asthma, lupus, chronic hypertension, Hashimoto's, Graves', coagulation defects) and pregnancy complications (gestational hypertension, preeclampsia, gestational diabetes and placenta previa)

incidence of chronic disease and pregnancy complications; (2) device utilization, both overall and stratified by actual utilization degree, is safe and in not associated with any maternal, obstetrical or neonatal adverse pregnancy outcomes.

Our results, both overall and in comparison, with existing literature, highlight several important aspects of device utilization, including its overall safety and safety when stratified by frequency of use.

Decision to use the device The different baseline demographics between users and non-users, suggest that users may view it as a way to handle their high-risk situation. This applies not only to women with chronic illnesses or high-risk pregnancies but also nulliparous women. Prior reports suggest that home ultrasound may assist in reducing maternal anxiety, increase reassurance and bonding, and alleviate concerns raised from personal and medical aspects. A small-scale study randomized 50 women with two or more prior pregnancy losses to either continue standard care or to receive additional twice-weekly, clinician-guided, home-ultrasound scans. The results affirm our assumption, as maternal anxiety was lower, and attachment was higher among the home-ultrasound intervention group [6].

Materna and neonatal outcomes Home ultrasound use was not significantly associated with any of the primary or secondary outcome measures. The rate of previous CD was slightly higher in the users' group (not statistically significant). It is known that previous CD accounts for 60% of elective CDs and 14% of emergency CDs [12]. This may explain the higher rate of current CD in the users' subgroup. The information about elective CD as well as other parameters related to CD indications were not available for this analysis. Hence, the data of slightly higher CD rate in the users' group, may not suggest a causal association with home ultrasound utilization.

The rate of labor induction in the users' group was slightly higher than in the non-users' subgroup. The overall observed rate of labor induction is in line with the literature. It is known that the rate of labor induction in the United States has increased from 9% of births in 1989 to 31.4% of births in 2020 [13]. Notably, the non-users' subgroup that had the induction data was only 2% of the original group and therefore the labor induction rate was underestimated. Data of multiple parameters affecting labor induction were not collected, and these findings warrant further investigation to determine whether they are reflective of clinical needs or just practice variations. While these differences may seem noteworthy, it is important to recognize that if the observed differences in induction rates were real, this could suggest underlying factors such as variations in clinical decision-making, healthcare system differences, or patient preferences, which may influence induction practices.

Ultrasound usage The average total ultrasound scan count was 8, with a median duration of use of 13.6 weeks. Most women (91%) used the device starting from their second trimester. Notably, despite not including pregnancy conditions such as preeclampsia or gestational diabetes from the multivariable models, which might have influenced scan count, we did not identify a significant linear relationship between scan count or duration of use and adverse outcomes.

Clinical and research implications

Applied as an adjunct tool to regular follow-up, in an apparent high-risk cohort, home ultrasound appeared to be safe. Prospects include its immediate utilization to

achieve a clinician-guided sonographic biophysical profile in a remote telehealth encounter, as a replacement for face-to-face frontal consultation.

This novel technology has the potential to evolve beyond simple tools for remote fetal surveillance to deliver comprehensive remote antenatal care. By incorporating advanced and quantitative features - such as fetal heart rate monitoring, amniotic fluid assessment, estimated fetal weight calculation, and Doppler studies - this system can provide enhanced care. These advancements are currently under development and are being evaluated for feasibility, safety, and accuracy.

While our study focused on clinical outcomes potentially influenced by outpatient ultrasound, there are other important endpoints - such as resource utilization, patient satisfaction, and parent-infant bonding which warrant further investigation.

Strengths and limitations

This is a study of a novel technology, with never before tested routine clinical use. It was tested in a large-scale, diverse, real-world scenario. over a 3-year period, which grants robustness to our results.

Nevertheless, retrospective real-world studies inherently have biases related to participant population, inaccuracies, reverse causation and missing data. The lack of randomization and differences in baseline characteristics between users and non-users introduces confounding effects and required matchings. While we matched and accounted for known confounders that are recorded and available in the dataset, some residual confounding effect may persist.

Conclusions

Multiple ultrasound scans during pregnancy are generally considered safe and do not pose a significant risk to the fetus or mother [14]. It is crucial to use ultrasound judiciously during pregnancy and follow medical recommendations, applying the principle of ALARA: As Low As Reasonably Achievable [15]. This study successfully demonstrates that the use of Pulsenmore's device in the context of a clinical home ultrasound service, during the second and third trimester, is safe and is not significantly associated with adverse outcomes.

Abbreviations

HMO	Health Maintenance Organization
ALARA	As Low as Reasonably Achievable
BMI	Body Mass Index
SGA	Small for Gestational Age
aOR	Adjusted Odds Ratio
CD	Cesarean Delivery
IQR	Inter Quartile Range

Supplementary Information

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Supplementary Material 1

Supplementary Material 2

Supplementary Material 3

Supplementary Material 4

Supplementary Material 5

Supplementary Material 6

Supplementary Material 7

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Author contributions

AP: Conception and Design, Data Acquisition, Analysis and Interpretation, Drafting and Revising, Final Approval; EK: Conception and Design, Analysis and Interpretation, Drafting and Revising, Final Approval; SH: Data Acquisition, Analysis and Interpretation, Drafting and Revising, Final Approval; MP: Data Acquisition, Analysis and Interpretation, Drafting and Revising, Final Approval; EKF: Data Acquisition, Analysis and Interpretation, Drafting and Revising, Final Approval; OLR: Data Acquisition, Analysis and Interpretation, Drafting and Revising, Final Approval; OS: Data Acquisition, Analysis and Interpretation, Drafting and Revising, Final Approval; RGT: Data Acquisition, Analysis and Interpretation, Drafting and Revising, Final Approval; AS: Data Acquisition, Analysis and Interpretation, Drafting and Revising, Final Approval; NP: Data Acquisition, Analysis and Interpretation, Drafting and Revising, Final Approval; TS: Conception and Design, Data Acquisition, Drafting and Revising, Final Approval; LW: Conception and Design, Data Acquisition, Drafting and Revising, Final Approval; AWa: Conception and Design, Analysis and Interpretation, Drafting and Revising, Final Approval; AWi: Conception and Design, Analysis and Interpretation, Drafting and Revising, Final Approval; EH: Conception and Design, Data Acquisition, Analysis and Interpretation, Drafting and Revising, Final Approval.

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Data availability

Due to national and organizational data privacy regulations, individual-level data such as those used for this study cannot be shared openly.

Declarations

Ethics approval and consent to participate

The research related to human use has been compiled with all the relevant national regulations, institutional policies and in accordance with the tenets of the Helsinki declaration. The study received approval from the local institutional review board at Rabin Medical Center, Petach-Tikva; Israel (Approval Number: 744-RMC-21). Informed consent was waived due to the retrospective nature of the study.

Consent for publication

Written informed consent for publication was obtained.

Competing interests

The authors declare no competing interests.

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