HHS Public Access

Author manuscript

Am J Obstet Gynecol. Author manuscript; available in PMC 2016 April 01.

Published in final edited form as:

Am J Obstet Gynecol. 2015 April ; 212(4): 542.e1–542.e127. doi:10.1016/j.ajog.2015.01.021.

nuMoM2b Sleep Disordered Breathing Study: Objectives and Methods

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Abstract

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DISCLOSURE: The authors report no conflict of interest

Objective—The objective of the Sleep Disordered Breathing substudy of the Nulliparous Pregnancy Outcomes Study Monitoring Mothers-to-be (nuMoM2b) is to determine whether sleep disordered breathing during pregnancy is a risk factor for adverse pregnancy outcomes.

Methods—nuMoM2b is a prospective cohort study of 10,037 nulliparous women with singleton gestations, conducted across 8 sites, with a central Data Coordinating and Analysis Center. The Sleep Disordered Breathing substudy recruited 3702 women from the cohort to undergo objective, overnight in-home assessments of sleep disordered breathing. A standardized Level 3 home sleep test was performed between 6^0–15^0 weeks of pregnancy (Visit 1) and again between 22^0–31^0 weeks of pregnancy (Visit 3). Scorings of tests were conducted by a central Sleep Reading Center. Participants and their health care providers were notified if test results met “urgent referral” criteria based on threshold levels of apnea hypopnea indices, oxygen saturation levels or ECG abnormalities, but otherwise were not notified of test results. The primary pregnancy outcomes to be analyzed in relation to maternal sleep disordered breathing are preeclampsia, gestational hypertension, gestational diabetes, fetal growth restriction, and preterm birth.

Results—Objective data were obtained at Visit 1 on 3261 women, 88.1% of studies attempted; and at Visit 3 on 2511 women, 87.6% of studies attempted. Basic characteristics of the substudy cohort are reported in this methods paper.

Conclusion—The substudy is designed to address important questions regarding the relationship of sleep disordered breathing on the risk of preeclampsia and other outcomes of relevance to maternal and child health.

Keywords

pregnancy; sleep; sleep disordered breathing; home sleep test; methods

2. Introduction/Background

Sleep disordered breathing (SDB) refers to conditions characterized by abnormal respiratory patterns (e.g., apneas, hypopneas) and abnormal gas exchange (e.g., hypoxemia) during sleep.[1–3] Obstructive sleep apnea (OSA), the most common type of SDB, is characterized by repetitive episodes of airway narrowing during sleep that lead to respiratory disruption, hypoxemia, and sleep fragmentation. Self-reported snoring and daytime sleepiness, reflecting turbulent airflow and sleep disruption, respectively, are cardinal symptoms of OSA. Although these sleep-related complaints are common in pregnancy,[4–7] there are very few studies that have comprehensively and objectively evaluated the prevalence, incidence, severity, or outcomes associated with OSA in pregnancy. Also, these studies have not evaluated other major, though less common, sleep-related breathing disorders such as central apnea and sleep related hypoventilation and hypoxemia.

Objective assessment of SDB requires in-laboratory or home sleep testing. SDB is generally diagnosed using the Apnea Hypopnea Index (AHI), a sum of the number of apneas (cessation of airflow) and hypopneas (pathologic limitation but not cessation of airflow) that occur per hour of sleep. In non-pregnant adults an AHI of ≥5 is a minimum criterion for defining SDB. Severity is classified by the number of events per hour with an AHI of 5–15 considered mild SDB, >15–30 moderate SDB, and >30 severe SDB.[3,8] SDB, most

commonly OSA, occurs in 2–15% of middle aged adults but there are certain populations who are at greater risk.[9,10] SDB may occur as often as 40% in obese individuals, and 70–90% of morbidly obese individuals are thought to suffer from the disorder.[11,12]

Epidemiologic data from cohorts of generally middle-aged and older adults, none of which included pregnant women, indicate that SDB is associated with incident and prevalent cardiovascular and cerebrovascular diseases and adverse events.[13] Both cross-sectional and prospective studies reported associations between SDB and hypertension.[13–16] Data from the Wisconsin Sleep Cohort Study demonstrated a dose-response association between SDB at baseline and the presence of hypertension four years later that was independent of known confounding factors (age; sex; BMI; and waist and neck circumference).[16] In this study, relative to the reference category of an apnea-hypopnea index (AHI) of 0 events/hour at baseline, the adjusted odds ratios (95% confidence intervals) for hypertension at follow-up were 2.03 (1.29–3.19) with an AHI of 5.0–14.9, and 2.89 (1.46–5.64) with an AHI of ≥15 (p=0.002, trend test). Other studies have reported associations between SDB and coronary artery disease, stroke, cardiac arrhythmia, heart failure and CVD-related mortality.[17–19] SDB also is associated with type 2 diabetes.[20–23] Cross-sectional data from the Wisconsin Sleep Cohort Study demonstrated that self-reported diabetes was three to four times more prevalent in subjects with an AHI ≥15 than in those with an AHI <5.[22] Another large prospective cohort study demonstrated that moderate-severe SDB was an independent risk factor for incident diabetes.[20]

The prevalence, incidence, and severity of SDB in pregnancy, and the impact of SDB on pregnancy remains undetermined. This is despite the fact that pregnant women may be particularly predisposed to OSA and other major sleep related breathing disorders, due to the physiologic changes associated with the gravid state. [24,25] Pregnancy is the only normal adult physiologic process in which body weight routinely increases by 20% or more in a short period of time. The high estrogen levels associated with pregnancy can cause vasomotor rhinitis. Hyperemia and edema of the nasal and pharyngeal mucosa can lead to increased airflow resistance and airway narrowing. Finally, uterine enlargement, diaphragmatic elevation and relaxation of costochondral ligaments leads to alterations in thoracic shape, compliance and capacity predisposing to ventilatory impairment. In fact, SDB symptoms are common during pregnancy, and worsen as the pregnancy progresses. [26–28] The prevalence of frequent snoring (≥ 3 nights/week) in general obstetrical populations has been reported to be around 7–11% in pre-pregnancy/early pregnancy states and 16–25% in the third trimester. [26–29] In addition, outcomes that have been linked to SDB in the non-pregnant population, such as hypertension and insulin-resistant diabetes, have correlates in pregnancy (e.g. gestational hypertension, preeclampsia, gestational diabetes).[16] Moreover, SDB has been linked to enhanced inflammatory and oxidative stress responses, endothelial damage and metabolic derangements.[30,31] These same biological pathways have been associated with adverse pregnancy outcomes.[29,32–36]

In a large retrospective cohort study, Bourjeily *et al* [37] found that frequent snoring was associated with gestational hypertension/preeclampsia, even after adjusting for multiple factors including BMI assessed at delivery (adjusted OR 2.3, 95% CI 1.4–4.0). In a large retrospective cohort of women with polysomnography-confirmed SDB within 1 year prior to

pregnancy (n=791, compared to 3955 age matched controls), Chen *et al* [32] reported that SDB was associated with an increased risk of gestational hypertension (adjusted OR 3.18, 95% CI 2.14–4.73), gestational diabetes (adjusted OR 1.63, 95% CI 1.07–2.48) and preterm birth (adjusted OR 2.31, 95% CI 1.77–3.01). This study, using data derived from Taiwan's National Health Insurance databases, adjusted for obesity using ICD-9 codes, but only 1.6% of this population was identified as obese. In a recent meta-analysis of studies published up to June 2012, Pamidi et al reported that maternal SDB was significantly associated with gestational hypertension/preeclampsia (pooled adjusted OR 2.34; 95% CI 1.60–3.09; 5 studies) and gestational diabetes (pooled adjusted OR 1.86; 95% CI 1.30–2.42; 5 studies).[38] Such data underscore the potential importance of SDB to pregnancy outcomes, and the importance of gaining a better understanding of the epidemiology of this disorder in pregnancy. However, most research regarding the epidemiology of SDB in pregnancy is retrospective, and the majority of studies have relied on self-reported symptom assessments rather than objective measures. Many studies did not adequately control for obesity, a strong risk factor for both SDB and adverse pregnancy outcomes, nor did they clearly define a temporal relationship between SDB and the subsequent development of preeclampsia and gestational diabetes. There are no large studies that have examined SDB in pregnancy using prospective, serial objective measures.

In summary, although data are emerging suggesting an association between SDB and adverse pregnancy outcomes, including preeclampsia and gestational diabetes, current evidence is limited and mostly correlational. Therefore, a substudy to the Nulliparous Pregnancy Outcomes Study: Monitoring Mothers-to-be (nuMoM2b), a study of adverse outcomes in pregnant nulliparous women, was undertaken to estimate the prevalence of and characteristics of SDB among women during pregnancy, and to determine whether SDB is a risk factor for adverse pregnancy outcomes. Serial, objective assessments of SDB across pregnancy were performed. This paper reports on the methods developed to obtain high quality sleep data across multiple sites in pregnant women.

3. Methods

A. The nuMoM2b Parent Study

The design of the nuMoM2b parent study is presented in detail elsewhere *[to be referenced, see cover letter]*. The nuMoM2b study enrolled 10,037 women between October, 2010 and September, 2013. The study was conducted at 8 clinical sites: Case Western Reserve University, Columbia University, Indiana University, University of Pittsburgh, Northwestern University, University of California at Irvine, University of Pennsylvania, and the University of Utah, and was managed by a Data Coordinating and Analysis Center at RTI International. Inclusion criteria for the parent study were nulliparity (no prior delivery at 20 weeks or greater gestational age), a viable singleton pregnancy, with estimated gestational age between 6^0–13^6 weeks, and intention to deliver at a participating clinical site hospital. Exclusion criteria included age <13 years, a history of 3 or more pregnancy losses, donor oocyte pregnancy, planned pregnancy termination, malformations likely to be lethal and aneuploidies known at or before enrollment, previous enrollment, and inability to provide informed consent.

Study visits were conducted at 4 times (Visits 1–4): 6^0–13^6, 16^0–21^6, 22^0–29^6 weeks' gestation, and at the time of delivery. Data were collected through interviews; self-administered questionnaires; clinical measurements including height, weight, and neck circumference; ultrasounds; and medical records review to ensure collection of pertinent demographic, psychosocial, dietary, physiologic, and pregnancy outcome information. *[parent study methods paper reference here]*. In addition, maternal serum, plasma, urine, and cervico-vaginal fluid were collected at each visit (1,2, and 3); maternal blood for DNA was collected at Visit 1; and maternal serum and plasma, cord blood plasma and placenta were collected at delivery. These samples were aliquoted and stored in a repository for later use.

All subjects enrolled in the nuMoM2b parent study were asked to complete a comprehensive sleep questionnaire at the 1st and 3rd study visit. These included questions regarding the timing of sleep and sleep duration, work schedules (e.g. shift work, night work), sleep positions, and previously diagnosed sleep disorders as well as questions from the following commonly used sleep questionnaires: 1) the Berlin Questionnaire (a screening instrument designed to identify adults likely to have OSA through a series of questions pertaining to snoring behavior and wake-time sleepiness);[39] 2) the Epworth Sleepiness Scale (providing a measurement of daytime sleep propensity, using estimates of the likelihood of dozing off or falling asleep in 8 different sedentary situations);[40,41] 3) the International Restless Legs Syndrome Study Group diagnostic criteria for restless legs syndrome;[42] and 4) the Women's Health Initiative Insomnia Rating Scale (quantifying insomnia symptom severity).[43,44]

B. Aims and Hypotheses

The nuMoM2b-SDB substudy was designed and powered to test the primary hypothesis that SDB occurring early and/or appearing late in pregnancy is associated with an increased incidence of preeclampsia (PE). The secondary aims are to (1) examine the association between SDB in pregnancy and gestational hypertension (GH) and gestational diabetes (GDM); (2) determine the prevalence of objectively measured SDB in early and late pregnancy; (3) delineate characteristics (i.e. risk profile) of women exhibiting SDB in early and late pregnancy; and (4) define the SDB subtype(s) (e.g. AHI threshold, degree of nocturnal hypoxemia) in pregnancy most strongly associated with maternal cardiovascular and metabolic disease (PE, GH, GDM). Exploratory aims are to evaluate SDB as a risk indicator for altered fetal growth and preterm birth (spontaneous and iatrogenic). Sleep questionnaire data, obtained as part of the parent study, will be used to examine the association between self-reported measures of sleep deficiency (e.g. sleep duration, timing, quality), sleep disorder symptoms (e.g. snoring, insomnia, restless legs), daytime function (e.g. daytime sleepiness), physician diagnosed sleep disorders, and the incidence of adverse pregnancy outcomes (e.g. PE, GH, GDM). Data from objective SDB assessments will be used to examine the sensitivity and specificity of self-reported SDB symptoms (e.g. snoring, gasping for air, daytime sleepiness), to determine the clinical utility of SDB symptom evaluation in pregnancy.

C. Design

The nuMoM2b-SDB substudy enrolled 3,702 nuMoM2b participants between March, 2011 and September, 2013. The inclusion criterion was enrollment in the parent study. Women excluded from the SDB substudy had the following conditions: current continuous positive airway pressure (CPAP) treatment for SDB; severe asthma requiring continuous oral steroid therapy for more than 14 days; and conditions requiring oxygen supplementation. Eligible women were approached for enrollment at the first nuMoM2b parent study visit. A trained study coordinator obtained written informed consent (and written assent for minors). Institutional Review Board approval was obtained at all sites.

Home sleep testing was performed using the Embletta-Gold device (Embla, Broomfield, CO, Figure 1) and was self-administered by the participant following nuMoM2b parent study visits 1 and 3. The pocket-sized device contains four recommended and validated sensors for measuring SDB parameters: a nasal pressure transducer (measuring nasal airflow and waveform, needed for detecting apneas and hypopneas and airflow limitation); thoracic and abdominal inductance plethysmography bands (XactTrace belts ™; measuring respiratory effort for distinguishing central from obstructive apneas and as a back-up for the nasal pressure signal); and finger pulse oximetry (to quantify level and duration of oxygen desaturation). In addition, a bipolar ECG and body position are recorded.

The participant was instructed on proper placement of the various Embletta-Gold device sensors during the study visits by trained and certified site staff. In particular, participants were instructed on how to place the thoracic and abdominal inductance plethysmography bands on their gravid abdomen (Figure 1). Application of sensors was demonstrated by the staff, and participants were then asked to apply them to demonstrate their understanding. Participants were instructed to apply the device before bed within 48 hours of the study visit while following a routine sleep schedule. They were provided instruction sheets and a staff phone number to use if questions arose during application or monitoring. Arrangements were made to retrieve the monitor (e.g. drop off, by prepaid mailer). The participant was also asked to complete a brief survey regarding her experience with the device after completion of each in-home sleep study. Once the device was returned, the sleep study data was downloaded at the clinical site and electronically transmitted to the Sleep Reading Center (Brigham and Women's Hospital, Boston, MA) via a secured interface.

All participants were given an educational pamphlet upon enrolling in the study. This pamphlet contained a general description of the importance of healthy sleep. The pamphlet stressed how insufficient sleep and excessive sleepiness can adversely affect daytime function, especially driving, and urged participants who were concerned about these symptoms to seek medical attention.

Pregnancy outcome data was collected by chart abstraction as described in the parent study methods paper [to be referenced]. Specifically, for any participant with documented hypertension, defined as systolic blood pressure ≥ 140 mmHg or diastolic blood pressure ≥ 90 mmHg on two occasions at least 6 hours apart, or on one occasion followed by antihypertensive medication therapy, a detail chart review was required that included assessment of blood pressure severity, new-onset cerebral and visual disturbances, epigastric

pain or pulmonary edema, proteinuria, platelet and hemoglobin values, liver enzymes, and creatinine. Preeclampsia and gestational hypertension will be able to be analyzed using both the 2002, and the updated 2013 ACOG criteria. [45,46]

D. Scoring and Quality Control

Quality control of data collection and analysis was established through several levels of training, certification and ongoing monitoring overseen by the central Sleep Reading Center. Detailed descriptions of the nuMoM2b SDB substudy responsibilities at the clinical sites and the Sleep Reading Center, training and certification requirements, and quality control and quality assurance procedures are given in the online appendices 1–3. Many of the study materials are also provided in Appendix 4. The scoring methods were adapted from the Sleep Heart Health Study[47] which are available through the National Sleep Research Resource web portal (sleepdata.org). Prior to beginning data collection, key staff attended a central training session where the scientific objectives of the study, the protocol and manual of operations, technical information on use of the Embletta-Gold device, and study software were reviewed. Most study staff had limited to no prior experience with sleep testing. Staff were required to become certified to administer home sleep testing by completing written and practical examinations on the study protocol and procedures, and successfully administering and transmitting a high quality practice home sleep test to the Sleep Reading Center. Maintenance of certification required transmission of at least one successful sleep study per month except towards the end of study period, when sleep test volume was declining, and then maintenance of certification was adjudicated by the Sleep Reading Center. Technicians at the Sleep Reading Center were also trained and certified on sleep study scoring and analysis, by showing evidence of 95% agreement with respiratory event identification in a test set of sleep studies. Technician performance was monitored over time with repeated scoring of test and practice sets to identify within and between scorer variation.

On receipt at the Sleep Reading Center, each study was examined to determine whether it met minimal criteria for acceptance (minimal of 2 hours of artifact free oximetry data plus concurrent signals from at least one breathing sensor); urgent referrals (see below) and quality grades were assigned. Each channel was graded as to the period of artifact free data, with an overall study grade assigned based on the absolute duration of artifact free data for the nasal pressure cannula, oximeter, and each respiratory effort band.

Level 3 sleep monitoring devices, as used in this study, do not record sleep directly (i.e. with EEG and electromyography signals). Therefore, sleep onset and offset and periods of prolonged wakefulness are identified by certified polysomnologists using information from both participant completed questionnaires on bed and wake times and the visualized patterns of heart rate, breathing pattern, movement and artifact. The sleep period is defined as the period between sleep onset and offset. Sleep onset is identified based on self-reported bedtime plus visualization of reduced signal artifact, decreased heart rate, regularization of breathing pattern, and stability of the position sensor (indicating a supine or lateral position). Conversely, sleep offset is identified by evidence of sustained movement artifact, changing position, increase in heart rate, and participant reported wake time. Following the initiation

of sleep, segments of the study were excluded from analysis if significant movement or artifact occurred for a period of ≥ 20 minutes.

The Embletta-Gold recordings were scored to quantify the types and number of sleep disordered breathing events that occurred during the estimated sleep period, using the following definitions:[1,48]

Obstructive apnea (Figure 2A): amplitude (peak to trough) of the nasal pressure signal flat for ≥ 10 seconds and accompanied by effort on either respiratory band.

Central apnea (Figure 2B): amplitude (peak to trough) of the nasal pressure signal flat for ≥ 10 seconds and accompanied by complete absence of effort on both respiratory bands.

Two classes of hypopneas (Figure 2C) were scored based on alternative amplitude reduction criteria: a) based on ≥ 30% or b) ≥ 50% reduction of amplitude in the nasal pressure signal or the respiratory sum channel (if nasal pressure signal is not present) for ≥10 seconds duration. Hypopnea events were annotated regardless of associated desaturation and later linked with oxygen saturation values using customized software so that apnea-hypopnea indices could be derived using a flexible range of criteria (e.g. ≥ 3% or ≥ 4% desaturation).

Apnea Hypopnea Index (AHI): Total number of apneas and hypopneas per hour of estimated sleep.

E. Blinding and Urgent Alerts

Currently there are no sanctioned pregnancy-specific guidelines for SDB treatment, no data on which to base fetal or maternal parameters for treatment, and no evidence that treatment in the short term impacts maternal or neonatal outcomes. Because SDB may particularly fluctuate during pregnancy, it is also important to cautiously interpret the clinical significance of any single assessment of SDB. Therefore, given the limited available data, clinical equipoise surrounds the issue of SDB in pregnancy, and participants and care providers were blinded to the sleep study results unless the Sleep Reading Center identified a study meeting Urgent Alert criteria. Sleep studies that showed an apnea hypopnea index >50 or severe hypoxemia (oxygen saturation of <90% for greater than 10% of the estimated sleep time) were identified as Urgent Alert studies. These studies were reviewed by a Sleep Reading Center physician, and reported to the clinical site and the Data Coordinating and Analysis Center within 14 days of study receipt. Other findings that triggered an urgent referral included:

- Baseline oxygen saturation (prior to sleep onset) of <88%.
- Heart rate for more than 2 continuous minutes that is <40 or >150 beats per minute.
- Presence of a sustained wide complex rhythm (≥ 3 consecutive beats) awake or asleep.
- Type 2 second degree and third degree atrio-ventricular heart block.

The site physician reviewed all urgent findings and identified appropriate resources for referral for the participant. The participant's obstetrical care provider was then notified of the results by phone and by letter so that arrangements for timely referral for full evaluation could be made. Similar urgent referral criteria have been used in several other large population based studies of SDB (e.g., The Sleep Health Heart Study).[49]

F. Power and Sample Size

A target sample size of 3630 was selected to ensure that there would be sufficient numbers of women with SDB in either early or late pregnancy to provide adequate power for assessment of the association between maternal SDB and preeclampsia. The calculations took into account a sleep study failure rate (allowing for a single attempted retest) of 9%, based on the previous experience of the Sleep Reading Center with the Embletta unit; a 10% study drop-out/loss to follow up [50], and a conservative assumption of 25% refusal to repeat the sleep study in the third trimester. Also, it was assumed that 3630 women would yield approximately 180 women (5%) with SDB (AHI ≥5) in early pregnancy and 360 (10%) in late pregnancy. [7,51] With these assumptions, and setting the Type I error at 2-sided $\alpha = 0.05$, the target sample size yields at least 80% power to detect a relative risk of 2.0 (1.8) for preeclampsia[13] for women with SDB in early (late) pregnancy, assuming a 7% incidence of preeclampsia among the unexposed.[46,50] Analysis of more common outcomes (e.g., growth restriction defined as birth weight below the 10th percentile for gestational age, preterm birth <37 weeks of gestation) will have greater than 80% power for similar effect sizes.

4. Results

A total of 3,702 women enrolled to nuMoM2b attempted to complete an objective sleep breathing assessment during the study. Table 1 gives the number of objective (home sleep test) and subjective (the questionnaire data) sleep assessments completed on this subcohort. Objective data were obtained at Visit 1 on 3261 women, 88.1% of studies attempted; and at Visit 3 on 2511 women, 87.6% of studies attempted. Across visits, objective data were obtained on 5581 of 6567 sleep studies (85.0%) in the first attempt. For the remaining 986, a second attempt was made on 224, and objective data were obtained on 191 (85%). There was little change in the failure rate over the course of data collection. The most common reasons for failed studies were: 1) failure of the participant to wear the equipment (n=244 studies, 30.7%); 2) less than 2 hours of oximetry (n=240 studies, 30.2%); and 3) equipment problems (n=200 studies, 25.2%). For the studies with objective data obtained, a breakdown on the signal quality for EKG, cannula flow, the thoracic effort band, the abdominal effort band, and oximetry is provided in Table 2. It should be noted that oximetry of at least 2 hours was required to score the study. All women in the nuMoM2b parent study were asked to complete a subjective sleep questionnaire. It was obtained on 2996 of the 3261 women with objective data at Visit 1 and on 2454 of the 2511 women with objective data at Visit 3. Both Visit 1 and Visit 3 objective measures were available for 2336 women and objective and subjective measures on 2152 women.

Demographic characteristics of the 3,702 women are presented in Table 3. The mean age of the women at entry into the study was 26.7 years (standard deviation 5.6). Sixty percent (59.6%) of the women were non-Hispanic white, 14.1% were non-Hispanic black, 17.7%

were Hispanic, 3.6% were Asian, and 5% were classified as other on race/ethnicity. In 49.0% of the women, their pre-pregnancy body mass index would classify them as of normal weight (BMI 18.5–24.9), 25.4% overweight (BMI 25.0–29.9), 23.4% obese or morbidly obese (BMI ≥ 30), and 2.3% underweight (BMI < 18.5). Eighteen percent (18.1%) of the participants smoked during the 3 months prior to the pregnancy, and 6.4% smoked in the month prior to the first study visit. Sixty percent (59.4%) of the women were 12–13 weeks gestation at screening.

5. CONCLUSIONS/DISCUSSION

The design of the nuMoM2b SDB substudy addresses two significant challenges: (1) ensuring high quality SDB assessments in a large sample size, accounting for the physiological changes of pregnancy which make SDB assessment more difficult; (2) providing an appropriate level of feedback to the participants.

While full in-laboratory polysomnogram (PSG) is considered the gold standard for the objective measurement of sleep, sleep-related breathing disorders and sleep-related movement disorders, it is often not feasible to use full PSG for large sleep-related studies given the cost and limited availability of sleep laboratory space as well as difficulties recruiting a larger number of participants in research requiring such in-laboratory monitoring. Recent data indicate that unattended sleep testing in non-pregnant individuals can reliably detect SDB at substantively lower cost compared to in-laboratory PSG.[52] Based on a review of the literature and consensus, the Portable Monitoring Task Force of the American Academy of Sleep Medicine (AASM) recently outlined guidelines for the use of portable monitor devices for the diagnosis of SDB.[53] While not specifically addressing pregnancy they did not specify pregnancy as a contraindication to home sleep testing. Most insurers now routinely require home sleep tests as the first line diagnostic modality for the majority of patients with suspected SDB and without certain co-morbidities.[53,54] Several recent studies compared the AHI estimated using the Embletta-Gold device with in-lab PSG.[55–57] Although each of these articles had some limitations, data suggest a high correlation (r>0.92) between the AHIs calculated using full PSG with EEG recording and limited channel Embletta studies. The overall bias in AHI averaged between 2 and 6 events per hour, with larger differences found in patients with very high AHI (>40) and with heart failure (possibly due to fragmented sleep). When using various cutoffs to define SDB, the overall sensitivity and specificity for the Embletta device in the non-heart failure population was reported to exceed 85%. As noted in the methods section, the Embletta like all other Level 3 portable sleep monitors, does not measure sleep directly. Our scoring algorithm for sleep and wake is described in detail, and a similar approach has been validated for a study in pregnancy using another portable monitoring device.[35]

Portable monitor devices for SDB have been validated in pregnancy.[35,58,59] The device used in this study has not been specifically tested in pregnancy but contains the identical sensors (pulse oximetry, nasal airflow, inductance plethysmography, and ECG) recommended for portable monitoring by the American Academy of Sleep Medicine for measurement of SDB.[53] As discussed before, full polysmonography only differs from the limited channel monitor in its capacity to also collect EEG and electromyography, which would enable more

precise estimation of actual sleep time and to detect periodic limb movements. Therefore, the direct measures of sleep disordered breathing would not differ with alternative devices, although the time estimates for sleep may be overestimated. Unattended home sleep testing may modestly under-estimate the AHI due to this over-estimation of sleep time.[60] The impact of this bias is likely to be larger when sleep is more fragmented, such as may occur due to pregnancy (e.g. due to nocturia). The process of recording sleep with a device such as the Embletta may also lead to more fragmented sleep. However, studies were scored after editing movement and artifact, reducing the impact of wake time on the AHI estimates.

Careful consideration was given to the SDB notification strategy as there are no pregnancy-specific guidelines for SDB treatment, and no evidence that treatment in the short term impacts maternal or neonatal outcomes. Given provider and participant anxiety when results with no clear clinical significance are reported, we employed a strategy of notification (unblinding) of only results deemed to require urgent medical attention. Criteria for urgent alerts was developed by expert consensus from members of the study team, and approved by the Advisory Safety and Monitoring Board. Even in non-pregnant adults, there are scant data from randomized controlled trials to inform the thresholds of OSA that are associated with improved long term health outcomes. [61,62] The benefit of treatment with CPAP has been consistently demonstrated when excessive daytime sleepiness and sleep quality is used as an endpoint.[63–65] The contribution of OSA to pregnancy associated fatigue, sleepiness and vigilance is not known, limiting use of sleepiness as a guideline for treatment. Furthermore, studies to examine the effect of CPAP treatment on pregnancy endpoints have been insufficiently powered or limited in the scope of endpoints. [66–71] The largest of these trials treated women with preeclampsia with CPAP and used improvements in fetal movement and cardiac output as primary clinical endpoints.[67,68]

In summary, the current evidence regarding the impact of SDB on pregnancy is limited. Many studies are not powered to detect the impact of SDB independent of BMI. Most data are cross-sectional or retrospective, and very few studies have used objective measures of SDB. The nuMoM2b-SDB substudy, whose staff had limited to no prior experience with sleep testing, demonstrated the feasibility of quantification of SDB in pregnancy using home sleep testing. This large scale, multi-centered, observational study will provide objective data regarding the prevalence and trend of SDB across pregnancy, and is designed to address important questions regarding the relationship of SDB on risk of preeclampsia and other outcomes relevant to maternal and child health.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

This study is supported by grant funding from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) and the National Heart Lung and Blood Institute.: U10 HD063036, Research Triangle Institute; U10 HD063072, Case Western Reserve University; U10 HD063047, Columbia University; U10 HD063037, Indiana University; U10 HD063041, Magee-Women's Hospital; U10 HD063020, Northwestern University; U10 HD063046, University of California Irvine; U10 HD063048, University of Pennsylvania; and U10 HD063053, University of Utah.

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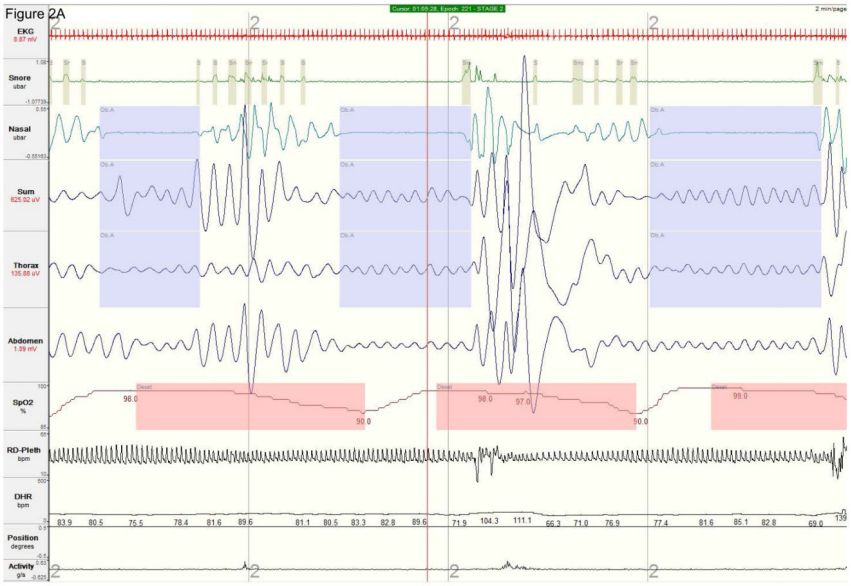
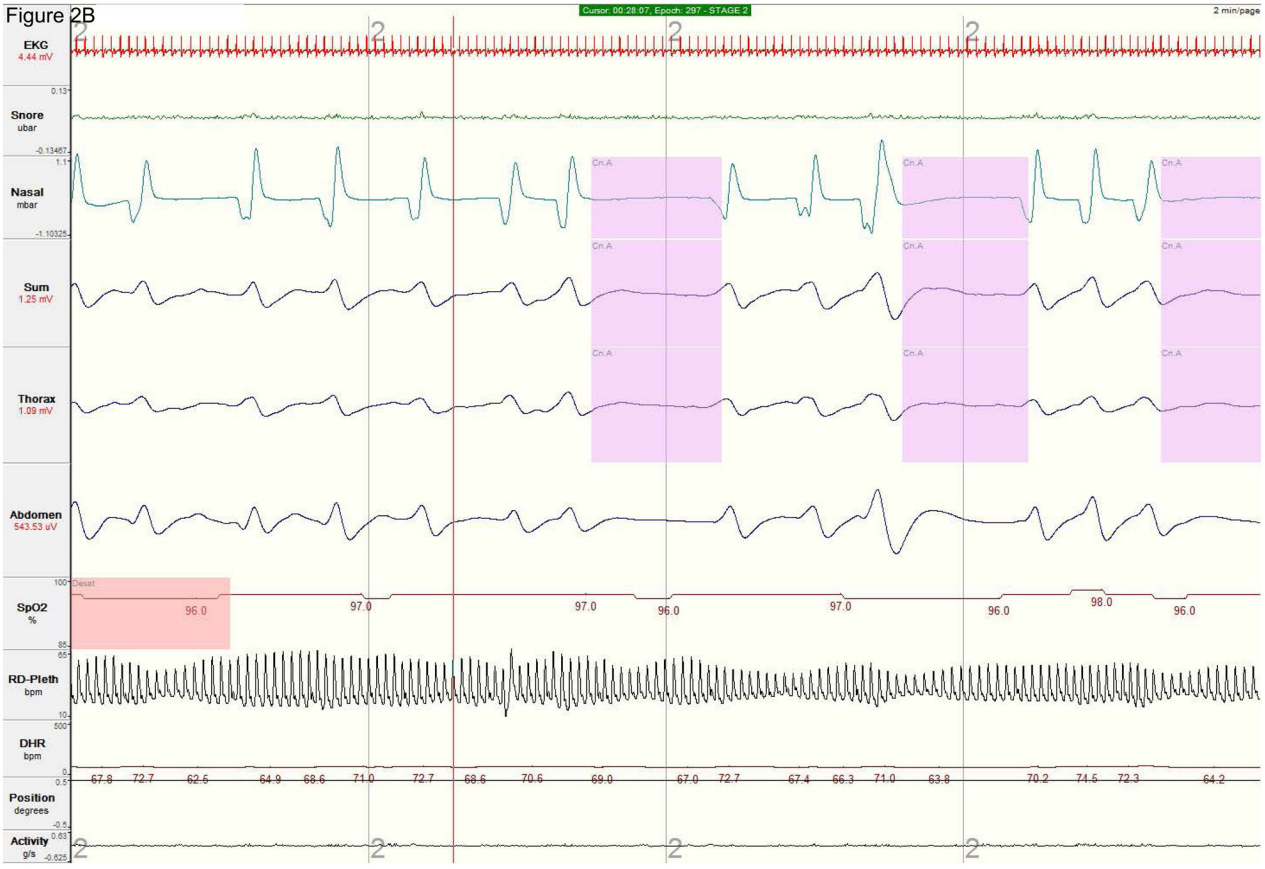
Figure 1.
Embletta set-up





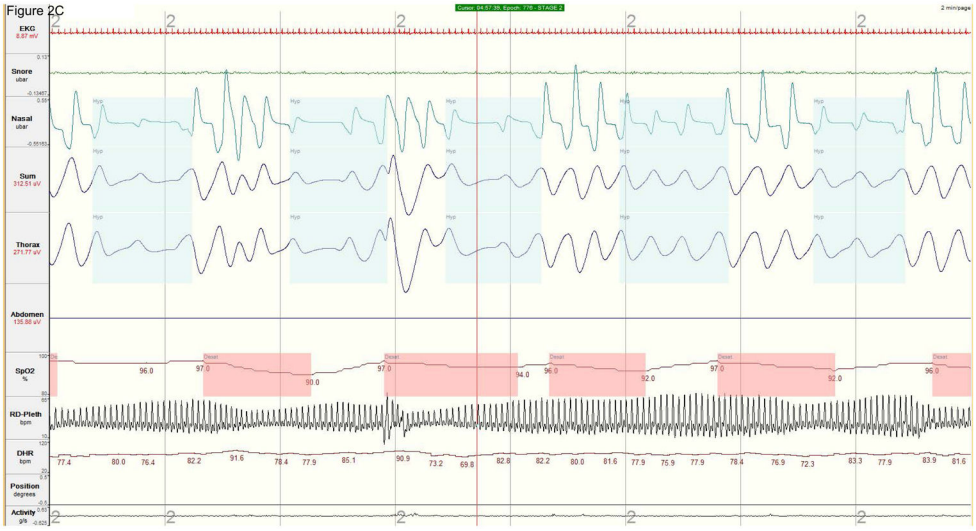


Figure 2.

Examples (from actual study recordings) of sleep disordered breathing events. Each figure representing 2 minutes of recorded sleep. Oxygen desaturations marked in red boxes (Desat) A: Obstructive apnea (Ob. A). B: Central apnea (Cn. A). C. Hypopnea (Hyp).

Table 1

Characteristic	n (%)
Visit 1	
Objective assessment attempted	3701
Objective data obtained	3261 (88.1)
Subjective data obtained	3372 (91.1)
Objective and subjective data available	2996 (81.0)
Visit 3	
Objective assessment attempted	2866
Objective data obtained	2511 (87.6)
Subjective data obtained	2780 (97.0)
Objective and subjective data available	2454 (85.6)
Both Visits	
Objective assessment attempted	2865
Objective data obtained	2336 (81.5)
Subjective data obtained	2603 (90.9)
Objective and subjective data available	2152 (75.1)

*1/*3702 women enrolled to nuMoM2b had at least one objective sleep disordered breathing assessment. In one case the woman decided against the sleep assessment at visit 1, but took the assessment at visit 3.

Table 2

Artifact-Free Data[1/] – n (%)	EKG	Cannula Flow	Thoracic Effort Band	Abdominal Effort Band	Oximetry
Visit 1					
<25%	35 (1.1)	203 (6.2)	512 (15.7)	500 (15.3)	0 (0.0)
25–49%	18 (0.6)	183 (5.6)	64 (2.0)	46 (1.4)	0 (0.0)
50–74%	42 (1.3)	382 (11.7)	154 (4.7)	97 (3.0)	32 (1.0)
75%–94%	344 (10.5)	575 (17.6)	579 (17.8)	353 (10.8)	174 (5.3)
≥95%	2822 (86.5)	1918 (58.8)	1952 (59.9)	2265 (69.5)	3055 (93.7)
Total	3261 (100.0)	3261 (100.0)	3261 (100.0)	3261 (100.0)	3261 (100.0)
Visit 3					
<25%	23 (0.9)	186 (7.4)	388 (15.5)	401 (16.0)	0 (0.0)
25–49%	14 (0.6)	159 (6.3)	32 (1.3)	60 (2.4)	0 (0.0)
50–74%	31 (1.2)	279 (11.1)	113 (4.5)	70 (2.8)	18 (0.7)
75%–94%	280 (11.2)	449 (17.9)	482 (19.2)	265 (10.6)	106 (4.2)
≥95%	2163 (86.1)	1438 (57.3)	1496 (59.6)	1715 (68.3)	2387 (95.1)
Total	2511 (100.0)	2511 (100.0)	2511 (100.0)	2511 (100.0)	2511 (100.0)
All Visits					
<25%	58 (1.0)	389 (6.7)	900 (15.6)	901 (15.6)	0 (0.0)
25–49%	32 (0.6)	342 (5.9)	96 (1.7)	106 (1.8)	0 (0.0)
50–74%	73 (1.3)	661 (11.5)	267 (4.6)	167 (2.9)	50 (0.9)
75%–94%	624 (10.8)	1024 (17.7)	1061 (18.4)	618 (10.7)	280 (4.9)
≥95%	4985 (86.4)	3356 (58.1)	3448 (59.7)	3980 (69.0)	5442 (94.3)
Total	5772 (100.0)	5772 (100.0)	5772 (100.0)	5772 (100.0)	5772 (100.0)

[1/] Percentage of artifact-free data based on estimated sleep time.

Table 3

Characteristic (N=3,702)	Statistic
Maternal age, in years	
Mean (standard deviation)	26.7 (5.6)
Median (interquartile range)	27.0 (22, 31)
Category: n (%)	
13–21	801 (21.6)
22–35	2659 (71.8)
>35	242 (6.5)
Maternal race/ethnicity: n (%)	
Non-Hispanic White	2208 (59.6)
Non-Hispanic Black	523 (14.1)
Hispanic	654 (17.7)
Asian	133 (3.6)
Other	184 (5.0)
Maternal education status: n (%)	
less than high school	270 (7.3)
completed high school or GED	478 (12.9)
some college	787 (21.3)
associate or technical degree	403 (10.9)
completed college	1014 (27.4)
degree work beyond college	750 (20.3)
Income and size of household relative to Federal poverty level: n (%)	
>200%	1975 (67.1)
100–200%	483 (16.4)
<100%	487 (16.5)
Method of paying for healthcare: n (%)[1/]	
government insurance	1070 (29.1)
military insurance	34 (0.9)
commercial health insurance	2495 (67.8)
personal household income	602 (16.4)
other	50 (1.4)
Prepregnancy BMI	
Underweight (<18.5)	83 (2.3)
Normal Weight (18.5–24.9)	1783(49.0)
Overweight (25.0–29.9)	922(25.4)
Obese (30.0–34.9)	440 (12.1)
Morbidly Obese (>35)	409(11.3)
Ever Smoked: n (%)	1503 (40.6)
Smoked during 3 months prior to pregnancy: n (%)	671 (18.1)
Among smokers during 3 months prior to pregnancy, cigarettes per day: n (%)	
<20 cigarettes per day	573 (85.7)

Characteristic (N=3,702)	**Statistic**
20–40 cigarettes per day	95 (14.2)
>40 cigarettes per day	1 (0.2)
Estimated gestational age at screening: n (%)	
< 8 weeks 0 days	69 (1.9)
8 weeks 0 days to 9 weeks 6 days	396 (10.7)
10 weeks 0 days to 11 weeks 6 days	1039 (28.1)
12 weeks 0 days to 13 weeks 6 days	2198 (59.4)

*1/*Percentages do not add up to 100% as participants were allowed to select multiple methods of payment for healthcare.