# Home Uterine Activity Monitoring in the Prevention of Very Low Birth Weight

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## SYNOPSIS

**Objectives.** Despite controversy regarding the efficacy of home uterine activity monitoring (HUAM), it is currently licensed for detection of preterm labor in women with previous preterm deliveries. In practice, however, it is being more widely utilized in an effort to prevent preterm delivery. This study seeks to determine which group of mothers delivering very low birth weight (VLBW) infants would have qualified for HUAM given three different sets of criteria and in which women it could have been used to help prolong gestation.

**Methods.** The authors reviewed the medical records of mothers of VLBW infants born in five U.S. locations ($N$=1440), retrospectively applying three sets of eligibility criteria for HUAM use: (*a*) the current FDA licensing criterion for use of HUAM, a previous preterm birth; (*b*) indications for HUAM commonly cited in published reports; (*c*) a broad set of criteria based on the presence of any reproductive or medical conditions that might predispose to premature delivery. The authors then analyzed the conditions precipitating delivery for each group to determine whether delivery might have been prevented with HUAM and tocolytic therapy.

**Results.** Only 4.4% of the total group of women delivering VLBW infants would have been eligible for HUAM under the FDA criterion *and* might potentially have benefited from this technology. If extremely broad criteria had been applied to identify those eligible for monitoring, under which almost 80% of all women who delivered VLBW infants would have been monitored, only 20.3% of the total group would have been found eligible and would potentially have benefited. If such broad criteria were applied to all pregnant women, a sizable proportion of pregnancies would be monitored at great expense with small potential clinical benefit.

**Conclusions.** Because VLBW births are usually precipitated by conditions that are unlikely to benefit from HUAM, this technology will have little impact on reducing VLBW and neonatal mortality rates. More comprehensive preventive strategies should be sought.

In 1991, the United States Food and Drug Administration (FDA) approved a device for monitoring uterine activity at home with the aim of detecting early preterm labor and therefore potentially prolonging gestation through immediate treatment. The device, an external tocodynamometer (Genesis Home Uterine Activity Monitor, Tokos Medical

Group), is used in conjunction with daily contact between patients and medical personnel. Although the Genesis monitor was approved by the FDA only for use in women with a prior preterm delivery, in clinical practice this technology is being used for a far broader spectrum of maternal indications and has been cast as a possible way to lower elevated rates of preterm birth in populations with risk factors associated with preterm delivery.[1–11] This expanded use of home uterine activity monitoring (HUAM) has emerged despite evidence that it does not prevent premature births and despite a lack of empirical data on its impact in large populations.[12,13]

Uterine activity monitoring is based on the premise that a woman will have an identifiable increase in uterine contractions before the onset of preterm labor and that she may not be able to recognize this activity without monitoring. The objective of monitoring is to identify these uterine contractions so that medications can be used to try to stop the contractions and prolong gestation. The efficacy of such medications, termed "tocolytic therapy," is optimized if they are initiated as early in the course of preterm labor as possible.

Most uterine monitoring programs screen women to identify those at risk for preterm labor. Once selected, women are generally monitored during the period between 24 and 36 weeks of gestation.[1,14,15] The home monitoring procedure involves attaching an external tocodynamometer, used to detect contractions, to the patient's abdomen twice a day, morning and evening, for one- to two-hour periods during which she remains in a reclining position. A recording of uterine activity is then transmitted to a central monitoring facility by computer. If uterine activity exceeds a specified level, the patient is asked to come in for evaluation. The monitoring is coupled with daily telephone contact with a nurse to determine if there are any premature contractions and to provide support to the patient.

Although a number of trials have found HUAM to be of benefit in preventing preterm birth or in the early detection of preterm labor,[1,3,4,8,11] others have failed to show a significant effect.[2,9] Methodological questions have been raised regarding the published randomized controlled trials of home uterine monitoring.[12,16,17] In addition, observers have questioned whether the apparent efficacy of the intervention relates partially or completely to daily contact with a health care provider rather than the use of the technology per se. Tocolytic therapy has also been shown to have limited efficacy in decreasing preterm delivery. A recent large collaborative study demonstrated no beneficial effect of ritodrine, the most commonly used tocolytic agent, on perinatal mortality, the frequency of prolongation to term, or birth weight.[18] Several other reports found that tocolytic therapy may be contraindicated in a large portion of preterm births.[19,20] Kempe et al.[21] examined the clinical conditions that precipitated delivery in pregnancies resulting in VLBW infants and found that almost two-thirds of the associated conditions precluded continued pregnancy.

In this study, we focused not on the efficacy of HUAM but on its application in women for whom it has the potential to be most beneficial. We estimated the percentages of women among those delivering very low birth weight (VLBW) (between 500 and 1499 grams [gm]) preterm infants who would have been eligible for home uterine monitoring using three different sets of eligibility criteria. We focused on women who delivered VLBW infants because this group of infants accounts for the majority of neonatal deaths in the United States.[22] VLBW is also associated with both high financial costs[23–28] and elevated rates of morbidity for infants who survive the neonatal period.[29–33]

The second step of our analysis was to determine which of these preterm births might have been delayed if abnormal uterine activity had been detected in time for therapy to be initiated. The population-based nature of this study allowed us to estimate the potential utilization and potential impact of this technology (assuming its efficacy) in reducing the incidence of VLBW.

## Methods

The data were collected as part of a larger study of infant mortality patterns,[21] in which the authors conducted

**Table 1. Live births, VLBW births, and mortality rates for VLBW infants in five U.S. areas**

| Area (years for which data collected) | Live births | VLBW births | | Deaths of VLBW infants | |
|---|---|---|---|---|---|
| | Number | Number | Percent of live births | Number | Percent of VLBW births |
| Boston (1984–1985) | 17,423 | 236 | 1.4 | 59 | 25.0 |
| Maine (1984–1985) | 33,494 | 264 | 0.8 | 79 | 29.9 |
| Two primarily rural health districts in Mississippi (1984–1985) | 16,332 | 219 | 1.3 | 64 | 29.2 |
| San Diego County (1985) | 37,167 | 322 | 0.9 | 111 | 34.5 |
| St. Louis and 38 contiguous Census tracts (1985–1986) | 16,232 | 399 | 2.5 | 118 | 29.6 |
| Total | 120,648 | 1440 | 1.2 | 431 | 29.9 |

VLBW=very low birth weight

a retrospective population-based medical record review in five areas of the United States.

**Study population.** We collected data on all infants with birth weights between 500 gm and 1499 gm who were born alive to residents of *(a)* the city of Boston in 1984 and 1985; *(b)* the state of Maine in 1984 and 1985; *(c)* two east central, primarily rural health districts (Districts II and VIII) of the state of Mississippi in 1984 and 1985; *(d)* San Diego County in 1985; *(e)* and the city of St. Louis and 38 contiguous Census tracks—in which, according to Vital Statistics data, the infant mortality and low birth weight rates were greater than 1.5 times the rate for the county—in 1985 and 1986. We excluded infants with birth weights below 500 gm because the criteria for reporting live births at birth weights below 500 gm and distinguishing between fetal and infant deaths differ between states. The 500-gm birth weight limit currently recommended by the American Academy of Pediatrics and the American College of Obstetrics and Gynecology[34] as the criterion for reporting perinatal mortality rates appeared to be consistent across the states from which we drew our samples.

**Sources of data.** We identified all births and VLBW births using Vital Statistics-linked birth and death certificate files. From these files we identified the names of the infants and their mothers and the names of the hospitals of birth. We then reviewed the mothers' medical records at all facilities providing care from the initiation of labor through delivery and the infants' records at the hospitals where they were born. The medical record reviews were performed on site at each hospital facility by physicians and nurses who received training in the use of a standard abstracting form. We employed between 5 and 10 record reviewers per study location, depending on sample size at the location, and reviews were performed over a three- to six-month period. Field coordinators supervised data collection at each site, and all aspects of data collection were coordinated by the principal author. A 10% duplicate record review at two of the study locations yielded greater than 90% concordance on variables critical to the study: birth weight (99%), prenatal maternal conditions (90%), prenatal medications (94%), and perinatal maternal conditions (92%). In order to maintain confidentiality, we assigned an identification number to each case after medical record review, and names were removed from the audit form.

**Eligibility criteria.** We looked at the records of VLBW infants to determine whether the pregnancy met one or more of the following eligibility criteria for HUAM use: *(a)* the *FDA criterion* for HUAM use, that is, women with a history of prior preterm delivery; *(b)* the criteria used in recently published efficacy trials *(published criteria)*,[1,2,4–6,8–10,11] including a history of preterm labor or delivery, incompetent cervix, diethylstilbestrol (DES) exposure or any uterine or cervical anatomical abnormality, and multiple gestation or preterm labor in the current pregnancy. *(c)* a set of *broad criteria* chosen to reflect the widest possible use of HUAM, including diagnoses that are potentially, but not definitively, associated with a higher risk of preterm delivery. In addition to the conditions included under *(a)* and *(b)*, these criteria included a previous history of stillbirth or fetal death; any chronic medical condition that might put the mother at medical risk such as asthma, diabetes, obesity, or hypertension; and risk factors in the current pregnancy including first or second trimester bleeding (not immediately preceding or potentially precipitating delivery), oligohydramnios (deficiency in the amount of amniotic fluid), polyhydramnios (excessive amniotic fluid), gestational diabetes, hypertensive disease, intrauterine growth retardation, multiple gestation, fetal structural abnormality, urinary tract infection or sexually transmitted disease, or labor at less than 37 weeks' gestation.

Once we determined which, if any, of these eligibility criteria were met, we examined case records to determine what conditions precipitated delivery and whether prolonging gestation might have been possible with the use of HUAM and tocolytic therapy. For those conditions precipitating delivery that would not have been detected by HUAM in time to be remedied clinically and would have necessitated delivery because of potential danger to the mother or infant, we determined HUAM would not have been of potential benefit. Conditions falling into this category included chorioamnionitis (infection of the amniotic fluid or chorionic membrane) or premature rupture of membranes (before the onset of labor in a pregnancy of less than 37 weeks' gestation); severe pregnancy-induced hypertension that required induction or cesarean delivery; intrauterine growth retardation that required induction or cesarean delivery; major acute hemorrhage including abruptio placenta or placenta previa; and prolapsed cord.

In our judgment, early detection of labor by HUAM was of *potential* benefit for women with precipitating diagnoses of uncomplicated preterm labor; minor hemorrhage; incompetent cervix; polyhydramnios; urinary tract infection or sexually transmitted disease without chorioamnionitis; fetal distress; pregnancy-induced hypertension not requiring induction or cesarean delivery; and intrauterine growth retardation not requiring induction or cesarean delivery.

**Statistical analyses.** We performed all tabulations using SAS statistical software. Rate calculations were performed using Microsoft Excel and Lotus 1-2-3 spreadsheet software. Chi-square testing and stratified analyses were conducted using SAS and Epistat statistical software.

## Results

The percentage of live-born VLBW infants for the combined study locations was 1.2%, and the risk of mortality in the first year of life for this group of infants was 29.9% (Table 1). Overall, 18.1% (260/1440) of mothers would

**Table 2. Women eligible for HUAM use under each of three sets of criteria, by geographic area (*N*=1440)**

| | Boston 1984–1985 (n=236) | | Maine 1984–1985 (n=264) | | 2 Mississippi health districts 1984–1985 (n=219) | | San Diego County 1985 (n=322) | | St. Louis and contiguous tracts 1985–1986 (n=399) | | Total N=1440 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent | Number | Percent |
| Met FDA criterion | 67 | 28.3 | 23 | 8.7 | 34 | 15.5 | 48 | 14.9 | 88 | 22.0 | 260 | 18.1 |
| *Incomplete information*[a] | 6 | 2.5 | 31 | 11.7 | 12 | 5.5 | 17 | 5.3 | 13 | 3.3 | 79 | 5.5 |
| Met published criteria | 106 | 44.9 | 88 | 33.3 | 82 | 7.4 | 111 | 34.5 | 183 | 45.9 | 570 | 39.6 |
| *Incomplete information*[b] | 4 | 1.7 | 30 | 11.4 | 4 | 1.8 | 12 | 3.7 | 1 | 0.3 | 51 | 3.5 |
| Met broad criteria | 199 | 84.3 | 210 | 79.5 | 163 | 74.4 | 241 | 74.8 | 321 | 80.5 | 1134 | 78.8 |
| Underlying risks[c] | 121 | 51.3 | 129 | 48.9 | 88 | 40.2 | 132 | 41.0 | 177 | 44.4 | 647 | 44.9 |
| Prenatal risks[d] | 167 | 70.8 | 168 | 63.6 | 121 | 55.3 | 201 | 62.4 | 265 | 66.4 | 922 | 64.0 |
| *Incomplete information*[e] | 4 | 1.7 | 30 | 11.4 | 4 | 1.8 | 12 | 3.7 | 1 | 0.3 | 51 | 3.5 |

[a] It could not be determined with certainty from the medical record whether a woman had a previous preterm birth.

[b] Information relevant to the published criteria was incomplete in the medical record.

[c] Underlying risks were defined as previous history of preterm labor or delivery, incompetent cervix, DES exposure, uterine or cervical abnormality, stillbirth or fetal death, or chronic medical conditions.

[d] Prenatal risks were defined as history in the current pregnancy of bleeding, oligohydramnios, polyhydramnios, gestational diabetes, hypertensive disease, intrauterine growth retardation, multiple gestation, fetal structural abnormality, urinary tract infection, sexually transmitted disease, or labor at less than 37 weeks.

[e] Information relevant to the broad criteria was incomplete in the medical record.

HUAM = home uterine activity monitoring

have been placed on home monitoring if the current FDA criterion for the use of HUAM had been applied (see Table 2). Using the published criteria increased the proportion of cases that would have been monitored to 39.6% (570/1440). With the most expansive monitoring indications, the broad criteria, 78.8% (1134/1440) would have been deemed eligible for monitoring; of these 44.9% (*n*=647) qualified on the basis of a preexisting underlying risk factor while 64.0% (*n*=922) qualified due to a prenatal risk factor.

The percentage of mothers who met each of the three sets of criteria varied between sites, but not dramatically. When the FDA criterion was used, the percentage eligible ranged from 8.7% in Maine to 28.3% in Boston. There was less variation by study location for the published criteria, under which the percent eligible ranged from 33.3% in Maine to 45.9% in St. Louis, and for the broad criteria, under which the percent eligible ranged from 74.4% in Mississippi to 84.3% in Boston.

In the second phase of our analysis, we reviewed all cases deemed eligible by the three criteria and examined the conditions precipitating delivery in each case. The clinical conditions were then categorized as to whether HUAM could potentially have been beneficial in prolonging pregnancy.

Of the group selected by the FDA criterion, only 24.6% (*n*=64) had the potential to benefit from monitoring according to our review of the conditions precipitating delivery (see Table 3), while 29.3% (*n*=167) of those identified with the published criteria and 25.8% (*n*=293) of those identified with the broad criteria might have benefited from monitoring. However, when the numbers of cases that might have benefited from HUAM were shown in relation to all pregnancies resulting in VLBW births (Table 3), the percentages were very small. If the FDA criterion had been used to identify pregnancies appropriate for monitoring, only 4.4% of all women delivering VLBW infants (64/1440) would potentially have benefited from the use of HUAM and tocolytic therapy. The corresponding figure for the published criteria was 11.6% (167/1440), and for the broad criteria it was 20.3% (293/1440).

Chorioamnionitis/premature rupture of membrane was the largest category of precipitating conditions, accounting for 51.0% of those not potentially benefiting from HUAM among women meeting the FDA criterion, 51.1% of those meeting the published criteria, and 41.4% of those meeting the broad criteria. (As shown, the percentage of the chorioamnionitis/premature rupture of membranes groups that had a diagnosis of premature rupture of membranes with or without chorioamnionitis was approximately 70% for each criteria group.)

Of the subjects both eligible and potentially benefiting from HUAM, 15.6% (10/64) of those selected by the FDA criterion, 8.4% (14/167) of those selected by the published criteria, and 7.2% (21/293) of those selected by the broad criteria were documented to have received no prenatal care prior to delivery. Without additional intervention to increase participation in prenatal care, therefore, these

**Table 3. Proportion of VLBW deliveries in which HUAM might have been beneficial (*N*=1440 women)**

| | *Women meeting FDA criterion for HUAM use (n=260)* | | *Women meeting published criteria for HUAM use (n=570)* | | *Women meeting broad criteria for HUAM use (n=1134)* | |
|---|---|---|---|---|---|---|
| | *Number* | *Percent* | *Number* | *Percent* | *Number* | *Percent* |
| HUAM not beneficial due to conditions precluding its use | 196 | 75.4 | 403 | 70.7 | 841 | 74.2 |
| Chorioamnionitis/PROM | 100[a] | 38.5 | 206[b] | 36.1 | 348[c] | 30.7 |
| Hypertensive disease leading to induction or cesarean delivery | 25 | 9.6 | 41 | 7.2 | 150 | 13.2 |
| Major hemorrhage[d] | 36 | 13.8 | 62 | 10.9 | 142 | 12.5 |
| Multiple conditions | 25 | 9.6 | 72 | 12.6 | 150 | 13.2 |
| Other[e] | 10 | 3.8 | 22 | 3.9 | 51 | 4.5 |
| HUAM potentially beneficial | 64 | 24.6 | 167 | 29.3 | 293 | 25.8 |
| Proportion of all VLBW births eligible and HUAM potentially beneficial | 64/1440 | 4.4 | 167/1440 | 11.6 | 293/1440 | 20.3 |

[a]PROM = 70/100 (70%)
[b]PROM = 143/206 (69%)
[c]PROM = 236/348 (68%)
[d]Abruptio placenta, placenta previa, or major hemorrhage directly preceding delivery.
[e]Prolapsed cord, intrauterine growth retardation leading to induction, or cesarean delivery, and miscellaneous low-prevalence conditions.
VLBW = very low birth weight
HUAM = home uterine activity monitoring
PROM = premature rupture of membrane

women could not have benefited from the use of HUAM, further reducing the proportion of women potentially benefiting from this technology.

## Discussion

HUAM is currently approved by the FDA for the early detection of preterm labor in women who have had a previous preterm delivery. Although numerous studies have cast doubt on the clinical efficacy of HUAM, the findings of the present study suggest that even if this technology were highly efficacious, its use would not substantially reduce the rate of VLBW births. In order for HUAM to prevent preterm delivery, the technology must successfully detect early uterine activity and tocolytic therapy must be successful in stopping this activity. In addition, there can be no contraindications to continuing the pregnancy. Although, in our study, a large number of the pregnancies resulting in VLBW infants would have been eligible for monitoring, the majority of the deliveries in these cases were precipitated by conditions that would not have been predicted by the use of HUAM or would have had indications for immediate delivery of the infant rather than attempts to prolong pregnancy. Only women who received early prenatal care had the chance to benefit from monitoring, and, as our data indicated, a sizable number of women did not receive early care. In addition, even when the broadest eligibility criteria for monitoring were utilized, according to which almost 80% of women delivering VLBW infants would have been monitored, only 20.3% of the total group of women might have benefited from prolonging gestation with HUAM and tocolytic therapy.

Our findings, combined with those of previous studies[1–4,8,9,11,28,32–34] may explain why, despite the widespread use of tocolytic agents and the growth of home uterine monitoring programs,[33,35] there has been only a slight decline in low birth weight (<2500 gm) births and no change in the number of VLBW births.[36–38]

The findings of the present study are limited by a reliance on clinical information obtained from a retrospective review of medical records. Information was generally available, however, on underlying medical and prenatal risk factors and obstetrical diagnoses. In almost every case, conditions precipitating delivery of a VLBW infant were documented. Nevertheless, the retrospective use of eligibility and exclusionary criteria must be interpreted with caution since as pregnancies progress, clinical judgments and diagnoses may prove more complex than is ultimately reported in the record. For this reason, we used a series of increasingly expansive eligibility criteria to minimize the possibility that our retrospective estimates were too restrictive.

Although most of the conditions in which HUAM was

judged not to be potentially beneficial are not controversial, the diagnosis of premature rupture of membranes is somewhat problematic. In the present study, by definition, none of the cases of prematurely ruptured membranes were preceded by clinically evident labor. However, whether subclinical uterine contractions sometimes precedes premature rupture of membranes rather than the rupture of membranes instigating premature labor is a subject of controversy.[39,40] If subclinical contractions caused rupture of membranes, theoretically this might have been prevented by early use of tocolytic therapy. For this reason, data were reported separately for this condition and conclusions regarding these results must be interpreted with caution.

The current study did not address the efficacy of HUAM but rather the relevance of this technology to the important public health issue of preventing VLBW. Our analyses help frame the findings of clinical trials in selected panels of patients by exploring the prevalences of indicative and contraindicative conditions in large populations. Our findings suggest that HUAM is of little relevance to a majority of VLBW births. They also suggest that HUAM could be seriously overused in general practice without clearly defined eligibility criteria and a better understanding of how such criteria relate to the epidemiology of preterm birth across populations.

Although indications for the use of home uterine monitoring in individual patients will continue to be assessed and refined, the findings of the present study suggest that this technology will not have a major impact on current levels of VLBW births in the United States. Even if HUAM coupled with tocolytic therapy were highly effective in prolonging pregnancy, they would not be beneficial in the majority of VLBW births. Effective approaches to the reduction of prematurity and VLBW will depend on linking therapeutic clinical interventions with more comprehensive prevention strategies to improve women's health.

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