Early Labor Assessment and Support at Home Versus Telephone Triage

A Randomized Controlled Trial

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OBJECTIVE: To compare rates of cesarean delivery among women who were triaged by obstetric nurses, either by telephone or by means of home visits.

METHODS: Healthy, nulliparous women in labor at term with uncomplicated pregnancies residing in the City of Vancouver, British Columbia, and suburbs between November 2001 and October 2004 were randomized when they sought advice about when to come to hospital. Women randomized to telephone triage (n=731) were provided with advice by telephone. Women randomized to a home visit (n=728) were triaged after a "hands-on" assessment in their homes.

RESULTS: The relative risk (RR) for cesarean delivery among home-triaged women compared with those receiving only telephone support was 1.12 (95% confidence interval [CI] 0.94–1.32). The study was designed to have 80% power to detect a RR less than 0.78 or greater than 1.27 for cesarean delivery. Significantly fewer women in the home visit group were admitted to hospital with cervical dilatation at 3 cm or less (RR 0.85, 95% CI 0.76–0.94). Significantly more women in the home visit group managed their labor without a visit to hospital for assessment (RR 1.54, 95% CI 1.23–1.92). There were no statistically significant differences in use of narcotic analgesia, epidural analgesia, and augmentation of labor. Adverse neonatal outcomes were rare and did not differ between study groups.

CONCLUSION: Early labor assessment and support at home versus support by telephone reduces the number of visits to hospital in latent phase labor but does not impact cesarean delivery rates among healthy nulliparous women.

CLINICAL TRIAL REGISTRATION: ISRCTN, www.controlled-trials.com/isrctn, MCT-44153

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LEVEL OF EVIDENCE: I

An interest in obstetric triage has been stimulated by its perceived potential to reduce rates of cesarean delivery. The time during labor at which women are admitted to hospital has been associated with progress of labor and need for obstetric intervention.[1,2] The goal of obstetric triage among healthy women is to delay admission to hospital until labor is established. This delay is intended to prevent the "cascade of interventions" that sometimes accompanies women who languish in hospital in latent phase labor and to enable resources to be focused on women who are in established labor. In some hospitals the proportion of nulliparous women admitted to hospital before active phase labor is as high as 45%.[3] The introduction of an obstetric triage unit has been associated with reduction in cesarean delivery rates and use of epidural anesthesia in a retrospective cohort study.[4] A randomized trial of hospital triage among nulliparous women reported reduced use of epidural analgesia and oxytocin augmentation in the triaged group.[5] Triage in these two studies occurred after the women presented at a hospital. A pilot trial by Janssen et al[3] demonstrated the utility of triage at home in delaying admission to hospital until the active phase of labor, but the trial lacked sufficient

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power to examine the effect on cesarean delivery. The purpose of the current study is to compare the effectiveness of obstetric triage at home compared with that performed by telephone on rates of cesarean delivery.

MATERIALS AND METHODS

The Early Labor Assessment and Support at Home trial was a multisite randomized controlled trial comparing telephone (the current standard of care) with home-based triage. Seven hospitals with obstetric services in the City of Vancouver, British Columbia, and surrounding suburbs took part. Only one hospital, geographically isolated from the other centers, did not participate. Enrollment took place between November 2001 and August 2004.

Women were considered to be eligible for the study if they 1) lived within a 30-minute drive of the hospital, 2) were between the ages of 16 and 42 years, 3) had completed 37–41 weeks of gestation, 4) were nulliparous, 5) were carrying a singleton fetus in the vertex position, and 6) spoke English, Cantonese, Mandarin, Punjabi, Korean, or Farsi. Women were also included in the study if their labor was being induced on an outpatient basis with prostaglandins.

Exclusion criteria included type 1 diabetes, cardiovascular disease, third-trimester bleeding, fetal anomalies, abnormal fetal biophysical profile, or any other condition arising from or coexisting with the pregnancy that were deemed to be a contraindication to laboring at home. Women whose primary caregivers were midwives were excluded because midwives routinely visit their clients in early labor at home.

As part of standard practice in the participating hospitals, women experiencing painful uterine contractions at term are advised by their physician and in prenatal classes to contact the labor and delivery suite by telephone to seek advice as to when to come to hospital. In spite of this, many women arrive unannounced. During the study period, women seeking advice by telephone were verbally assessed for eligibility for the study. Verbal consent was obtained before randomization in both trial arms. Written consent was obtained during the home visit for women randomized to the home visit group. Written consent was obtained from the telephone triage group when these women were admitted to hospital for delivery. Women who arrived in hospital without prior telephone contact were assessed for eligibility after their attending physician had informed them that they were not in established labor and were to be discharged. Written consent was obtained, and they were randomized before discharge.

A dedicated cohort of experienced obstetric nurses employed by the study recruited 24 hours per day. A nurse was stationed at each of the three largest hospitals and was notified of potentially eligible patients at the smaller hospitals by cellular telephone.

Between 40% and 50% of women giving birth in Vancouver and the surrounding suburbs speak English as a first language. For women not fluent in English, consent forms were translated into the six study languages and back-translated by a second translator to check for accuracy and appropriate cultural context. The study was approved by the University of British Columbia Clinical Ethics Review Board and the Research Review Boards of participating hospitals. All participants provided informed written consent.

Computer-generated randomization was achieved by using a centralized randomization service accessed via a dedicated telephone line. Randomization was stratified within participating hospitals, with randomly generated block sizes of 6, 8, and 10. Randomization occurred when women phoned the hospital, expressing uncertainty as to whether or not to come in. Women who had been assessed in hospital and discharged because they were not in labor were not randomized until they had returned home and had once again arrived at a dilemma as to whether or not to go back to hospital.

Women randomized to the telephone triage group were asked over the phone by study nurses about the nature (frequency, duration, and strength) of their contractions, the presence of bloody show, the status of their membranes, color of amniotic fluid (if present), the presence of bleeding per vagina, the nature (normal, increased, or decreased) of fetal movements, and their own assessment of how they were coping. Responses were documented on standard hospital forms. Women were advised to come in if amniotic fluid was colored, if they were experiencing bleeding per vagina, if fetal movements were decreased, if they were no longer able to cope with contractions, or if the contractions were more frequent than every 5 minutes or lasting longer than 1 minute. If membranes were ruptured but the fluid was clear, women were advised to contact their own physicians for direction. Suggestions for coping with contractions were made over the phone.

Women randomized to the nurse visit group were told that a nurse would be leaving the hospital immediately. The nursing assessment at home was identical to that over the phone but, in addition, included assessment of maternal vital signs, abdominal palpation, auscultation of the fetal heart rate,

assessment of contractions, and an examination of the cervix. Comfort measures were taught to the woman and her support persons as needed. After the home assessment, the study nurse contacted the primary physician by telephone. Together with the laboring woman, they decided whether she should remain at home longer. Women were given the same advice as the telephone triage group, and in addition, any woman whose cervix was dilated 3 cm or more was advised to proceed to hospital. If needed, women in the home assessment arm were visited more than once. Similar to the telephone group, they could also access the study nurse via cell phone at any time.

Women remaining at home in either arm were advised to proceed to hospital if the amniotic fluid was colored, vaginal bleeding occurred, contractions were more frequent than 2 in 10 minutes or lasted longer than 60 seconds, or if they were simply too uncomfortable to manage at home.

The primary outcome was rate of cesarean delivery. Secondary outcomes included rates of admission to hospital in the latent phase of labor (3 cm or less of cervical dilatation), number of visits to hospital not resulting in admission, ability to cope with pain on arrival as assessed by the admitting nurse, rates of intrapartum interventions, including 1) augmentation of labor, 2) use of narcotic, and 3) use of epidural analgesia. Newborn outcomes included Apgar scores less than 7 at 1 and 5 minutes, administration of oxygen by intermittent positive pressure or tracheal intubation, and admission to a level II or III nursery. Outcomes were ascertained from study data collected prospectively and from review of hospital charts within 24 hours of discharge. Charts were reviewed by trained nursing research assistants.

Sample size calculations were based on the objective of detecting a 20% relative reduction in cesarean delivery rate from 28% to 22% with a type I error, two-sided, set at $P<.05$, and a type II error, set at $P=.20$. Prior studies of obstetric triage have reported reductions ranging from 20%[4] to 28%.[5] To obtain 80% power to detect a RR less than 0.78 or greater than 1.27 for cesarean delivery, we planned to enroll 817 women per group for a total of 1,634 women.

Data analysis was by intention to treat. A subgroup analysis stratified on spontaneous compared with induced labor was planned a priori. An interim analysis was planned when 50% of the planned recruitment was complete using the O'Brian-Fleming approach, in which a conservative value for the type I error of $P=.005$ was used, followed by a type I error of $P=.048$ at the final analysis to give an overall $P=.05$.[6] Relative risks and 95% confidence intervals were calculated. A multivariate analysis was undertaken to explore the role of sociodemographic factors and pregnancy characteristics in the association of early labor care and cesarean delivery. We used logistic regression to estimate odds ratios and calculated 95% confidence intervals from the β estimates generated by the logistic model.

RESULTS

In total, 1,459 women were enrolled among seven participating hospitals during the study period, August 14, 2001, to October 30, 2004. An interim analysis did not provide evidence of difference among the groups. After the enrolment of 1,400 women, the data monitoring committee was asked by the trial steering committee to undertake a futility analysis. The recommendation was to discontinue enrollment because there was effectively no chance that the study would show benefit to either arm of the trial if the remainder of the planned enrollment was undertaken.

Among the 728 women allocated to a home visit, 654 received a home visit. Among the 74 women who did not have a home visit, five women did not receive one because there was no study nurse available at the time the visit was requested; 54 women decided to come to hospital instead of having a home visit, and 12 women at home declined a home visit but stayed home in labor for an additional period of time on their own (Fig. 1). In three cases the reason for not having a home visit was not documented. All 731 women allocated to telephone support received a call except for six women who chose to come to the hospital without contacting the study nurse again by phone. Women having labor induced on an outpatient basis numbered 40 (5.5%) in the home visit group and 50 (6.8%) in the telephone triage group.

Women in each of the trial arms were comparable with respect to age, marital status, education, family income, employment status and employment of spouse, and ethnicity (Table 1). Study groups did not differ with respect to obstetric characteristics including mean prepregnant weight, weight gain, maternal height, attendance at prenatal classes, use of a doula, reported contractions of greater than 24 hours before hospital admission, receipt of narcotics before randomization, and status of membranes (intact, ruptured, or unsure) (Table 2). None of these variables nor the addition of study site to a multivariate model altered the estimate of odds ratios more than 10%; therefore, unadjusted relative risks are presented.

The rate of cesarean delivery did not differ between women randomized to receive a home visit

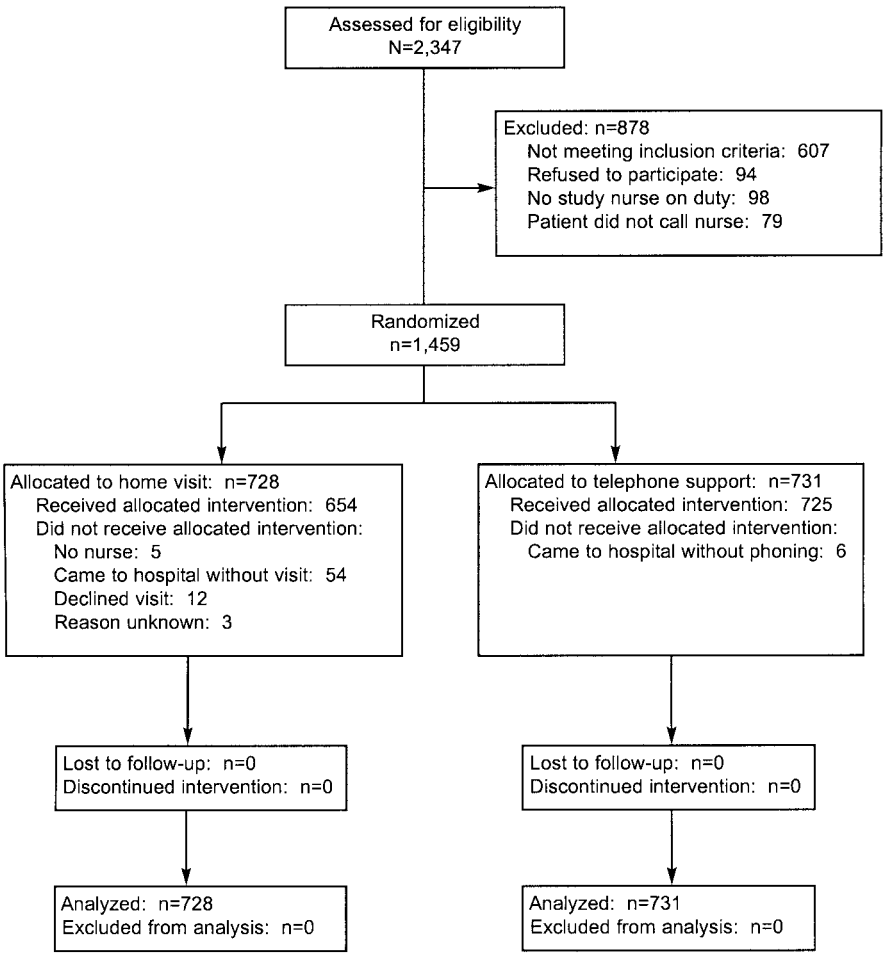

Fig. 1. Flow diagram of women assessed for eligibility.
Janssen. Early Labor Care at Home Versus Via Telephone. Obstet Gynecol 2006.

(28.6%, n=208) and those receiving only telephone support (25.4%, n=186) (Table 3). The RR for cesarean delivery for women receiving home support compared with those receiving telephone support was 1.12 (95% CI 0.94–1.32). The risk difference in cesarean delivery rates was 3.2% (95% CI 0–7.5%). The primary reason for cesarean delivery was distributed similarly among home compared with telephone triage: 73.4% versus 75.2% for nonprogressive labor, 23.2% versus 22.6% for fetal distress, and 2.9% versus 1.6% for breech position diagnosed during labor. Among women laboring spontaneously, the RR for cesarean delivery in the home visit group compared with the telephone triage group was 1.14 (95% CI 0.96–1.41).

Significantly fewer women were admitted to hospital with cervical dilatation at 3 cm or less (RR 0.85, 95% CI 0.76–0.94) in the home visit group. Significantly more women in the home visit group managed their labor without a preadmission visit to hospital (RR 1.54, 95% CI 1.23–1.92). Women randomized to receive early labor assessment and support at home were significantly less likely to be assessed as not coping with their labor on arrival (RR 0.74, 95% CI 0.62–0.90). The mean total time (minutes) spent in hospital from final admission (the admission for the visit in which they delivered) to delivery was not different in women overall, 634.2 (496.3) for the home visit group and 669.1 (503.9) for the telephone triage group. Among spontaneously laboring patients, women in the home visit group spent on average 50 minutes less in hospital, 614.2 (447.0), than the telephone triage group, 664.7 (499.9), P=.049. There were no statistically significant differences in use of narcotic analgesia, epidural analgesia, and augmentation of labor. Rates of Apgar scores less than 7 at 1 and 5 minutes, need for neonatal resuscitation, and admission to a level II or level III nursery were not different (Table 4).

DISCUSSION

In the current study, cesarean delivery rates did not differ among healthy nulliparous women triaged for hospital admission by telephone interview as com-

Table 1. Sociodemographic Characteristics by Study Groups

Characteristic	Home Visit (n=728)	Telephone Triage (n=731)
Age (y, mean±standard deviation)	28.6±5.1	28.3±5.1
Marital status*		
Partner	704 (97.0)	695 (95.3)
Lone parent	22 (3.0)	34 (4.6)
Missing	2	2
Education		
Some high school	66 (9.2)	80 (11.2)
High school diploma	130 (18.0)	108 (15.1)
Some post secondary	67 (9.3)	72 (10.1)
Trade school/college diploma	171 (23.8)	151 (21.1)
Some university education	63 (8.8)	65 (9.1)
University degree	222 (30.9)	240 (33.5)
Missing	9	15
Family income		
Less than $20,000	119 (17.9)	135 (20.6)
21,000–39,000	162 (24.4)	144 (22.0)
40,000–59,000	130 (19.5)	119 (18.2)
60,000 or more	254 (38.2)	256 (39.1)
Missing	63	77
Employment		
Full time	473 (65.7)	460 (64.2)
Part time	59 (8.2)	76 (10.6)
Unemployed	188 (26.1)	181 (25.2)
Missing	8	14
Partner employment		
Full time	596 (85.6)	587 (86.8)
Part time	34 (4.9)	34 (5.0)
Unemployed	66 (9.5)	55 (8.1)
No partner	16	30
Missing	16	25
Ethnicity		
White	342 (47.0)	309 (42.3)
East Asian	158 (21.7)	151 (20.7)
South Asian	177 (24.3)	223 (30.5)
First Nation†	10 (1.4)	10 (1.4)
Black	6 (0.8)	10 (1.4)
Other	35 (4.8)	27 (3.7)
Missing	0	1

Data are expressed as n (%) unless otherwise indicated.
* Data on marital status, education, income, and employment was by self-report; some women chose not to answer these questions.
† First Nation = Native American.

pared with a "hands on" assessment at home. These findings were contrary to our expectations. Intermediate outcomes, including cervical dilatation, ability to cope with labor, and proportion of women who did not have hospital visits resulting in discharge with a diagnosis of latent or no labor, were significantly different in favor of the home visit group. Once in hospital, however, rates of intervention, including use of narcotic analgesia, epidural analgesia, and labor augmentation, were not different. Adverse neonatal outcomes were rare in this study and did not differ between study groups.

Nursing support and triage in each of our study arms were apparently equally successful in managing women in latent phase labor at home. It appears that factors other than preadmission support were more important in the causal pathway to cesarean delivery. A Canadian study of singleton cephalic deliveries at term reported an association between cervical dilatation on presentation and cesarean delivery for nulliparous women.[7] Other studies have supported the association between prolonged latent phase labor and cesarean delivery.[8,9] Among women presenting in our study at less than 0–3 cm dilatation, the use of epidural analgesia was 82% compared with 60.9% in those presenting at 4–10 cm. Time from labor onset to first vaginal examination and use of oxytocin was also higher in the early-presenting group, suggesting that this group may have been experiencing labor that was progressing more slowly and more painfully. Benefit of early labor assessment and support in reducing rates of intervention may be restricted to a subset of women, for example those experiencing a short latent phase of labor.

In this effectiveness trial, we did not evaluate whether women receiving cesarean delivery for dystocia met the criteria for this diagnosis outlined in clinical practice guidelines.[10] It is possible that benefit of delayed admission was masked by physician threshold for performing cesarean delivery.

Another plausible explanation for a lack of observed difference in cesarean delivery rates is that our "usual care" group, telephone triage, did not truly receive standard care. Nurses volunteered to work in our study and were highly motivated to provide excellent nursing care. In addition, these nurses did not have other duties that competed with their time available for study participants. In our earlier pilot study, "usual care" provided by obstetric nurses who were not employed by the study was compared with that of nurses who were hired specifically to undertake home visits. That study showed significant differences in need for analgesia and admission of newborns to a level III nursery.[3] Investigators of obstetric triage might be well advised to undertake a trial of "usual care" compared with a focused program of early labor management, with contact as needed by either telephone or home visits. Lastly, 10.2% of women allocated to the home visit arm did not receive a home visit, potentially biasing our results toward the null.

Our study is limited by our inability to blind nurses and physicians to study allocation. Given the

Table 2. Obstetric Characteristics by Study Group

Characteristic	Home Visit (n=728)	Telephone Triage (n=731)
Prepregnancy weight (kg, mean±SD)	61.0±15.5	60.1±13.9
Weight gain (kg, mean±SD)	16.0±5.6	16.3±6.4
Maternal height (cm, mean±SD)	163.1±7.1	163.0±7.3
Attended prenatal classes*		
Yes	366 (52.7)	368 (53.0)
No	328 (47.3)	326 (47.0)
Missing	34	37
Employed a doula		
Yes	36 (5.2)	47 (6.7)
No	662 (94.8)	653 (93.3)
Missing	30	31
Outpatient induction of labor in progress at randomization	40 (5.5)	50 (6.8)
Patient reported contractions more than 24 hours before admission	265 (36.4)	253 (34.7)
Narcotic analgesics prior to randomization	125 (17.3)	155 (21.3)
Gestational age at randomization (d, mean±SD)	279.7±9.3	280.1±9.5
Status of membranes at randomization		
Intact	555 (76.2)	539 (73.7)
Unsure	158 (21.7)	173 (23.7)
Ruptured	15 (2.1)	19 (2.6)

SD, standard deviation.
Data are expressed as n (%) unless otherwise indicated.
* Missing data for attendance at prenatal classes and use of a doula are due to the fact that these two questions were not asked of study participants for the first 4 months of the study.

Table 3. Maternal Outcomes by Study Group

Maternal Outcome	Home Visit (n=728)	Telephone Triage (n=731)	Home Versus Hospital [RR (95% CI)]
Mode of delivery (all participants)			
Vaginal	336 (46.2)	329 (45.0)	1.03 (0.92–1.15)
Forceps or vacuum vaginal delivery	184 (25.3)	216 (29.5)	0.86 (0.73–1.02)
Cesarean delivery	208 (28.6)	186 (25.4)	1.12 (0.94–1.32)
Mode of delivery (spontaneously laboring participants)			
Vaginal	319 (46.4)	312 (45.8)	1.00 (0.89–1.12)
Forceps or vacuum vaginal delivery	177 (25.7)	203 (29.8)	0.88 (0.74–1.04)
Cesarean delivery	192 (27.9)	166 (24.4)	1.14 (0.96–1.41)
Number of visits to assessment room			
No visits	260 (35.7)	194 (26.5)	1.54 (1.23–1.92)
One visit	331 (45.5)	368 (51.8)	0.82 (0.67–1.01)
Two to five visits	137 (18.8)	169 (23.1)	0.77 (0.60–0.99)
Not coping with contractions on admission	146 (20.9)	197 (28.3)	0.74 (0.62–0.90)
Cervical dilatation on admission, 3 cm or less	324 (44.7)	385 (52.8)	0.85 (0.76–0.94)
Use of narcotic analgesia IM or IV	304 (41.8)	310 (42.5)	0.97 (0.79–1.12)
Use of epidural analgesia	476 (65.4)	499 (68.3)	0.95 (0.89–1.01)
Augmentation of labor with prostaglandins/oxytocin (spontaneously laboring participants)	421 (61.2)	439 (64.5)	0.95 (0.88–1.04)

RR, relative risk; CI confidence interval; IM, intramuscularly; IV, intravenously.
Data are expressed as n (%).

similar findings between study groups in our primary outcome, it is unlikely that lack of blinding influenced our results.

The current trial does not show benefit of early labor assessment and support in the home compared with that provided by telephone for avoiding cesarean delivery among healthy nulliparous women. It does show benefit, however, in supporting women's ability to cope with their labor. It remains a concern that at least half of women admitted to obstetric units are not in active labor.[3,11] A focus of future studies addressing this concern will have to be the discernment of factors

Table 4. Newborn Outcomes by Study Group

Newborn Outcome	Home Visit (n=728)	Telephone Triage (n=731)	Home Versus Hospital [RR (95% CI)]
Apgar score less than 7 at 1 min	90 (12.4)	92 (12.5)	0.97 (0.75–1.30)
Apgar score less than 7 at 5 min	9 (1.2)	6 (0.8)	1.52 (0.54–4.23)
Suction with endotracheal tube	56 (7.7)	62 (8.5)	0.91 (0.64–1.28)
Intermittent positive pressure with endotracheal tube	13 (1.8)	5 (0.7)	2.62 (0.93–7.31)
Admit to level II nursery	45 (6.2)	48 (6.6)	0.93 (0.63–1.37)
Admit to level III nursery	14 (1.9)	6 (0.8)	2.35 (0.90–6.08)

RR, relative risk; CI confidence interval.
Data are expressed as n (%).

contributing to painful, slowly progressing, or nonprogressing latent phase labor. Early labor triage and support may prove to be of value only in women experiencing "normal" latent phase labor. Future trials may also evaluate focused attention to early labor care in settings where usual care more closely represents real world circumstances. Trials of efficacy as opposed to effectiveness will set strict criteria for the definition of nonprogressive labor and the decision to undertake cesarean delivery.

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