A Randomized Trial of One-to-One Nurse Support of Women in Labor

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ABSTRACT: Background: *Health researchers and provider groups have recommended that women in labor should receive continuous professional support. The objective of our study was to compare the risks and benefits of one-to-one nurse labor support with usual intrapartum nursing care.* **Methods:** *A randomized, controlled trial was conducted in a 637-bed university hospital in Montreal, Quebec, with 413 nulliparous women who were at more than 37 weeks' gestation, carrying singletons, and in labor. Women with scheduled cesarean section, scheduled induction, breech presentation, presence of paid labor support, or cervical dilatation over 4 cm were excluded. One-to-one care consisted of the presence of a nurse during labor and birth who provided emotional support, physical comfort, and instruction for relaxation and coping techniques. Usual care consisted of care for two or three laboring women with various types of supportive activities.* **Results:** *A beneficial trend due to one-to-one nurse support was found with a 17 percent reduction in risk of oxytocin stimulation (relative risk of experimental vs control = 0.83; 95% confidence interval = 0.67, 1.04). No significant differences were found in overall labor durations and overall rates of total cesarean section, cesarean section for cephalopelvic disproportion, epidural analgesia, admission to the neonatal intensive care unit, instrumental vaginal delivery, and perineal trauma.* **Conclusions:** *The beneficial trend attributed to one-to-one nursing in reduction of oxytocin stimulation suggests that implementation of recommendations for continuous professional support by intrapartum nursing staff may be appropriate in North America. (BIRTH 24:2, June 1997)*

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The Society of Obstetricians and Gynaecologists of Canada and researchers recently recommended that women in labor be provided with continuous professional support (1–3). Meta-analyses of randomized trials examining the effects of the continuous presence of an individual with a woman during labor have shown beneficial effects for women and their infants (4–13). The most dramatic effects occurred in trials of lay (doula) support of women who were unattended by family or friends during labor (10–13). These studies reported reductions in cesarean section rates, operative vaginal births, and admissions to neonatal intensive care units; decreased use of oxytocin, epidural analgesia, and analgesia or anesthesia; improved Apgar scores; and longer breastfeeding duration. In other trials, support was given by educated lay women (5), lay midwives (7,8), midwifery students (4,6), or professional midwives (4). These latter studies showed a reduction in use of epidural analgesia and any analgesia or anesthesia, fewer episiotomies, and an increased sense of control during labor.

To implement recommendations for continuous professional support in the United States, Canada, or elsewhere, the particular caregiver must be identified. In the context of most North American intrapartum units, that health care professional is likely to be a nurse. No randomized, controlled trial has been identified that examined the effect of professional nurse support on maternal or infant health outcomes.

The potential for professional nurses to provide continuous labor support is important because they are part of the existing intrapartum unit personnel. Furthermore, their knowledge base makes it likely that they can provide care with an added degree of safety beyond that of lay personnel. Most important, perhaps, experienced nurses and midwives possess skills that supplement those of labor partners (expectant father, family member, friend), who are generally present in North American hospitals. These skills may contribute to additional benefits beyond those probably derived from the usual presence of a labor partner, and in light of the widespread use of epidural analgesia.

An experienced intrapartum unit nurse trained in supportive care techniques may reduce the risk for cesarean section and other procedures associated with dystocia or fetal distress. This caregiver is more likely to use intermittent rather than continuous fetal monitoring, which was shown in randomized, controlled trials to be associated with a 50 percent increase in cesarean section rates and a 23 percent increase in operative vaginal deliveries (14). The nurse can appropriately respond to fetal distress by repositioning the laboring woman, administering oxygen, or adjusting the rate of oxytocin, activities that may reduce fetal distress and associated cesarean sections. The nurse can transmit the woman's wishes regarding care to the entire team, which could lead to a reduction in anxiety and consequent cesarean section, and can also employ various noninvasive pain control methods. In conjunction with these methods of pain control, a nurse can encourage or discourage use of epidural analgesia by the laboring woman; in randomized, controlled trials epidural analgesia is associated with an elevenfold increase in cesarean sections, a doubling of oxytocin augmentation, and a 60 percent increase in operative vaginal births (15). An experienced intrapartum nurse trained in supportive care techniques can provide information about labor and birth that may lessen maternal anxiety and the likelihood of a consequent cesarean section.

We designed a randomized trial to examine the effect of one-to-one intrapartum nursing care on total cesarean section rate, cesarean section due to cephalopelvic disproportion or failure to progress, epidural analgesia, oxytocin stimulation, admission to the neonatal intensive care unit, duration of labor, instrumental delivery, and perineal trauma.

Methods

Subjects

The study was conducted at the Sir Mortimer B. Davis-Jewish General Hospital, a 637-bed tertiary care hospital at McGill University in Montreal, Quebec, with 4000 births per year. Approval was given by the hospital research ethics committee before recruitment of participants. Study women were recruited from the intrapartum unit and randomized in blocks of eight, using a list of computer-generated random numbers. Group assignments were placed in sequentially numbered, sealed, opaque envelopes.

Although blinding of the subject and the attending health professionals to the allocated intervention was not possible, guidelines were drafted to keep the recruitment process as neutral as possible. Outcome data were not collected by clinical staff, and self-administered rather than interviewer-assisted questionnaires were used. Furthermore, research staff were instructed by the investigators to review nurses' notes after other data from medical records were collected to delay knowledge of group assignment until most data were collected. Only women assigned to the experimental group received care from the one-to-one nurses. In addition, these nurses were asked not to discuss the specifics of the intervention with any intrapartum unit staff.

Eligibility criteria were established before initiation of the study, and were applied at the time of randomization. Inclusion criteria were nulliparity, singleton, more than 37 weeks' gestation, and in labor (experiencing regular painful contractions $\leq$5 min apart). Exclusion criteria were scheduled cesarean section, scheduled induction, intrauterine growth retardation, preeclampsia, presence of paid labor support, cervical dilatation more than 4 cm, nonreactive nonstress test, and absence of fetal heart tones. Intrapartum unit nurses recruited women into the study, completed baseline data forms, and contacted the on-call nurse if the woman was assigned to the one-to-one group. In addition, they recorded reasons for ineligibility and nonparticipation.

Intervention

The intervention consisted of almost continuous one-to-one nursing care from the time of randomization until one hour after birth. During this time, in addition to the usual intrapartum care (including fetal monitoring and intravenous regulation), the nurse provided physical comfort, emotional support, and instruction on relaxation and coping techniques to the woman; gave support to the expectant father; contacted the attending physician; contacted the anesthesiologist when appropriate; and updated the unit staff on the

progress of labor. Physical comfort measures included applying cold or warm compresses, assisting with bathing or shower, changing linen, positioning for comfort, massage, reassuring touching, and assisting with ambulation. Support of the father or partner varied according to the couples' wishes and depending on how active a role he or she wanted to assume. Emotional support consisted of reassurance, encouragement, praise, and distraction.

One-to-one nurses could take up to 20 minutes out of the room for meals and up to 10 minutes during each 4-hour period for breaks. In the case of labors lasting more than 10 hours from the time of randomization, the nurse could either remain with the laboring woman or call in another supportive nurse to replace her.

Nurse Participants

Nurses participating in the study were required to possess a license to practice nursing (RN) in Quebec, be bilingual (English and French), have at least one year's experience in an intrapartum unit, be acceptable to the intrapartum unit leadership, and be competent in fetal heart assessment as judged by the clinical nurse educator from the intrapartum unit. These are the criteria normally used to hire new staff in the intrapartum unit of SMBD–Jewish General Hospital. To avoid contamination of the control group with the experimental intervention, intrapartum unit staff of the hospital were not eligible to be hired into these positions.

During the 30-hour initial training period and the quarterly refresher workshops, nurses hired to provide the experimental intervention were asked to do a critical review of the existing scientific literature concerning the effects of nursing and medical practices on labor. Methods to incorporate nursing care changes arising from them were then sought and fostered. Specific topics of discussion included stress and pain management, use of physical comfort measures, and relaxation and coping techniques. The general approach to care that was suggested was to determine and respond to the couples' wishes, concerns, and learning needs for labor and birth.

Depending on the census, staff nurses working in the intrapartum unit are usually assigned to two patients at a time, normally one in early labor and the other near delivery. Labor support techniques provided to women in the control group during the trial varied by nurse, because they are not standardized on the unit.

Data Collection

One-to-one nurses were required to record the labor support techniques that were used with each woman. Consistency of approach was monitored by reviewing the one-to-one nursing care records weekly at the outset of the study and at 2- to 3-week intervals thereafter. To capture variation in obstetric care that may have been associated with times of the day or days of the week, the labor support nurses were on call at various times (not 24 hrs/day, 7 days/wk) to all three shifts and all days of the week.

All outcomes were assessed by medical record review. The primary outcome was overall cesarean section rate. We estimated a required sample size of 208 subjects per group to detect, with a power of 0.75, a reduction of one-half (from 20 to 10%) in total rate of cesarean sections. This level of reduction was seen in previous studies of lay support (10). Secondary outcomes included cesarean section due to cephalopelvic disproportion or failure to progress, epidural analgesia, oxytocin stimulation, admission to the neonatal intensive care unit, duration of labor (from time of randomization to time of birth), instrumental delivery (forceps or vacuum extraction), and perineal trauma (episiotomy or second- or higher degree tear). Collected data were reviewed by one of the investigators (KW) for completeness and consistency within a single data form and among data forms, and were corrected against the medical record. Discrepancies in indication for cesarean section were reviewed by an independent clinician blinded to group assignment, who made the final determination; this occurred in only three cases. Once each subject's record was thought to be complete, data coding and computer entry began, the accuracy of which was assured by comparing the computerized data with the original data for all outcomes and a 10 percent random sample of other data, and by reentering the data when discrepancies occurred.

Statistical Analysis

All analyses were by intention-to-treat, so that subjects were analyzed according to which group they were assigned by the randomization procedure, regardless of the care they actually received. Differences in group means were calculated for continuous outcomes with their corresponding 95 percent confidence intervals. (These include all the information necessary for those interested in statistical significance testing, but offer additional information concerning likely effect sizes.) Relative risks (RR) and 95 percent confidence intervals (CI) were calculated for binary outcomes. Alpha was set at 0.05; no adjustments for multiple testing were made. Estimates for variables with missing values were calculated, excluding the subject with the missing data in the analysis of the particular variable, rather than using imputation procedures, which would have required additional assumptions. Secondary multivariate analyses were conducted to adjust for differences in

baseline characteristics. SAS PC (17) was used for all analyses.

Results

Of the 2387 nulliparous women admitted to the intrapartum unit from January 17, 1993, to July 17, 1994, 50 declined to participate, 413 entered the study, and 1924 were not recruited, of whom 955 did not meet medical inclusion criteria. Medical criteria were met by 317 women who did not meet other criteria, including those more than 4 cm cervical dilatation on admission to the unit ($n = 292$), inability to understand the consent form due to language ($n = 14$), and paid labor support person in attendance ($n = 11$). Entry criteria were met by 652 women, but they were not recruited for other reasons, including no nurse on call ($n = 563$), and recruiters forgot or were too busy to recruit ($n = 89$). Of the 413 women who entered the study, 209 were randomized to the experimental group and 204 to the control group. Of the experimental group women, 198 received the intervention and 11 did not (in 2 cases the women gave birth before the nurse arrived, and in 9 the intervention nurses were unavailable).

Table 1 shows a comparison of participants receiving one-to-one nursing care with usual care recipients on several baseline characteristics. Hypotheses of group differences were not tested, because any differences arising between randomized groups were as-

Table 1. Baseline Characteristics of Experimental versus Control Group Subjects at Randomization

Characteristic	*One-to-One Nursing Care (n = 209)*		*Usual Nursing Care (n = 204)*	
	No.	*(%)*	*No.*	*(%)*
Presence of labor partner	206	(98.6)	198	(97.1)
Spouse	175	(83.7)	176	(86.3)
Mother or sister	21	(10.1)	18	(8.8)
Friend	10	(4.8)	4	(2.0)
None	3	(1.4)	6	(2.9)
Epidural analgesia before randomization	36	(17.2)	41	(20.1)
Oxytocin stimulation	55	(26.3)	45	(22.1)
Membranes rupture before randomization	128	(61.1)	126	(61.8)
Family practitioner at birth	11	(5.3)	19	(9.3)
Attendance at prenatal classes	104	(49.8)	119*	(59.2)
Religion				
Roman Catholic	99	(47.4)	96	(47.1)
Jewish	34	(16.3)	27	(13.2)
Protestant	22	(10.5)	20	(9.8)
Greek Orthodox	17	(8.1)	11	(5.4)
None	7	(3.4)	13	(6.4)
Other	30	(14.4)	37	(18.1)
Income (Canadian dollars)				
$0–24,999	51	(24.4)	60	(29.4)
$25,000–49,999	43	(20.6)	44	(21.6)
$50,000–74,999	35	(16.8)	29	(14.2)
$75,000–99,999	16	(7.7)	16	(7.8)
$100,000 or more	11	(5.3)	7	(3.4)
$Not reported	53	(25.4)	48	(23.5)
Living with a partner	186	(89.0)	181	(88.7)
Mean maternal age (yrs) (SD)	27.6	(4.6)†	27.8	(5.0)‡
Mean maternal education (yrs) (SD)	13.7	(3.2)†		
Mean maternal height (cm) (SD)	163.2	(6.6)†	162.2	(6.9)*
Mean maternal weight gain (kg) (SD)	16.6	(5.0)*	15.6	(4.9)†
Mean infant birthweight (g) (SD)	3425	(474)	3399	(420)
Mean gestational age (wks) (SD)	39.8	(1.1)	39.8	(1.1)
Mean cervical dilatation (cm) (SD)	2.7	(1.0)*	2.7	(1.0)
Mean time from hospital admission to randomization (hrs) (SD)	5.0	(3.8)‡	5.1	(4.1)‡

* *Data missing for 3 women.*
† *Data missing for 2 women.*
‡ *Data missing for 1 woman.*

sumed to be due to chance. The groups were similar for most characteristics, including presence of a labor partner, epidural analgesia at randomization, oxytocin stimulation, ruptured membranes, presence of family practitioner at birth, maternal height, maternal weight gain during pregnancy, gestational age, and cervical dilatation. Compared with control group women, 10 percent fewer experimental group women attended prenatal classes, and their infants weighed an average of 26 g more at birth.

Table 2 shows primary results. A trend was detected toward a 17 percent reduction in risk of oxytocin stimulation with one-to-one nursing support (RR of experimental vs control = 0.83; 95% CI = 0.67, 1.04). No other important trends or significant differences were seen. The relative risk for total cesarean section was 0.86 (0.54, 1.36); cesarean section due to cephalopelvic disproportion or failure to progress, 1.02 (0.59, 1.77); epidural analgesia postrandomization, 0.96 (0.84, 1.09); admission to the neonatal intensive care unit, 1.46 (0.67, 3.18); instrumental delivery, 1.06 (0.74, 1.53); perineal trauma, 0.98 (0.89, 1.08); and duration of labor from randomization, an average of 18 minutes shorter in the one-to-one group (−60, 24). Multivariate analyses showed no evidence of confounding by the two characteristics differing at baseline. Since one of the concerns of clinicians in reducing the cesarean section rate is a consequent rise in negative outcomes to newborns, we looked at the specific reasons for neonatal intensive care unit admission. No clinically important differences were found in any reasons for admission, although the event rates in both groups were small (0–2%) and confidence intervals wide, suggesting caution in their interpretation.

After the study began, additional studies of continuous labor support were published in which effects were seen in outcomes not included in our original study protocol. We began to gather data on these outcomes during the trial. Results of these and other relevant secondary effects are shown in Table 3. No clinically important differences were noted in outcomes for any analgesia or anesthesia, Apgar score at 1 minute, Apgar score at 5 minutes, and urinary catheterization postpartum.

Discussion

Limitations of this study include the potential for analytical bias due to our inability to blind health professionals to group assignment, the lasting effects of care initiated before randomization, the possibility of suboptimum support by one-to-one nurses, and reduced statistical power. Because intrapartum unit nursing staff knew when a woman was assigned to the usual care group, they could have purposely spent more time with those women in an effort to ensure that effects of usual care were shown in a favorable light. In a related study (16), however, we found that intrapartum unit nurses spent an average of only 21.4 percent of their time in the rooms of women in labor. This figure was based on 3367 observations of nurses' work, randomly selected within strata defined by shift and day of the week over a 3-week period that included the last 2 weeks of this trial. These data suggest that care

Table 2. Comparison of Primary Effects on One-to-One versus Usual Care Groups

Outcome	*One-to-One Nursing Care (n = 209)* *No.*	*(%)*	*Usual Nursing Care (n = 204)* *No.*	*(%)*	*RR or Mean Difference (95% CI)*
Total cesarean section	29	(13.9)	33	(16.2)	0.86 (0.54, 1.36)
Cesarean section for cephalopelvic disproportion or failure to progress	23	(11.0)	22	(10.8)	1.02 (0.59, 1.77)
Postrandomization epidural analgesia	139	(66.5)	142	(69.6)	0.96 (0.84, 1.09)
Postrandomization oxytocin stimulation	82	(39.2)	96	(47.1)	0.83 (0.67, 1.04)
Neonatal intensive care unit admission	15	(7.2)	10	(4.9)	1.46 (0.67, 3.18)
Instrumental delivery (forceps, vacuum extraction)	48	(23.0)	44	(21.6)	1.06 (0.74, 1.53)
Perineal trauma	168*	(81.4)	166†	(83.0)	0.98 (0.89, 1.08)
Mean duration of labor from randomization (hrs) (SD)	9.1	(4.1)	9.4	(4.7)	−0.3 (−1.0, 0.4)

** Data missing for 2 women.*
† Data missing for 4 women.
RR = relative risk; CI = confidence interval.

Table 3. Comparison of Secondary Effects on One-to-One versus Usual Care Groups

Outcome	*One-to-One Nursing Care (n = 209)* No. (%)	*Usual Nursing Care (n = 204)* No. (%)	*RR or Mean Difference (95% CI)*
Any postrandomization analgesia or anesthesia	141 (67.5)	142 (69.6)	0.98 (0.86, 1.11)
Mean Apgar at 1 min (SD)	8.0 (1.4)	8.3 (0.9)	−0.3 (−0.5, −0.1)
Mean Apgar at 5 min (SD)	8.9 (0.9)	9.0 (0.8)	−0.1 (−0.3, 0.1)
Postpartum urinary catheterization	28* (13.5)	26* (12.8)	1.05 (0.64, 1.73)

** Data missing for 1 woman.*
RR = relative risk; CI = confidence interval.

given to the usual care group was not intentionally altered.

Five hours were spent in the intrapartum unit before randomization because all inclusion criteria were not yet met. The women were randomized once they were in active labor. Some components of care initiated before randomization may have reduced the effectiveness of one-to-one nurse labor support, including epidural analgesia and oxytocin stimulation administered to 17.2 and 26.3 percent, respectively, of women in the experimental group. The tertiary care nature of a North American university hospital setting appears to have an important impact on care provided during the initial 5 hours, even though our study criteria defined these women as experiencing normal, uncomplicated labors. Furthermore, epidural analgesia is available for almost 24 hours a day, as is common in many hospitals in North America, and women are often asked at the time of admission, and several times thereafter, if they plan to have epidural analgesia; this offer could have undermined the effectiveness of nurse labor support.

The nurses providing one-to-one support may not have provided optimum support. They were required to have a minimum of one year of intrapartum unit experience, which could suggest that they were technically oriented. These nurses, however, voiced a greater interest in the supportive nature of their work than in the technical aspects, which was a primary motivation for participating in this trial. That interest was fostered and developed through a training program and quarterly refresher workshops on supportive care. We know from the records of care that support was provided in various forms for the duration of labor, although these reports of care were not validated and quality of care was not verified. We thought that the validation procedures themselves would be intrusive and interfere with the support being given. We know that the distribution of supportive care activities was similar among the one-to-one nurses and similar to the distribution of such activities by usual intrapartum unit nurses, although the time the one-to-one nurses spent with the women was much greater.

The enrollment of 413 women in this study is surpassed by only two other trials of labor support, a European multicenter trial (4) and a doula support trial in Guatemala (11). Limited statistical power is demonstrated, however, by the wide confidence intervals around some of the estimates of effect. More women could not be recruited into the study because of the absence of 24-hour coverage by one-to-one nurses. The on-call nature of the work resulted in nurses being reluctant to make themselves available for too many hours because a salary could not be guaranteed during this time due to limited resources.

Although we cannot definitely confirm previous trial results partly because of limited statistical power, three other issues are also important: first, the absence of information on the availability of epidural analgesia for women in most previous studies; second, the absence of information on the presence or absence of labor partners in most previous studies, which may differ from whether or not the hospital permits someone to be with laboring women, although this may be a useful way to group the studies for meta-analyses; and third, of most importance, the absence of any studies of professional nurse support, which would be most relevant to United States and Canadian intrapartum units as currently structured.

When compared with reports of previous randomized controlled trials of continuous labor support, this trial is likely to be the most relevant to current North American intrapartum practice, since it is the only study known to us that looks at the effect of nursing presence, nurses being the group of professional caregivers most readily available to support women in labor in North American intrapartum units; since partners were present in this study; and since epidural analgesia was readily available. Therefore, these re-

sults showing trends in the reduction of oxytocin stimulation due to one-to-one intrapartum nurse labor support are useful in discussing the implementation, in a North American setting, of recommendations from the Society of Obstetricians and Gynaecologists of Canada (1) and of those by Thornton and Lilford (3) for continuous professional support during labor.

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