Effectiveness of Nurses as Providers of Birth Labor Support in North American Hospitals

A Randomized Controlled Trial

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Context North American cesarean delivery rates have risen dramatically since the 1960s, without concomitant improvements in perinatal or maternal health. A Cochrane Review concluded that continuous caregiver support during labor has many benefits, including reduced likelihood of cesarean delivery.

Objective To evaluate the effectiveness of nurses as providers of labor support in North American hospitals.

Design Randomized controlled trial with prognostic stratification by center and parity. Women were enrolled during a 2-year period (May 1999 to May 2001) and followed up until 6 to 8 postpartum weeks.

Setting Thirteen US and Canadian hospitals with annual cesarean delivery rates of at least 15%.

Participants A total of 6915 women who had a live singleton fetus or twins, were 34 weeks' gestation or more, and were in established labor at randomization.

Intervention Patients were randomly assigned to receive usual care (n=3461) or continuous labor support by a specially trained nurse (n=3454) during labor.

Main Outcome Measures The primary outcome measure was cesarean delivery rate. Other outcomes included intrapartum events and indicators of maternal and neonatal morbidity, both immediately after birth and in the first 6 to 8 postpartum weeks.

Results Data were received for all 6915 women and their infants (n=6949). The rates of cesarean delivery were almost identical in the 2 groups (12.5% in the continuous labor support group and 12.6% in the usual care group; $P=.44$). There were no significant differences in other maternal or neonatal events during labor, delivery, or the hospital stay. There were no significant differences in women's perceived control during childbirth or in depression, measured at 6 to 8 postpartum weeks. All comparisons of women's likes and dislikes, and their future preference for amount of nursing support, favored the continuous labor support group.

Conclusions In hospitals characterized by high rates of routine intrapartum interventions, continuous labor support by nurses does not affect the likelihood of cesarean delivery or other medical or psychosocial outcomes of labor and birth.

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As a consequence of widespread recognition of the health, economic, and social costs of the rising cesarean delivery rates in the United States, both *Healthy People 2000* and *Healthy People 2010* included targets of lower cesarean rates.[1,2] Considerable research attention has been given to the influence of physician behavior, institutional variations, patient characteristics, and types of insurance coverage.[3-5] The potential impact of the quality of intrapartum nursing care on the cesarean delivery rate has received little attention, although a large, retrospective, observational study concluded that the nurse who provided intrapartum care was an independent predictor of the risk of cesarean delivery.[6]

See also Patient Page

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Labor support is a term used to describe the presence of an empathic person who offers advice, information, comfort measures, and other forms of tangible assistance to help a woman cope with the stress of labor and birth.[7] A Cochrane Review, first published in 1995, currently includes 14 trials involving over 5000 women, conducted in a wide range of settings in 10 countries.[7] Support was provided by a variety of women: midwives, student midwives, nurses, doulas, lay women, or female relatives. Continuous labor support was associated with significant reductions in the likelihood of cesarean delivery (relative risk [RR], 0.80; 95% confidence interval [CI], 0.68-0.93), operative vaginal delivery (RR, 0.81; 95% CI, 0.72-0.92), use of intrapartum analgesia or anesthesia (RR, 0.87; 95% CI, 0.83-0.92), and a 5-minute Apgar score of less than 7 (RR, 0.50; 95% CI, 0.29-0.89).

The results of the Cochrane Review have been widely disseminated in practice guidelines in the United States, Canada, and the United Kingdom, which recommend continuous caregiver support for all women during labor.[8-10] However, 3 issues were barriers to implementation of the guidelines in North American hospitals. The first issue was generalizability. The largest effect sizes were in the trials of labor support in settings where family members were not permitted, support was provided by a woman who was not part of the hospital staff, and routine intrapartum medical intervention rates were low.[7] In the United States and Canada, 1 or more family members are usually present during labor, and interventions such as continuous electronic fetal monitoring, oxytocin infusion, and epidural analgesia are often routine.

The second issue was the cost of staffing labor wards for 1:1 patient-nurse ratios. In all of the trials in the Cochrane Review,[7] the continuous support was provided by caregivers who were not part of the existing staff complement. Adding additional staff, to implement a policy of continuous support for all laboring women, would have considerable cost implications under current conditions, where staffing is usually based on an average patient-nurse ratio, despite the fact that the patient census is highly variable and largely unpredictable.[9]

The third issue concerns the providers of labor support. Many nurses have not received formal training in labor support techniques,[11] and providing labor support was but one part of the labor nurse's role. Work sampling studies have found that the average labor nurse spent 6% to 24% of work time in supportive care activities.[11-13]

A pragmatic trial was needed, to determine the effectiveness of support by staff nurses with training in labor support, within a system of staffing that was sufficiently flexible to allow continuous support without adding staff.

METHODS

The Nursing Supportive Care in Labor trial was a multicenter, randomized controlled trial with prognostic stratification for parity and hospital. Prior to conducting the study, nurses at each participating hospital who volunteered were trained in labor support to ensure 24-hour availability throughout the trial. The 2-day training program was conducted by an expert labor nurse and doula trainer. Prior to and throughout the trial, the nurses had opportunities to practice their skills, meet regularly with their colleagues for case reviews, and communicate with the labor support trainer and with each other on an electronic listserv. The principal investigator (E.D.H.) visited each center, for formal and informal meetings with staff, at which she stressed the importance of maintaining clear distinctions between the nursing care provided to the 2 study groups. Periodic videoconferences and teleconferences promoted compliance and maintained morale. A consultant visited each hospital and recommended changes that would allow more efficient staff deployment, thereby allowing women to have continuous nursing support during labor, without jeopardizing the safety of other patients or requiring additional nursing staff.

The study was approved by the research ethics committees at the University of Toronto and all participating hospitals. Women gave informed consent before being enrolled and were informed of the uncertainty about the benefits of continuous nursing support compared with usual nursing care.

Eligibility Criteria

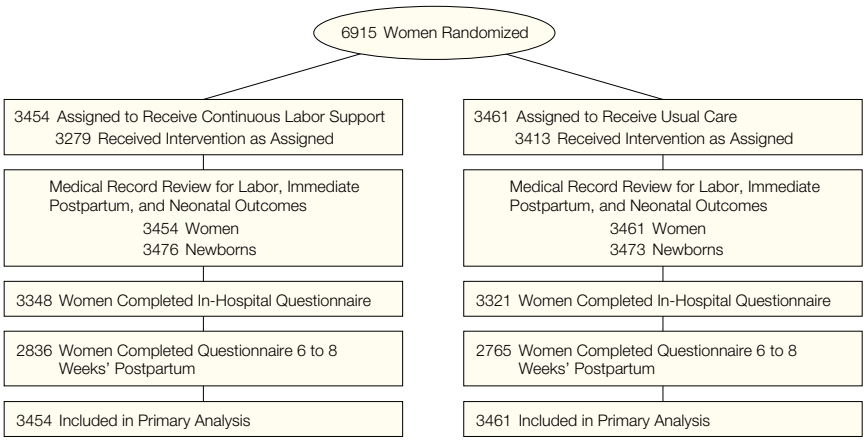
Participating hospitals had to have overall cesarean delivery rates of at least 15%, a 24-hour epidural analgesia service, and a willingness to introduce flexibility to their staffing systems in delivery suites. Women were eligible for the study if they had a live singleton fetus or twins, no contraindications to labor, were competent to give informed consent, and in established labor but second stage was not imminent. Women were not eligible if the gestational age was less than 34 weeks at labor onset or if they were planning a cesarean delivery, were already enrolled in a labor/delivery management study and the study protocols were incompatible, were expecting continuous support from either midwives or doulas/labor coaches, or were at such high-risk that a 1:1 patient-nurse ratio was deemed medically necessary.

Treatment Protocol

Women who consented to participate were randomly assigned to either continuous support by a trained labor support nurse (experimental group) or usual care by a nurse who had not received the labor support training (control group). Randomization was centrally controlled with the use of a computerized randomization program at the data coordinating center, accessible by means of a touch-tone telephone. For women in the experimental group, the nurse was expected to provide continuous support to the woman for a minimum of 80% of the time from randomization to delivery. The 80% minimum was chosen to reflect the realities of everyday nursing practice, in which nurses need time for meal and rest breaks, and unit emergencies may dictate temporary changes to nurses' assignments. For women in the control group, the usual nursing care was provided. Usual nursing care depended on many factors,

including the stage of labor, the condition of the mother and fetus, and the nurses' workload. The nurses were part of the regular staffing complement on that shift. When the shift ended, if the woman had not delivered, the appropriate nurse (eg, with/without training in labor support) from the next shift took over the woman's care. Only the amount and nature of nursing support varied between groups; all other nursing and medical care was in accordance with usual hospital practices and policies.

Figure. Flow Diagram



Outcomes

Study outcomes were derived from those reported in the Cochrane Review.[7] The primary outcome was cesarean delivery. Secondary outcomes were epidural analgesia, length of time from randomization to delivery, spontaneous vaginal delivery, women's reports of personal control during childbirth, and newborns with evidence of intrapartum asphyxia. Other outcomes included indicators of physical and psychological maternal morbidity (in-hospital and within 6-8 postpartum weeks), other perinatal morbidities up to 6 to 8 weeks, women's evaluations of their experiences, and costs.

Information about medical outcomes was abstracted from the medical records by the center research nurses. Because the data collection form included a question about compliance (eg, whether a nurse with training in labor support provided continuous support to the participant), research nurses may not have been fully blinded during retrieval of medical record data. However, the primary and other medical outcomes were objective data that were recorded in the medical records as part of routine practice. Audits of selected medical records were conducted at every site during the 2-year recruitment period to assess and promote accuracy of data abstraction. Physicians were not explicitly informed of their patients' group assignments, but they could not be blinded to the continuous presence of a nurse.

Trial participants completed 2 questionnaires. The Labor Support Questionnaire was completed before hospital discharge. Its purpose was to determine if the 2 study groups received different amounts and types of nursing support. The Labor Support Questionnaire consisted of 23 items concerning physical comfort measures (11 items), emotional support (6 items), information/advice (3 items), and advocacy (3 items). Participants were asked, "How often did a nurse do this for you or to you?" and item scores were 1 (never), 2 (occasionally), and 3 (often). The second questionnaire, completed between 6 to 8 postpartum weeks, assessed maternal physical and psychological morbidity, neonatal morbidity, breastfeeding, and views of their birth experiences. Two validated, summated measures, the Labour Agentry Scale and the Edinburgh Postnatal Depression Scale, assessed women's sense of control during labor and postpartum depression, respectively.[14,15] An Edinburgh Postnatal Depression score of more than 12 is strongly associated with postpartum depression.[15] A systematic review concluded that a sense of personal control is an important psychological outcome of the birth experience.[16] Other questions, developed and used in a prior multicenter trial,[17] asked women about their future preferences for labor support and their likes and dislikes regarding participation in the study. Future preferences, to the extent that they differ from one's experience, are indicators of dissatisfaction.[16,18] The questions about likes and dislikes regarding study participation included opportunities to indicate pleasure or disappointment in their study group assignment.

Statistical Analysis

Surveys of the participating hospitals during protocol development indicated that their overall cesarean rates ranged from 18% to 25%, and the cesarean rates for women who would meet trial eligibility criteria were 11% to 13%. The sample size was calculated to provide 80% power to detect a reduction of 2 percentage points in the cesarean rate for those who would meet trial eligibility criteria. This reduction would represent a 15% relative change in the proportion of cesarean to vaginal delivery, which is slightly more conservative than the 20% reduction in RR found in the Cochrane meta-analysis.[7] A 1-sided test of hypothesis was chosen for the primary outcome, because there was neither any empirical evidence nor a theoretical basis for considering support as potentially harmful, and type I error protection was unnecessary since the health care implications of any result other than benefit would be the same (no change in practice would be warranted). A second 1-sided test was used to rule out the possibility of harm. Tests of significance for all other outcomes were 2-sided. The total required sample size was 6728.

The results were analyzed according to the intention-to-treat; all women who were randomized were included in the main analyses. The groups were compared via contingency table χ^2 analyses for categorical and binary variables. Due to potential skewness with continuous variables such as time durations, Wilcoxon rank sum tests were used. $P<.05$ for the primary outcome, $P<.01$ for the secondary outcomes, and $P<.001$ for the other outcomes were considered to indicate statistical significance. Logistic regression explored interaction effects between baseline variables and cesarean rate, using the Wald χ^2 statistic. All statistical procedures were performed using SAS version 8.2 (SAS Institute, Cary, NC).

Table 1. Baseline Characteristics of Women in the Continuous Labor Support and Usual Care Groups*

Characteristic	Women, No. (%)	
	Continuous Labor Support (n = 3454)	Usual Care (n = 3461)
Age, mean (SD) [range], y	29.4 (5.5) [15.2-45.8]	29.5 (5.7) [15.2-47.7]
Race/ethnicity		
White	2561 (74.2)	2594 (75.0)
Asian/Pacific Islander	335 (9.7)	333 (9.6)
Black	158 (4.6)	130 (3.8)
Hispanic	182 (5.3)	183 (5.3)
Native American/Native Canadian	124 (3.6)	137 (4.0)
Other	94 (2.7)	83 (2.4)
Unknown	0	1 (0)
Education		
<High school	301 (8.7)	300 (8.7)
Completed high school	965 (27.9)	997 (28.8)
Postsecondary	2140 (62.0)	2110 (61.0)
Unknown	48 (1.4)	54 (1.6)
Married/common-law	3196 (92.5)	3180 (91.9)
Parity		
0	1701 (49.3)	1694 (49.0)
1	1121 (32.5)	1083 (31.3)
2	440 (12.7)	485 (14.0)
>2	192 (5.6)	199 (5.8)
Gestational age, wk		
34-36	157 (4.6)	125 (3.6)
37-40	2831 (82.0)	2811 (81.2)
≥41	466 (13.5)	525 (15.2)
Previous cesarean delivery	188 (5.4)	153 (4.4)
Twin pregnancy	22 (0.6)	12 (0.3)
Diabetes mellitus	122 (3.5)	146 (4.2)
Hypertension	160 (4.6)	182 (5.3)
No prenatal care	3 (0.1)	7 (0.2)
Cervical dilation, cm†		
<3	706 (20.4)	718 (20.8)
3-6	1732 (50.1)	1772 (51.2)
>6	72 (2.1)	80 (2.3)
Unknown	944 (27.3)	891 (25.7)
Labor onset		
Spontaneous	2567 (74.3)	2515 (72.7)
Induced	887 (25.7)	946 (27.3)
Reasons for induction‡		
Postterm	336	403
Pregnancy complication	359	363
Elective	281	293
Augmented after spontaneous onset of labor	245 (7.1)	238 (6.9)
Epidural analgesia	217 (6.3)	196 (5.7)

*Percentages may not sum to 100 due to rounding.
†Assessed within 1 hour prior to randomization.
‡More than one reason could be given.

RESULTS

Thirteen hospitals in the United States and Canada participated in the trial (9 were tertiary care and 4 were community hospitals). The annual birth census at the hospitals ranged from 2200 to 8500. Two US hospitals were in the East, 2 in the Midwest, and 1 in the Southwest. The 8 Canadian hospitals were geographically distributed from coast to coast. We enrolled 6915 women between May 19, 1999, and May 25, 2001. Data were received for all 6915 women, of whom 3454 were assigned to the continuous labor support group and 3461 to the usual care group (FIGURE). For reasons of cost and feasibility, we did not collect data on the approximately 60 000 eligible but nonparticipating women. However, center staff informed us that women rarely refused to participate. The main reason for nonenrollment of eligible women was logistical: either the unit staff were too busy or an intervention nurse was unavailable and therefore a woman could not be randomized.

The mean (SD) age of the sample was 29.5 years (5.6), ranging from 15 to 48 years (TABLE 1). Although the majority were white, the sample represented a variety of racial and ethnic groups, including black, Asian, Hispanic, and Native American/Canadian. More than 60% had some postsecondary education. Slightly more than 49% (n=3395) were giving birth for the first time. Labor onset was spontaneous for 73.5% (n=5082). At the time of enrollment, 7.0% were undergoing augmentation of labor and 6.0% were receiving epidural analgesia. Thirty-four women (0.5%) were known to have twin pregnancies and 4.9% had had a prior cesarean delivery.

The appropriate form of intrapartum nursing care was provided to 94.9%

(n=3279) of the experimental group and 98.6% (n=3413) of the control group. The median length of time from admission to delivery was 8.1 hours (TABLE 2). The median length of time from randomization to delivery was 6.6 hours. In 73.5% of the sample (n=5080), cervical dilation had been assessed in the hour prior to randomization; for 97% of these women, randomization occurred in early or early active labor. More than 96% of the participants completed the Labor Support Questionnaire. For each of the 23 nursing support activities, women in the experimental group reported more nursing support than women in the control group ($P<.001$ for each comparison).

Maternal, Perinatal, and Neonatal Outcomes

The rate of cesarean delivery was almost identical in the 2 groups: 432 (12.5%) in the continuous labor support group and 437 (12.6%) in the usual care group ($P=.44$). Reasons for cesarean delivery are listed in Table 2. Women in the continuous labor support group were less likely to have continuous electronic fetal monitoring, although the absolute difference was small (75.0% vs 79.2% in the usual care group; $P<.001$). There were no other significant differences in maternal events during labor, delivery, or the in-hospital postpartum period that met our preset criteria for statistical significance, including length of time from randomization to delivery, length of time from initiation of epidural analgesia to delivery, spontaneous vaginal delivery, perineal trauma, health problems during the postpartum hospital stay, or length of postpartum hospital stay (Table 2). There were no significant differences in immediate neonatal outcomes, including evidence of intrapartum asphyxia, need for higher level of nursery care, or length of hospital stay (TABLE 3). All newborns were born alive; there were 3 neonatal deaths.

Outcomes at 6 to 8 Postpartum Weeks

The 6 to 8 postpartum week questionnaire response rate was 81% (82.1% in

Table 2. Labor and Delivery Events After Randomization*

Event	No. (%) Continuous Labor Support (n = 3454)	No. (%) Usual Care (n = 3461)	*P* Value†
Labor augmentation	1040 (30.1)	942 (27.2)	.008
Medication for pain relief‡			
Epidural	2282 (66.1)	2352 (68.0)	
Intramuscular/intravenous opioid	946 (27.4)	933 (27.0)	
Nitrous oxide	459 (13.3)	513 (14.8)	
Combined spinal/epidural	49 (1.4)	54 (1.6)	
Pudendal/paracervical/saddle block	41 (1.2)	38 (1.1)	
Spinal	26 (0.8)	34 (1.0)	
General	8 (0.2)	13 (0.4)	
Other	5 (0.1)	1 (0.03)	
Regional analgesia/anesthesia§	2349 (68.0)	2436 (70.4)	.03
Continuous electronic fetal heart monitoring	2590 (75.0)	2741 (79.2)	<.001
Method of delivery			
Cesarean delivery	432 (12.5)	437 (12.6)	.44
Reasons‡			
Dystocia	351	338	
Fetal heart rate abnormality	118	145	
Failed induction	30	31	
Breech	10	10	
Abnormal bleeding	4	14	
Suspected chorioamnionitis	9	6	
Cord prolapse	2	4	
Other	5	4	
Operative vaginal delivery	541 (15.7)	561 (16.2)	.54
Vacuum	299 (8.7)	316 (9.1)	
Low forceps	149 (4.3)	161 (4.6)	
Mid forceps	93 (2.7)	84 (2.4)	
Spontaneous vaginal delivery	2481 (71.8)	2463 (71.2)	.54
Perineal trauma‖	1828 (52.9)	1860 (53.7)	.50
Episiotomy	894	919	
Second-degree laceration	868	873	
Third- or fourth-degree laceration	186	207	
Health problems during postpartum stay			
Fever¶	23 (0.7)	16 (0.5)	
Antibiotics	415 (12.0)	419 (12.1)	
Hemorrhage#	93 (2.7)	91 (2.6)	
Transfusion	12 (0.3)	17 (0.5)	
Other	39 (1.1)	30 (0.9)	
Time to delivery, median (IQR), h			
Admission to delivery	8.0 (4.9-12.3)	8.2 (4.8-12.5)	
Randomization to delivery	6.6 (3.9-10.7)	6.6 (3.9-10.5)	.89
Active labor to delivery	7.1 (4.4-10.8)	6.9 (4.3-10.6)	
Epidural analgesia to delivery	4.5 (2.6-7.3)	4.5 (2.6-7.3)	
Delivery to discharge	47.4 (39.9-59.7)	47.3 (39.9-60.2)	.95

*Percentages may not sum to 100 due to rounding. For cases with twins, if one twin had an outcome (eg, cesarean delivery), the case was considered to have that outcome, with one exception, spontaneous vaginal delivery, which had to have occurred with both twins.
†Presented only for prespecified comparisons. Except for the primary outcome (cesarean delivery), which was 1-sided, all *P* values were derived from 2-sided tests of significance.
‡More than one may be given.
§Epidural, combined spinal/epidural, or spinal block.
‖Episiotomy and/or laceration requiring suturing.
¶Oral temperature of 38°C or higher on 2 occasions at least 24 hours apart, not including the first 24 hours after delivery.
#Blood volume of 1000 mL or greater.

the continuous labor support group and 79.9% in the usual care group). The median length of time from delivery to completion of the questionnaire was 6.8 weeks; 90% were completed within less than 12 weeks.

A statistically significant difference was noted in mean scores on the measure of experienced control during childbirth, but the actual difference in mean scores was less than 1 point (mean [SD], 54.1 [9.7] for continuous labor support vs 53.2 [9.9] for usual care; $P<.001$). A comparison of the numbers of women who reported low levels of control, defined a priori as 2 SDs or more from the mean, yielded nonsignificant differences (3.4% of the continuous labor support vs 4.3% of the usual care; $P=.10$). Two hundred forty-five women (8.7%) in the continuous labor support group had evidence of postpartum depression compared with 277 women (10.1%) in the usual care group ($P=.08$).

There was no significant difference in the numbers of women reporting they were not breastfeeding at 6 weeks' postpartum (1027 women in the continuous labor support group and 937 women in the usual care group; $P=.25$). In the continuous labor support group, 738 women (26.0%) visited their physicians for a health problem in the first 6 to 8 postpartum weeks, as did 738 (26.7%) in the usual care group. Forty-two women (1.5%) in the continuous labor support group and 39 (1.4%) in the usual care group were admitted to the hospital, and 23 women in each group (0.8%) had surgery. In the continuous labor support group, 120 infants (4.2%) were admitted to the hospital vs 103 (3.7%) in the usual care group.

Indicators of participants' satisfaction with their birth experiences favored the continuous labor support group (TABLE 4). Few women chose "I was not randomized to the group I wanted" (0.4% of the continuous labor support vs 11.4% of the usual care), while 33.7% of the continuous labor support group and 11.0% of the usual care group chose "I was randomized to the group I wanted." Although responses to the question "If you had it to do over again, would you participate in the Nursing Supportive Care in Labor Trial?" favored the continuous labor support group, 91.3% of the usual care group indicated they definitely or probably would participate. While the majority of women (63.4%) in the continuous labor support group would like continuous labor support in a future labor, nearly one half (46.6%) of the group that was randomized to usual care also would prefer continuous labor support the next time.

Table 3. Immediate Neonatal Outcomes*

Measure	Neonates, No. (%)		*P* Value
	Continuous Labor Support (n = 3476)	Usual Care (n = 3473)	
Alive at birth	3476 (100)	3473 (100)	
Sex			
Female	1613 (46.4)	1718 (49.5)	
Male	1863 (53.6)	1754 (50.5)	
Ambiguous	0	1	
Mean (SD) birth weight, g	3474 (488)	3491 (478)	
Apgar score of less than 7			
1-minute	317 (9.1)	367 (10.6)	.04
5-minute	30 (0.9)	25 (0.7)	.50
Resuscitation†	1246 (35.9)	1325 (38.2)	.05
Oxygen	1183	1254	
Bag and mask	275	278	
Intubation and/or ventilation	97	121	
Narcotic antagonist	49	37	
Cardiopulmonary	5	5	
Asphyxia‡	60 (1.7)	43 (1.2)	.09
Major congenital anomaly	12 (0.3)	11 (0.3)	
Neonatal death§	2	1	
Higher level of care‖	246 (7.1)	254 (7.3)	.70
Reasons†			
Respiratory distress	174	192	
Suspected sepsis/meningitis	80	66	
Preterm	42	25	
Jaundice	22	26	
Congenital defect	19	28	
Hypoglycemia	17	16	
Major birth trauma	13	10	
Hypotonia	8	7	
Feeding problem	8	5	
Low birth weight	9	1	
Seizures	4	5	
Abnormal level of consciousness	2	5	
Other	16	17	
Length of hospital stay, median (interquartile range), h	47.7 (40.1-61.4)	47.5 (40.1-61.5)	

*All outcomes are reported for individual newborns. In the continuous labor support group, there were 3454 mothers and 3476 newborns (22 sets of twins); in the usual care group, there were 3461 mothers and 3473 newborns (12 sets of twins).
†More than one may be given.
‡Cord blood base deficit of 12 or higher, cord blood pH of less than 7.15, or 5-minute Apgar score of less than 7.
§During postbirth hospital stay. Causes of death were transposition of the great vessels, did not survive heart surgery, died at 12 days of age (n = 1) and hypoxic ischemic encephalopathy, died at 3 days of age (n = 1) for continuous labor support group; found not breathing, possible sudden infant death syndrome, inconclusive autopsy, died at 12 hours of age (n = 1) for usual care group.
‖Intermediate and/or neonatal intensive care nursery.

Additional Analyses

For the primary outcome of cesarean delivery, there were no significant in-

teractions between treatment group and country, center, race/ethnicity, education, parity, pregnancy complications, cervical dilation, onset of labor (spontaneous or induced), epidural analgesia, or use of oxytocin (TABLE 5).

COMMENT

Most of our results are contrary to the current Cochrane Review[7]; continuous labor support by nurses did not affect cesarean delivery rates or other medical or psychosocial outcomes. The one outcome that did differ, participants' evaluations of their experiences, may be either a true treatment difference or a function of the fact that they were not blinded to the intervention. However, in the usual care group, less than 12% reported disappointment with their study group assignment and more than 91% would definitely or probably participate in the trial again, suggesting that disappointment did not exert a large effect on responses.

In trials of behavioral interventions, the inability to blind, the challenges in ensuring that the intervention is applied appropriately, and the possibility of contamination are serious potential threats to validity. Neither the research nurses abstracting medical records nor the patients' physicians were fully blinded. However, since the primary outcomes were objective, it is unlikely that this affected the results. Also, unblinding tends to bias results away from the null hypothesis, which was not the case here.

We took several steps to ensure that the intervention and control conditions were applied appropriately, and we used several measures to assess whether they were. To ensure a strong intervention, the nurses who were trained were volunteers who wished to provide continuous labor support, the training was from an expert, and we used a variety of approaches to reinforce training throughout the trial. Compliance was high with more than 97% of the sample receiving the appropriate form of care. The intervention period began at the appropriate time, when the woman was in early or early-active labor.

It was equally important that the usual care group received usual nursing care. Prior to beginning the trial, we held formal and informal meetings with the nursing staff to explain the importance of retaining 2 distinct study groups throughout the trial. Participants' reports indicated that each of the nursing supportive activities was provided significantly more often to women in the experimental group. As a further check to determine if control nurses began to adopt the behaviors of the intervention nurses, we divided the sample into those recruited in the first year of the trial and those enrolled in the second year; the comparisons of participants' reports of supportive activities yielded the same results.

Another reason for discounting contamination as a factor in the trial results stems from a prior large multicenter trial of a strategy specifically aimed at encouraging nurses to provide more labor support.[19] Twenty hospitals participated in the trial. The intervention at the 10 hospitals in the intervention group involved small groups of nurses who were selected by their peers as opinion leaders and who worked to change their colleagues' practice during a 1-year period. There were

Table 4. Comparisons of Participants' Evaluations of Their Experiences*

	No. (%)		
	Continuous Labor Support (n = 2836)	Usual Care (n = 2765)	*P* Value
What I liked			
Contacts with research staff	944 (33.3)	726 (26.3)	<.001
Randomized to group I wanted	957 (33.7)	304 (11.0)	<.001
Nurses who cared for me	2550 (89.9)	2067 (74.8)	<.001
Few extra demands on my time	914 (32.2)	862 (31.2)	.40
Participation caused me to feel reassured about my health/newborn's health	1076 (37.9)	616 (22.3)	<.001
Helped to answer an important research question	1705 (60.1)	1751 (63.3)	.01
There was nothing I liked	33 (1.2)	73 (2.6)	<.001
Other likes	306 (10.8)	181 (6.5)	<.001
What I disliked			
Contacts with research staff	12 (0.4)	21 (0.8)	.10
Not randomized to group I wanted	11 (0.4)	315 (11.4)	<.001
Nurses who cared for me	49 (1.7)	92 (3.3)	<.001
Extra demands on my time	45 (1.6)	77 (2.8)	.002
Participation caused worry about my health/newborn's health	9 (0.3)	24 (0.9)	.007
There was nothing I disliked	2262 (79.8)	1912 (69.2)	<.001
Other dislikes	170 (6.0)	204 (7.4)	.04
If you had it to do over, would you participate in the SCIL Trial?			
Definitely yes	2064 (72.8)	1611 (58.3)	<.001
Probably yes	628 (22.1)	913 (33.0)	
Probably not	33 (1.2)	63 (2.3)	
Definitely not	13 (0.5)	21 (0.8)	
Unsure	80 (2.8)	125 (4.5)	
No response	18 (0.6)	32 (1.2)	
Preferred amount of nursing support for the next labor			
Almost all the time	1798 (63.4)	1288 (46.6)	<.001
Frequently	984 (34.7)	1396 (50.5)	
Occasionally	45 (1.6)	68 (2.5)	
No response	9 (0.3)	13 (0.5)	

*SCIL indicates Supportive Care in Labor.

Table 5. Interaction Analyses of Baseline Obstetrical Characteristics With Treatment Group*

Baseline Variable	Cesarean Deliveries, No. (%)		*P* Value†
	Continuous Labor Support	Usual Care	
Country			
United States	166 (11.2)	177 (11.9)	.53
Canada	266 (13.5)	260 (13.2)	
Parity			
Nulliparous	335 (19.7)	330 (19.5)	.52
Multiparous	97 (5.5)	107 (6.1)	
Onset of labor			
Spontaneous	301 (11.7)	280 (11.1)	.21
Induced	131 (14.8)	157 (16.6)	
Oxytocin infusion			
No	182 (16.1)	191 (16.1)	>.99
Yes	250 (10.8)	246 (10.8)	
Epidural analgesia			
No	402 (12.4)	405 (12.4)	.49
Yes	30 (13.8)	32 (16.3)	
Cervical dilation, cm‡			
<3	130 (18.4)	122 (17.0)	.07
3-6	169 (9.8)	163 (9.2)	
>6	3 (4.2)	5 (6.3)	
Unknown	130 (13.8)	147 (16.5)	

*Tests for center (n = 13) interactions were also all nonsignificant. They are not presented here to protect the confidentiality of center-specific information.
†Calculated with the Wald test.
‡Assessed within 1 hour prior to randomization.

no significant changes in the amount of time nurses spent in labor support and no changes in patient outcomes. One of the trial's conclusions was that nursing care was powerfully influenced by the organizational culture. Therefore, our results are unlikely to be a function of a weak intervention or contamination.

Another possibility is that the 2 groups received the same amount of support, because the usual care group received more support from husbands or partners and family members. We did not measure the amount of support provided by husbands or partners and other family members. It is possible that husbands in the experimental group provided less support because a nurse was continuously present, although the nurses' training program included specific content about how to help partners to support their wives. A prior small Canadian trial of labor support (n=150) found that compared with the control group, women in the experimental group reported more support from their husbands or partners in all categories except information/advice.[20] Their husbands or partners explained that they were encouraged by the caregiver, who acted as a role model and showed them how to help their wives. There have been no published trials to our knowledge that evaluated the effect of partner support on cesarean delivery. Regardless, it does not change our conclusion that continuous labor support by nurses had no effect on the cesarean rate in our trial.

Another possibility for the discrepancy between our results and that of the other labor support trials is that the results of the Cochrane Review[7] are incorrect. The results of a large, well-controlled trial may be more reliable than those of a meta-analysis, if the meta-analysis is small or involves poor-quality trials.[21] However, the trials in the Cochrane Review[7] were methodologically sound, the test for heterogeneity was not significant, and the sample was large (14 trials with more than 5000 women).

A more plausible explanation for our results is that the benefits of continuous labor support are overpowered by the effects of birth environments characterized by high rates of routine medical interventions. In our sample of primarily low-risk healthy women, 62% of labors were induced or augmented with oxytocics, 77% had continuous electronic fetal monitoring, and 75% had regional analgesia. A smaller trial, evaluating continuous support by nurses in a setting characterized by high intrapartum intervention rates, reported similar results and conclusions.[22]

Our results call into question the usefulness of national practice guidelines in the United States, Canada, and the United Kingdom,[8-10] which recommend that all women receive continuous 1:1 support from specially trained caregivers during labor. The results of a recent study of Ontario hospitals with below-average cesarean rates provide further evidence that the effectiveness of labor support may depend on the setting in which it is provided.[23] The hospitals had annual overall cesarean rates of 12% to 17% (well below the current provincial rate of 20%), and in addition to a commitment to 1:1 labor support by nurses, the organizations shared many characteristics, including regular audits of their practices, shared decision-making by multidisciplinary teams, active consumer involvement in policy setting, and a belief system based on labor and birth as healthy life events.[23] These organizational characteristics are consistent with those of other birth environments with low cesarean rates, such as in-hospital and freestanding birth centers.[24-26]

Those who wish to improve women's evaluations of their care during labor and birth may want to ensure that all women have continuous intrapartum nursing support. However, reducing US and Canadian cesarean delivery rates cannot be accomplished solely through a policy of continuous nursing support. Those who wish to decrease cesarean rates and rates of other intrapartum interventions would be advised to work with all of the stakeholders to implement comprehensive changes to the routine care of women during labor and birth. Large well-controlled evaluations of such complex changes would be helpful.

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REFERENCES

1. Department of Health and Human Services. *Healthy People 2000.* Boston, Mass: Jones & Bartlett Publishers; 1987.
2. Office of Disease Prevention and Promotion, Department of Health and Human Services. *Healthy People 2010.* Pittsburgh, Pa: US Government Printing Office; 2000.
3. National Institutes of Health. *Cesarean Childbirth.* Bethesda, Md: National Institutes of Health Consensus Development Conference; 1981. NIH Publication No. 82-2067.
4. Gould JB, Davey B, Stafford RS. Socioeconomic differences in rates of caesarean section. *N Engl J Med.* 1989;321:233-239.
5. Lomas J. Retailing research: increasing the role of evidence in clinical services for childbirth. *Milbank Q.* 1995;71:439-476.
6. Radin TG, Harmon JS, Hanson DA. Nurses' care during labor: its effect on the cesarean birth rate of healthy, nulliparous women. *Birth.* 1993;20:14-21.
7. Hodnett ED. Caregiver support for women during childbirth [Cochrane Review on CD-ROM]. Oxford, England: Cochrane Library, Update Software; 2002: issue 1.
8. Society of Obstetricians and Gynaecologists of Canada. SOGC policy statement: fetal health surveillance in labour. *SOGC News.* 1995:41-45. Available at: http://sogc.medical.org/SOGCnet/sogc_docs/common/guide/index_e.shtml. Accessed February 21, 2002.
9. Association of Women's Health, Obstetric, and Neonatal Nurses. Professional nursing support of laboring women. Available at: http://www.awhonn.org/awhonn/?pg=875-4810-4900. Accessed July 29, 2002.
10. MIDIRS and the NHS Centre for Reviews and Dissemination. Support in labor: informed choice for professionals leaflet. Bristol, England: Midwives Information and Resource Service; 1999.
11. Davies B, Hodnett E, Hannah M, et al. Fetal health surveillance: evaluation of a community-wide approach and a tailored intervention for the implementation of clinical practice guidelines. *CMAJ.* In press.
12. Gagnon A, Waghorn K. Supportive care by nurses: a work sampling study in an intrapartum unit. *Birth.* 1996;23:1-6.
13. McNiven P, Hodnett E, O'Brien-Pallas LL. Supporting women in labor: a work sampling study of the activities of labor and delivery nurses. *Birth.* 1992; 19:3-8.
14. Hodnett E, Simmons-Tropea D. The Labour Agentry Scale: psychometric properties of an instrument measuring control during childbirth. *Res Nurs Health.* 1987;10:301-310.
15. Cox J, Holden J, eds. *Perinatal Psychiatry: Use and Misuse of the Ediburgh Postnatal Depression Scale.* London, England: Gaskell; 1994.
16. Hodnett ED. Pain and women's satisfaction with the experience of childbirth: a systematic review. *Am J Obstet Gynecol.* 2002;186(suppl 5):S160-S172.
17. Hodnett E, Hannah M, Weston J, et al. Women's evaluations of induction of labor versus expectant management for prelabor rupture of the membranes at term. *Birth.* 1997;24:214-220.
18. Lumley J. Assessing satisfaction with childbirth. *Birth.* 1985;12:141-145.
19. Hodnett E, Kaufman K, O'Brien-Pallas L, et al. A randomized trial of a strategy to promote research-based nursing care: effects on childbirth outcomes. *Res Nurs Health.* 1996;19:13-20.
20. Hodnett E, Osborn RW. Effects of continuous intrapartum support on childbirth outcomes. *Res Nurs Health.* 1989;12:289-297.
21. Flather MD, Farkouh ME, Pogue JM, Yusuf S. Strengths and limitations of meta-analysis: larger studies may be more reliable. *Control Clin Trials.* 1997; 18:568-579.
22. Langer A, Campero L, Garcia C, Reynoso S. Effects of psychosocial support during labour and childbirth on breastfeeding, medical interventions, and mothers' wellbeing in a Mexican public hospital: a randomised clinical trial. *Br J Obstet Gynaecol.* 1998; 105:1056-1063.
23. Ontario Women's Health Council. Attaining and maintaining best practices in the use of caesarean sections: an analysis of four Ontario hospitals. Available at: http://www.womenshealthcouncil.on.ca/scripts/index_.asp?action=31&P_ID=1475&N_ID=1&PT_ID=13&U_ID=0. Accessed July 29, 2002.
24. Rooks JP, Weatherby NL, Ernst EK, et al. Outcomes of care in birth centers: the National Birth Center Study. *N Engl J Med.* 1989;321:1804-1811.
25. Rooks JP, Weatherby NL, Ernst EKM. The National Birth Center Study: part III—intrapartum and immediate postpartum and neonatal complications and transfers, postpartum and neonatal care, outcomes, and client satisfaction. *J Nurse Midwifery*. 1992;37: 361-397.
26. Hodnett ED. Home-like versus conventional institutional settings for birth [Cochrane Review on CD-ROM]. Oxford, England: Cochrane Library, Update Software; 2002:issue 1.