A Randomized, Controlled Trial of Nurse-Midwifery Care

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ABSTRACT: **Background:** *In 1990 a pilot nurse-midwifery program was implemented in a tertiary care hospital in a major western Canadian city. A randomized, controlled trial was conducted to determine if, when maternal and newborn patient outcomes were compared, the midwifery program was as effective as traditional, low-risk health care available in the city.* **Methods:** *All low-risk women who requested and qualified for nurse-midwifery care were randomly assigned to an experimental or control group.* **Results:** *One hundred one women received care from nurse-midwives and 93 received standard care from either an obstetrician or family physician. The rate of cesarean delivery in the nurse-midwife group was 4 percent compared with 15.1 percent in the physician group. The episiotomy rate, excluding cesarean deliveries, for the nurse-midwife group was 15.5 percent compared with 32.9 percent in the physician group. The rates of epidural anesthesia for pain relief in labor were 12.9 percent and 23.7 percent, respectively. Statistically significant differences were found for ultrasound examinations, amniotomy, intravenous drug administration during labor, dietary supplements, length of hospital stay, and admission of infants to the neonatal intensive care unit.* **Conclusions:** *The results clearly support the effectiveness of the pilot nurse-midwifery program and suggest that more extensive participation of midwives in the Canadian health care system is an appropriate use of health care dollars. (BIRTH 23:3, September 1996)*

In most countries of the world, including the most highly developed European nations and the United States, midwifery is a recognized and generally accepted health profession. The need for rigorous evaluation of the effectiveness of midwifery care has not been regarded as a priority due to its long-standing professional status. In Canada midwifery has not been a recognized profession. Nevertheless, a few courageous midwives have always practiced. Because of the lack of recognition, their practice was unregulated and unsupported, resulting in some accusations that midwifery is unsafe. In response to increasing pressure from childbearing women and changing attitudes of health care providers, however, several provinces are in the process of incorporating midwifery into their health care systems. For these same reasons, a pilot nurse-midwifery program was implemented at a tertiary care center in a major western Canadian city. The pilot program became the city's only midwifery care available within the health care system.

As a result of the lack of recognition, data on the effectiveness of midwifery care in the Canadian system are limited. The two published studies were

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retrospective and descriptive, with the attendant drawbacks of inconsistent recording and missing data (1,2). However, both reports suggest that midwifery can be a safe and effective health care option for Canadian women.

The authors reviewed a meta-analysis of 15 nonrandomized studies (3) and three other published reports of studies, all from the United States (4–6), comparing nurse-midwifery with physician care. Three of the four reports showed rates of cesarean section significantly lower for women cared for by nurse-midwives than for those cared for by physicians (3–5). The fourth report did not address cesarean section rates (6). All studies reported lower rates of common interventions for nurse-midwifery patients, including forceps deliveries (3–6), analgesia (3–6), induction and augmentation of labor (3,5,6), episiotomy (3,6), and amniotomy (3,6). Neonatal outcomes were at least as good for nurse-midwife care as for physician care in all studies.

Only two randomized trials of midwifery appear in the literature (7,8). The focus of one study was limited to intrapartal care only. Chambliss et al conducted a trial in which 487 low-risk women, admitted to a major California hospital, were randomly assigned at the onset of labor to either the nurse-midwifery or physician service for labor and delivery care (7). No statistically significant difference was reported for cesarean delivery rates. A statistically significant increase in rate of operative vaginal deliveries, episiotomies, and third- and fourth-degree lacerations was reported for the women cared for by physicians. No differences occurred in neonatal outcomes.

The trial by Rowley et al in Newcastle, Australia, studied the impact of continuity of care by a team of midwives throughout the perinatal period compared with routine care by a variety of doctors and midwives working in the prenatal clinic, delivery suite, and postnatal areas (8). In this trial 814 nonchargeable women, stratified according to parity and risk, were randomly assigned to one of the types of care. No significant differences in maternal outcomes were reported between the low-risk groups. The reduction in neonatal resuscitation and Apgar scores below 7 at 1 minute for infants in the midwifery team care group was statistically significant.

Due to the lack of research in Canada, an objective of this pilot project was to evaluate midwifery care within the Canadian health care system. The implementation of the pilot project provided an opportunity for rigorous evaluation of midwifery as it had never been evaluated before. The introduction of midwifery to a country where it was not legally recognized made it possible to designate it as a new treatment. Consequently, a randomized, controlled trial was designed. It was approved by the conjoint medical ethics committee. One of the principal objectives was to determine if nurse-midwifery care was as effective as medical care for low-risk women with respect to clinical outcomes. The two primary hypotheses were that the rate of episiotomy and the rate of epidural anesthesia would be less for women who received nurse-midwifery care than for those who received physician care.

Methods

Subjects

Women were recruited to the study by community wide advertising through newspapers and television, and posters in public health facilities. Women who requested midwifery care, who were at low risk for medical complications according to the Alberta perinatal risk scoring system, and who provided informed consent were eligible. Women were excluded if they had undergone cesarean section, were primigravidas under 17 or over 37 years of age, or were at greater than 20 weeks' gestation at time of entry into the study. A total of 218 women were recruited between February 1992 and August 1994.

Intervention

Women who met inclusion criteria were randomly assigned to either nurse-midwife care (experimental group) or physician care (control group), using a series of consecutively numbered, sealed, opaque envelopes containing a computer-generated random allocation. Once entered, the outcomes for a woman were retained in the group to which she was allocated.

Those women assigned to the control group selected their physician through standard referral processes, as they would have if nurse-midwifery care was not available. They were free to use any family practice physician or obstetrician in the area. All city hospitals were represented in the physician selections.

Women assigned to the experimental group received care from a team of seven nurse-midwives who provided complete management of those with uncomplicated pregnancies. Protocols and guidelines for the care were based on the midwifery philosophy and standards of practice developed by the Alberta Association of Midwives. Women were seen for antenatal visits in the nurse-midwifery clinic. The clinic's rotation schedule was designed to ensure that the women would meet as many of the nurse-midwives as possible. The women were seen routinely by an obstetrician on

their initial visit to the nurse-midwives and at 36 weeks' gestation to confirm their low-risk status.

Apart from the two mandatory obstetrician visits, the nurse-midwives made autonomous decisions on the care they provided. They made referrals to, or consulted with, obstetricians and other health team members when the need arose. Women in labor were admitted to a birthing room on the labor and delivery unit of one tertiary care hospital. A member of the nurse-midwifery team provided care throughout the labor, delivery, and immediate postpartum period. Postpartum follow-up was carried out on the postpartum unit or at home by a member of the team, and a six-week follow-up visit was carried out in the nurse-midwifery clinic.

The nurse-midwifery program worked in close cooperation with a group of obstetricians, one of whom was assigned as a liaison to the program and saw most of the women for their routine visits. One obstetrician from the group was available on call in the hospital at all times for consultation or referral as required by the nurse-midwives. A process of delegation of health care, approved by the hospital medical advisory committee, was used to facilitate the provision of primary care by nurse-midwives in a country where licensing was not available.

Data Collection

Data were collected prospectively using the Nurse-Midwifery Clinical Data Set developed by the Division of Research of the American College of Nurse-Midwives. It was minimally revised, with permission, to adapt it to the Canadian setting, and renamed the Foothills Perinatal Clinical Data Set. This tool was chosen because it addresses all three components of quality assurance, namely, structure, process, and outcomes. It has been tested and demonstrated to have both criterion-related and construct-related validity (9).

The outcome variables for this trial were neonatal morbidity, maternal morbidity, and intervention rates. Outcomes for subjects were evaluated on an intent-to-treat basis.

Statistical Analysis

The target sample size was 100 per group, which was calculated to provide power of 80 percent to detect a reduction in episiotomy rates from 35 to 17.5 percent (i.e., 50% reduction). The major demographic and pre-randomization clinical variables were compared between groups to assess comparability. Fisher's exact test was used to compare categorical outcomes between groups. Confidence limits for the difference in rates (physician rate vs nurse-midwife rate) between groups were calculated using the normal approximation to the binomial. For length of stay and birthweights, comparisons were based on Student's t test and corresponding intervals for the difference in means (physician mean vs nurse-midwife mean).

Delimitations

One of the major problems identified in midwifery research is the provision of an appropriate comparison group (10,11). Both the experimental and control groups were drawn from a population of women who sought midwifery care. Women who seek alternative care have been shown to desire active participation in the birth and minimization of interventions (12,13). These beliefs can affect the frequency of many of the variables being measured in this study. Drawing both groups from the same population reduces the chance that differences between them are a result of different health care beliefs rather than different treatment modalities.

The setting in which a delivery takes place has an impact on the style of care provided. It has been suggested that the easy availability of technology and interventions increases the rates of their use (1,14,15). In this trial, all deliveries in the nurse-midwife group occurred in a tertiary-level hospital. It is recognized that nurse-midwives practicing in a tertiary care center may have intervention rates greater than would be reported by those practicing in a variety of settings. Comparison with the general care available to low-risk women in the area was selected to avoid the bias that can result from comparison with one group of physicians who may provide care in a manner different from the general care available (10).

Results

Of the 218 subjects recruited, 194 were retained to completion, 101 in the nurse-midwife group and 93 in the physician group. There were 24 attritions. Eight subjects, four in each group, experienced spontaneous abortion after randomization but before 20 weeks' gestation. Two subjects, one in each group, were excluded after randomization at the first antenatal visit; one had anti-kel antibodies, and the other showed a fetal anomaly on ultrasound examination and thus did not meet the inclusion criteria. Four women assigned to physician care ultimately rejected physician care and selected out-of-hospital births. They did not meet the trial inclusion criteria for standard care available within the health care system. Four subjects moved out of the research area, one in the nurse-midwife group and

Table 1. Demographic Characteristics of Study Women

Characteristic	*No. (%) in Nurse-Midwife Group n = 101*	*No. (%) in Physician Group n = 93*
Nulliparas	56 (55.4)	44 (47.35)
Multiparas	45 (44.6)	49 (52.7)
Age (yrs)	30.26 (SD 3.77)	30.9 (SD 4.33)
Education (yrs)	16.0 (SD 2.49)	15.23 (SD2.32)*
Caucasian	97 (96.1)	91 (97.8)
Asian	3 (2.8)	2 (2.2)
Aboriginal	1 (1.1)	0
History of spontaneous abortion	14 (13.9)	17 (18.3)
Smokers at conception	5 (4.9)	9 (9.7)
Prepregnant weight (kg)	72.44 (SD 26.57)	71.29 (SD 25.55)
Hemoglobin (g/L) at start of pregnancy	134.7 (SD 8.21)	133.4 (SD 8.57)

**Significant at p = 0.03.*

three in the physician group. Four selected physicians who declined to complete the data-collection tool. Two withdrew from the nurse-midwife group; one was unable to attend the day of the nurse-midwife clinic and the other developed severe psychiatric problems and felt she needed obstetrician care. It was not possible to obtain prospective birth data for these women.

The two groups did not differ significantly on demographic factors theorized to affect the outcome variables (Table 1); the exception was years of education. The difference in this variable was statistically significant but was not considered to be relevant clinically.

Maternal Outcomes

The major observations were related to intrapartum interventions (Table 2). The rates of cesarean delivery between the groups showed a statistically significant difference (p = 0.01, 95% CI for the difference 2.9–19.3%). One cesarean delivery in each group was performed for placenta previa. The other three cesarean deliveries in the nurse-midwife group were performed for failure to progress in the first stage of labor. Reasons given for cesarean sections in the physician group were failure to progress in the first stage, 2 women; failure to progress in the first stage and fetal distress, 2 women; failure to progress in the second stage, 3 women; fetal distress, 1 woman; breech presentation, 1 woman; footling breech presentation, 3 women; and fetal arrhythmia, 1 woman.

The rate of spontaneous vaginal delivery was 88.2 percent in the nurse-midwife group, compared with 76.3 percent in the physician group. Two vaginal breech deliveries occurred in the nurse-midwife group and one in the physician group. The rate of instrumental vaginal deliveries was 5.9 percent in the nurse-midwife group and 7.6 percent in the physician group. The episiotomy rate, excluding cesarean deliveries, also was significantly different between groups (p = 0.007, 95% CI for the difference 4.83–30.1%). No statistical difference

Table 2. Comparison of Obstetric Interventions

Intervention	*No. (%) in Nurse-Midwife Group n = 101*	*No. (%) in Physician Group n = 93*	*95% Confidence Interval*
Cesarean section	4 (4.0)	14 (15.1)	2.89 to 19.3%
Episiotomy*	15/97 (15.5)	26/79 (32.9)	4.85 to 30.1%
Epidural for labor	13 (12.9)	22 (23.7)	−0.044 to 27.6%
Ultrasound	59 (58.4)	75 (80.6)	9.7 to 34.8%
Biophysical profile	23 (22.8)	25 (26.9)	−8.06 to 16.3%
Dietary supplements	23 (22.8)	58 (62.4)	26.8 to 52.4%
Amniotomy	17 (16.8)	28 (30.1)	1.44 to 25.1%
Induction of labor	8 (8)	14 (15.6)	−1.84 to 16.1%
Labor augmentation	14 (14)	19 (21.1)	−4.04 to 17.2%
Intravenous in labor	27 (26.7)	39 (42.9)	1.97 to 28.4%

**After cesarean sections were removed.*

was noted between groups for perineal integrity (Table 3) when compared hierarchically using none, minor, and first-, second-, and third-degree lacerations ($p = 0.21$). The rates of epidural anesthesia for pain relief in labor were not significantly different between groups ($p = 0.06$, 95% CI for the difference -0.044 to 21.6%).

Differences were noted in rates of some interventions used during the antepartum period. The difference in the rate of ultrasound examinations between nurse-midwife and physician groups was statistically significant ($p = 0.001$, 95% CI for the difference 9.7–34.8%). It should be noted that 21 of the ultrasound examinations reported for the nurse-midwife group were ordered by a physician, as a routine, before entry into the trial. If these were to be removed from the analysis, the rate of ultrasound examinations for the nurse-midwife group would be 37.6 percent. Rates for the prescription of dietary supplements were also significantly lower in the nurse-midwife group. For this study iron, folic acid, calcium, vitamins B_6, C, and E, and multivitamin preparations were classed as dietary supplements. Problems and complications diagnosed during pregnancy did not differ significantly between the groups.

No major postpartum complications were reported in either group, and minor complications did not differ significantly between the groups (Table 4). When pain relief measures were compared, a tendency was toward less use of pharmacologic pain relief in the nurse-midwife group (Table 5).

Data were also collected on length of stay in hospital. The average total length of stay was 39.47 hours in the nurse-midwife group and 59.99 hours in the physician group when all subjects were included. In each group one woman had a prolonged antepartum hospitalization for complete placenta previa. When they were removed from the sample, the average length of stay was 29.04 hours for the nurse-midwife group and 59.47 hours for the physician group ($p < 0.0001$, 95% CI for the difference 21.6 to 39.1 hr). The difference between groups is directly related to the length of stay postpartum, for which the nurse-midwife group had an average stay of 21.77 hours and the physician group 51.68 hours ($p < 0.0001$, 95% CI for the difference 22.4 to 38.2 hr). When the women with placenta previa were excluded, the antepartum length of stay was similar, 7.16 and 7.76 hours, respectively.

Neonatal Outcomes

Fourteen neonates in the nurse-midwife group had Apgar scores of less than 7 at 1 minute, compared with 27 in the physician group ($p = 0.013$, 95% CI for the difference 3.75–26.6%); four in each group had Apgar scores of less than 7 at 5 minutes. Eight (7.9%) of the nurse-midwife group neonates were transferred to either special or intensive neonatal care, compared with 18 (9.35%) in the physician group ($p = 0.02$, 95% CI for difference 1.8 to 21%). Average birthweight for nurse-midwife group neonates was 3502g (range 1970–4667 g), compared with 3492 g for the physician group (range 1700–4586 g; $p = 0.886$, 95% CI for mean difference -150 to 130 g).

Discussion

In general, the findings of this trial are consistent with those of previous studies of midwifery care, with the

Table 3. Comparison of Antenatal Complications

Complication	*No. (%) in Nurse-Midwife Group*	*No. (%) in Physician Group*
Bleeding before 20 wks	3 (3)	4 (4.3)
Bleeding after 20 wks	1 (1)	1 (1.1)
Placenta previa	1 (1)	1 (1.1)
Abruptio placentae	0	1 (1.1)
Gestational diabetes	6 (5.9)	6 (6.5)
Mild pregnancy-induced hypertension	4 (4)	4 (4.3)
Herpes	0	3 (3.2)
Urinary tract infection	7 (6.9)	2 (2.2)
Pyelonephritis	0	3 (3.2)
Influenza	3 (3)	3 (3.2)
Decreased fetal movement	2 (2)	1 (1.1)
Postdates	4 (4)	5 (5.4)
Preterm labor	1 (1)	4 (4.3)
Malpresentation	2 (2)	4 (4.3)
LGA suspected or confirmed	2 (2)	1 (1.1)
SGA suspected or confirmed	4 (4)	2 (2.2)
Polyhydramnios	0	1 (1.1)

LGA = large-for-gestational age infant; SGA = small-for-gestational age infant.

Table 4. Comparison of Postpartum Complications

Complication	No. (%) in Nurse-Midwife Group n = 101	No. (%) in Physician Group n = 93
Postpartum hemorrhage	6 (5.9)	3 (3.2)
Retained placenta	3 (2.9)	2 (2.2)
Temperature >38°C	1 (1)	2 (2.2)
Severe hemorrhoids	0	2 (2.2)
Lacerations (episiotomies removed)		
1st-degree	16/82 (19.5)	13/53 (24.5)
2nd-degree	23/82 (28)	20/53 (37.7)
3rd-degree	0	0
4th-degree	0	0
Labial	3/82 (3.7)	2/53 (3.8)
Periurethral	1/82 (9.2)	0
Vaginal	8/82 (9.2)	0*

*$p = 0.022$.

Table 5. Comparison of Pain-Relief Measures

Method	No. (%) in Nurse-Midwife Group	No. (%) in Physician Group	p
Massage	47 (46.5)	18 (19.4)	<0.000
Bath	28 (27.7)	7 (7.5)	<0.000
Jacuzzi (whirlpool bath)	3 (3)	0	0.247
Shower	73 (72.2)	39 (41.9)	<0.000
Hypnosis	0	1 (1)	0.497
TENS	7 (6.9)	6 (6.5)	0.894
Entonox	23 (22.8)	31 (33.3)	0.101
Narcotic	16 (15.8)	17 (18.3)	0.652
Epidural	13 (12.9)	22 (23.7)	0.062

TENS = transcutaneous electrical nerve stimulation.

exception of the two randomized trials. As in previous studies, the women in the nurse-midwife group experienced fewer interventions in the intrapartal period. Nurse-midwives in this study performed significantly fewer intravenous infusions and amniotomies during labor and episiotomies than physicians. They also induced and augmented labor less frequently, although the difference was not statistically significant. A tendency toward less pharmacologic pain relief was also noted in the nurse-midwife group, but the difference in the administration of epidural anesthesia did not reach statistical significance. It has been suggested that epidural rates may be influenced by the availability of epidural anesthesia (14). A 24-hour obstetric anesthesia service is available in the hospital where all nurse-midwifery subjects delivered, but not in two of the other area hospitals where 28 percent of the physician group delivered.

In contrast to Chambliss et al (7) and Rowley et al (8), nurse-midwifery care in this trial resulted in significantly fewer cesarean deliveries without a proportionate increase in the number of operative vaginal deliveries. Several differences can be seen between the methods of those studies and this trial. In one trial, differences included the stage of pregnancy when low-risk status was assessed, the span of care studied, and the care used for comparison (7). The focus was exclusively on intrapartal care of women at low risk at the onset of labor. No indication was given on who provided antenatal care. Thus, all women who developed problems during pregnancy were excluded. The authors had one resident physician group as a comparison for the nurse-midwifery care, and one-third of operative vaginal deliveries in the physician group were performed, at least in part, for resident teaching (7). The other trial used a comparison group that received shared care between midwives and physicians, and reported testing only the continuity of caregiver rather than a different style of care (8). One of the investigators identified a potential problem with experimental treatment delivery (MW Brinsmead, personal communication, October 20, 1995). These methodologic variations may account for the difference in reported results between the two studies and this trial.

In our study the difference between groups for

admissions to neonatal intensive care nurseries was statistically significant. The reason for this difference, in view of the similarity of 5 minute Apgar scores, is not readily apparent. It may reflect a difference in practice, with midwives highly committed to keeping mothers and babies together while providing necessary observation and care. This difference is noteworthy because of the significant increase in cost incurred in a higher-level nursery.

The nonintervention style of care received by the nurse-midwife group is reflected in the significantly fewer discretionary interventions such as ultrasonography and dietary supplements compared with the physician group. However, the rate of problems and complications diagnosed prenatally did not differ significantly. This, combined with the maternal and neonatal outcomes, demonstrates that midwives can effectively detect complications with more selective use of technology and interventions.

Although data were collected on the rate of consultations with physicians for the nurse-midwife group, they are not reported because it is not possible to make any meaningful comparison between the groups. Criteria for consultation are different for nurse-midwives and physicians in Canada. Because of the position of midwifery practice at the time of the study, it was necessary for midwives to consult physicians for reasons that would not be necessary for family practice physicians. In addition, some women in the physician group were cared for by obstetricians and no consultations were necessary. Data on satisfaction of women with the care they received were also collected and will be reported at a later date.

Cultural differences could exist among the three secondary-level hospitals where some of the physician group subjects delivered and the tertiary-level hospital where all the nurse-midwife subjects gave birth. Different cultures may result in different intervention rates and could have influenced the results of this trial. A review of available statistics on intervention rates in the area hospitals during the period when the trial took place, however, suggests that the hospital in which the nurse-midwives practiced reported intervention rates well within the citywide range for low-risk primigravidas (16). Statistics for intervention rates for multiparas were not available.

A complete intent-to-treat analysis, which included the 24 women who were lost to the trial, would have strengthened the validity of the results, but unfortunately this was not possible. The protocol was that, although women were screened by self-report before randomization, low-risk status was confirmed at the time of the first antenatal visit. Women found to be high risk at that visit became attritions because they did not meet the trial criteria. Women choosing home birth were excluded because this option is not available within the health care system, and home birth and hospital birth are not comparable. Women whose physicians declined to participate were excluded because the trial design involved prospective data collection during the entire childbearing course, and some of those data were available only with the cooperation of the physicians. It was impossible to obtain data on women who moved out of the area.

Conclusion

The results of this study show that nurse-midwives working in a tertiary care center can provide safe and effective care for low-risk women. Comparison with standard physician care demonstrated a lower application of technologic assessment, fewer interventions, shorter hospital stays, fewer neonatal intensive care unit admissions, and less maternal morbidity in the nurse-midwife group, even with the increased pressure to use interventions that was present in the tertiary care environment.

These practice variations and outcomes have the potential to reduce costs of maternity care to women, their infants, and the health care system. The results of this trial clearly support the safety and effectiveness of the pilot nurse-midwifery program, and suggest that more extensive use of midwives in the Canadian health care system is an appropriate use of health care dollars.

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