Is Paracervical Block Safe and Effective?
A Prospective Study of Its Association with Neonatal Umbilical Artery pH Values

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BACKGROUND. Paracervical blocks (PCBs) relieve labor pain, but reports of associated complications have caused many physicians to question their safety.

METHODS. We designed a prospective observational study to examine the association between PCBs and umbilical artery hydrogen ion concentration (pH) values. A total of 261 healthy women in labor were recruited from a community hospital. Physicians used 1% lidocaine for the PCBs. We used multivariate linear regression to model predictors of umbilical artery pH at birth.

RESULTS. Of the women studied, 238 (91%) received analgesia during labor (nalbuphine, PCB, pudendal, caudal, or epidural). Of these, 126 (48%) received at least one PCB (191 were given), and 197 (76%) received at least one dose of nalbuphine (237 were given). Univariate analyses showed no significant differences in mean 1-minute Apgar scores, 5-minute Apgar scores, umbilical artery pH, resuscitation with oxygen by mask, or length of newborn stay according to either PCB or nalbuphine exposure. Factors significantly associated with lower umbilical artery pH in a linear regression analysis included longer second stage of labor (-0.032 pH units for each 1-hour increase; 95% confidence interval [CI], -.046 to -.018), pudendal block (-0.022; 95% CI, -.040 to -.004), intrauterine pressure catheter use (-0.029; 95% CI, -0.053 to -.006), nuchal cord (-0.027; 95% CI, -.051 to -.004), and midforceps delivery (-0.080; 95% CI, -.159 to .000). Increasing maternal age and induction with either artificial rupture of membranes or gel were associated with higher umbilical artery pH values.

CONCLUSIONS. After adjusting for other variables, neither PCB nor nalbuphine use were associated with umbilical artery pH at birth. PCBs using 1% lidocaine injected superficially should be considered a safe and effective form of obstetric analgesia. PCBs may be especially useful for women giving birth in hospitals where other obstetric anesthesia services are not readily available.

KEY WORDS. Prospective studies; anesthesia, obstetrical; nalbuphine; umbilical arteries. *(J Fam Pract 1999; 48:778-784)*

Many women want medical management of pain during labor.[1] There are several commonly used interventions, including intravenous narcotics, epidural anesthesia, and pudendal blocks.[2] Effective pain management is important, because obstetric pain can lead to harmful effects, such as reduced uterine blood flow and decreased fetal oxygenation.[3,4] Pharmacologic pain control should be viewed as an adjunct to psychological support.[5]

Paracervical blocks (PCBs) have been in use for several decades and are routinely used for obstetric analgesia in Scandinavian countries.[6,7] They effectively relieve pain during the first stage of labor,[8-12] but reports of complications, such as fetal bradycardia[13-15] and intrapartum fetal or neonatal death,[15-18] have caused many physicians to question their safety. Two extensive reviews involving more than 70,000 PCBs found that many of the fetal and neonatal deaths associated with them could be explained by factors unrelated to the PCBs.[19,20] Additionally, the standard technique for PCB use has changed. Submucosal injection in the vaginal fornices to a depth of no more than 2 to 4 mm and the use of lower concentrations of local anesthetics reduce risks to the woman and the fetus.[8,9,11,12,21-24]

Fetal bradycardia following a PCB administered with submucosal injection has a reported incidence of 2% to 13%.[8,11,12] Bradycardia can lead to fetal acidosis, which resolves in utero.[14,15,20] It is difficult to accurately compare bradycardia rates among studies, because some studies have used a variety of agents for PCBs or varying definitions of post-PCB bradycardia.[8,11,12]

Several larger nonrandomized studies using uni-

Submitted, revised, August 2, 1999.
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This paper was presented at the 32nd Society of Teachers of Family Medicine Annual Spring Conference, April 29, 1999, Seattle, Washington.
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variate techniques to compare Apgar scores in women given a PCB with a control group have reported either better scores in the PCB group[25] or no difference.[8,11]

Umbilical acid-base status at delivery is recognized as a reliable indicator of fetal oxygenation and well-being[26,27] and is more objective than the Apgar score.[28,29] We reasoned that if PCB use has a significant impact on the fetus, this could be assessed by examining the umbilical artery hydrogen ion concentration values (pH) at birth. There is controversy about the level of pH below which a neonate is at significantly greater risk for neurologic sequelae or death, and a variety of values have been proposed.[26,30,31] However, increasing severity of metabolic acidosis at birth is associated with an increased likelihood of newborn encephalopathy and motor and cognitive deficits at the age of 1 year.[32,33] Thus, umbilical artery pH is an appropriate intermediate outcome to assess the potential risks of PCB.

Our purpose was to determine whether there is an association between use of a PCB and umbilical artery pH values at birth. A MEDLINE search of the literature written in English from 1966 to the present using the terms "analgesia, obstetric," "neonatal outcome(s)," and "acid-base status" revealed no studies of PCBs that prospectively examined them with an appropriate comparison group and reported on neonatal umbilical artery blood gas values while simultaneously controlling for possible confounders. Our study expands on previous studies of PCB anesthesia by using umbilical artery pH at birth as the main outcome variable and by prospectively collecting information about and controlling for use of analgesics other than PCBs and other prenatal and obstetric factors that may confound results.

METHODS

Women presenting for childbirth at a community hospital from May 1992 to April 1994 were invited by a labor and delivery nurse to participate in this prospective observational study. PCBs were regularly used for pain relief, making this an ideal study setting. By using a prospectively designed study, it was possible to make sure that information on likely confounding variables was collected uniformly on all of the patients in the study. Exclusion criteria included scheduled cesarean delivery, multiple gestation, less than 37 or more than 42 weeks' gestation, allergy to lidocaine or other local anesthetic, and suspicion of or known placenta previa or premature separation of placenta. Potential subjects were informed of the study when they arrived at the Labor and Delivery department, and gave their informed consent if they chose to participate. Our study was approved by the Institutional Review Board. Of the 263 women recruited, 2 had cesarean deliveries: 1 for failure to progress, and 1 for fetal distress. Neither of these women received a PCB, but they were eliminated from further analysis since the anesthesia used for cesarean delivery could adversely affect umbilical artery pH values.[34,35] This left 261 women in the study.

Labor management was left up to the attending physicians (all of whom were board certified in obstetrics and gynecology or family practice). The attending physician chose the type of analgesia to be used in conjunction with the patient's needs and desires, as is standard practice. Through special discussions held at the monthly hospital maternal/child health meeting (for all physicians involved in obstetrics and pediatrics), physicians using PCBs agreed to use 1% lidocaine injected in 1 to 2 locations submucosally on each side of the cervix (at the 3 to 4 o'clock and 8 to 9 o'clock positions) for a total dosage of 100 to 200 mg lidocaine. A 10-mg dose of nalbuphine hydrochloride was given intravenously when needed for parenteral pain relief. Mepivacaine 1% was used for pudendal and local blocks. Physicians recorded the types, amounts, and concentrations of all anesthetics used, and the obstetric nurses recorded when they were given and the degree of pain relief they produced.

Standard practice was for the fetal heart rate (FHR) to be recorded by handheld Doppler ultrasonography every 15 minutes during the active phase of labor and every 5 minutes during the second stage. For our study, external continuous FHR monitoring was used for 5 minutes before and for 30 minutes after each PCB to detect any decrease, unless a fetal scalp electrode was already in place. We defined bradycardia using the conservative criteria of a decrease in FHR to less than 100 beats per minute lasting at least 1 minute and occurring within 30 minutes of anesthesia. Decreased FHR was defined as a drop to less than 120 beats per minute lasting at least 1 minute and occurring within 30 minutes of anesthesia.

The obstetric nurse asked the participating women to rate the degree of perceived relief obtained from any analgesics approximately 15 minutes after these medications were given. They used a 4-point scale of "excellent," "good," "fair," and "poor." "Excellent" indicated complete pain relief and inability to feel contractions; "good" was complete pain relief with ability to feel contractions; "fair" was definite but incomplete relief of pain; and "poor" was little or no relief. Following delivery, the umbilical cord was double-clamped, arterial cord blood was drawn into a heparinized syringe, and the sample was sent on ice to the hospital laboratory for immediate determination of pH, partial pressure of carbon dioxide (pCO_2), and partial pressure of oxygen (pO_2) using an Instrumentation Laboratory pH/Blood Gas Analyzer Model 1306 (Instrumentation Laboratory, Lexington, Mass).

We extracted data from the woman's record, including demographics, specialty of delivering physician

(obstetrician or family physician), information on events during labor (eg, type and amount of all analgesics used), and neonatal outcomes (such as weight, 1- and 5-minute Apgar scores, umbilical artery blood gas values, and resuscitation with oxygen by mask). Data extracted from the infant's record included the length of stay. When data was missing, it was because it could not be found in the medical record. We did statistical analyses using the Statistical Package for the Social Sciences 7.5 (SPSS Incorporated, Chicago, Ill). We used descriptive statistics to characterize the distribution of each variable (dependent and independent). We explored bivariate relationships using chi-square tests and used 2-sided *t* tests to compare means between groups. We used forward stepwise linear regression using umbilical artery pH values at birth to estimate the effect of a PCB while testing for the effect of a number of factors which might affect pH. The covariates we tested were maternal age (years), weight gain during pregnancy (kilograms), tobacco use, preeclampsia, diabetes, parity, induction of labor with artificial rupture of membranes as sole method, induction with gel, oxytocin use, intrauterine pressure catheter use, artificial amniotomy, meconium-stained amniotic fluid, dystocia, first stage length, second stage length, mode of delivery (spontaneous vertex, vaginal breech, midforceps, outlet forceps, vacuum assisted), analgesia used during the first or second stage (nalbuphine, PCB, epidural, caudal, pudendal, local), nuchal cord, knotted cord, specialty of delivering physician (obstetrician or family physician), and infant weight (grams) and sex. We tested the use of PCB and nalbuphine as indicator variables (none, 1 only, 2 or more doses) in the stepwise regression to determine potential dose response. To verify that PCB and nalbuphine use were not associated with umbilical artery pH at birth, we forced them into the final stepwise equation. *P* values <.05 were considered statistically significant.

RESULTS

The characteristics of the 261 study participants are summarized in Table 1. No fetal or neonatal deaths occurred. Umbilical artery cord blood was inadvertently not collected for one subject. Of the 261 women studied, 238 (91%) received pharmacologic analgesia during labor (nalbuphine, PCB, pudendal, caudal, or epidural) and 23 (9%) received none (not including local anesthesia). One hundred twenty-six (48%) received at least one (of a total 191 PCBs administered). One hundred ninety-seven (76%) received at least one dose of intravenous nalbuphine (a total of 237 doses were given). No narcotics other than nalbuphine were given. Ninety-nine women (38%) received both nalbuphine and a PCB.

Table 2 shows the reported degree of pain relief fol-

TABLE 1

Characteristics of the Study Population (N = 261)

Characteristic	No.	(%)
Prenatal		
LMP known	248	(95)
Early obstetric ultrasound	173	(67)
Multiparous	154	(59)
Tobacco use during pregnancy	31	(12)
Diabetes (gestational or otherwise)	13	(5)
Preeclampsia	2	(1)
Obstetric		
Artificial rupture of membranes	187	(72)
Induction of labor	115	(44)
Fetal scalp electrode	94	(36)
Intrauterine pressure catheter	43	(17)
Nuchal cord	40	(15)
Meconium stained amniotic fluid	16	(6)
Knotted cord	3	(1)
Anesthesia Used During Labor		
Local	228	(87)
Nalbuphine hydrochloride	197	(76)
Pudendal	145	(56)
Paracervical block	126	(48)
Epidural	11	(4)
Caudal	7	(3)
Delivery		
Normal spontaneous vaginal delivery	217	(83)
Outlet forceps	20	(8)
Vacuum	20	(8)
Midforceps	3	(1)
Vaginal breech	1	(<1)
1-minute Apgar Score		
≤6	16	(6)
7 to 8	188	(72)
9 to 10	57	(22)
5-minute Apgar Score		
≤6	1	(<1)
7 to 8	7	(3)
9 to 10	253	(97)
UA pH		
<7.2	55	(21)
≥7.2	205	(79)
UA pH		
<7.15	27	(10)
≥7.15	233	(89)
Oxygen by mask	11	(4)

LMP denotes last menstrual period; UA pH, umbilical artery hydrogen ion concentration.

TABLE 2

Reported Pain Relief Following Paracervical Block or Intravenous Nalbuphine Hydrochloride

Analgesia	Number Receiving Dosage*	Reported Pain Relief no. (%)			
		Excellent	Good	Fair	Poor
Paracervical block					
1st dose	104	19 (18)	53 (51)	13 (13)	19 (18)
2nd dose	41	2 (5)	26 (63)	10 (24)	3 (7)
3rd dose	7	0 (0)	6 (86)	1 (14)	0 (0)
Nalbuphine hydrochloride					
1st dose	175	4 (2)	118 (67)	39 (22)	14 (8)
2nd dose	31	0 (0)	9 (29)	9 (29)	13 (42)

Note: The degree of pain relief was reported by the patients after each dose of analgesic medication. Aggregate responses after each dose (for women who had this information recorded) are shown.
*Of those for whom pain relief information was recorded. Information was not available for 20% paracervical block and 13% nalbuphine administrations.

lowing administration of a PCB or nalbuphine. Including all doses, a substantial proportion of women reported excellent or good relief following PCB analgesia (70%) or nalbuphine (64%). Since nalbuphine is typically given earlier in the active phase of labor than a PCB, analysis was not appropriate to compare pain relief reported by medication type.

Using doses for which tracings were available, the best estimate overall incidence of bradycardia following PCB analgesia was 6.3% (10 of 157). Tracings were unavailable for 34 (18%) PCB administrations. If we were to make the unlikely assumption that all the doses with unavailable tracings had bradycardia, the rate could be as high as 23% (44 of 191).

TABLE 3

Population Parameters According to Paracervical Block Treatment

Variable	All (n = 261) Mean ± SD	PCB (n = 126) Mean ± SD	No PCB (n = 135) Mean ± SD	P*
Age, years	28.2 ± 4.4	28.1 ± 4.2	28.3 ± 4.6	ns
Gestational age, days	280 ± 13	281 ± 13	279 ± 13	ns
Gravidity	2.3 ± 1.3	2.4 ± 1.3	2.2 ± 1.2	ns
Parity	0.9 ± 1.0	1.0 ± 1.0	0.8 ± 0.9	ns
Weight gain, kilograms	15.1 ± 5.2	15.3 ± 5.2	14.9 ± 5.3	ns
Postpartum hematocrit	34.7 ± 3.4	34.9 ± 3.6	34.5 ± 3.3	ns
Length of first stage, minutes	372 ± 217	409 ± 227	338 ± 202	.008
Length of second stage, minutes	35 ± 38	34 ± 37	37 ± 39	ns
Newborn weight, grams	3520 ± 441	3540 ± 444	3502 ± 439	ns
1-minute Apgar score	7.9 ± 1.0	7.9 ± 1.0	7.9 ± 0.9	ns
5-minute Apgar score	9.0 ± 0.4	9.0 ± 0.5	9.1 ± 0.3	ns
Arterial cord blood pH	7.25 ± 0.08	7.24 ± 0.08	7.26 ± .08	ns
Arterial cord blood pCO_2, mm Hg	47.6 ± 8.7	49.2 ± 8.8	46.1 ± 8.4	.004
Arterial cord blood pO_2, mm Hg	22.5 ± 11.8	21.6 ± 11.8	23.4 ± 11.8	ns
Oxygen by mask, %	4.2	4.8	3.7	ns
Newborn hospital stay, days	3.0 ± 0.5	3.02 ± .44	3.02 ± 0.50	ns

PCB denotes paracervical block; SD, standard deviation; pH, hydrogen ion concentration; pCO_2, partial pressure of carbon dioxide; pO_2, partial pressure of oxygen; Hg, mercury.
*Two-tailed *t* test or Pearson chi-square comparing women who received a PCB with those who did not.

TABLE 4

Forward Stepwise Linear Regression Equation for Umbilical Artery pH

	Parameter Estimate* (β)	*t*	*P*	95% CI for β
Constant	7.236	246.6	.000	7.178 to 7.294
Second stage, hours†	-.032	-4.5	<.001	-.046 to -.018
Pudendal	-.022	-2.5	.015	-.040 to -.004
Intrauterine pressure catheter	-.029	-2.4	.016	-.053 to -.006
Nuchal cord	-.027	-2.3	.025	-.051 to -.004
Gel	.055	2.2	.030	.005 to .105
AROM induction‡	.021	2.0	.045	.001 to .042
Midforceps delivery	-.080	-2.0	.049	-.159 to .000
Diabetes	-.038	-1.9	.055	-.078 to -.001
Age	.002	1.8	.066	.000 to .004
Forcing in any PCB and any nalbuphine use				
PCB use	-.009	-.928	.355	-.028 to .010
Nalbuphine use	.004	.043	.966	-.020 to .020

pH denotes hydrogen ion concentration; CI, confidence interval; PCB, paracervical block.

*Parameter estimates for patient risk factors were derived without "paracervical block use" and "nalbuphine use" in the model. Parameter estimates for the patient risk factors changed very little when anesthesia variables were forced in, indicating there was no significant confounding of patient risk factors with PCB and nalbuphine.

†The parameter estimate is -0.032 for each 1-hour increase in the length of the second stage.

‡Induction solely by artificial rupture of membranes, with no prostaglandin gel or oxytocin used.

Table 3 compares mean parameters according to whether women received a PCB. Prenatal factors were not significantly different between groups. There was no significant difference in mean umbilical artery pH, 1-minute Apgar score, 5-minute Apgar score, resuscitation with oxygen by mask, or length of newborn stay according to PCB exposure. Length of the first stage of labor was significantly longer (409 vs 338 minutes, P = .008) and arterial cord blood pCO_2 was higher (49.2 vs 46.1 mm Hg, P = .004) among those who received a PCB.

There was no significant difference in umbilical artery cord blood gas values, 1-minute Apgar score, 5-minute Apgar score, need for resuscitation with oxygen by mask, or length of newborn stay according to nalbuphine exposure (data not shown). Women who received nalbuphine had a significantly longer first stage of labor (403 vs 278 minutes, P <.001), and tended to have a longer second stage of labor (38 vs 28 minutes, P = .052), but these women also had lower gravidity (2.2 vs 2.6, P = .040) and parity (0.8 vs. 1.3, P = .001).

To estimate the effect of PCB use on umbilical artery pH, we performed a forward stepwise linear regression (Table 4). After adjusting for multiple possible confounders, the use of a PCB had no association with umbilical artery pH. The constant can be interpreted as the umbilical artery pH that would be expected in the absence of any of the predictor variables. The parameter estimates can be summed if 2 or more predictors are present. For example, if a woman had a second stage of labor lasting 1 hour and a pudendal block, the umbilical artery pH would be predicted to be 7.182 [7.236 + (-.032 + -.022) = 7.212]. When any PCB use was forced into the stepwise model, the regression coefficient (β) for PCB use was -.009 (P = 0.355.) The 95% confidence interval (CI) for the effect of a PCB on umbilical artery pH was very narrow (- 0.028 to 0.010), making it very unlikely we missed a clinically important effect.

DISCUSSION

We found no statistically significant association between the use of a PCB and umbilical artery pH at birth. The results were similar in both the univariate analysis and in a regression analysis after adjusting for confounders. This suggests that known confounders do not affect the results, which makes it less likely that the results are affected by unknown confounders. The 95% CI for the effect of PCB is very narrow, making it unlikely that we have missed a clinically significant

effect. Supporting the lack of significant effect of PCB use is the bradycardia rate of only 6% in the 30 minutes afterward, using a very sensitive definition for bradycardia. This study is important, because we could not find any published studies of PCBs that used multivariate techniques to study their relationship with arterial cord blood gases and health of the neonate at birth. By using a prospectively designed study, it was possible to make certain that the information on likely confounding variables was collected uniformly for all of the patients in the study.

Our multivariate analysis showed that several factors are significantly associated with lower umbilical artery pH at birth. Among these were longer second stage of labor, intrauterine pressure catheter use, nuchal cord, and midforceps delivery. In agreement with our results, Yudkin and colleagues[36] found that increasing length of second stage of labor, vaginal operative delivery for fetal distress, and cord entanglement were associated with lower umbilical artery pH values at birth in multivariate analyses of unselected deliveries.

LIMITATIONS

Although a double-blind clinical trial with women randomized to a PCB or an alternative form of analgesia would be the best way to study the safety of PCBs, such a study would be very difficult and would require millions of dollars. We decided, therefore, to take advantage of the types of analgesia used at our hospital to study the safety of PCBs with an observational prospective design. The main limitation of this design is that an adverse effect of a PCB could be obscured if patients who received a PCB had characteristics that would put them at a lower risk than other patients in our study. However, detailed clinical comparisons of the 2 groups of patients did not reveal significant differences. In addition, the effect of the use of a PCB was very similar in the multivariate and the univariate analyses, providing evidence that differences between these groups were unlikely. Our results may not apply to high-risk pregnancies, since the women in our study were very healthy (high-risk patients were referred to the nearby tertiary-care hospital). However, this type of referral pattern is not uncommon.

CONCLUSIONS

We found that neither PCB nor nalbuphine use were associated with significantly lower umbilical artery pH values in univariate or multivariate analyses. Both PCB and intravenous nalbuphine provide effective obstetric analgesia, since substantial proportions of women reported excellent or good relief following PCB use (70%) or following nalbuphine use (64%) in this and other studies. Because of strong evidence for its safety, submucosal injection of a PCB using 1% lidocaine should be considered a viable form of obstetric analgesia. PCBs may be especially useful for women giving birth in hospitals where obstetric anesthesia services are not readily available.

ACKNOWLEDGMENTS

Our study was partially supported by a grant from the American Academy of Family Physicians/American Academy of Family Physicians Foundation (G9415), the University of Iowa Department of Family Medicine, the Iowa Academy of Family Physicians Foundation, and Mercy Hospital, Iowa City, Iowa. This study would not have been possible without the support of the nurses and obstetricians at Mercy Hospital.

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