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Obstetrical Caudal Anesthesia:

II. A Randomized Study Comparing 1 Per Cent Mepivacaine with 1 Per Cent Mepivacaine Plus Epinephrine

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In 1,946 obstetrical patients, mepivacaine alone, mepivacaine with epinephrine, and lidocaine with epinephrine were equally effective in relieving the pain of labor. Anesthesia was longer when epinephrine was included, and was also longer for nulliparas than for multiparas with all three anesthetic preparations. The duration of first-stage labor was significantly prolonged by epinephrine. This prolongation averaged 28 minutes for mepivacaine–epinephrine and 39 minutes for lidocaine–epinephrine in nulliparas, and 26 minutes for both combinations in multiparas. Approximately twice as many patients needed oxytocic augmentation of labor with the caudal anesthesia when epinephrine was used. (Key words: Obstetrics; Caudal anesthesia; Mepivacaine; Epinephrine; Lidocaine.)

THE EFFECT of caudal anesthesia on labor has been disputed. We previously reported that when 1 per cent mepivacaine (Carbocaine) was compared with 1 per cent lidocaine (Xylocaine) with epinephrine (Suprarenin), although the two drugs were equally effective in relieving labor pain, the duration of anesthesia was slightly longer for lidocaine–epinephrine, and was longer for nulliparas than for multiparas with both drugs.[1] The most important finding, however, was that the duration of the first stage of labor after caudal administration of lidocaine—epinephrine was significantly longer than when mepivacaine without epinephrine was used. From this study, it was impossible to determine whether the prolongation of labor was the result of differences between the local anesthetics or the addition of epinephrine. We have done a study using mepivacaine alone and combined with epinephrine. Because of the many variables and the obvious bias of individuals concerning labor, obstetrical anesthesia, and drug effects, this was a double-blind, randomized study. The numbers of patients were sufficient to permit reliable statistical comparisons. Furthermore, since the patients who received mepivacaine without epinephrine in this study did not differ significantly from those who received mepivacaine alone in the previous study, these two groups were combined in the final statistical analysis. The use of the mepivacaine patients from Study I as historical controls gives us more confidence in our conclusions, and the combination of the two studies permits comparison of the effects on labor of three drug preparations: mepivacaine alone, mepivacaine–epinephrine, and lidocaine–epinephrine.

TABLE 1. Results of Anesthesia, 1,104 Patients in Study II

Ineffective caudal anesthesias	117 (10.5 per cent)
Excluded for other reasons	76
Complete dilatation (43)	
Cesarean section before complete (8)	
Twins (8)	
Miscellaneous (17)	
Effective caudal anesthesias	911

Materials and Methods

Caudal analgesia is administered continuously via catheter to most patients whose infants are delivered at the Stanford University

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TABLE 2. Maternal and Fetal Characteristics and Variables Related to Labor and Anesthesia

	Nulliparas			Multiparas		
	Mepivacaine Alone	Mepivacaine with Epinephrine	Lidocaine with Epinephrine	Mepivacaine Alone	Mepivacaine with Epinephrine	Lidocaine with Epinephrine
Number of patients	370	332	255	378	351	260
Mean age (years)	23.3	23.5	23.1	27.6	27.2	27.1
Mean height (inches)	64.5	64.8	64.6	64.4	64.5	64.8
Mean weight (pounds)	149	149	147	151	151	151
Mean parity	0	0	0	1.76	1.73	1.64
Mean gestation (weeks)	39.8	39.8	39.8	39.6	39.5	39.5
Mean birth weight of infant (pounds, ounces)	7'4	7'4	7'4	7'7	7'5	7'6
Number weighing less than 2,500 g	13	10	11	15	18	9
Mean Apgar score of infant	8.2	8.2	8.4	8.3	8.4	8.6
Number of scores less than 6	21	13	12	15	14	4
Stillbirths	2	7	1	6	0	0
Neonatal deaths	2	2	1	1	1	2
Mean dilatation (cm)	6.0	6.1	6.1	5.3	5.2	5.4
Mean station	+0.83	+0.82	+0.76	+0.10	+0.10	+0.24
Number less than 0	8	20	9	67	69	39
Mean skin anesthetic level	T9.9	T9.4	T9.7	T9.6	T9.7	T9.5
Mean systolic blood pressure change	16	18	18	15	17	16
Number less than 80	14	18	19	15	30	14
Vasopressor (number of patients)	1	4	4	2	1	1
Supplemental anesthesia (number of patients)	24	9	7	21	7	13

Patient–doctor evaluation (per cent)	Nulliparas						Multiparas					
	Pt.	Dr.	Pt.	Dr.	Pt.	Dr.	Pt.	Dr.	Pt.	Dr.	Pt.	Dr.
Excellent	85.4	88.1	93.4	92.8	89.0	89.8	79.1	80.7	88.6	88.9	89.2	90.0
Good	10.5	7.8	5.7	5.7	7.1	6.7	13.8	14.0	9.1	9.4	6.6	7.3
Fair	4.1	4.1	.9	1.5	3.9	3.5	7.1	5.3	2.3	1.7	4.2	2.7

Medical Center. Stanford Clinic patients and private patients participated in this study, upon approval of their anesthesiologists.

METHOD OF ADMINISTRATION

Caudal analgesia was administered during active labor by a continuous catheter technique previously described.[2] At the time of administration, 0.5 ml of coded epinephrine or 0.5 ml of coded Ringer's solution was added to the coded mepivacaine, providing 100 ml of either 1 per cent mepivacaine plus 0.5 ml of Ringer's solution or 1 per cent mepivacaine plus 0.5 ml of 1:1,000 epinephrine (a final concentration of 1:200,000 epinephrine), respectively. The usual anesthetic technique consisted of a 5-ml test dose followed by a 20-ml full dose. Supplemental doses were given as necessary to attain a satisfactory anesthetic level for complete relief of first-stage pain. Repeat doses of 15–20 ml or more were given if the patient became uncomfortable.

Data Recording

A special Obstetrical Caudal Anesthesia Record was provided for numerical recording of all data concerning labor, delivery, and caudal anesthesia. A shaded area of the form pertaining to the anesthesia was completed by the anesthesiologist, and the remainder completed by the nurses. The one-page form, which had space for 240 possible numerical entries and for written comments concerning anesthetic or obstetrical complications, was recorded in triplicate. The third copy, containing numbers only, was used by punch-card operators to produce cards for computer input. (These forms have been described.[1]) A registered nurse ‡ was employed part-time in the delivery room to check for accurate completion of the caudal study records. The cards were run through a carefully designed error-check program, where any errors of sequence, calculation, or omission were detected, listed, and corrected, and the data transferred to new cards.

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Table 3. Other Variables Related to Drug and Delivery (Percentages)

	Nulliparas			Multiparas		
	Mepivacaine Alone	Mepivacaine with Epinephrine	Lidocaine with Epinephrine	Mepivacaine Alone	Mepivacaine with Epinephrine	Lidocaine with Epinephrine
Number of patients	370	332	255	378	351	260
Patients given narcotics	74.1	74.7	67.8	32.8	40.4	36.2
Before caudal	71.4	72.3	64.7	29.1	33.9	31.9
Mean time to caudal (min)	106	102	110	91	86	64
After caudal	2.7	2.4	3.1	3.7	6.6	4.2
Patients given barbiturates	26.2	21.7	28.6	16.1	15.1	15.9
Oxytocic						
None	58.4	56.3	51.4	60.1	52.4	48.1
Induction	13.5	13.6	12.2	20.9	23.9	22.8
Augmentation	28.1	30.1	36.5	19.0	23.6	29.6
Before caudal	20.8	15.4	15.7	9.5	11.1	13.8
After caudal	7.3	14.8	20.8	9.5	12.5	15.8
Membrane rupture						
Spontaneous	43.5	39.5	37.6	37.0	29.9	30.8
Artificial	56.5	60.5	62.4	63.0	70.1	69.2
Before caudal	78.4	79.2	80.0	55.3	64.9	63.5
After caudal	21.6	20.8	20.0	44.7	35.0	36.5
Delivery method						
Spontaneous	3.6	1.2	2.0	18.8	15.1	14.2
Low forceps	79.2	74.1	75.7	66.1	74.9	71.5
Mid forceps	3.8	7.2	4.7	2.6	1.7	3.1
Forceps rotation	12.4	16.0	14.9	10.3	6.8	10.4
High forceps	0	0	0.4	0	0	0
Breech	0.8	1.5	1.5	1.8	1.4	0.8
Cesarean section	0.3	0	0.8	0.3	0	0
Episiotomy						
None	2.7	0.9	3.5	18.0	15.4	14.2
Midline	64.3	75.9	64.3	71.2	74.9	69.2
Mediolateral	32.2	22.0	30.6	10.0	9.1	15.5
Intentional 3 or 4 degrees	0.8	1.2	1.6	0.8	0.6	1.2

TABLE 4. Complications of Anesthesia
(Percentages)

	Mepivacaine Alone	Mepivacaine with Epinephrine	Lidocaine with Epinephrine
Number of patients	748	683	515
Chills or body tremors	21.9	19.8	32.2
Vomiting–retching	2.3	3.7	4.9
Hypotension–shock	1.8	2.6	1.7
Lowest systolic BP (mm Hg)	70	60	70
Mean change (mm Hg)	35	32	44
Headache	0	0.4	0.8
Somnolence	0.3	1.9	0.2
Confusion, disorientation	0.7	0.1	0.2
Tinnitus	0.1	0.4	0.2
Convulsion	0	0	0
Numbness chest, right arm	0	0	0.4
Bell's palsy	0.1	0	0
Horner's syndrome	0.1	0	0
Dyspnea	0.1	0.4	0.2
Respiratory depression	0.3	0.2	0
Chest pain	0	0	0.4
Tachycardia	0	1.3	1.0
Arrhythmia	0	0	0.2
Cyanosis	0	0	0.2
Dural puncture	0.1	0	0
Intrathecal injection	0.1	0	0
Broken section of caudal catheter lost	0	0	0.2

TABLE 5. Obstetric Complications
(Percentages)

	Mepivacaine Alone	Mepivacaine with Epinephrine	Lidocaine with Epinephrine
Number of patients	748	683	515
Antepartum bleeding	0.4	0	0
Intrapartum bleeding <500	0.3	0.1	0
Intrapartum bleeding 500–1,000	0.3	0.1	0
Intrapartum bleeding >1,000	0	0	0
Postpartum bleeding >500	1.3	0.6	1.2
Postpartum uterine atony	0	0	0.2
Retained placenta	0	0.1	0.2
Placenta previa	0.7	0	0.6
Abruptio placentae	2.3	1.2	0.8
Prolapsed cord	0.4	0.1	0.2
Prolapsed cord, occult	0.1	0	0.2
Cord around neck	21.0	20.5	24.5
True knot in cord	0.5	0	0.2
Velamentous insertion of cord	0	0	0.2
Meconium staining	8.7	8.5	10.5
Mean Apgar score (*not per cent*)	7.5	7.89	7.8
Circumvallate placenta	0.3	0	0.2
Fetal HR <100 stage 1	2.8	1.3	2.1
Fetal HR <100 Stage 2	2.7	2.2	2.7
Fetal HR >180 stage 1	0	0.3	0.6
Fetal HR >180 Stage 2	0.4	0.1	0.6
Fetal malformation	1.2	0.4	0.8
Stillbirths	1.1	1.1	0.2
Midtransverse arrest	0.1	0	0.4
Uterine inertia	0.4	0.1	0.8
Cervical laceration	2.5	1.3	2.3
Vaginal laceration	7.6	9.8	7.0
Third-degree laceration	4.0	4.2	4.3
Fourth-degree laceration	3.3	3.4	1.2
Rh sensitization	0.4	0.3	0.4
Hydramnios	0.1	0.4	0.2
Maternal diabetes	0.8	0.4	0.4
Maternal cardiac disease	0	0.3	0.2
Pre-eclampsia	1.6	0.9	1.6
Intrapartum fever	0.1	0.3	0.6

DATA ANALYSIS

After the data had cleared the error-check program, they were analyzed. During the prospective study, the data were frequently called from the computer for summary and analysis. However, the medication code was not broken until the study had been completed, after all decisions concerning errors and editing had been made.

Results

There were 1,862 deliveries (excluding 135 cesarean sections) during the study period from June 9, 1967 through April 22, 1968. During this period, 1,403 patients received caudal analgesia (75 per cent of the deliveries) and 1,104 of these were included in the study. Therefore, the patients studied represented 79 per cent of all caudal anesthesias given, and 60 per cent of all deliveries during the study period.

Among the 1,104 patients in this, our second randomized, double-blind study, there were 911 effective caudal anesthesias and 117 ineffective caudal anesthesias, and 76 patients were excluded for other reasons (table 1), an overall success rate of 89 per cent. The 911 effective caudal anesthesias were divided into two groups: 444 nulliparous patients, of whom 112 received mepivacaine and 332 received mepivacaine–epinephrine; and 467 multiparous patients, of whom 116 received mepivacaine and 351 received mepivacaine–epinephrine.

Patients (nulliparas and multiparas) who received mepivacaine alone in Study I and Study II were compared. When the time from the last exam to complete dilatation was studied for patients according to cervical dilatation at the time the mepivacaine was administered, there was no significant difference in the mean times from last exam to complete dilatation for cervical dilatations ranging from

TABLE 6. Duration of Anesthesia Following Repeated Injection

	Injection Number	Number of Patients Needing Repeat Dose			Mean Dose (ml)			Mean Duration (min)		
		Nulli-paras	Multi-paras	Total	Nulli-paras	Multi-paras	Grand Mean	Nulli-paras	Multi-paras	Grand Mean
Mepivacaine alone (748 cases)										
	1	244	163	407	27	28	27	91	79	86
	2	98	38	136	18	17	18	77	67	72
	3	19	9	48	18	17	18	62	57	62
	4	17	2	19	20	17	19	56	55	56
	5	4	1	5	24	20	23	49	60	50
Mepivacaine with epinephrine (683 cases)										
	1	297	133	430	26	27	26	141	121	135
	2	50	23	73	17	17	17	101	90	98
	3	16	8	24	17	16	17	91	83	88
	4	6	2	8	18	18	18	73	100	80
	5	1	0	2	24	—	24	115	—	115
Lidocaine with epinephrine (515 cases)										
	1	187	136	323	26	26	26	102	92	97
	2	85	42	127	17	17	17	92	79	88
	3	35	11	46	17	17	17	73	66	71
	4	17	4	21	17	19	17	62	62	62
	5	8	2	10	16	18	16	55	67	57

3 to 9 cm. Furthermore, the patients of Study I and those of Study II did not differ significantly in any other variable recorded. Therefore, the data for the patients of Study I who received mepivacaine alone were combined with the data for patients of Study II who re-

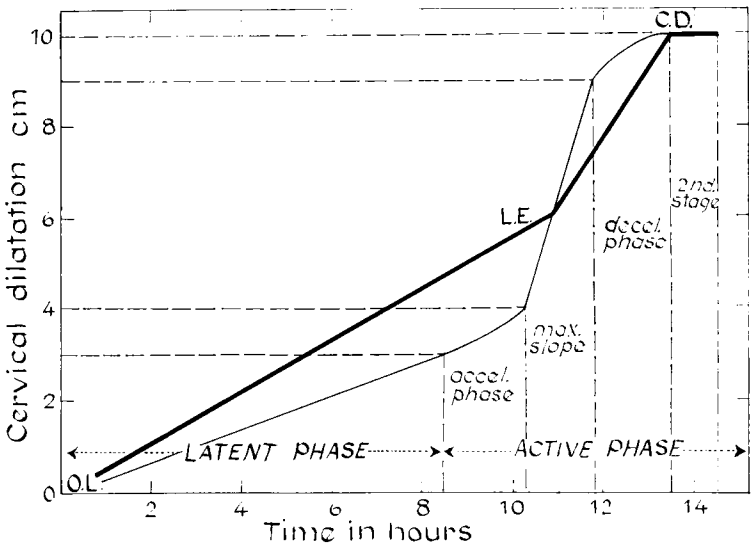

FIG. 1. Time variables measured in this study, superimposed on Friedman's labor curve for nulliparas. O.L. = time of onset of labor; L.E. = time of last vaginal examination and cervical dilatation before caudal medication was injected; C.D. = time of complete cervical dilatation. Times of caudal injection, membrane rupture, delivery, and times of administration of other medication were also recorded.

TABLE 7. Time Course of Labor Related to Anesthesia

	Nulliparas			Multiparas		
	Mepivacaine Alone	Mepivacaine with Epinephrine	Lidocaine with Epinephrine	Mepivacaine Alone	Mepivacaine with Epinephrine	Lidocaine with Epinephrine
Number of patients	370	332	255	378	351	260
Average dilatation when caudal anesthesia was given (mean)	6.0 cm	6.1 cm	6.1 cm	5.3 cm	5.2 cm	5.4 cm
Amount of drug given (mean)	48 ml	41 ml	49.5 ml	40 ml	35 ml	40.1 ml
Onset of labor—complete dilatation (first-stage) (min) (mean)	529	548	594	350	378	384
Complete dilatation—delivery (second-stage) (min) (mean)	57	65	58	34	35	39
Onset of labor—delivery (total labor) (min) (mean)	587	613	652	384	412	423
Onset of labor—last examination (min) (mean)	417	407	442	266	269	275
Last examination—caudal anesthesia started (min) (mean)	19.7	18.4	19.6	18.2	17.0	18.0
Last examination—complete dilatation (min) (mean)	113	141	152	83	109	109
Difference*	28 min		39 min	26 min		26 min
Slope cm/hour	2.2	1.6	1.5	3.4	2.6	2.5

* Difference between mepivacaine alone and mepivacaine with epinephrine or lidocaine with epinephrine.

ceived mepivacaine alone. Thus, there was a total of 2,386 patients, of whom 1,946 received effective caudal anesthesia, while 259 (10.8 per cent) did not have effective caudal anesthesia. There were 181 patients who were excluded for other reasons, 105 in Study I and 76 in Study II. Of the patients who received effective caudal anesthesia, 748 received mepivacaine alone (520 in Study I; 228 in Study II), 683 received mepivacaine–epinephrine, and 515 received lidocaine–epinephrine.

The 1,946 caudal anesthesias were analyzed in detail. Tables 2–5 show the similarities in the groups that received mepivacaine alone, mepivacaine–epinephrine, and lidocaine–epinephrine. Randomization balanced out most precaudal variables not otherwise controlled in the study. However, some of these variables, like "narcotics after caudal" and "oxytocic after caudal" were influenced by the caudal anesthetic. The data were subjected to statistical analyses. Only a few variables, discussed below, showed significant differences among lidocaine–epinephrine, mepivacaine–epinephrine, and mepivacaine-alone groups.

The caudal anesthesias were given during the active phase of labor, and adequate analgesic levels were obtained in most cases (table 2). Hypotension was not a major problem, and vasopressors were given to only 13 patients. A sign test based on the binomial distribution was applied to a small number of cases in which the patients needed supplemental anesthesia. This showed a significant increased need among nulliparas and multiparas receiving mepivacaine alone, compared with those receiving epinephrine.

The narcotics variables (table 3) were similar for all groups. Of importance, however, was the significant difference concerning the

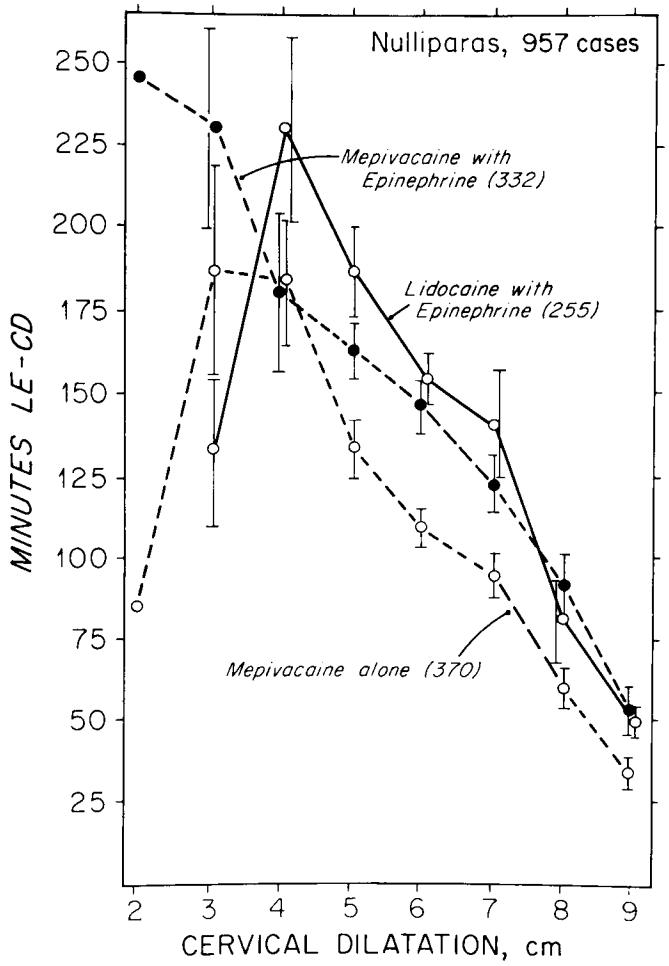

FIG. 2. Subsequent duration of first-stage labor in nulliparas, measured from the time of the last vaginal examination before caudal injection to complete cervical dilatation, plotted for the various cervical dilatations at which the caudal anesthesia were administered. Vertical lines indicate standard errors of the means.

use of oxytocics. The groups were similar in induction and augmentation of labor before administration of caudal anesthesia. But, comparing percentages of patients, more than twice as many nulliparas receiving lidocaine–epinephrine or mepivacaine–epinephrine needed augmentation after caudal anesthesia, compared with those receiving mepivacaine alone. The multiparous patients who received epinephrine showed the same trend, although it was less marked.

The anesthetic complications specifically recorded by the anesthesiologists are listed in table 4. No patient convulsed. There were significantly more chills or body tremors among the patients who received lidocaine–epinephrine. These patients also experienced significantly more vomiting and retching, as did the patients who received mepivacaine–epinephrine.

Obstetric complications were similar in all three groups (table 5). The patients receiving lidocaine experienced the fewest placental abruptions, while those receiving mepivacaine alone experienced the most.

The mean Apgar scores of the infants of the 9–10 per cent of patients who had meconium-stained amniotic fluid were significantly different from the overall mean Apgar scores for each of the three groups. As stated previously, this could reflect bias of the scorer in the face of meconium-stained fluid. All intra-

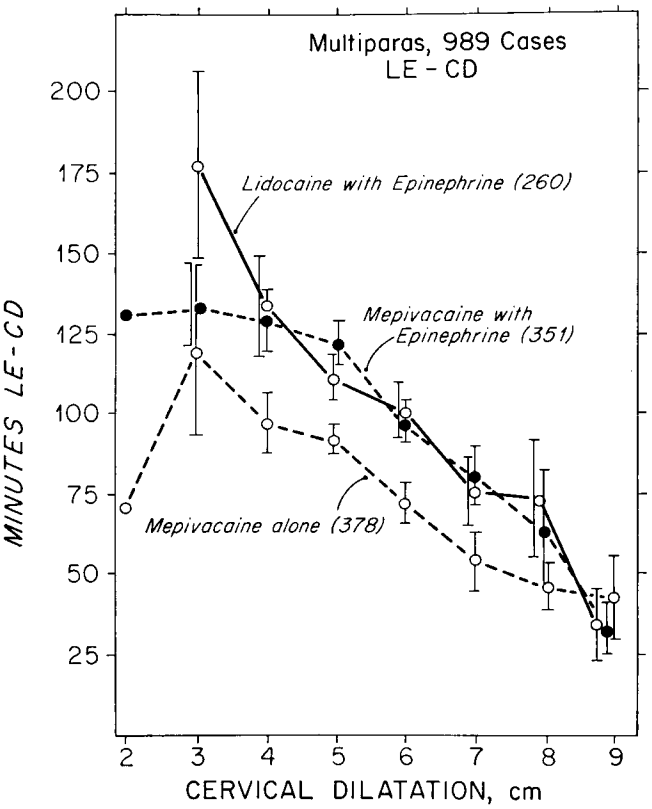

FIG. 3. Subsequent duration of first-stage labor in multiparas, measured from the time of the last vaginal examination before caudal injection to complete cervical dilatation, plotted for the various cervical dilatations at which the caudal anesthesias were administered. Vertical lines indicate standard errors of the means.

uterine deaths occurred and were diagnosed before administration of caudal anesthesia, and the corrected neonatal mortality for the combined studies is zero.

The duration of caudal anesthesia can be measured best by the times between medications in large numbers of patients (table 6). When nulliparas and multiparas were combined, mepivacaine–epinephrine anesthesias were found to last slightly longer than lidocaine–epinephrine anesthesias, which in turn lasted longer than the anesthesias with mepivacaine alone. The tachyphylaxis observed previously[1,3] was again demonstrated convincingly for all three preparations. The initial mean drug dose included the test dose.

Our observations in Study I that there was a difference between durations of anesthesia in nulliparas and multiparas was borne out in Study II. With each dose the nulliparous patients received a longer duration of effect than did multiparous patients (table 6). This was true for each of the three medications ($P < 0.001$).

We believe the most important comparative measurements in the study was the duration of labor from the time of administration of caudal anesthesia to complete cervical dilatation. This is illustrated in figure 1, superimposed on the normal Friedman's curve of labor for nulliparas.[4] LE represents the last vaginal examination before the caudal anesthesia was started. It was important to be sure that the delays between LE and the actual injection of the caudal medication were the same for both groups. These delays were measured and were similar for both groups, as indicated in table 7. Complete dilatation, rather than delivery, was used as the important end-point so that possible wide variation in the obstetricians' management of the second stage of labor would not confound the data. This would not have presented a problem, however, because second-stage durations in the three

TABLE 8. Effect on Subsequent First-stage Labor of Nulliparas and Multiparas of Caudal Anesthesia as Related to Oxytocic

	Number of Patients		Dilatation (cm)		Amount of Drug (ml)		LE − CD		P	
	Nulli-paras	Multi-paras	Nulli-paras	Multi-paras	Nulli-paras	Multi-paras	Nulli-paras	Multi-paras	Nulli-paras	Multi-paras
All groups										
Mepivacaine alone	370	378	6.0	5.3	48	40	113	83		
Mepivacaine with epinephrine	332	351	6.1	5.2	41	35	141	109	<0.0005	<0.0005
Mepivacaine alone	370	378	6.0	5.3	48	40	113	83		
Lidocaine with epinephrine	255	260	6.1	5.4	50	40	152	109	<0.0005	<0.0005
Mepivacaine with epinephrine	332	351	6.1	5.2	41	35	141	109	0.25	N.S.
Lidocaine with epinephrine	255	260	6.1	5.4	50	40	152	109		
No oxytocic										
Mepivacaine alone	216	227	6.3	5.6	44	38	103	78		
Mepivacaine with epinephrine	187	184	6.5	5.7	38	35	125	103	<0.005	<0.0005
Mepivacaine alone	216	227	6.3	5.6	44	38	103	78		
Lidocaine with epinephrine	131	125	6.4	5.7	46	37	139	101	<0.0005	<0.0005
Mepivacaine with epinephrine	187	184	6.5	5.7	38	35	125	103	0.25	N.S.
Lidocaine with epinephrine	131	125	6.4	5.7	46	37	139	101		
Oxytocic induction										
Mepivacaine alone	50	79	5.8	4.8	51	40	111	71		
Mepivacaine with epinephrine	45	84	6.0	4.6	36	34	101	101	N.S.	<0.005
Mepivacaine alone	50	79	5.8	4.8	51	40	111	71		
Lidocaine with epinephrine	31	58	6.1	4.9	44	37	115	86	N.S.	0.25
Mepivacaine with epinephrine	45	84	6.0	4.6	36	34	101	101	0.50	0.25
Lidocaine with epinephrine	31	58	6.1	4.9	44	37	115	86		

groups, compared for both nulliparas and multiparas, were similar.

Patients who received lidocaine–epinephrine or mepivacaine–epinephrine had longer first-stage labor. Also, when the mean times from last examination to complete cervical dilatation in nulliparous patients receiving mepivacaine alone and nulliparous patients receiving mepivacaine–epinephrine are compared, the difference is 28 minutes; for lidocaine–epinephrine this difference is 39 minutes. Among multiparous patients, both lidocaine–epinephrine and mepivacaine–epinephrine were followed by a first stage of labor 26 minutes longer than that in patients receiving mepivacaine alone. The differences between the preparations containing epinephrine and mepivacaine alone were significant ($P < 0.001$). Furthermore, when the cases are divided according to the various cervical dilatations at which the caudal anesthesias were given, the differences (except for cervical dilatations 3 and 4 among nulliparous patients) show consistently shorter subsequent labor with mepivacaine alone, as indicated in figures 2 and 3.

The groups were further partitioned to

study the administration of oxytocin (table 8). For all groups combined, and for patients who did not receive oxytocic (assumed predominantly-normal labors), there were significant differences in the durations of labor (measured from last examination before the caudal anesthetic to complete dilatation) when mepivacaine was compared with the preparations containing epinephrine, but not between the two preparations containing epinephrine. When oxytocin was administered either electively for induction or for augmentation before the caudal anesthesia (almost all received oxytocin iv), the difference between any two of the three preparations with respect to duration of labor was not statistically significant. Even though the oxytocic obscures the difference between the preparations with and without epinephrine with respect to the time from the last examination to complete dilatation, seen in every group, the more important statistic in table 8 is that there was an increase in the need for oxytocic augmentation following drugs with epinephrine compared with mepivacaine alone. This increased need for oxytocic augmentation was significant for both lidocaine–epinephrine and mepivacaine–epinephrine compared with mepivacaine alone.

Discussion

Randomization effectively balanced out the effects of exogenous factors affecting labor, such as maternal height, weight, parity, station, fetal weight, gestational age, and status of the membranes, and made the probability computations meaningful. The random medication selection also obviated the effects of other exogenous factors that can affect labor, such as analgesic and sedative agents and the important oxytocic variable. Physician bias was minimized and balanced between treatment groups by combining the double-blind technique with the randomization. (Previous clinical studies comparing durations of caudal anesthesia with various agents should be questioned unless they incorporated the double-blind technique and randomization of drug administration.)

The results of these two studies, conducted over different periods of time, indicate that the anesthesia practice in this institution is quite uniform. Caudal failure rate, patient age, parity, etc., were stable with time. We have combined data from the two studies in this report. In general, this practice is not to be condoned, since it is often done with little attention to study design, quality control of data, and randomization. When these considerations have been observed and it can be shown that the practice and population have not changed from one study to the next, as we have done here, then it may be possible to use previous data to augment the data for a current study. This is advantageous in that if a standard compound is carried through clinical pharmacologic studies, it need not be given with the same frequency as the test compound, and more information about the compound under investigation can be obtained in a shorter time.

Although the prolongation of first-stage labor observed in patients receiving epinephrine may not seem impressive, it has important clinical implications. The need for oxytocic augmentation of labor has been demonstrated, as well as the need for additional amounts and administrations of local anesthetic. This additional oxytocic and anesthesia is certainly not desirable. There is also evidence, not evaluated in this study, to suggest that prolongation of labor is undesirable.

It has been known for some time that epinephrine inhibits uterine contractility.[5-11] However, it was previously thought that the concentration of 1:200,000 was too low to affect labor.[12] We believe that this study is the first *definitive* clinical study to indicate that the inclusion of epinephrine in the concentration of 1:200,000 in the caudal anesthetic solution will significantly prolong labor. We have confidence in this hypothesis, since it is based upon a study employing mepivacaine alone versus mepivacaine–epinephrine, as well as a study wherein mepivacaine was compared with another local anesthetic (lidocaine) which contained epinephrine. Thus, in both studies the same trends were observed. Our hypothesis is further strengthened by findings in earlier laboratory work.[7]

This study reinforces our conclusion that parity, especially as related to duration of anesthesia (previously investigated), must be

taken into consideration in the analysis of data from obstetric studies. The study suggests differences between local anesthetic agents, and reveals large differences between the effects on labor of agents containing epinephrine and those not containing epinephrine. Conclusions from previous studies of the effects of caudal anesthesia on labor must be questioned unless careful consideration has been given to parity, anesthetic agent, and the use of epinephrine.

Conclusions

Mepivacaine alone appeared to be as effective in relieving labor pain as mepivacaine–epinephrine or lidocaine–epinephrine. Anesthesia lasted slightly longer with lidocaine–epinephrine than with mepivacaine alone, but was significantly longer with mepivacaine–epinephrine. Anesthesia was longer for nulliparas than for multiparas with all three medications studied. Tachyphylaxis was demonstrated for all three medications. The anesthetic and obstetric complications were generally benign and were similar with the two drugs. The drugs appeared to be equally safe for both mothers and babies. The effect of caudal anesthesia on the duration of active first-stage labor depended upon the drug utilized. The duration of first-stage labor was shortest after caudal administration of mepivacaine without epinephrine. The addition of epinephrine to mepivacaine or to lidocaine significantly prolonged it. Approximately twice as many patients needed oxytocic augmentation after caudal anesthesia administered with solutions containing epinephrine.

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