

Obstetrical Caudal Anesthesia:

I. A Randomized Study Comparing 1% Mepivacaine with 1% Lidocaine plus Epinephrine

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A prospective double-blind randomized study of obstetrical caudal anesthesia was done to compare the effects on labor of lidocaine-plus-epinephrine and mepivacaine without epinephrine. The 1,282 patients in the study represented 88 per cent of all caudal anesthetics given and 67 per cent of all deliveries. The two drugs appeared equally effective in relieving labor pain, and the anesthetic and obstetrical complications were generally benign and similar. The duration of anesthesia was slightly longer for lidocaine-plus-epinephrine and was longer for nulliparas as compared with multiparas for both drugs. Tachyphylaxis was demonstrated for both drugs. The duration of first-stage labor after caudal administration of lidocaine-plus-epinephrine was significantly prolonged as compared with mepivacaine without epinephrine. This prolongation averaged 37 minutes for nulliparas and 28 minutes for multiparas. Approximately twice as many patients required oxytocic augmentation of labor after the caudal anesthesia was administered when lidocaine-plus-epinephrine was used. Conclusions from other clinical studies concerning the effect on labor of caudal anesthesia must now be questioned unless some consideration is given to the drugs utilized.

THE EFFECT of caudal anesthesia on labor is disputed. Some investigators have shown that caudal anesthesia enhances cervical dilatation and shortens labor¹⁻¹⁴; others indicate that labor is slowed or prolonged¹⁵⁻²²; still others claim that caudal anesthesia has no effect on

the duration of labor.²³⁻²⁴ Such disagreements have been attributed to different obstetrical conditions, the many variables inherent in labor, preferences concerning resort to oxytocics, use of forceps, and other factors. However, much of the confusion is due to poorly-designed studies with small numbers of patients, problems in interpretation of retrospective studies, and lack of attention to the characteristics of the anesthetic drugs employed.

Early clinical experience with single-injection caudal anesthesia employing 1 per cent mepivacaine (Carbocaine)^{25, 26} as compared with continuous caudal anesthesia with 1 per cent lidocaine (Xylocaine) plus 1:200,000 epinephrine (Suprarenin) led us to suspect that the effect of caudal anesthesia on labor could be related to the type of drug utilized. Therefore, an attempt was made to verify this conjecture. Because of the many variables and the obvious bias of individuals concerning labor, obstetrical anesthesia, and drug effects, a double-blind randomized prospective study was designed. The study involved enough patients to provide reliable statistical comparisons. It is felt that the patients in the study were representative enough to furnish a good basis for firm conclusions.

Materials and Methods

Continuous-catheter caudal analgesia is administered to the majority of patients whose infants are delivered at the Stanford University Medical Center. Stanford Clinic and private patients participated in this study, upon approval of the on-call anesthesiologist.

DRUG PREPARATION

One per cent lidocaine and one per cent mepivacaine were purchased and, on separate days, transferred to a three-gallon, stainless

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Received from Stanford University School of Medicine, Stanford, California 94305. Accepted for publication March 5, 1969. Supported in part by funds contributed by Sterling Winthrop Research Institute and NIH Grant GM 12527.

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OBSTETRICAL CAUDAL ANESTHESIA RECORD

ANESTHESIOLOGISTS

CARD 1	DRUG CODE	DRUG	GRAVIDA	PARA	WKS. GEST.	11	1. SPONT. 2. ART.	DAY	TIME	A.P.	MEMBRANE RUPTURE	30	METHOD	DRUG	OXYTOXIC	0 - None 1 - Synthec. 2 - IM, S.O. 3 - Other	OXYTOXIC STARTED	40	ONSET OF LABOR	50	DILATATION COMPLETE	50	DELIVERY	80	LAST EXAM. BEFORE CAUDAL	STATION	DILATATION	AGE	C.C.	DAY	TIME	A.P.	30	TEST	FIRST	CAUDAL MEDICATIONS
1																																				

HT. FT. - IN. 41

WT. LBS. 51

0 - None 2 - Mediolateral 3 - Intentional 3 or 4 deg.

1 - Midline

EPISTOMY

MIN. SYST. B.P. IN 1st 30 MIN.

MAX. SYST. B.P. IN 1st 30 MIN.

INITIAL SYST. B.P.

1

2

1 - Spontaneous 2 - Low Forceps 3 - Mid Forceps 4 - High Forceps 5 - Forceps Rotation 0 - Other Specify.

6 - Breech 7 - Cesarean 8 - Twin 9 - Twin with version

DELIVERY METHOD

AVER. SKIN LEVEL AFTER 15 MIN.

DRUG CODE

ANESTHESIA COMPLICATIONS		REASON		EVALUATION		SUPPL. ANES.		V. R.		SECOND		THIRD		FOURTH		FIFTH		SIXTH		TOTAL OVER 6		LAST DOSE (OVER 6)	
00 - None	08 - Tachycardia	0 - None	0 - None	1 - Excellent	1 - Excellent	0 - None	0 - None	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent
01 - Dural Puncture	09 - Arrhythmia	1 - Labor	1 - Labor	2 - Good	2 - Good	1 - Labor	1 - Labor	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good
02 - Spinal	10 - Chest Pain	2 - Delivery	2 - Delivery	3 - Fair	3 - Fair	2 - Delivery	2 - Delivery	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair
03 - Confusion	11 - Dyspnea	3 - Epidural	3 - Epidural	4 - Ineffect.	4 - Ineffect.	3 - Epidural	3 - Epidural	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.
04 - Symplocy	12 - Bronchospasm	4 - Rel. Placenta	4 - Rel. Placenta	5 - Anesthetic	5 - Anesthetic	4 - Rel. Placenta	4 - Rel. Placenta	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic
05 - Convulsion	13 - Shock	5 - Other	5 - Other	6 - Other	6 - Other	5 - Other	5 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other
06 - Resp. Depression	14 - Cardiac Arrest	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:
07 - Cyanosis	22 - Other Specify:																						

OBSTETRICAL COMPLICATIONS		REASON		EVALUATION		SUPPL. ANES.		V. R.		SECOND		THIRD		FOURTH		FIFTH		SIXTH		TOTAL OVER 6		LAST DOSE (OVER 6)	
00 - None	11 - Fetal Malformation	0 - None	0 - None	1 - Excellent	1 - Excellent	0 - None	0 - None	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent
01 - Antepartum Bleeding	12 - Fetal H.R. <100 Stage 1	1 - Labor	1 - Labor	2 - Good	2 - Good	1 - Labor	1 - Labor	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good
02 - Intrapartum Bleeding <500 c.c.	13 - Fetal H.R. <100 Stage 2	2 - Delivery	2 - Delivery	3 - Fair	3 - Fair	2 - Delivery	2 - Delivery	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair
03 - Intrapartum Bleeding 500-1000 c.c.	14 - Fetal H.R. >180 Stage 1	3 - Epidural	3 - Epidural	4 - Ineffect.	4 - Ineffect.	3 - Epidural	3 - Epidural	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.
04 - Intrapartum Bleeding >1000 c.c.	15 - Fetal H.R. >180 Stage 2	4 - Rel. Placenta	4 - Rel. Placenta	5 - Anesthetic	5 - Anesthetic	4 - Rel. Placenta	4 - Rel. Placenta	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic
05 - Postpartum Bleeding >500 c.c.	16 - Maternal Hypert. (Hx)	5 - Other	5 - Other	6 - Other	6 - Other	5 - Other	5 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other
06 - Placenta Previa	17 - Cervical Laceration	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:
07 - Vase Previa	18 - Vaginal Laceration																						
08 - Abruptio Placenta	19 - 3rd Deg. Laceration																						
09 - Prolapsed Cord	20 - 4th Deg. Laceration																						
10 - Cord Around Neck																							

OBSTETRICAL COMPLICATIONS		REASON		EVALUATION		SUPPL. ANES.		V. R.		SECOND		THIRD		FOURTH		FIFTH		SIXTH		TOTAL OVER 6		LAST DOSE (OVER 6)	
00 - None	21 - RH Sensitization	0 - None	0 - None	1 - Excellent	1 - Excellent	0 - None	0 - None	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent	1 - Excellent
01 - Antepartum Bleeding	22 - Hydrops Fetalis	1 - Labor	1 - Labor	2 - Good	2 - Good	1 - Labor	1 - Labor	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good	2 - Good
02 - Intrapartum Bleeding <500 c.c.	23 - Hydramnios	2 - Delivery	2 - Delivery	3 - Fair	3 - Fair	2 - Delivery	2 - Delivery	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair	3 - Fair
03 - Intrapartum Bleeding 500-1000 c.c.	24 - Maternal Diabetes	3 - Epidural	3 - Epidural	4 - Ineffect.	4 - Ineffect.	3 - Epidural	3 - Epidural	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.	4 - Ineffect.
04 - Intrapartum Bleeding >1000 c.c.	25 - Maternal Cardiac Dis.	4 - Rel. Placenta	4 - Rel. Placenta	5 - Anesthetic	5 - Anesthetic	4 - Rel. Placenta	4 - Rel. Placenta	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic	5 - Anesthetic
05 - Postpartum Bleeding >500 c.c.	26 - Maternal Hypert. (Hx)	5 - Other	5 - Other	6 - Other	6 - Other	5 - Other	5 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other	6 - Other
06 - Placenta Previa	27 - Pre-Eclampsia	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:	Specify:
07 - Vase Previa	28 - Eclampsia																						
08 - Abruptio Placenta	29 - Uterine Inertia																						
09 - Prolapsed Cord	30 - Other Specify:																						
10 - Cord Around Neck																							

Fig. 1. Obstetrical Caudal Anesthesia Record form designed for this study. The second or study copy was identical to the chart copy.

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OBSTETRICAL CAUDAL ANESTHESIA RECORD

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TABLE 1. Distribution of Study Patients

Number of Patients in Study	1,282
Ineffective caudal anesthetics	142 (11 per cent)
Lidocaine (64)	
Mepivacaine (78)	
Excluded for other reasons	105
Complete dilatation (44)	
Cesarean section before complete (6)	
Twins (11)	
Code broken and drug changed (33)	
Lidocaine (17)	
Mepivacaine (16)	
Miscellaneous (5)	
Incomplete information (6)	
Effective caudal anesthetics	1,035

steel reservoir. Under a laminar flow hood, the solution was filtered through a 0.45-micron millipore filter with prefilter into new 100-ml glass serum vials. The bottles had been machine-washed and rinsed with distilled water in the pharmacy. New rubber stoppers which had been washed and boiled in distilled water were inserted in the bottles, and a multiple-dose aluminum seal was placed on each and crimped. The bottles were then autoclaved for 20 minutes at 120 C at 15-lb pressure in the Central Service Department, using autoclave-sensitive tape on each bottle. Sample bottles from the batch were sent for sterility check to the infectious-disease laboratory. The bottles were then coded, using a random-number table.³⁵ To each coded bottle of 1 per cent lidocaine was attached a one-ml coded vial of epinephrine (1:1,000), and to each coded bottle of 1 per cent mepivacaine was attached a one-ml coded vial of Ringer's solution. These vials were identical in appearance, and were especially prepared by Winthrop Laboratories. The bottles with attached vials were then wrapped and reautoclaved as before. The wrapped caudal solutions were kept in specially-prepared boxes in the delivery area so that they could be used in the specified random order. Neither staff nor the patient

could distinguish the lidocaine from the mepivacaine.

METHOD OF ADMINISTRATION

Caudal analgesia was administered during the active phase of labor by a continuous catheter technique previously described.³⁶ At the time of administration, 0.5 ml of the coded epinephrine or 0.5 ml of the coded Ringer's solution was added to the coded lidocaine or mepivacaine, respectively, providing 100 ml of either of the following: 1 per cent mepivacaine plus 0.5 ml of Ringer's solution or 1 per cent lidocaine plus 0.5 ml of 1:1,000 epinephrine (a final concentration of 1:200,000 epinephrine). The usual anesthetic technique consisted of a 5-ml test dose followed by a 20-ml full dose. Supplemental doses were given in an amount necessary to attain a satisfactory anesthetic level for complete relief of first-stage pain. Repeat doses of a minimum of 15-20 ml were given if the patient became uncomfortable.

DATA RECORDING

A specially prepared Obstetrical Caudal Anesthesia Record was provided for numerical recording of all data concerning the labor, delivery and caudal anesthesia. A shaded area of the form pertaining to the anesthetic was completed by the anesthesiologist, and the remainder completed by the nurses. There was room for 240 possible numerical entries on the one-page form, which was recorded in triplicate (fig. 1), with additional space for written remarks concerning anesthetic or obstetrical complications. The third copy of the form, containing numbers only, was used by punch card operators to produce cards for computer input (fig. 2). It was necessary to employ a registered nurse* part-time in the delivery room to check for accurate completion of all 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 to new cards.

* The authors are grateful to Jan Choyce, RN, for her meticulous checking of the patient report forms.

FIG. 3. Distribution and grouping of study patients by parity and caudal medication used.

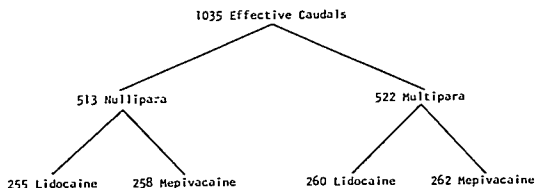


TABLE 2. Distribution of Maternal and Fetal Variables

	Nulliparas		Multiparas	
	Lidocaine with Epinephrine	Mepivacaine Alone	Lidocaine with Epinephrine	Mepivacaine Alone
Number of cases	255	258	260	262
Mean age (years)	23.1	23.2	27.1	27.3
Mean height (inches)	64.6	64.5	64.8	64.3
Mean weight (pounds)	147	149	151	152
Mean parity	0	0	1.64	1.70
Mean gestation (weeks)	39.8	39.8	39.5	39.6
Mean birth weight (pounds, ounces)	7'4	7'3½	7'6	7'6
Number weighing less than 2,500 gm	11	9	9	12
Mean Apgar score	8.4	8.2	8.6	8.2
Number of scores lower than 6	12	14	4	12
Stillbirths	1	2	0	6
Neonatal deaths	1	0	2	1

TABLE 3. Distribution of Variables Related to Labor and Anesthesia

	Nulliparas		Multiparas	
	Lidocaine with Epinephrine	Mepivacaine Alone	Lidocaine with Epinephrine	Mepivacaine Alone
Number of cases	255	258	260	262
Mean dilatation	6.1	6.0	5.4	5.4
Mean station	+0.76	+0.88	+0.24	+0.18
Number less than 0	9	3	39	38
Mean skin anesthetic level	T9.7	T9.7	T9.5	T9.8
Mean systolic BP change	18	16	16	14
Number less than 80	19	9	14	8
Vasopressor (number of patients)	4	0	1	1
Supplemental anesthesia (number of patients)	7	18	13	17
Patient-doctor evaluation	Pt. Dr.	Pt. Dr.	Pt. Dr.	Pt. Dr.
Excellent	227 229	216 225	232 234	207 208
Good	18 17	32 22	17 19	38 42
Fair	10 9	10 11	11 7	17 12

TABLE 4. Distribution of Other Drug and Membrane Variables

	Nulliparas		Multiparas	
	Lidocaine with Epinephrine	Mepivacaine Alone	Lidocaine with Epinephrine	Mepivacaine Alone
Number of cases	255	258	260	262
Patients given narcotics	173 (68 per cent)	190 (74 per cent)	94 (36 per cent)	93 (35 per cent)
Before caudal	165	182	83	83
Mean time	110	95	64	66
After caudal	8	8	11	10
Patients given barbiturates	73	66	40	50
Oxytocic				
None	131	155	125	161
Induction	31	34	58	54
Augmentation	93	69	77	47
Before caudal	40	48	36	26
After caudal	53	21	41	21
Membrane rupture				
Spontaneous	96	115	80	100
Artificial	159	143	180	100
Before caudal	204	185	165	146
After caudal	51	73	95	116

DATA ANALYSIS

After the data had cleared the error-check program, they were analyzed.† During the course of the prospective study, the data were

† Analyses were carried out at the Stanford Computer Center employing an IBM 7090.

frequently called from the computer for summary and analysis of various variables. However, the medication code was not broken until the study had been completed, after all decisions concerning errors and editing had been made.

TABLE 5. Distribution of Delivery Variables

	Nulliparas		Multiparas	
	Lidocaine with Epinephrine	Mepivacaine Alone	Lidocaine with Epinephrine	Mepivacaine Alone
Number of cases	255	258	260	262
Delivery method				
Spontaneous	5	11	37	55
Low forceps	193 (76 per cent)	205 (79 per cent)	186 (71 per cent)	166 (63 per cent)
Mid forceps	12	10	8	9
Forceps rotation	38 (20 per cent)	29 (15 per cent)	27 (13 per cent)	28 (14 per cent)
High forceps	1	0	0	0
Breech	4	3	2	7
Cesarean section	2	0	0	0
Episiotomy				
None	9	7	37	37
Midline	164 (64 per cent)	150 (58 per cent)	180 (69 per cent)	192 (73 per cent)
Mediolateral	78 (31 per cent)	99 (38 per cent)	40 (15 per cent)	31 (12 per cent)
Intentional 3 or 4°	4	2	3	2

TABLE 6. Anesthesia Complications

	Lidocaine with Epinephrine	Mepivacaine
Number of cases	515	520
Chills or body tremors	166 (33 per cent)	133 (26 per cent)
Vomiting-retching	25	12
Hypotension-shock	9	18
Lowest systolic BP	70	78
Mean change	44	34
Headache	4	0
Somnolence	1	2
Confusion, disorientation	1	1
Tinnitus	1	0
Convulsion	0	0
Numbness chest, right arm	2	0
Bell's palsy	0	1
Horner's syndrome	0	1
Dyspnea	1	1
Respiratory depression	0	1
Chest pain	2	0
Tachycardia	5	0
Arrhythmia	1	0
Cyanosis	1	1
Dural puncture	0	1
Intrathecal injection	0	1
Broken section of caudal catheter lost	1	0

Results

There were 1,904 deliveries (excluding 108 cesarean sections) during the study period from July 26, 1966 through June 9, 1967. During this period, 1,453 patients received caudal analgesia (76 per cent of the deliveries) and 1,282 of these were in the study. Therefore, the study patients represent 88 per cent of all caudal anesthetics given and 67 per cent of all deliveries during the study period.

Of the 1,282 patients in the randomized, double-blind study, there were 1,035 effective caudal anesthetics, 142 ineffective caudal anesthetics, and 105 excluded for other reasons (table 1), an overall success rate of 89 per cent. Of the 105 patients excluded for other reasons, the cervixes of 44 were completely dilated when the caudal anesthesia was given, six had cesarean sections before being completely dilated, 11 delivered twins, 33 were excluded because the code was broken and the drug changed before complete dilatation because of adverse reactions or poor results (17 lidocaine, 16 mepivacaine), five were excluded for miscellaneous reasons (hydatidiform mole, caudal anesthesia allowed to wear off, patient pulled caudal catheter out herself, etc.), and six were excluded because of incomplete information.

The 1,035 effective caudal anesthetics were divided into groups, as indicated in figure 3, and analyzed in detail. Tables 2, 3, 4, and 5

TABLE 7. Obstetrical Complications

	Lidocaine with Epinephrine	Mepivacaine
Number of Cases	515	520
Antepartum bleeding	0	2
Intrapartum bleeding	0	2
<500	0	2
500-1,000	0	2
>1,000	0	0
Postpartum bleeding >500	6	7
Postpartum uterine atony	1	0
Retained placenta	1	0
Placenta previa	3	4
Abruptio placentae	1	14
Prolapsed cord	1	1
Prolapsed cord, occult	1	1
Cord around neck	126 (25 per cent)	114 (22 per cent)
True knot in cord	1	4
Velamentous insertion of cord	1	0
Meconium staining	54 (10 per cent)	51 (10 per cent)
Mean Apgar score	7.8	7.6
Circumvallate placenta	1	1
Fetal IIR <100 stage 1	11	13
Fetal IIR <100 stage 2	14	18
Fetal IIR >180 stage 1	3	0
Fetal IIR >180 stage 2	3	3
Fetal malformation	4	9
Stillbirths	1	8
Mid transverse arrest	2	0
Uterine inertia	4	2
Cervical laceration	12	15
Vaginal laceration	36	34
Third degree laceration	22	16
Fourth degree laceration	6	14
Rh sensitization	2	3
Hydramnios	1	0
Maternal diabetes	2	1
Maternal cardiac disease	1	0
Pre-eclampsia	8	9
Intrapartum fever	3	1

TABLE 8. Duration of Anesthesia Following Repeated Injection

	Injection Number	Number of Patients Needing Repeat Dose	Mean Dose (ml)	Mean Duration (Min.) before Repeat Dose
Lidocaine with epinephrine (515 cases)	1	323	26	97
	2	127	17	88
	3	46	17	71
	4	21	17	62
	5	9	16	57
Mepivacaine alone (520 cases)	1	290	27	87
	2	105	18	71
	3	39	18	59
	4	16	18	53
	5	5	23	50

TABLE 9. Duration of Anesthesia Following Repeated Injection

	Injection Number	Number of Patients		Mean Dose (ml)		Mean Duration (min)	
		N*	M*	N	M	N	M
Lidocaine with epinephrine (515 cases)	1	187	136	26	26	102	92
	2	85	42	17	17	92	79
	3	35	11	17	17	73	66
	4	17	4	17	19	62	62
	5	8	2	16	18	55	67
Mepivacaine alone (520 cases)	1	181	109	27	28	92	79
	2	78	27	18	17	74	64
	3	32	7	18	17	59	56
	4	74	2	18	17	53	55
	5	4	1	24	20	49	60

* N = nullipara; M = multipara.

show the similarities between the lidocaine and mepivacaine groups with respect to most variables. It is evident that randomization balanced out variables not otherwise controlled. The data were subjected to statistical analysis. Only a small number of variables, discussed below, showed significant differences between the lidocaine and mepivacaine groups.

Using a two-sample *t* test, differences in Apgar scores (table 2) were not significant in nulliparas but were significant in multiparas ($P < 0.005$). There were four neonatal deaths in this sample of patients; but when corrected

for severe erythroblastosis and marked prematurity, the perinatal mortality as related to the anesthesia was zero. The stillbirths also were not related, as in every case the diagnosis of intrauterine death was made before the caudal anesthetic was administered.

The caudal anesthetics were given during the active phase of labor, and adequate analgesic levels were obtained in most cases (table 3). Hypotension was not a major problem, and vasopressors were given to only six patients. A test based on the binomial distribution was applied to a small number

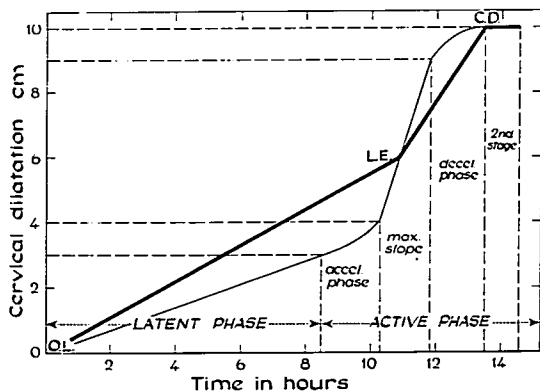


FIG. 4. Time variables measured in this study superimposed on Friedman's labor curve for nulliparas. O.L. = time of onset of labor; L.E. = time of last vaginal examination and cervical dilatation before caudal medication was injected; C.D. = time of complete cervical dilatation. Times of caudal injection, membrane rupture, delivery and times of other medication administration were also recorded.

TABLE 10. Time Course of Labor Related to Anesthesia

		Nulliparas		Multiparas	
		Lidocaine with Epinephrine	Mepivacaine Alone	Lidocaine with Epinephrine	Mepivacaine Alone
Number of cases		255	258	260	262
Average dilatation when caudal anesthesia was given	Mean	6.1	6.0	5.4	5.4
	SD	1.3	1.3	1.2	1.3
	Max.	9	9	9	9
	Min.	3	3	3	2
Amount of drug given (ml)	Mean	49.5	50.0	40.1	40.7
	SD	22	23	16	15
	Max.	153	148	109	108
	Min.	20	18	20	15
Onset of labor—complete dilatation (first stage)	Mean	594	536	384	357
Complete dilatation—delivery (second stage)	Mean	58	61	39	35
Onset of labor—delivery (total labor)	Mean	652	597	423	392
Onset of labor—last examination	Mean	442	420	275	275
Last examination—caudal anesthesia started	Mean	19.6	20.0	18.0	18.8
Last examination—complete dilatation	Mean	152	115	109	81
	Difference	37"		28"	
	Slope cm/hr	1.5	2.1	2.5	3.4

cases which required supplemental anesthesia. This showed a barely significant increased need only for nulliparas receiving mepivacaine ($P < 0.05$).

The narcotics variables (table 4) were similar for both groups. Of importance, however, was a significant difference concerning the use of oxytocics. The groups were similar for induction and augmentation of labor before administration of caudal anesthesia. But more than twice as many patients receiving lidocaine-plus-epinephrine required augmentation after the caudal anesthesia as those receiving mepivacaine alone.

The anesthesia complications specifically recorded by the anesthesiologist are shown in table 6. None of the patients convulsed. There were significantly more chills or body tremors among the patients who received lidocaine ($P < 0.01$). These patients also experienced significantly more vomiting and retching ($P < 0.05$).

Obstetrical complications were similar with both drugs (table 7). The patients receiving lidocaine experienced significantly fewer placental abruptions ($P < 0.05$). The mean Apgar scores of the 10 per cent of patients who showed meconium-stained amniotic fluid were significantly different for both drugs when

compared with the overall mean Apgar score ($P < 0.005$). This may reflect bias of the scorer in the face of meconium-stained fluid. Again, all intrauterine deaths occurred and were diagnosed before administration of caudal anesthesia, and the corrected neonatal mortality for this group was also zero.

The duration of anesthesia can only be measured by the time between repeat doses in large numbers of patients (tables 8 and 9). When nulliparas and multiparas were combined (table 8), the lidocaine-plus-epinephrine caudal anesthetics were noted to last slightly longer than the caudal anesthetics with mepivacaine alone. The commonly-suspected tachyphylaxis was demonstrated convincingly for both drugs. The initial mean drug dose included the test dose.

An unexpected finding was the difference between nulliparas and multiparas in durations of anesthesia with both drugs (table 9). Weighted linear regression was used to test whether the two sets of means were significantly different or due to chance fluctuation. The differences were significant in all directions ($P < 0.001$).

The most important comparative measurement in the study was the duration of labor from the time of administration of caudal an-

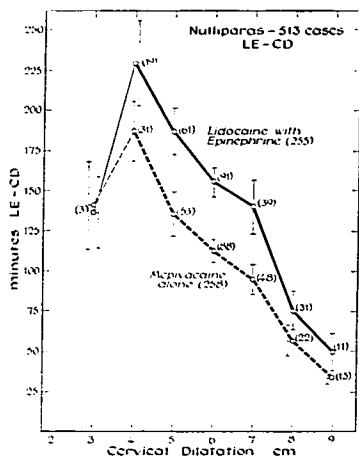


FIG. 5. Subsequent duration of first-stage labor in nulliparas, measured from the time of the last vaginal examination before caudal injection to complete cervical dilatation, plotted for the various cervical dilatations at which the caudal anesthetics were administered. Vertical lines indicate standard errors of the means and the numbers in parentheses indicate the numbers of cases given caudal anesthetics at each cervical dilatation.

esthesia to complete cervical dilatation. This is illustrated in figure 4, superimposed on the normal Friedman's curve of labor for nulliparas.²⁰ 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 10. Complete dilatation rather than delivery was used as the important end point because of the fear of wide variation in the obstetricians' management of the second stage of labor. This was unfounded, however, as shown by the similar second-stage durations for the groups compared.

As noted in table 10, patients who received lidocaine-plus-epinephrine had longer first-stage labors than those receiving mepivacaine without epinephrine, as measured from the

last examination before caudal anesthesia to complete cervical dilatation. The mean differences were 37 minutes for nulliparas and 28 minutes for multiparas. The differences were significant ($P < 0.001$). Further, when the cases are divided according to the various cervical dilatations at which the caudal anesthetics were given, the differences show consistently shorter subsequent labor with mepivacaine, as indicated in figures 5 and 6.

The groups were further partitioned with respect to oxytocin administration (tables 11 and 12). For all groups combined and for those who did not receive any oxytocin (assumed predominantly normal labors), there were significant differences in the duration of labor as measured from the last examination before administration before the caudal anesthesia to complete dilatation (LE-CD). When oxytocin was administered either electively for induction or for augmentation (almost all received intravenous oxytocin), the difference in duration of labor tended to be smaller, though it was still close to statistical significance. More important, it can be seen that more pa-

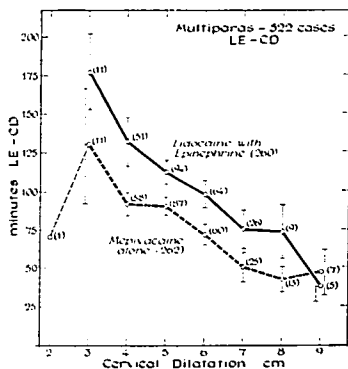


FIG. 6. Subsequent duration of first-stage labor in multiparas, measured from the time of the last vaginal examination before caudal injection to complete cervical dilatation, plotted for the various cervical dilatations at which the caudal anesthetics were administered. Vertical lines indicate standard errors of the means and the numbers in parentheses indicate the numbers of cases given caudal anesthetics at each cervical dilatation.

TABLE 11. Effect on Subsequent First-stage Labor of Caudal Anesthesia as Related to Oxytocic Variable

	Number of Patients	Dilatation	Amount of Drug (ml)	LE-CD	Significance (p)
All groups					
Lidocaine with epinephrine	255	6.1	49.5	152	<0.001
Mepivacaine alone	258	6.0	50	115	
No oxytocic					
Lidocaine with epinephrine	131	6.4	46	139	<0.001
Mepivacaine alone	155	6.2	47	108	
Oxytocic induction					
Lidocaine with epinephrine	31	6.1	44	115	Not significant
Mepivacaine alone	34	5.8	49	103	
Oxytocic before caudal					
Lidocaine with epinephrine	40	5.9	45	125	<0.05
Mepivacaine alone	48	5.8	51	100	
Oxytocic after caudal					
Lidocaine with epinephrine	53	5.7	65	227	Not significant
Mepivacaine alone	21	5.4	73	228	

TABLE 12. Effect on Subsequent First-stage Labor of Multiparas of Caudal Anesthesia as Related to Oxytocic Variable

	Number of Patients	Dilatation	Amount of Drug (ml)	LE-CD	Significance (p)
All groups					
Lidocaine with epinephrine	260	5.4	40.1	109	<0.001
Mepivacaine alone	262	5.4	40.7	81	
No oxytocic					
Lidocaine with epinephrine	125	5.7	37	101	<0.001
Mepivacaine alone	161	5.6	39	77	
Oxytocic induction					
Lidocaine with epinephrine	58	5.9	37	85	<0.10
Mepivacaine alone	54	5.0	41	68	
Oxytocic before caudal					
Lidocaine with epinephrine	36	5.1	40	91	<0.05
Mepivacaine alone	26	4.8	40	75	
Oxytocic after caudal					
Lidocaine with epinephrine	41	5.2	52	186	Not significant
Mepivacaine alone	21	4.8	52	159	

tients required augmentation of labor after the caudal anesthesia was given when lidocaine-plus-epinephrine was used. This increased need for oxytocic augmentation following lidocaine-plus-epinephrine was significant ($P < 0.01$).

Discussion

Only a double-blind prospective study such as this, utilizing a truly randomized medica-

tion selection with a large representative sample of obstetrical patients, allows reliable statistical analysis of comparative caudal anesthetic drug effects on labor. The randomization balances out the effects of endogenous factors affecting labor, such as maternal height and weight, parity, station, fetal weight, gestational age and status of the membranes, and makes the probability computations meaningful. The random medication selection also obviates the

effects of 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.

The caudal anesthetic agents compared in this study were similar in effectiveness of pain relief, but the duration of anesthesia was slightly longer with lidocaine-plus-epinephrine than with mepivacaine without epinephrine. In addition, duration of anesthesia was greater in nulliparas than in multiparas, for both drugs. Clinical studies of the past comparing durations of caudal anesthesia with various drugs should be questioned unless the parity variable was taken into consideration in analysis of the data.

The duration of active first-stage labor was significantly prolonged after caudal anesthesia when lidocaine-plus-epinephrine was used, compared with mepivacaine without epinephrine. Whether this difference was due to possible inhibitory effects of lidocaine or epinephrine or their combination, or to possible stimulatory effects of mepivacaine, is not known, but is being investigated in a study currently in progress. Results of other studies suggest that epinephrine is the important variable because it is known to inhibit uterine contractility.^{17, 19, 21, 25, 37-40}

Conclusions from previous clinical studies concerning the effect on labor of caudal anesthesia must now be questioned unless some consideration is given to the drugs utilized.

Conclusions

Lidocaine-plus-epinephrine and mepivacaine alone appeared to be equally effective in relieving labor pain. The duration of anesthesia was slightly longer for lidocaine-plus-epinephrine. The duration of anesthesia was longer for nulliparas than for multiparas with both drugs. Tachyphylaxis was demonstrated for both drugs.

The anesthetic and obstetrical complications were generally benign and were similar for both 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 on the drug utilized. The duration of first-stage labor

after caudal administration of lidocaine-plus-epinephrine was significantly prolonged, compared with mepivacaine without epinephrine. This prolongation averaged 37 minutes for nulliparas and 28 minutes for multiparas. Approximately twice as many patients required oxytocic augmentation after the caudal anesthesia was administered when lidocaine-plus-epinephrine was used.

The authors gratefully acknowledge the essential contributions to this study from many sources—the patients, physicians, nurses, programmers, and secretaries. Special acknowledgment is due Dr. J. Weldon Bellville and Dr. William Forrest of the Department of Anesthesia at Stanford for their advice and help in the design and implementation of the study. The advice and help of Dr. Byron W. Brown, Professor of Biostatistics at Stanford, and Dr. Siegfried Schach, Visiting Assistant Professor of Statistics, in statistical evaluation of the data are also gratefully acknowledged.

References

1. Ball, H. C. J., and Chambers, J. S. W.: Primary cervical dystocia treated with caudal analgesia, *Brit. Med. J.* 1: 1275, 1956.
2. Ellis, C. J., and Sheffrey, J. B.: Continuous caudal anesthesia as an analgesic and therapeutic agent, *Anesth. Analg.* 24: 193, 1945.
3. Calley, A. H.: Continuous caudal analgesia in obstetrics, *Anaesthesia* 4: 154, 1949.
4. Gunther, R. E., and Harer, W. B., Jr.: Long acting single injection caudal anesthesia. 1208 obstetrical deliveries with mepivacaine, *Calif. Med.* 105: 424, 1966.
5. Gunther, R. E., and Harer, W. B., Jr.: Single injection caudal anesthesia, *Amer. J. Obstet. Gynec.* 92: 305, 1965.
6. Hallet, R. L.: The conduct of labor and results with continuous caudal anesthesia, *Int. J. Anesth.* 1: 91, 1953.
7. Harer, W. B., Jr., Gunther, R. E., and Stubblefield, C. T.: Long acting single injection caudal anesthesia, *Amer. J. Obstet. Gynec.* 87: 236, 1963.
8. Hingson, R. A., Cull, W. A., and Benzinger, M.: Continuous caudal analgesia in obstetrics, *Anesth. Analg.* 40: 119, 1961.
9. Hodges, W. R.: Continuous caudal analgesia in obstetrics: 300 cases, *J.A.M.A.* 125: 336, 1944.
10. Johnson, C. T.: Continuous caudal analgesia. Experiences in the management of disordered uterine function in labour, *Brit. Med. J.* 1: 627, 1954.
11. Johnson, C. T.: Prolonged labour (a clinical trial of continuous caudal analgesia), *Brit. Med. J.* 2: 386, 1957.
12. Lewis, M. S., and Austin, R. B.: Continuous caudal versus saddleblock anesthesia in ob-

- stetrics, *Amer. J. Obstet. Gynec.* 59: 1146, 1950.
13. Lull, C. B.: Some observations in use of continuous caudal analgesia, *Amer. J. Obstet. Gynec.* 47: 31, 1944.
14. Moir, D. D., and Willocks, J.: Management of incoordinate uterine action under continuous epidural analgesia, *Brit. Med. J.* 3: 396, 1967.
15. Alexander, J. A., and Franklin, R. R.: Effects of caudal anesthesia on uterine activity, *Obstet. Gynec.* 27: 436, 1966.
16. Bush, R. C.: Caudal analgesia for vaginal delivery. II. Analysis of complications, *ANESTHESIOLOGY* 20: 186, 1959.
17. Filler, W. W., Jr., Hall, W. C., and Filler, N. W.: Analgesia in obstetrics. The effect of analgesia on uterine contractility and fetal heart rate, *Amer. J. Obstet. Gynec.* 98: 832, 1967.
18. Friedman, E. A.: Labor in multiparas: A graphico-statistical analysis, *Obstet. Gynec.* 8: 691, 1956.
19. Reynolds, S. R. M., Harris, J. S., and Kaiser, I. H.: Clinical Measurement of Uterine Forces in Pregnancy and Labor. Springfield, Charles C Thomas, 1954, p. 232.
20. Ritmiller, L. F., and Rippman, E. T.: Caudal analgesia in obstetrics: Report of thirteen years' experience, *Obstet. Gynec.* 9: 5, 1957.
21. Rucker, J. P.: The action of adrenalin on the pregnant uterus, *Southern Med. J.* 18: 412, 1925.
22. Siever, J. M., and Mousel, L. H.: Continuous caudal anesthesia in three hundred unselected obstetric cases, *J.A.M.A.* 122: 424, 1943.
23. Bromage, P. R.: Continuous lumbar epidural analgesia for obstetrics, *Canad. Med. Ass. J.* 85: 1136, 1961.
24. Brown, H. O., Thompson, J. M., and Fitzgerald, J. E.: An analysis of 500 obstetrical cases with continuous caudal anesthesia using pontocaine, *ANESTHESIOLOGY* 7: 355, 1946.
25. Caldeyro-Barcia, R., and Poseiro, J. J.: Physiology of the uterine contraction, *Clin. Obstet. Gynec.* 3: 366, 1960.
26. Cibils, L. A., and Spackman, T. J.: Caudal analgesia in first-stage labor: Effect on uterine activity and the cardiovascular system, *Amer. J. Obstet. Gynec.* 84: 1042, 1962.
27. Evans, T. N., Morley, G. W., and Helder, L.: Caudal anesthesia in obstetrics, *Obstet. Gynec.* 20: 726, 1962.
28. Fernandez-Sepulveda, R., and Gomez-Rogers, C.: Single-dose caudal anesthesia. Its effect on uterine contractility, *Amer. J. Obstet. Gynec.* 98: 847, 1967.
29. Friedman, E. A.: Primigravid labor, *Obstet. Gynec.* 6: 567, 1955.
30. Friedman, E. A., and Sachtleben, M. R.: Caudal anesthesia. The factors that influence its effect on labor, *Obstet. Gynec.* 13: 442, 1959.
31. Henry, J. S., Jr., Kingston, M. B., and Maughan, G. B.: The effect of epidural anesthesia on oxytocin-induced labor, *Amer. J. Obstet. Gynec.* 97: 350, 1967.
32. Kandel, P. F., Spoerel, W. E., and Kinch, R. A. H.: Continuous epidural analgesia for labour and delivery: Review of 1,000 cases, *Canad. Med. Ass. J.* 95: 947, 1966.
33. Moore, D. C., Bridenbaugh, L. D., Bagdikian, P. A., Bridenbaugh, P. O., and Stander, H. O.: The present status of spinal (subarachnoid) and epidural (peridural) block: A comparison of the two techniques, *Anesth. Analg.* 47: 40, 1968.
34. Vasicka, A., and Kretschmer, H.: Effect of conduction and inhalation anesthesia on uterine contractions, *Amer. J. Obstet. Gynec.* 82: 600, 1961.
35. Rand Corporation: A Million Random Digits with 100,000 Normal Deviates. Glencoe, Ill., Free Press, 1955.
36. Bush, R. C.: Caudal analgesia for vaginal delivery. I. Organization, medication, technique, maternal and perinatal infant mortality, *ANESTHESIOLOGY* 20: 31, 1959.
37. Kaiser, I. H., and Harris, J. S.: The effect of adrenaline on the pregnant human uterus, *Amer. J. Obstet. Gynec.* 59: 775, 1950.
38. Reynolds, S. R. M.: Physiology of the Uterus. New York, Hafner, 1965, p. 143.
39. Wansbrough, H., Nakanishi, H., and Wood, C.: Effect of epinephrine on human uterine activity in vitro and in vivo, *Obstet. Gynec.* 30: 779, 1967.
40. Zuspan, F. P., Cibils, L. A., and Pose, S. V.: Myometrial and cardiovascular responses to alterations in plasma epinephrine and nor-epinephrine, *Amer. J. Obstet. Gynec.* 84: 841, 1962.