Tokai J Exp Clin Med., Vol. 29, No. 3, pp. 79-90, 2004

Developing and Establishing an Ideal Method of Continuous-Infusion Epidural Analgesia for Delivery Using the Double-Catheter Method

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(Received April 28, 2004; Accepted June 9, 2004)

We evaluated the efficacy of a new method of induction of epidural obstetric analgesia devised by us. The upper and lower catheters used for the epidural double-catheter method were connected to a compression-type disposable injector (Coopdech Syrinjector). 0.125 % bupivacaine + 2 μg/ml fentanyl (6 ml/h) were serially injected via the upper catheter. In the latter half of Stage 1 of labor, the same drugs were continuously infused via the lower catheter (4 ml/h).

The mean number of additional drug doses administered via the upper catheter was 0.67 ± 0.90 (range: 0-3) when the analgesia induction was commenced after the cervix was dilated to 8 cm in nulliparous women or 6 cm in multiparous women. The method of analgesia was found to be more effective than the conventional method (uncombined continuous infusion of a local anesthetic) for alleviating the pain of the latter half of Stage 1, and Stage 2 of labor. The mean number of additional drug doses injected via the lower catheter was 0.37 ± 0.57 (range: 0-2). The number of additional doses in the 49 women averaged 0.16 per hour and 1.04 per delivery. Thus, good results were obtained.

Key words : Bupivacaine, Fentanyl, Continuous infusion epidural analgesia, Double catheter method, Obstetric analgesia

INTRODUCTION

Epidural anesthesia is considered to be an ideal method for the induction of obstetric analgesia using drugs [19]. In addition to the effect of continuous infusion of a drug using the single catheter method, the efficacy of combined use of patient-controlled epidural analgesia (PCEA) [3, 12, 17, 30] and combined spinal-epidural analgesia (CSE) [10, 23] has also been studied. Attempts have also been made to develop and establish a new method of induction of obstetric analgesia using the double-catheter method.

When the PCEA method, which involves drug infusion by the pregnant woman herself, is combined with the conventional single-catheter method, the frequency of additional drug doses that requires to be injected by the medical team is reduced, thus allowing manpower saving. However, from the anatomical and physiological points of view, in theory, the single catheter method is unfit for clinical use. The shortcomings of the single-catheter method can be overcome by the use of the double-catheter method, but it is difficult for pregnant women to judge which of the two catheters, upper or lower, should be first used for additional drug infusion. Furthermore, if additional infusion is made via both the upper and lower catheters at the same time, the amount of the drug administered may become excessive. The greatest advantage of CSE lies in that the combined use of spinal anesthesia using the needle-through-needle method (with puncture at one point) allows rapid induction of the anesthetic effects, satisfying the pregnant

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woman. The present study on continuous infusion epidural analgesia (CIEA) using the double-catheter method [20] was aimed at determining the optimum concentration and volume of the drugs required at the start of analgesia, evaluating the reduction in burden on the medical team and adequacy of the anesthetic effects, and investigating the adverse reactions and complications in clinical cases, with the goal of establishing a method of obstetric analgesia that would be highly satisfactory for pregnant women.

SUBJECTS AND METHODS

During the period from October 2001 to March 2003, 54 pregnant women received consent for conducting epidural analgesia for deliveries at the Tokai University Hospital or at facilities affiliated with the Department of Obstetrics and Gynecology of Tokai University School of Medicine. Of these women, 52 underwent full-term transvaginal delivery of a single fetus in cephalic presentation. In 49 of these women, the cervix had dilated to 8 cm or less at the start of the epidural analgesia, and infusion via the lower catheter was continued for 1 hour or longer (less than 1 hour in the remaining 3 women). These 49 women, excluding the 2 women who underwent Cesarean section or other procedures, were the subjects of this study. There were 38 nulliparous women and 11 multiparous women (one previous delivery in 10 women and 2 previous deliveries in 1 woman). The physical status according to the American Society of Anesthesiologists criteria, was I or II in all the women. For women who required induction of delivery or elective induction of labor, an intravenous line was established, and oral intake was prohibited from 0:00 A.M. on the day of the delivery, and oxytocin (10 U) dissolved in 500 ml of 5 % glucose solution was administered.

It would be desirable to insert the epidural tube before the onset of labor pain. If the tube must be inserted after the onset of labor pain, it should be inserted smoothly during an interval between the contractions, usually using the loss-of-resistance method. When inserting the catheter, the patient is placed in the lateral decubitus position, with the spinal column bent to the maximum possible degree, and the area between the lumbar vertebra 1 (L1) and L5 is marked with oily magic pen, referring to the Jacoby line. The upper catheter is inserted through the L2-3 space up to 5 cm in the cranial direction, so that its tip reaches the thoracic vertebral space 11-12 (Th11-12). The lower catheter is inserted via L4-5 down to about 4 cm in the caudal direction, so that its tip reaches the sacral vertebral space 1-2 (S1-2).

Analgesia is usually started after confirming that the Friedman curve has entered the active phase and labor pain has begun. However, the degree of pain during labor is not always proportional to the degree of dilatation of the cervix and varies from individual to individual. In the present study, the visual analogue pain scale (hereafter simply referred to as the "pain scale") was employed as the pain scale (100 mm at the maximum). From the start of analgesia, a tocomonitor was attached to monitor the uterine contractions and the fetal heart rate continuously. Before and after the infusion of the local anesthetics, the vital signs, level of analgesia, and motor nerve block were monitored. A mixture of bupivacaine (Marcain®) and fentanyl (Fentanest®, a narcotic analgesic) was used as the local anesthetic. Bupivacaine has a prolonged duration of action and allows for excellent differential block.

Analgesia was induced in accordance with the manual shown in Table 1. The upper and lower catheters used for the epidural double-catheter method were connected to a pressure- type disposable injector (Coopdech Syrinjector). When the pain scale score was 30-40 mm, continuous infusion of 0.125 % bupivacaine + 2 μg/ml fentanyl (6 ml/h) was started via the upper catheter. To alleviate the pain caused by extension and compression of the lower birth canal as the fetal head tip descends in the latter half of Stage 1 of labor, the same drug mixture was continuously infused via the lower catheter (4 ml/h). If the analgesic effect was not adequate, additional infusion of 0.25 % bupivacaine (3 ml) via the upper catheter and 0.125 % bupivacaine + 2 μg/ml fentanyl via the lower catheter (4 ml) was administered.

The clinical background, course of delivery, manner of delivery, parameters of the newborns (Apgar score at 1 and 5 minutes, and neonatal neurologic adaptive capacity score (NACS)), amounts of drugs used for the obstetric analgesia, frequency

Table 1 Bilateral continuous-infusion epidural analgesia (using low-does bupivacaine combined with fentanyl)

- Double-catheter method
  Upper catheter: Inserted at L2-3 up to 4-5 cm in the cranial direction
  Lower catheter: Inserted at L4-5 down to 3-4 cm in the caudal direction
- Test dose: 3 ml of 1% lidocaine (15-minute interval or greater between the infusions via the upper and lower catheters)
- Upper catheter (initial dose after appearance of pain; continuous infusion bigins 30 minutes later)
  Initial dose: 0.25% bupivacaine (5 ml)
  Continuous infusion: 0.125% bupivacaine + 2 μg/ml fentanyl at the rate of 6 ml/h
- Lower catheter (bilateral continuous infusion starts when the cervix has dilated to 7-8 cm in nulliparous women and 5-6 cm in multiparous women)
  Initial dose: 0.125% bupivacaine + 2 μg /ml fentanyl (4 ml)
  Continuous infusion: 0.125% bupivacaine + 2 μg /ml fentanyl at the rate of 4 ml/h (starts immediately after the initial dose)
- Additional doses (if analgesic effect is inadequate)
  Upper catheter: 0.125% bupivacaine + 2 μg /ml fentanyl (6 ml) or 0.25% bupivacaine (3 ml)
  Lower catheter: 0.125% bupivacaine + 2 μg /ml fentanyl (4 ml)
- Criteria for discontinuation of continuous infusion
  1) If the dermatome above T6-7 (xiphoid process) level is involved.
  2) If the motor block level is over Bromage score II (only ankle is movable; unable to bend the knees).

Table 2 Patient Data

Age(yr)	30.6±3.5	(21~38)
Weight(kg)	61.9±7.3	(48.0~83.0)
Height(cm)	158.6±3.6	(149.0~164.0)
Gestational age(wk)	39.9±1.1	(37.4~41.6)
B.P.S before epidural analgesia	6.4±1.4	(3~10)
Cervical dilatation before initial dose(cm)	4. 0 ±1.6	(1.5~8.0)
	Mean±SD	(Range)

of additional anesthetic doses, degree of patient satisfaction (on a two-grade scale: excellent/good and poor) and complications associated with the analgesia were analyzed in the entire study population. Data were statistically analyzed using the Fisher's exact test and the F- test. $P < 0.05$ was regarded as denoting statistical significance. All data are reported as mean values ± standard deviation (mean ± SD).

RESULTS

1) Background variables

The mean age, body weight, height, gestational age, Bishop score before the start of epidural analgesia, and the degree of dilatation of the cervix in the patients are shown in Table 2.

2) Duration of labor

The mean time required for delivery was 835.0 ± 513.8 min (766.7 ± 496.2 min

in Stage 1, 63.2 ± 55.4 min in Stage 2, and 7.2 ± 2.6 min in Stage 3 of labor). Delayed delivery (defined as delivery after 30 hours or more of labor in nulliparous women and 15 hours or more of labor in multiparous women) was seen in 2 nulliparous and 2 multiparous women. The time required for delivery in these 4 cases was: 2204 min in one nulliparous woman (Case 11), 2425 min in the other nulliparous woman (Case 41), 1111 min in one multiparous woman (Case 15), and 1103 min in the other multiparous woman (Case 17). Cases 15 and 17 had undergone one delivery before.

Prolongation of Stage 2 of labor while using epidural analgesia (defined as Stage 2 of labor lasting 3 hours or more in nulliparous women and 2 hours or more in multiparous women [26]) was seen in two nulliparous women (235 min, Case 8 and 266 min, Case 40).

3) Blood loss during delivery

The mean volume of blood loss during delivery in the patients was 245.4 ± 128.4 ml. Blood loss of over 500 ml, rated as abnormal blood loss during delivery, was seen in 4 women (500 ml in 2 women, 577 ml in one woman, and 600 ml in one woman).

The hemoglobin level before delivery was greater than 11 g/dl in all the women. If it fell to below 11 g/dl after delivery, an oral iron preparation was prescribed.

4) Neonatal parameters

The average birth weight of the neonates was 3087.5 ± 285.8 g. Two of the neonates, however, weighed less than 2500 g (2478 and 2408 g, respectively).

The neonatal mean Apgar score at one minute was 8.6 ± 0.9. The score was less than 7 in one neonate (Case 7: score 4), although the 5-minute score increased to 10. The NACS was normal in all the neonates at two hours after the vaginal delivery, suggesting that the method of analgesia induction used in the study did not affect the neurological prognosis of the neonates.

5) Precipitate labor

Of the 51 women who received continuous infusion via the lower catheter for one hour or longer, 2 were taken up for cesarean section because of variable deceleration caused by umbilical cord factors. The percentage of women who underwent cesarean section was thus 3.9 %. Of the remaining 49 women, 24 (49.0 %) underwent vacuum extraction as an aid to delivery. Twenty-six women (53.1 %) had induction of labor, 21 (42.8 %) underwent elective induction of labor, and 2 (4.1 %) had spontaneous delivery.

6) Duration of analgesia

The duration of epidural analgesia achieved following drug injection via the upper catheter was 388.9 ± 193.5 min (102.0-976.0 min) and that achieved by drug injection via the lower catheter was 299.1 ± 204.8 min (60.0-967.0 min).

7) Amounts of anesthetics used and the frequency of additional doses

The total amount of the drug administered was 92.4 ± 42.4 mg for bupivacaine and 121.5 ± 66.0 μg for fentanyl.

The number of additional drug doses injected via the upper catheter to alleviate labor pain after the cervix had dilated to 8 cm in nulliparous women or 6 cm in multiparous women was 0.67 ± 0.90 (range: 0-3). For alleviating pain during the latter half of Stage 1 or Stage 2 of labor, the number of additional doses injected via the lower catheter was 0.37 ± 0.57 (range: 0-2). Of the 49 women, 21 (42.9 %) required no additional dose, 10 (20.4 %), 12 (24.5 %), 5 (10.2 %), and 1 (2.0 %) women required 1, 2, 3, and 4 additional doses, respectively (Fig. 1).

8) Patient satisfaction and complications

Of the 49 women who received CIEA by the double-catheter method, while 45 (91.8 %) showed good or excellent level of satisfaction, 4 complained of pubic pain.

The most frequent complication was hypotension (20 % or greater decrease in blood pressure) which was seen in 6 women (12.2 %). In addition, 4 women (8.2 %) complained of pubic pain, one patient (2.0 %) complained of itching sensation [2], and one woman (2.0 %) developed nausea (Table 3). Reduction in bearing-down was seen in 14 women (28.6 %). When motor nerve block was evaluated, several women showed reduced muscular strength in the lower extremities, but all of these women were able to raise their thigh, and their Bromage score [5] was IV (Table 4).

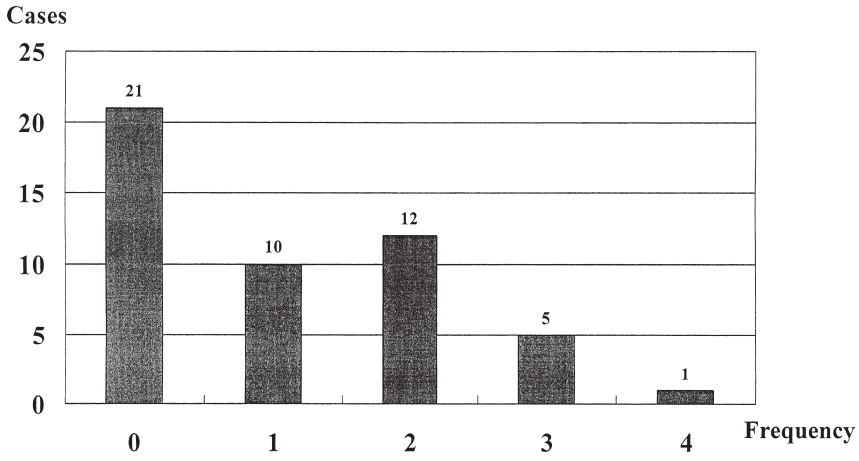

Fig. 1 Additional top-up frequencies during CIEA

Table 3 Incidence of Side Effects

	Case	%
Hypotension	6	12.2
Pubic pain	4	8.2
Pruritus	1	2.0
Nausea	1	2.0

n=49

Table 4 Intensity of Motor Block (Bromage score)

Ⅰ.	Complete	: Unable to move feet or knees
Ⅱ.	Almost complete	: Able to move feet only
Ⅲ.	Partial	: Just able to move knees
Ⅳ.	None	: Full flexion of knees and feet

(Bromage, Epudural Analgesia, p.144, 1978)

DISCUSSION

1) Comparison between the single-catheter and double-catheter methods

The double-catheter method was devised and began to be clinically used for the following reasons. Of the spinal nerves, the nerves Th10-L1 are involved in the pain caused by uterine contractions, and sacral nerves S2-4 are involved in the pain experienced during passage of fetus in the soft birth canal between the lower part of the uterus and the vulva. The sensory nerves of L2-S1 are not involved in the pain associated with delivery. Thus, spinal nerves can be segmented depending on their involvement in delivery-associated pain, and it is possible to effectively use two (upper and lower) catheters for segmental anesthesia at different stages of delivery [15]. This is, however, not possible with the use of a single catheter. CIEA is superior to the conventional top-up administration method for sustained alleviation of delivery-associated pain. If CIEA is performed with infusion of 0.25 % bupivacaine (5 ml/h) via the upper catheter alone, adequate alleviation of pain is not possible in nulliparous women with cervical dilatation of over 8 cm or multiparous women with cervical dilatation of over 6 cm [16]. In the past, for obstetric analgesia in nulliparous women, 0.125 % bupivacaine (4 ml) was initially administered via the lower catheter when the cervix was dilated to 7-8 cm and CIEA with 0.125 % bupivacaine (4.2 ml/h) was started 30 minutes later. It has been reported that epidural analgesia can cause abnormal rotation of the fetus due to relaxation of the muscles of the pelvic floor [24]. In our double-catheter method for CIEA, continuous infusion via the lower catheter is started during the latter half of Stage I of labor, reducing the likelihood of relaxation of the pelvic floor muscles during the early Stage 1 of labor. Epidural anesthesia for obstetric analgesia provides an excellent means

for segmental anesthesia during delivery.

However, depending on the amount and concentration of the anesthetic agents used, this method may suppress smooth delivery. The motor efferent nerves Th4-12 are involved in uterine contractions. To avoid reduction of the strength of uterine contractions and allow the woman to bear down effectively, only the nerves below Th10 (nerves involved in delivery-associated pain) should be anesthetized and minimal concentrations of the local anesthetic agents should be used. There is also a need to improve the devices used to allow more ideal patient management during delivery. Under these circumstances, we attempted to use a combination of a narcotic analgesic fentanyl + local anesthetic agent and a precision serial injector to allow infusion of small amounts of drugs for maintaining obstetric analgesia.

The lightweight compression-type continuous injector (Coopdech Syrinjector, Fig. 2), in which the atmospheric pressure is used as the driving force, allows changes of the hourly dose level (three levels possible with the type of injector used in this study; 2, 4, and 6 ml/h) of the drugs without change of the injector. A pressure-type syrinjector is made of a plastic. Infusion rate of the drug in a pressure-type is kept to a steady speed compared to balloon-reservoir-type injectors (e.g., Baxter Infuser), and has an error range of ± 10 %. And also this injector allows easy checks of the residual drug volume and a constant flow rate. It can be connected to an epidural catheter for continuous infusion of drugs. Continuous infusion provides a better means of controlling delivery-associated pain than intermittent drug injection, since the former allows uninterrupted administration of fixed amounts of drugs [16].

The motor block level was rated on a 4-grade scale (Bromage score), on the basis of the mobility of the hip, knee, and ankle joints. CIEA was discontinued and replaced by the top-up method when the motor block reached level II or higher. Regarding the use of the single-catheter method for continuous infusion of a single local anesthetic, Elliott *et al.* reported inserting a catheter at L2-3 and infusing 0.25 % bupivacaine continuously at the rate of 7 ml/h reduced the dose level from 7 to 4 ml/h in several women in whom the Bromage score reached II or higher during Stage I of labor [11].

Li *et al.*, on the other hand, reported favorable results with continuous infusion of 0.125 % bupivacaine (10 ml/h) via a catheter in L2-3 or L3-4, adding that the anesthetic effect did not differ significantly even when the drug dose was increased to 15 ml/h [14].

Regarding relief of pain during Stage 2 of labor, pain control is often difficult with the single-catheter method even if the amount of local anesthetic continuously infused is large and the bupivacaine concentration used is 0.125 %. Chestnut *et al.* administered a mixture of 0.0625 % bupivacaine and 0.0002 % fentanyl at the rate of 12.5 ml/h, beginning at the time-point when the cervix became fully dilated. They reported that this method significantly alleviated pain as compared to

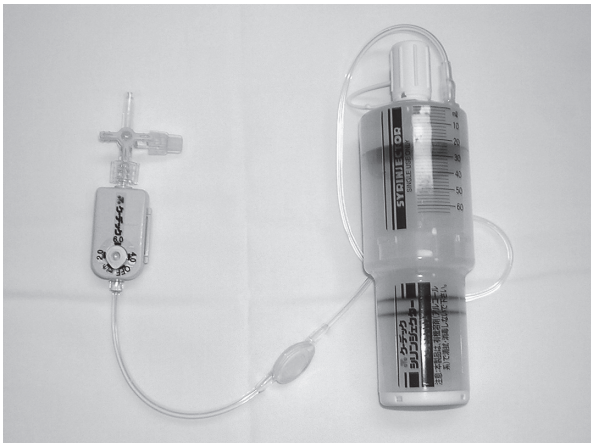

Fig. 2 Pressure-type disposable injector (Coopdech syrinjector)

that in a placebo group when the duration of Stage 2 of labor lasted for 60 minutes or longer, but not when it lasted 30 minutes or less. In their study, no increase was observed in the duration of Stage 2 of labor or the percentage of women requiring forceps delivery or vacuum extraction delivery [7]. Pain involving nerves S2-4 begins to occur when the cervix has dilated to 8 cm in nulliparous women and to about 6 cm in multiparous women. Therefore, better pain control may be achieved if continuous infusion at the above-mentioned dose level is started when the uterine opening has dilated to this level.

2) Type and dose of the drugs

Regarding the dose level required of the local anesthetics used for continuous infusion, it has been reported that bupivacaine infused at the rate of 12.5 mg/h (corresponding to 10 ml/h at a concentration of 0.125 %) into the subarachnoid space is unlikely to be distributed along the entire length of the spine [14].

Regarding continuous infusion of a mixture of a low-concentration local anesthetic and an opioid, Terui *et al.* reported that after puncture at L2-3 or L3-4, 0.25 % bupivacaine (12 ml) was administered in four divided doses (two 3-ml doses while the patient lay on the right side and two 3-ml doses with the patient lying on the left side). After the level of Th10 was confirmed, a mixture of 0.125 % bupivacaine and 0.0002 % fentanyl (2 μg /ml) was continuously infused at the rate of 10 ml/h to alleviate pain during delivery [28]. However, when the infusion is continued for prolonged periods of time, the increase in the total drug dose injected may affect the mother and the fetus. In view of this possibility, Bader *et al.* examined the passage of drugs to fetuses by checking the drug levels in maternal venous blood and umbilical venous blood samples during continuous infusion of the drugs at the same dose levels as those used in the present study (continuously infusion of bupivacaine at the rate of 12.5 mg/h through the upper and lower catheters). This study revealed no marked elevation of the drug levels in either the maternal or umbilical blood samples, even after prolonged infusion [4].

In the present study, continuous infusion of a mixture of 0.125 % bupivacaine and fentanyl through the upper catheter (6 ml/h) and the lower catheter (4 ml/h) allowed satisfactory pain control (10 ml/h in using both of the catheters at the same time). With the combined use of a narcotic analgesic, the frequency of additional drug doses required was 0 or 1 in 63.3 % of the women, and 2 or more in 36.7 % (maximum frequency: 4 in one woman) of the women. The mean frequency of additional drug doses was 0.16 per hour and 1.04 per delivery. These results can be deemed as favorable. Furthermore, the combined use of a narcotic analgesic with a local anesthetic is expected to reduce the amount as well as the concentration needed of the latter (to below 0.125 % if bupivacaine is used). It is also expected to allow the woman to continue bearing-down effectively during Stage 2 of labor and have spontaneous delivery.

We do not use sacral epidural analgesia at the sacral level for alleviating delivery-associated pain which involves S2-4, because this area is likely to become contaminated if punctured, and because puncture through the sacral hiatus is sometimes difficult in pregnant women. As a rule, we introduce the lower catheter down to 3-4 cm with its tip directed caudally through puncture of the skin with an epidural needle almost perpendicularly at L4-5 (retrograde continuous sacral nerve block [27]). In cases where it is difficult to insert the catheter due to the shape of the epidural cavity, attaching primary importance to safety, the catheter is inserted with its tip directed cranially, even though more effective analgesia of S2-4 is obtained if the catheter tip is directed caudally than when it is directed cranially. However, we do not make it a rule to confirm that the epidural catheter has been inserted in the caudal direction. It is considered difficult to adequately block the A-δ fibers (involved in pain due to extension of the perineum during the latter half of Stage 1 and Stage 2 of labor) using bupivacaine alone at low concentrations (0.125 % or lower) which do not weaken bearing-down or labor (usually, the concentration needs to be 0.25 % or higher). Therefore, in the present study, we attempted continuous infusion of bupivacaine in combination with fentanyl (a narcotic analgesic). The synergism between these two drugs produces a similar degree of pain alleviation at half the concentration of bupivacaine used conventionally. Fentanyl

was used at a low but effective concentration (2 μg/ml) [6], and favorable results were obtained as expected.

Also, in cases where the cervical canal of the uterus has not adequately matured (with the cervix dilated to less than 3 cm), painless insertion of a Mini-metreu (new typed metreurynter) is possible about 15 minutes after infusion of 0.25 % bupivacaine (5 ml) via the upper catheter before the start of delivery under continuous-infusion epidural analgesia (this is possible if the cervix has dilated to at least 1 cm). Therefore, there are no particular problems even when the analgesia is started at a time-point when the cervix has dilated to less than 3 cm. One of the major advantages of CSE lies in that spinal anesthesia exerts its effects rapidly.

However, CSE is not always the better alternative, because satisfactory anesthetic effects were obtained in all women in the present study within 15 minutes after the first dose, even if the analgesia was started at a point desired by the woman without relying on the degree of dilatation (usually 1 cm or greater dilatation is deemed as a sign for starting analgesia).

3) Actions and complications

Hypotension sometimes occurs even when the double-catheter method is used. To ensure safety, we administered a test dose (3 ml of 1 % lidocaine), and the drug injection via the upper and lower catheters were administered at an interval of 15 minutes or more. Epinephrine, which induces vascular constriction was not used, in view of the fact that the placental blood flow in some women is below normal (e.g., in cases with intrauterine growth retardation). None of the women who showed no hypotension in response to a test dose showed hypotension during the subsequent continuous infusion.

However, care is needed to ensure that the epidural catheters do not erroneously enter blood vessels or the subarachnoid space after the start of epidural analgesia. When the local anesthetic bupivacaine is administered alone, its action lasts for 70 minutes when a concentration of 0.25 % is used, and for 45 minutes when a concentration of 0.125 % is used. The duration of action also varies from individual to individual when the drug is administered in combination with a narcotic analgesic. For continuous infusion, a lock-out time (the shortest additional dosing interval; 30 minutes in the present study) should be used, so that additional doses may be administered according to the need of the woman while avoiding excessive dosing. Because serious complications associated with intravascular infusion of 25 mg bupivacaine have been reported [1], it would be safe to keep the single dose level as low as possible. A single dose of greater than 20 mg of bupivacaine should be avoided. If a large amount of the drug needs to be administered, it should be administered in divided doses (appropriate single dose of bupivacaine = about 7.5 mg). Regarding the safety of this anesthetic, it has been reported that administration of about 15-20 mg bupivacaine into the subarachnoid space via a catheter inserted at the level of L2-3 or L3-4 usually did not result in distribution of the drug to a level above Th4 [14].

When bilateral CIEA is used, the total dose level injected of the local anesthetics is large. In the present study, the total bupivacaine dose was 92.4 ± 42.4 mg, and the infusion rate was 7.5 mg/h when only the upper catheter was used, and 12.5 mg/h when both the upper and lower catheters were used. Epidural anesthesia poses few problems in relation to the passage of local anesthetics. With ordinary bilateral CIEA (total bupivacaine dose: about 100 mg), the umbilical venous blood drug level was 100-150 ng/ml. This dose level seems to be safe for the mother, considering that the maternal blood bupivacaine level is 25-30 % of its level in the umbilical venous blood and that the lowest toxic level of bupivacaine in adults is over 1 μg/ml [25]. In our previous study, the bupivacaine level in umbilical venous blood at the time of delivery was 82.96 ± 21.96 ng/ml (mean ± SD) in cases where no additional dose of local anesthetics was injected within 30 minutes of the delivery. These findings suggest that the dose level used in the present study was highly safe for the fetuses and the mothers.

PCEA is used in cases where the analgesic effect of CIEA is insufficient. The lock-out time for PCEA is often set at 15-30 minutes, since the serum bupivacaine level reaches its peak from 15-24 minutes after a single epidural dose [21]. In the present study, bilateral CIEA required the medical team to administer 1.04 additional doses per delivery,

on average. In PCEA, on the other hand, the drug is infused by the woman herself during labor. If an electric PCA pump is used for PCEA, the single dose level of the local anesthetic used and the lock-out time can be set by the doctor for individual cases, to ensure against excessive dosing. Although PCEA can cut the manpower needed for additional drug doses, it is not really useful unless two or more additional doses are needed. Some women hesitate to push the dosing button during labor. Viscomi reported that the frequency of use of the top-up method, the percentage of women requiring top-ups, and the frequency of top-ups per hour were significantly lower in the CIEA + PCEA group [30]. Aoki *et al*. evaluated the safety and efficacy of infusion of 0.125 % bupivacaine containing 1 μg/ml fentanyl (20 ml/2 hrs DIB (Drug Infusion Balloon)) at the rate of 10 ml/h using a PCEA-system-DIB, and pointed out the necessity of a system that can be used for many consecutive hours [3]. The portable electronic minute infusion pump (Baxter AP II) can be used for many consecutive hours, but it is expensive and weighs 350 g (although it is designed as a portable device). Thus, further improvement of the devices is required.

In the present study, the highest level of the thoracic spinal nerve region blocked by the anesthetic averaged 9.4 ± 0.9 (Th8-11). In two women, the highest level blocked was Th11, but none of the women studied had clinically significant pain involving Th11. Clinically, catheter insertion at the L2-3 level is easier, because it is associated with less danger of injury to the spinal nerves. Therefore, to ensure safety, we inserted the upper catheter at the L2-3 level and advanced it to 5 cm in the cranial direction. For the lower catheter, it would seem optimal to insert it at the L4-5 level and advance it to 4 cm in the caudal direction, similar to that in the previously used procedure.

4) Comparison with the single-anesthetic group

The women anesthetized by our method were compared with the 30 women treated with bupivacaine alone (0.25 % bupivacaine via the upper catheter at the rate of 5 ml/h and 0.125 % bupivacaine via the lower catheter at the rate of 4.2 ml/h) and 30 women undergoing spontaneous delivery, in terms of four parameters. The following results were obtained.

1) The percentage of women requiring vacuum extraction delivery differed significantly between the spontaneous delivery group (3 cases, 10.0 %) and the single ($p = 0.003$) or combined anesthetic group ($P = 0.0003$), but it did not differ significantly between the single anesthetic (bupivacaine) group (13 cases, 43.3 %) and the combined anesthetic (bupivacaine + fentanyl) group (24 cases, 49.0 %) ($P = 0.62$).

2) The percentage of women showing reduced bearing-down was significantly lower in the combined anesthetic group (14 cases, 28.6 %) than in the single anesthetic group (18 cases, 60.0 %) ($P = 0.005$).

3) Prolongation of Stage 2 of labor was seen in two women from the combined anesthetic group, but the duration of Stage 2 did not differ significantly between the single anesthetic group (57.2 ± 77.1 min) and the combined anesthetic group (63.2 ± 55.4 min) ($P = 0.42$).

4) There was no significant difference in the frequency of atonic bleeding among the spontaneous delivery group (3 cases, 10.0 %), single anesthetic group (4 cases, 13.3 %) ($P = 0.68$), and combined anesthetic group (4 cases, 8.2 %) ($P = 0.78$). And it did not differ significantly between the single anesthetic group and combined anesthetic group ($p = 0.45$).

With our method of analgesia, due to the combined use with fentanyl, the concentration of the local anesthetic needed was reduced, which contributed to retention of the bearing-down capacity of the women during labor.

5) Other problems

The significance of analgesia during delivery lies in that it can alleviate the pain associated with delivery, and thereby reduce the mental stress (tension and fear) associated with delivery. This leads to suppression of excessive catecholamine secretion and maternal hyperventilation, favorably affecting the vascular circulation in the feto-placental system. As a result, delivery may be expected to proceed more smoothly.

Craft *et al*. reported a reduction in the strength of uterine contractions 10-20 minutes after infusion of a local anesthetic into the epidural cavity, and called it “lidocaine

effect" [9]. Interestingly, the cervical canal of the uterus dilated despite weakening of the uterine contractions in these women.

In some cases, Bromage score II or more severe motor nerve paralysis of the lower extremities is induced by a high concentration of the local anesthetic (0.25 % or more in the case of bupivacaine) [11]. In such cases, drug infusion into the epidural cavity should be discontinued, to allow the woman to gradually recover from the motor nerve paralysis and resume bearing-down for delivery [18].

It is known that the secretion of endogenous oxytocin does not increase if S2-4 nerves are blocked during lumbar epidural analgesia. Because this can cause uterine inertia, treatment with oxytocin is sometimes needed to stimulate pain and reinforce uterine contractions. It has long been known that epidural analgesia can cause prolongation of the latter half of Stage 1 or Stage 2 of labor. According to the report from the committee in the American College of Obstetricians and Gynecologist, the mean duration of Stage 2 of labor is 54 minutes in nulliparous women and 19 minutes in multiparous women. If Stage 2 of labor lasts for more than 3 hours in the case of nulliparous women or more than 2 hours in the case of multiparous women during epidural analgesia, Stage 2 of labor is judged to be prolonged [26]. Because the incidence of fetal distress increases if Stage 2 of labor lasts for 2 hours or more, we endeavor to achieve delivery within 2 hours in both nulliparous and multiparous women.

Regarding the question of whether or not epidural analgesia affects the duration of labor or the percentage of women requiring cesarean section, Thorp *et al*. compared, in 1993, 48 women receiving epidural analgesia and 45 women receiving intravenous meperidine, and reported that the percentage of women requiring cesarean section was higher in the epidural analgesia group (25 %) than in the meperidine group (2 %) [29]. However, Chestnut *et al*. reported what even when epidural analgesia was started before the cervix dilated to 3-5 cm in nulliparous women with a cephalic presentation, no significant difference was observed in the duration or type of delivery in these women as compared to that in non-anesthetized women [8]. Of the 51 women in the present study in whom infusion via the lower catheter was continued for one hour or longer, 2 women required cesarean section due to variable deceleration with umbilical cord factors. In the other women, no abnormalities were noted of any of the parameters in the tocomonitoring records. The percentage of women requiring cesarean section in the present study was 3.9 % (2/51), which did not differ significantly from the percentage requiring cesarean section among women undergoing spontaneous delivery during the same period (3.6 %, 12/336). We therefore believe that epidural analgesia is not associated with any increase in the percentage of women requiring cesarean section, unless it causes uterine inertia.

The essential characteristics of ideal obstetric analgesia include:

1) adequate pain control during delivery,
2) adequate consciousness level of the mother to allow active commitment in delivery,
3) no adverse effects on fetuses,
4) no significant motor paralysis,
5) no interference with smooth delivery.

The method of analgesia used in this study was associated with marked alleviation of pain during the latter half of Stage 1 and Stage 2 of labor, which is conventionally difficult to achieve without change in the posture of the woman during labor. Except for 4 women who complained of pubic pain, all the women in this study rated this technique as good or excellent. This method was found to be highly safe for both the mother and the fetus. The degree of satisfaction in the mothers was high (91.8 %).

Among the cases in which the cervix had dilated to only 3 cm or less at the start of this analgesia and analgesia needed to be continued for many hours (about 7 hours or more), the percentage of women requiring two or more additional doses of drugs tended to be high [13]. Ropivacaine is a long-acting amide local anesthetic, related structurally to bupivacaine. There have been few formal investigations of dose requirements on ropivacaine for epidural analgesia in labor. It therefore remains an open question as to whether or not ropivacaine (with less cardiotoxicity and better rating for segmented anesthesia) [22] can be used instead of bupivacaine to reduce the frequency of additional drug doses, retain the bearing-down capability, and reduce the necessity for

mechanical aids during the delivery.

For valid and safe obstetric analgesia, adequate education of pregnant women before delivery is essential. Furthermore, establishment of a medical care system supporting obstetric analgesia is indispensable. Although the demand to obstetric analgesia varies greatly among different pregnant women, we think it essential to control the pain associated with delivery, at least to the extent of not hampering a desirable course of delivery, while taking care to avoid complications, such as motor nerve paralysis (reduced bearing-down capability).

CONCLUSION

We attempted to manage obstetric analgesia using a method of epidural anesthesia, which we believe is the best at present. The results were almost ideal, as summarized below.

(1) The double-catheter method was superior to the single-catheter method. The former was particularly useful in alleviating the pain during the latter half of Stage 1 and Stage 2 of labor.
(2) Continuous infusion of anesthetics was superior to single injections of anesthetics.
(3) Combined bupivacaine + fentanyl treatment was superior to single bupivacaine treatment in terms of the pharmacologic efficacy and dose level needed.
(4) The method used in this study seemed to be ideal for administering obstetric analgesia. We propose, therefore, to apply it clinically.

ACKNOWLEDGEMENT

The authors are indebted to the physicians, midwives, and nurses of the Obstetric Ward of the Tokai University Hospital and the facilities affiliated with the Department of Obstetrics and Gynecology of Tokai University School of Medicine, for their cooperation with this study.

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