Investigation on delivery analgesia effect of combined spinal epidural anesthesia plus Doula and safety of mother and baby

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Summary

Objective: To explore the effect of patient-controlled lumbar epidural combined anesthesia with Doula for labor analgesia with ropivacaine and sufentanil, and its influence on the progress of labor, and outcomes of mother and infant. *Materials and Methods:* Two hundred parturients that requested labor analgesia were randomly selected by patient-controlled lumbar epidural combined anesthesia with Doula as the observation group, meanwhile another 200 parturients were selected as the control group without any analgesic measurements. Labor pain score, labor duration, blood gas analysis results, the incidence of cesarean section, neonatal asphyxia, and postpartum hemorrhage were compared between the two groups. *Results:* Compared with the control group, labor analgesic effect was remarkable, the cesarean section rate was significantly reduced in observation group, and the difference was statistically significant ($p < 0.05$), but with respect to the duration of labor, maternal, postpartum hemorrhage, and neonatal asphyxia, there was no statistical significance between the two groups ($p > 0.5$). In the observation group regarding maternal and neonatal blood gas analysis results, PO_2 was higher and PCO_2 was lower than those in the control group. The differences were statistically significant ($p < 0.05$). *Conclusion:* Labor analgesia by patient-controlled lumbar epidural combined anesthesia accompanied with Doula with ropivacaine and sufentanil is effective, safe, reliable, has no adverse effects, and reduces cesarean section rate.

Key words: Lumbar epidural combined anesthesia; Labor analgesia; Doula; Effects; Outcomes.

Introduction

Pain due to delivery is a normal physiological phenomenon, but severe persistence causes primiparas to experience fear along with pain, but it is also a neuroendocrine reaction induced by this stress that causes adverse effects in puerperant delivery process and fetuses [1]. Due to fear of delivery pain, partial primiparas will select cesarean section to avoid it. As a result, cesarean section rate of China with dominant primiparas constantly increases, and short- and long-term complications are increasingly apparent, which has become a serious public social problem [2]. With the progress of society, development of medicine, and change of obstetrics service, a safe, effective, and pain-relieving delivery has become an urgent need for gravidas, and it is an important issue in clinical researches. In recent years, although the delivery analgesia technology is increasingly effective, its popularity rate is still low in China: less than ten percent. So far, there is still no satisfactory, safe, simple, economical, and popular delivery analgesic method and drug suitable for the national conditions of China. In addition, it is always contestable whether it will delay labor and increase cesarean section, postpartum hemorrhage, and neonatal asphyxia rates [3].

Therefore, the authors use the delivery analgesia method with spinal epidural anesthesia plus a psycological Doula support in a prospective study in order to investigate its analgesic effect and its influences on mother and baby in providing a reference for promoting natural delivery and reducing cesarean section rate.

Materials and Methods

Clinical data

The primiparas laboring in the present hospital from May 2010 to May 2012 were selected, and their ages ranged from 20 to 34 years. For all primiparas, pregnancy months were adequate. Also, each primipara only delivered one fetus through cephalic presentation. In addition, there was no cephalopelvic disproportion, obstetric or internal medicine complications, and epidural anesthesia contraindications. During labor, 200 primiparas voluntarily selected to deliver with analgesia (observation group). At the same time, 200 primiparas delivered without analgesia (control group). For age, gestational week, and fetal size, there was no significant difference between the two groups. This study was conducted in accordance with the Declaration of Helsinki, and with the approval of the Ethics Committee of Beijing Tongren Hospital of Capital Medical University. Written informed consent was also obtained from all participants.

Doula and anesthesia analgesia

In the observation group, from initial labouring to two hours postpartum, each primipara was accompanied with one Doula midwife. During the delivery accompanying process, Doula midwife conducted psychological, physiological, and physical care, and explained delivery-related concepts to primiparas and their families and provided mental and spiritual support. When uterine orifice of the primiparas was dilated by about two to

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three cm, a catheter was positioned for spinal analgesia. A first dose of anesthetic solution (ropivacaine 2.5 mg plus sufentanil 2.5 μg) was infused in the subarachnoid space. Subsequently, a solution of 0.1% ropivacaine plus one μg/ml sufentanil was infused into epidural cavity via the epidural catheter using a micro self-controlled pump at a rate of five to six ml/h for maintaining analgesia until uterine orifice was completely opened and during episiorrhaphy oxytocin intension and amniotomy were performed to maintain satisfactory uterine contraction frequency and intensity. If the labor was complicated with fetal distress, abnormal fetal position, and protracted labor without resolution, cesarean section was performed.

Analgesic effect

Pain indicator: the visual analogy scoring method (VAS, 0-10 scores) was used [4], 0: no pain; below 3 scores: slight pain, tolerable; 4 to 6 scores: pain affected sleep, tolerable; 7 to 9 scores: intolerable; 10 scores: sharp pain. According to the scores, pain situations of two groups of primiparas in the latent period, the active phase, and the second and third stages of labor were evaluated.

Blood gas analysis

As it was confirmed that primiparas were in the second stage of labor, one-ml radial artery blood specimen was acquired, sealed, and immediately sent for testing. After a fetus was delivered and before crying, one-ml of umbilical artery blood specimen was immediately acquired, sealed, and sent for testing.

Recording clinical data

Vital signs, labor times, visual analogy scores, amniotomies, oxytocin applications, delivery modes, neonatal asphyxia, and postpartum hemorrhage were recorded.

Statistical analysis

SPSS10.0 software was used for t-test and chi-square (χ^2) test. If $p < 0.05$, a significant difference could be observed.

Results

Comparison of pain situations between two groups of primiparas

During labor, there were respectively, 20 and 38 cases receiving cesarean section due to fetus, delivery force, and other factors in the observation and control groups, and pain scoring was not conducted in them. For VAS score of pain before analgesia, there was no significant difference between two groups ($p > 0.05$). After analgesia, the pain of the observation group was significantly relieved. Between two groups, there was a significant difference for VAS score of pain ($p < 0.05$) (Table 1).

Comparisons of labor time and medical intervention measures between two groups

For the active phase time, the time of the second and third stages of labor, amniotomy intervention rate, and oxytocin application rate, there was no significant difference between two groups ($p > 0.05$) (Table 2). In addition, two groups of primiparas receiving cesarean section were excluded from the statistics.

Table 1. — *Comparison of pain VAS scores at different times between the two groups ($\bar{x} \pm s$).*

Groups	Cases	Latent period	Active phase	Second stage of labor	Third stage of labor
Observation	180	8.1 ± 1.3	3.6 ± 1.1#	3.2 ± 1.1#	2.6 ± 1.4#
Control	162	8.3 ± 1.7	8.8 ± 1.0	9.1 ± 0.6	5.4 ± 1.6

For comparison between two groups, #$p < 0.05$.

Table 2. — *Comparison of labor time and medical intervention measures between the two group ($\bar{x} \pm s$) n (%).*

Group	Case	Active phase (h)	Second stage of labor (min)	Third stage of labor (min)	Amniotomy n (%)	Oxytocin n (%)
Observation	180	6.1 ± 2.1	86.6 ± 20.1	11.2 ± 3.1	61 (33.9)	38 (21.1)
Control	162	5.8 ± 1.7	82.6 ± 29.2	10.1 ± 1.6	54 (33.3)	35 (21.6)

Table 3. — *Comparison of delivery mode and delivery outcome between the two groups [n (%)].*

Group	Case	Natural delivery	Assisted vaginal delivery	Cesarean section	Neonatal asphyxia	Postpartum hemorrhage
Observation	200	145 (72.5)	35 (17.5)#	20 (10.0)#	9 (4.5)	13 (6.6)
Control	200	141 (70.5)	21 (10.5)	38 (19.0)	11 (5.5)	11 (5.5)

For comparison between two groups, #$p < 0.05$.

Comparisons of delivery mode and delivery outcome between two groups

Although the assisted vaginal delivery rate of the observation group was higher than that of the control group, the cesarean section rate was low and there was a significant difference between two groups ($p < 0.05$). However, there was no significant difference for neonatal asphyxia and postpartum hemorrhage rates between two groups ($p > 0.05$) (Table 3).

Comparisons of blood gas analysis results of primiparas and their neonates between two groups

For comparison of blood gas analyses, results of primiparas and their neonates, there was no significant difference between two groups ($p > 0.05$) (Table 4). In addition, two groups of primiparas receiving cesarean section were excluded from the statistics.

Discussion

The ideal delivery analgesia should cause minor psycological impact to mother and baby and it should be easily administered. Furthermore, it should satisfy all the operative requirements of delivery analgesia and avoid complications [5]. According to this analysis, the delivery analgesia method of self-controlled combined spinal epidural anesthesia of low-concentration ropivacaine and low-dose sufentanil analgesia plus Doula, is a method with satisfactory effectiveness.

In the delivery process, drastic uterine contraction pain cause primiparas to feel anxious, frightened, and nervous. Primiparas hope to receive treatment from healthcare providers to relieve psychological tension. Doula delivery

Table 4. — *Comparison of blood gas analysis results of primiparas and their neonates between the two groups.*

Group	Case	pH value Primiparas	Neonates	PO_2 (mmHg) Primiparas #	Neonates #	PCO_2 (mmHg) Primiparas #	Neonates #
Observation	180	7.41 ± 0.02	7.25 ± 0.03	105.32 ± 13.45	25.48 ± 3.51	30.45 ± 3.51	43.32 ± 2.51
Control	162	7.39 ± 0.07	7.23 ± 0.04	102.38 ± 12.51	24.31 ± 4.53	36.37 ± 3.35	46.21 ± 4.82

For comparison between two groups, $^{\#}p < 0.05$

[6] provides a one-to-one new delivery care service mode for primiparas. It not only relieves emotional tension of primiparas and provides a spiritual pillar, but personalizes the assistance throughout the delivery process. This methodology was applied to the observation group. Therefore, the whole labor process was conducted under the active management and close cooperation of anesthetist, obstetrician, and midwife. In addition, the drug effect apparently mitigated or entirely relieved pain sensation of primiparas. This kind of delivery also appears to mitigate tension and anxiety of primiparas that can better cooperate with the obstetrical team enabling the delivery progression.

Application time, type, and dose of analgesic drugs, extension of analgesia, and blocking range determine the results of delivery anesthesia [7]. Local anesthetic is a most widely-used painless delivery of epidural anesthesia. Gormar *et al.* [8] reported that the action of this method was slow, not always satisfactory, and it could block motor nerves. In the two groups, during labor, a pain VAS scoring was conducted. Pain VAS scores of the observation group in various stages were respectively, 8.1 ± 1.3, 3.6 ± 1.1, 3.2 ± 1.1, and 2.6 ± 1.4, and pain VAS scores of the control group were respectively, 8.3 ± 1.7, 8.8 ± 1.0, 9.1 ± 0.6, and 5.4 ± 1.6. Based on the pain VAS score, no significant difference before analgesia was found between two groups ($p > 0.05$) (Table 1). After analgesia, the pain of in the observation group was mitigated, with a sustainable self-control and with a low pain VAS score. The difference between the two groups has a statistical significance. Yaakov *et al.* [9] suggested that ropivacaine is a novel long-acting amide local anesthetic. It has lesser cardiac toxicity and has no apparent influence on uterine and placental blood flow. Also, it has a high-degree of blocking and dissociation of sensory and motor nerves, and it can effectively relieve pain. In addition, there are fewer microvessels in subarachnoid space, and drug absorption is slower, which makes local anesthetic ropivacaine play a role for a lengthy period of time with only minimal motor blocking. Its subsequent effect lies in its synergy with epidural medication and generates a stronger analgesic effect. Therefore, it not only avoids shortcomings of slow-action of simple epidural anesthesia and analgesic imperfection and reduces the dosage, but also avoids some side-effects, such as nausea, emesia, and blood pressure drop caused by simple subarachnoid space anesthesia and headache after anesthesia. After infusion is terminated, muscle function is rapidly restored. The addition of sufentanil into local anesthetic does not only reduce the concentration and dosage of local anesthetics, but can also enhance the analgesic effect, mitigate motor blocking, and generate apparent motion sensory dissociation isolation to achieve the purpose of rapid action and long analgesic time [10]. It is generally thought that as anesthesic level is controlled below T1, it does not affect uterine contraction, but causes obstetric canal relaxation, which is in favor of fetal head drop and expansion of uterine orifice [11]. After anesthesic analgesia, a self-controlled pump is used to adjust medication according to the situations. In the condition without uterine contraction pain, primiparas can conduct activity, feeding, and micturition. In the second stage of labor, they can freely use abdominal pressure to actively participate in the delivery process. Therefore, uterine inertia, postpartum hemorrhage, and other complications can be avoided.

Some authors [12] believe that painless delivery would not delay labor, while others [13] believe that painless delivery would not delay the second stage of labor and that it could be useful for natural delivery. The key reason for controversy is possibly related to the type and dose of analgesic drugs, level of anesthesia, control of blocking range, and other factors. Some studies [14] suggest that if anesthetic dose was higher, anesthetic could block pelvic floor muscle and rectal sensory nerves, reducing motility and could inhibit uterine contraction and thus weaken delivery force, delay labor, and increase the possibility of cesarean section and assisted vaginal delivery. The solution is to mainly add opioid drugs such as sufentanil, to reduce the dosage of local anesthetic. In this study, the delivery analgesic method of self-controlled combined spinal epidural anesthesia of ropivacaine and low-dose sufentanil was used to observe the time of the active phase, and the second and third stages of labor. The time of various stages of the observation group was respectively, 6.1 ± 2.1 h, 86.6 ± 20.1 min and 11.2 ± 3.1 min, and the time of various stages of the control group was respectively, 5.8 ± 1.7 h, 82.6 ± 29.2 min, and 10.1 ± 1.6 min. Between the two groups, there was no significant difference for the time of various stages of labor. In addition, some studies [15] showed that painless delivery increased the artificial amniotomy and oxytocin intervention rates during labor. This study reports that the artificial amniotomy and oxytocin intervention rates of the observation group were respectively, 33.9% and 21.1%, and those of the control group were respectively, 33.3% and 21.6%. For the oxytocin intervention rate during labor, there was no significant difference between the two groups. According to the aforementioned results, it can be suggested that painless delivery does not affect labor progression and does not increase artificial amniotomy and oxytocin intervention rates. For the influence of painless delivery on delivery mode, one study [16] reports that painless delivery obviously increased the rates of assisted vaginal delivery and cesarean section. This group of data show that assisted vaginal delivery rate and ce-

sarean section rate of the observation group are respectively, 17.5% and 10.0%, and those of the control group are respectively, 10.5% and 19.0%. Although painless delivery of the observation group increases the assisted vaginal delivery rate to a certain extent, its cesarean section rate is significantly lower than that of the control group; there is a significant difference between the two groups. It is indicted that this delivery analgesic method cannot obviously influence labor progression, but can reduce cesarean section rate and promote vaginal delivery. The present analysis results are possibly related to the applications of novel local anesthetic ropivacaine and low-dose opioid sufentanil and the control of implementation and closing time of analgesia. Under the premise of good analgesic effect, the combination of sufentanil and low-concentration ropivacaine reduces ropivacaine concentration and thus mitigates blocking of motor nerves. Delivery analgesia begins in the latent period in cases of uterine orifice of two to three cm, and primiparas justly feel obvious pain; at this time, it is best to conduct analgesia. Primiparas keep quiet and can actively cooperate. As uterine orifice is nearly fully open, analgesia pump is timely closed. At the second stage of labor, the relaxation effect of analgesia on vagina and perineum fades away incompletely. Therefore, it reduces the resistance to birth canal and mitigates the inhibition of analgesic to abdominal muscle and levator ani muscle. At this time, primiparas have accumulated their energy, which helps them to hold force in case of uterine contraction and is useful for smooth progress of labor. In addition, the authors believe that even if painless delivery increases a certain cesarean section rate, its influence is minor when compared with cesarean section rate caused by other factors, such as the ratio of primiparas fearing pain that require cesarean section (16.69%), as reported by the literature [17]. High cesarean section rate caused by this kind of social factor has an important significance especially in China. Primiparas in China are numerous, and fear and anxiety towards delivery increase cesarean section rate to a larger extent. Painless delivery updates the concept that delivery is certainly pained and it reduces unnecessary cesarean section. In this sense, it undoubtedly reduces cesarean section rate.

Neonatal asphyxia and postpartum hemorrhage incidence rates are the objective indicators of directly evaluating influences of delivery analgesia on mother and baby. For the influence of spinal analgesia on fetal heart rhythm, it is always contestable. Lee *et al.* [18] thought that the infusion of opioid drugs into subarachnoid space used for delivery analgesia could increase the risks of slow fetal heartbeat and postpartum hemorrhage, but it could not increase cesarean section rate. The study of Grondin *et al.* [19] showed that epidural low-concentration sufentanil infusion had no inhibition to neonate breathing. Ropivacaine used in this study is a novel long-acting local anesthetic. After the delivery analgesic method of self-controlled combined spinal epidural anesthesia with low-concentration ropivacaine and low-dose sufentanil analgesia plus Doula, the results showed that neonatal asphyxia and postpartum hemorrhage rates of the observation group were respectively, 4.5% and 6.6%, and those of the control group were respectively, 5.5% and 5.5%; between two groups, there was no significant difference. It is suggested that this delivery analgesic method is effective and exact and it has no influence on postpartum hemorrhage and neonatal asphyxia incidence rates and its safety is also high. Sufentanil belongs to opioid drugs, and its application in small amounts can reduce ropivacaine dosage in order to achieve the purpose of minimal motor block and no influence on uterine contraction and labor progress. During delivery, mother and baby are treated as a single entity. Fetal oxygenation status is not only influenced by the fetus' own metabolism, but is also related to maternal acid-base status and uteroplacental blood flow. Therefore, blood gas results of mother and baby can accurately reflect maternal acid-base status and fetal intrauterine anoxia inhibition extent. In this study, blood gas analysis result showed that PO_2 of primiparas and neonates in the observation group were respectively, 105.32 ± 13.45 mmHg and 25.48 ± 3.51 mmHg, and PO_2 of primiparas and neonates in the control group were respectively, 102.38 ± 12.51 mmHg and 24.31 ± 4.53 mmHg; blood gas analysis result showed that PCO_2 of primiparas and neonates in the observation group were respectively, 30.45 ± 3.51 mmHg and 43.32 ± 2.51 mmHg, and PCO_2 of primiparas and neonates in the control group were respectively, 36.37 ± 3.35 mmHg and 46.21 ± 4.82 mmHg. According to the aforementioned results, partial pressures of oxygen of primiparas and neonates of the observation group are higher than those of the control group, while partial pressures of carbon dioxide primiparas and neonates are lower than those of the control group. Between the two groups, there are significant differences. It is suggested that delivery analgesia cannot only relieve pain, but can also increase vital capacity, improve lung function, and facilitate fetal oxygen supply. Simultaneously, it can mitigate stress reaction, avoid neonatal hypoxemia, and acidosis caused by apnea of gravidas in case of uterine contraction, improve uterine blood flow, and increase PO_2 of umbilical arterial blood, which is useful for both mother and baby. Bolukbasi *et al.* [20] also found that self-controlled epidural delivery analgesia could decrease the stress reaction and oxygen consumption of primiparas and reduce fetal acidosis incidence rate, by detecting plasma adrenaline and noradrenaline, blood sugar, and blood gas of umbilical arterial blood of primiparas; it is in line with the viewpoint of this study.

In conclusion, the delivery analgesia method of self-controlled combined spinal epidural anesthesia applying the mixture solution of low-concentration and low-dose ropivacaine and trace sufentanil plus Doula has a rapid action and an exact analgesic effect, and it is also easily administered. It can meet the analgesic requirements of the entire labor process, and greatly mitigate related delivery pain. In addition, its influence on mother and baby is small, and its safety is high, therefore, it is easy for primiparas to accept it. As a result, it reduces the cesarean section rate caused due to the "social factor" fear to pain, saves medical costs, and avoids medical risks.

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