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Application of lidocaine in alleviating breakthrough pain during epidural labor analgesia in obese primiparas

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Abstract: Objective To evaluate the clinical efficacy of lidocaine in alleviating breakthrough pain during labor in obese parturients and its effect on maternal and infant outcomes. **Methods** A total of 120 obese parturient underwent epidural analgesia during delivery at Nanjing Women and Children's Healthcare Hospital from October 2022 to December 2023 were selected and all primiparas experienced breakthrough pain during the first stage of labor. All patients were randomly divided into two groups, with 60 cases in each group. The experimental group received 6 mL of 1% lidocaine administered by epidural injection when breakthrough pain occurred (VAS score≥4), while the control group received 6 mL of 0.15% ropivacaine by epidural injection. The following parameters were recorded: time for VAS scores decreasing to 3 or below, cervical dilation at the onset of the first breakthrough pain, number of additional drug administrations during labor, VAS pain scores at various time points, delivery-related outcomes (duration of labor, use of oxytocin, postpartum hemorrhage within 2 hours after delivery, mode of delivery), and adverse events. **Results** The experimental group had a shorter time for the VAS pain score decreasing to 3 or below [7(6,7) min *vs* 16(16,17) min, Z=52.624, P<0.01]. There was no statistically significant difference in the cervical dilation at the onset of the first breakthrough pain and number of additional drug administrations during labor (P>0.05). At 5 min (T_1), 10 min (T_2), and 15 min (T_3) after administration, the VAS scores of the experimental group were lower than those of the control group (P<0.05). There was no statistically significant difference in the duration of labor, use of oxytocin, postpartum hemorrhage within 2 hours after delivery, mode of delivery, and adverse events during analgesia between the two groups (P>0.05). **Conclusion** Both 6 mL of 1.0% lidocaine and 6 mL of 0.15% ropivacaine administered by epidural injection have been shown to effectively suppress breakthrough pain in obese parturient during epidural labor analgesia and improve maternal and neonatal outcomes. And lidocaine demonstrates a shorter onset time, faster decrease in VAS pain scores.

Keywords: Labor analgesia, epidural; Breakthrough pain; Lidocaine; Ropivacaine; Obese primiparas; Maternal and infant outcomes

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Epidural analgesia for labor is currently the preferred method of pain relief for delivery in China. However, in clinical practice, it has been observed that some women still experience breakthrough pain during the first stage of labor. The incidence of breakthrough pain varies across different studies, with rates as high as 55% [1-3]. The causes of breakthrough pain include progressively stronger uterine contractions and continuous downward head compression. Additionally, physiological, psychological, and genetic factors of the parturient may also influence pain perception [4]. After breakthrough pain occurs, adding drugs from the original analgesia pump (low-concentration local anesthetic combined with low-concentration opioid) typically does not significantly reduce the pain level [5]. Previous research found that breakthrough pain during intrathecal labor analgesia can be effectively suppressed with an additional epidural dose of 0.15% ropivacaine, but the downside is that the onset time is relatively long, and parturients' satisfaction with this approach is low [5].

Lidocaine is an ester-type local anesthetic with a rapid onset, strong anesthetic effect, and minimal impact on uterine contractions, making it suitable for labor analgesia without interfering with the progression of labor. Additionally, at low concentrations, it has a mild effect on motor nerve block and can be safely used for obstetric epidural analgesia [6]. However, there is relatively limited large-scale research on the use of lidocaine for alleviating breakthrough pain in labor analgesia. Currently, the global population of obese individuals is increasing, including a significant number of obese parturients. Obese women have complex pathophysiological changes, and perinatal risks and related complications are correspondingly elevated. Studies showed that obese parturients have a lower pain threshold and are more likely to experience breakthrough pain during labor [7]. Therefore, this study focuses on obese parturients and investigates the clinical efficacy of 1.0% lidocaine epidural bolus in relieving breakthrough pain during labor in obese women.

1 Material and methods

1.1 Study subjects

This study has been approved by the hospital's ethics committee (approval number: 2021KY-097), and all participants provided informed consent. The study enrolled nulliparous women with a singleton pregnancy, full-term gestation, and breakthrough pain during the first stage of labor after receiving epidural analgesia at Nanjing Women and Children's Healthcare Hospital between October 2022 and December 2023.

Inclusion criteria**:** BMI between 35 and 45 kg/m², age between 20 and 35 years, and ASA classification of I or II. Exclusion criteria: Ultrasound diagnosis of macrosomia before delivery; history of chronic pain; long-term use of analgesics before delivery; history of psychiatric disorders; poor communication; allergy to lidocaine or other amide or ester local anesthetics; epidural block failure; or need for emergency cesarean section for obstetric reasons. Exclusion after enrollment: newborn birth weight ≥4000 g or premature termination of epidural analgesia.

1.2 Grouping and intervention

Participants were randomly divided into two groups using a random number table. Sample size calculation was based on preliminary pilot data, with the time for VAS to decrease to 3 or below being 7.6±1.4 minutes in the experimental group and 15.8±3.9 minutes in the control group. A two-tailed test with $\alpha = 0.05$ and $\beta = 0.1$ was used. Using the formula for sample size calculation, $n = 2[(\mu\alpha + \mu\beta)^2\sigma^2]/\delta^2$, the required sample size was estimated to be 50 per group, adjusted for a 20% loss rate, resulting in 60 participants per group.

This trial initially enrolled 126 obese primiparous women. In the experimental group, 3 newborns had a birth weight ≥ 4 000 g, while in the control group, 2 newborns had a birth weight ≥ 4,000 g, and 1 woman had her epidural catheter reset. A total of 120 participants were included in the final analysis, with 60 women in each group. There were no statistically significant differences in the general demographic data of the two groups, including age, BMI, gestational age, and baseline cervical dilation at the time of labor analgesia initiation ($P > 0.05$). **See Table 1**.

Tab.1 Comparison of general information between two groups of primiparas (n=60)

Group	Age(years)[a]	BMI(kg/m²)[a]	Gestational age (week)[b]	cervical dilation (cm)[b]
Experimental group	30.51±3.03	39.22±2.37	39.50(39.00, 40.00)	2(2, 2)
Control group	30.73±2.74	38.51±1.95	40.00(39.00, 40.25)	2(2, 2)
t/*z* value	0.411	1.785	0.997	0.572
P value	0.682	0.077	0.319	0.567

Note: [a]data were expressed in $\bar{x}\pm s$; [b]data were expressed in M (P_{25}, P_{75}).

After entering the delivery room, fetal heart monitoring was initiated, and an intravenous access in the upper limbs was established. Ringer's acetate solution was administered at a rate of 6-8 mL/(kg·h) for hydration. The parturient's heart rate, blood pressure, and saturation of peripheral oxygen (SpO_2) were monitored. When the parturient requested labor analgesia, the obstetrician and anesthesiologist jointly assessed the feasible epidural analgesia plan. The parturient was then transferred to the anesthesia procedure room. During the procedure, the parturient maintained a left lateral position, and the anesthesiologist used a handheld ultrasound device to locate the intervertebral space between the L2-L3 or L3-L4 vertebrae, marked the site, disinfected the area, draped, and performed epidural puncture. Once successful, a 3-4 cm epidural catheter was inserted. After confirming no cerebrospinal fluid or blood was aspirated, a test dose of 1% lidocaine (Hubei Tiansheng Pharmaceutical, Approval No. H42021839) 3 mL (with 1:200,000 epinephrine) was administered via the epidural catheter. The catheter placement was confirmed to be correct after 3–5 minutes, ensuring that the catheter was not misplaced into the subarachnoid space or a blood vessel. Subsequently, an epidural bolus was administered: 12 mL of 0.08% ropivacaine (Zhejiang Xianju Pharmaceutical, Product Batch No. EE2335) combined with 0.4 μg/mL sufentanil (Yichang Renfu Pharmaceutical, Product Batch No. 31A021312). The sensory blockade level was assessed using the alcohol swab test to confirm bilateral sensory blockade up to the T10 level. Labor pain was assessed using the Visual Analogue Scale (VAS). When VAS ≤ 3, it was considered that analgesia was effective. If VAS remained >3, potential causes for inadequate analgesia such as poor catheter position or incomplete nerve block were ruled out. All parturients were connected to an analgesia pump for continuous epidural analgesia, using a solution of 0.08% ropivacaine + 0.4 μg/mL sufentanil, total volume 150 mL. The pump was set to a programmed intermittent epidural bolus (PIEB) mode: background dose 2 mL/h, initial dose 12 mL, and 10 mL boluses every hour with a self-administered dose of 8 mL per bolus. The lockout time was 30 minutes. The analgesia pump was turned off 2 hours after the third stage of labor.

When breakthrough pain (VAS ≥ 4) occurred, the position and patency of the epidural catheter, fetal position, and use of oxytocin were evaluated. After excluding these factors, the parturients were randomly divided into experimental group and control group. The experimental group received a bolus of 6 mL of 1.0% lidocaine, and the control group received a bolus of 6 mL of 0.15% ropivacaine. Both groups were observed for 20 min. If VAS remained ≥ 4, the same dose was administered again, and the response was observed for another 20 min. If VAS ≥ 4 persisted, it indicated inadequate analgesia, requiring re-puncture and adjustment of the epidural catheter, and the parturient would be excluded from the study.

1.3 Outcome measures

Primary outcome: VAS pain score was assessed every 1 minute after drug administration, and the time to achieve VAS ⩽ 3 was recorded. Secondary outcomes included:

cervical dilation at the onset of breakthrough pain, the number of additional doses required during labor. VAS scores were recorded at baseline (0 min, T_0), 5 minutes (T_1), 10 minutes (T_2), 15 minutes (T_3), and 20 minutes (T_4) post-administration. Delivery-related data (labor duration, oxytocin use, blood loss 2 hours post-delivery, delivery mode) were also recorded. Adverse effects during analgesia, including nausea and vomiting, skin itching, urinary retention, postpartum fever, hypotension, chills, and motor nerve block, were monitored. Neonatal data including birth weight, Apgar scores at 1 and 5 minutes, and umbilical artery blood gas values were collected.

1.4 Statistical Methods

Statistical analysis was performed using SPSS 23.0. Normally distributed continuous variables were expressed as $\bar{x}\pm s$ and compared using independent samples *t*-test. Non-normally distributed variables were expressed as *M* (P_{25}, P_{75}) and analyzed using the Mann-Whitney *U* test. Categorical data were expressed as *n* (%), and group differences were tested using χ^2 or Fisher's exact test. $P < 0.05$ was considered statistically significant.

2 Results

2.1 Pain-related indicators

There were no statistically significant differences in cervical dilation at the time of the first occurrence of breakthrough pain or in the number of additional epidural drug doses between the two groups ($P > 0.05$). Compared to the control group, the experimental group had a significantly shorter time to reach a VAS score of 3 or below after epidural drug supplementation ($P < 0.05$). Additionally, at T_1, T_2, and T_3, the VAS scores in the experimental group were lower than those in the control group ($P < 0.05$). **See Table 2 and Table 3.**

2.2 Labor-related outcomes

There were no statistically significant differences between the two groups in terms of first, second, and third stage labor duration, postpartum hemorrhage at 2 hours, the proportion of oxytocin use during labor, delivery method, or adverse reactions ($P > 0.05$). No cases of hypotension, chills, or motor nerve block were observed in either group. **See Tables 4 and 5.**

2.3 Neonatal outcomes

There were no statistically significant differences between the two groups in neonatal birth weight, Apgar scores at 1 and 5 minutes, or umbilical artery blood gas analysis values ($P > 0.05$). **See Table 6.**

Tab.2 Comparison of breakthrough pain scores between two groups of primiparas [*n*=60, *M* (P_{25}, P_{75})]

Group	Cervical dilation at the first occurrence of breakthrough pain(cm)	Time to reach a VAS score of 3 or below(min)	Number of additional epidural drug
Experimental group	5.00(5.00, 6.00)	7(6, 7)	2(1, 2)
Control group	6.00(5.00, 6.25)	16(16, 17)	2(1, 2)
Z value	1.050	52.624	1.380
P value	0.294	<0.001	0.168

Tab.3 Comparison of VAS pain scores between two groups of primiparas in different times [*n*=60, *M* (P_{25}, P_{75})]

Group	T_0	T_1	T_2	T_3	T_4
Experimental group	6(6,7)	3(3,4)[a]	2(1,2)[a]	2(1,2)[a]	2(1,2)
Control group	6(6,7)	6(5,7)	5(4,6)	3(3,4)	2(1,2)
$F/P_{Intergroup}$	201.993/<0.001				
F/P_{Time}	645.905/<0.001				
$F/P_{Interaction}$	117.558/<0.001				

Note: compared with the control group, [a]*P*<0.05.

Tab.4 Comparison of delivery-related outcomes between two groups of primiparas (*n*=60, $\bar{x}\pm s$)

Group	First stage labor duration(min)	Second stage labor duration(min)	Third stage labor duration(min)	Postpartum hemorrhage at 2 hours(mL)	Oxytocin use [case(%)]
Experimental group	541.82±111.25	57.52±12.32	7.93±2.27	286.5±30.12	26(43.3)
Control group	503.27±105.36	57.33±13.07	7.85±1.95	287.8±25.94	35(58.3)
t/x^2 value	1.949	0.036	0.216	0.146	2.701
P value	0.054	0.971	0.829	0.884	0.100

Tab.5 Comparison of delivery mode and adverse reaction between two groups of primiparas [*n*=60, case (%)]

Group	Mode of delivery			Adverse reactions			
	Natural childbirth	Instrumental delivery	Lateral episiotomy	Nausea and vomiting	Itchy skin	Urinary retention	Intrapartum fever
Experimental group	54(90.00)	2(3.33)	4(6.67)	4(6.67)	4(6.67)	5(8.33)	8(13.33)
Control group	52(86.67)	3(5.00)	5(8.33)	6(10.00)	3(5.00)	6(10.00)	5(8.33)
χ^2 value		0.458		0.436	0.152	0.100	0.776
P value		0.836		0.509	0.697	0.752	0.378

Tab.6 Comparison of newborn-related outcomes between two groups of primiparas (*n*=60)

Group	Neonatal weight (g, $\bar{x}\pm s$)	Apgar score [*M*(P_{25}, P_{75})]		Umbilical artery blood gas($\bar{x}\pm s$)			
		1 min	5 min	pH	PaO_2 (mmHg)	$PaCO_2$(mmHg)	Lac(mmol/L)
Experimental group	3 261.51±282.22	10(9,10)	10(9,10)	7.27±0.04	17.75±0.42	53.03±0.44	3.61±0.31
Control group	3 318.61±266.23	10(9,10)	10(10,10)	7.26±0.03	17.7±0.41	52.91±0.52	3.52±0.23
t/z 值	1.140	0.092	1.146	0.903	0.766	1.425	1.814
P 值	0.257	0.926	0.252	0.368	0.445	0.157	0.072

3 Discussion

Breakthrough pain refers to a pain condition that occurs during painless labor and is severe enough to require additional interventions for management [4]. Breakthrough pain has a profound impact on women, causing them to experience tension and anxiety, which may hinder their confidence in natural childbirth. It can also trigger excessive stress responses, increasing the risks for both the mother and the fetus [7]. A study on risk factors for the failure of intrathecal anesthesia during cesarean section conversion from vaginal delivery noted that the occurrence of breakthrough pain was a significant cause of failure of spinal anesthesia in cesarean section [8]. Furthermore, research has found a correlation between inappropriate labor analgesia and the development of postpartum depression, which imposes significant burdens on society and families [9]. In recent years, obesity continues to affect the general population's quality of life, and obesity during pregnancy not only affects the mother, with a significantly higher incidence of hypertension, congestive heart failure, and pulmonary embolism compared to normal-weight women, but also impacts the neonate, with increased risks of macrosomia and neonatal hypoglycemia. Clinically, it has been observed that obese women are more likely to experience breakthrough pain, possibly due to the increased weight during pregnancy, which is often accompanied by chronic back pain, leading to pain sensitization. As a result, these women report lower satisfaction with labor analgesia [7]. Therefore, it is crucial to effectively manage breakthrough pain during labor analgesia, especially for this specific group of obese women.

Currently, there are many studies on the management of breakthrough pain, but some controversies remain. For example, Lee *et al.* [11] compared the use of 100 μg clonidine and 100 μg fentanyl in managing breakthrough pain during labor analgesia, and found that both drugs had similar analgesic success rates and pain score reductions within 15 minutes. In another study, Ji *et al.* [12] compared the use of 1.5% chloroprocaine and 0.15% ropivacaine for epidural administration in managing breakthrough pain, and concluded that both drugs were equally effective in relieving breakthrough pain, with no differences in labor outcomes or maternal-neonatal outcomes. However, a study by Li *et al.* [13] found that chloroprocaine was more effective in managing breakthrough pain and had better maternal and neonatal outcomes. Despite the discrepancies, it is generally agreed that high-concentration local anesthetics are more effective than low-concentration ones in managing breakthrough pain during labor analgesia.

Lidocaine is a commonly used local anesthetic, can rapidly provide analgesia during labor without adverse effects on maternal or neonatal outcomes [14]. In some studies, on the management of breakthrough pain during labor analgesia [11,15], lidocaine is often used as a rescue medication. However, clinical data specifically addressing lidocaine for managing breakthrough pain are limited. Therefore, this study selected 1.0% lidocaine to observe its effectiveness in managing breakthrough pain and its impact on maternal and neonatal outcomes.

In this study, no significant differences were observed in the VAS scores between the two groups at the time of breakthrough pain onset and 20 minutes after breakthrough pain management. However, at 5-, 10-, and 15-minutes post-analgesia, the VAS scores in the experimental group were significantly lower than those in the control group. Furthermore, the time taken for the VAS score to drop below 3 was significantly shorter in the experimental group. This could be due to the rapid and complete absorption of lidocaine into the epidural space, leading to faster onset of analgesia [14], as well as the potential for lidocaine to effectively reduce pain sensitization [16].

According to the results of this study, there were no significant differences between the two groups in vital signs, fetal heart rate variability, labor duration, oxytocin use, or delivery method. There were also no significant adverse reactions such as motor nerve block or chills. This suggests that the use of 1.0% lidocaine or 0.15% ropivacaine for epidural administration to manage breakthrough pain did not have a significant negative impact on the mothers. Neonates in both groups had normal Apgar scores at 1 and 5 minutes, and umbilical artery blood gas analysis did not show signs of neonatal hypoxia. Thus, the approach used in this study to manage breakthrough pain had no significant adverse effects on the neonates, consistent with previous clinical studies [5,11-12].

However, this study has some limitations. Further research is needed to confirm the optimal concentration and volume of 1.0% lidocaine for managing breakthrough pain during labor analgesia. Additionally, this study included only obese primiparous women, and whether the analgesia protocol would be effective for multiparous or women with multiple pregnancies remains to be verified.

In conclusion, epidural injection of 1.0% lidocaine or 0.15% ropivacaine can effectively suppress breakthrough pain during epidural labor analgesia in obese parturients, with good maternal and infant outcomes. However, 1.0% lidocaine has a faster onset of action and a more rapid decrease in VAS scores.

Conflict of interest None

Reference

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·论　著·

利多卡因在缓解肥胖初产妇硬膜外分娩镇痛中爆发痛的临床应用

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摘要：目的　评价利多卡因在缓解肥胖初产妇硬膜外分娩镇痛中爆发痛的效果及对母婴的影响。**方法**　选择 2022 年 10 月至 2023 年 12 月在南京市妇幼保健院进行硬膜外分娩镇痛的 120 例肥胖[身体质量指数(BMI) 35.0~45 kg/m^2]，且在第一产程中发生爆发痛的初产妇。所有患者随机分为两组，每组 60 例，试验组接受硬膜外推注 1.0%利多卡因 6 mL，对照组接受硬膜外推注 0.15%罗哌卡因 6 mL。记录视觉模拟评分(VAS)下降到 3 分或以下的时间、首次爆发痛发生时的宫口扩张值、产程中追加药物的次数、不同时间点 VAS 评分、分娩相关情况(产程时间、缩宫素使用率、分娩后 2 h 出血量、分娩方式)及分娩镇痛期间不良反应的发生情况。**结果**　与对照组比较，试验组产妇的 VAS 疼痛评分下降到 3 分或以下的时间显著缩短[7(6,7) min *vs* 16(16,17) min，$Z=52.624$，$P<0.01$]。两组首次爆发痛发生时的宫口扩张值和产程中追加药物的次数差异无统计学意义($P>0.05$)。给药后的5 min(T_1)、10 min(T_2)、15 min(T_3)时，试验组的 VAS 评分低于对照组($P<0.05$)。两组产妇的产程时间、缩宫素使用率、分娩后 2 h 出血量、分娩方式以及镇痛期间不良反应的发生率差异无统计学意义($P>0.05$)。**结论**　硬膜外给予 6 mL 1.0%利多卡因或 6 mL 0.15%罗哌卡因均能有效抑制肥胖产妇硬膜外分娩镇痛中的爆发痛，并改善母婴转归。且利多卡因的起效时间更短，VAS 评分下降更迅速。

关键词：分娩镇痛，硬膜外；爆发痛；利多卡因；罗哌卡因；肥胖初产妇；母婴转归

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Application of lidocaine in alleviating breakthrough pain during epidural labor analgesia in obese primiparas

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Abstract: Objective　To evaluate the clinical efficacy of lidocaine in alleviating breakthrough pain during labor in obese primiparas and its effect on maternal and infant outcomes. **Methods**　A total of 120 obese primiparas (body mass index being 35 to 45 kg/m^2) underwent epidural analgesia during delivery at Nanjing Women and Children's Healthcare Hospital from October 2022 to December 2023 were selected and all primiparas experienced breakthrough pain during the first stage of labor. All patients were randomly divided into two groups, with 60 cases in each group. The experimental group received 6 mL of 1.0% lidocaine administered by epidural injection when breakthrough pain occurred (VAS score≥4), while the control group received 6 mL of 0.15% ropivacaine by epidural injection. The following parameters were recorded: time for VAS scores decreasing to 3 or below, cervical dilation at the onset of the first breakthrough pain, number of additional drug administrations during labor, VAS scores at various time points, delivery-related outcomes (duration of labor, use rate of oxytocin, blood loss within 2 hours after delivery, mode of delivery), and adverse events

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during analgesia. **Results**　Compared with the control group, the experimental group had a shorter time for the VAS score decreasing to 3 or below [7(6,7) min *vs* 16(16,17) min, $Z=52.624$, $P<0.01$]. There was no statistically significant difference in the cervical dilation at the onset of the first breakthrough pain and number of additional drug administrations during labor ($P>0.05$). At 5 min (T_1), 10 min (T_2), and 15 min (T_3) after administration, the VAS scores of the experimental group were lower than those of the control group ($P<0.05$). There was no statistically significant difference in the duration of labor, usage rate of oxytocin, blood loss within 2 hours after delivery, mode of delivery, and adverse events during analgesia between the two groups ($P>0.05$). **Conclusion**　Both 6 mL of 1.0% lidocaine and 6 mL of 0.15% ropivacaine administered by epidural injection can effectively suppress breakthrough pain in obese parturient during epidural labor analgesia, and improve maternal and neonatal outcomes. And lidocaine demonstrates a shorter onset time, and a faster decrease in VAS score.

Keywords: Labor analgesia, epidural; Breakthrough pain; Lidocaine; Ropivacaine; Obese primiparas; Maternal and infant outcomes

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硬膜外分娩镇痛是目前国内首选的分娩镇痛技术,然而仍有产妇在第一产程中出现爆发痛的情况。关于爆发痛的发生率,各文献的报道有所不同,最高可达 55%[1-3]。爆发痛的发生原因包括不断增强的宫缩和持续下降的抬头压迫等,产妇的生理、心理和遗传因素也与疼痛感知有关[4]。在爆发痛发生后,追加原有镇痛泵中的药物(低浓度局麻药复合低浓度阿片类药物)通常无法显著降低疼痛程度[5]。笔者先前的研究发现,在椎管内分娩镇痛过程中发生的爆发痛,可以通过硬膜外追加 0.15%罗哌卡因有效抑制,但缺点是起效时间较长,产妇对此满意度不佳[5]。利多卡因属于酯类局部麻醉药,其起效迅速、麻醉效能强,对宫缩的影响较小,不会干扰产程;并且在低浓度使用时,对运动神经阻滞轻,可安全用于产科硬膜外镇痛[6]。然而,利多卡因在缓解分娩镇痛中爆发痛方面的研究数据相对较少。目前,全球肥胖人群日益增多,其中不乏肥胖产妇,肥胖产妇具有复杂的病理生理改变,围产期的风险和相关并发症也相应增加。有研究表明,肥胖产妇的痛阈降低,分娩过程中更容易出现爆发痛[7]。因此,本研究选择肥胖产妇这一特殊人群,探讨 1.0%利多卡因硬膜外推注在缓解其分娩镇痛中爆发痛方面的临床效果。

1　对象与方法

1.1　*研究对象*　本研究已获得医院伦理委员会的批准(批准号:2021KY-097),所有入组产妇均已签署知情同意书。选择 2022 年 10 月至 2023 年 12 月在南京市妇幼保健院进行硬膜外分娩镇痛并在镇痛后的第一产程出现爆发痛的足月、单胎初产妇作为研究对象。纳入标准:身体质量指数(body mass index, BMI) 35~45 kg/m^2,年龄 20~35 岁,并且美国麻醉医院学会(American Society of Anesthesiologists, ASA)分级符合Ⅰ或Ⅱ级标准。排除标准:产前超声诊断提示巨大儿;有慢性疼痛病史;产前长期使用镇痛类药物;有精神类疾病史;沟通不佳;有利多卡因等酰胺类或酯类局麻药过敏史;存在硬膜外神经阻滞不全以及因产科因素需要中转剖宫产的产妇。剔除标准:新生儿出生后体重≥4 000 g或硬膜外镇痛被提前终止。

1.2　*分组及干预*　采用随机数字表法将产妇分为两组。根据前期预试验的结果进行样本量计算,试验组 VAS 下降到 3 分或 3 分以下所需时间为(7.6±1.4) min,对照组为(15.8±3.9) min。在进行双侧检验时,取 $\alpha=0.05$, $\beta=0.1$。根据样本量计算公式 $n=2\times[(\mu_\alpha+\mu_\beta)^2\sigma^2]/\delta^2$,计算得到 $n=49.86\approx50$。考虑到可能的 20%的丢失率,每组预计纳入产妇为 60 例。初始纳入 126 例肥胖初产妇,试验组中 3 名产妇的新生儿出生体重≥4 000 g,对照组 2 名产妇的新生儿出生体重≥4 000 g、1 名产妇重置硬膜外导管,最终纳入统计 120 例,每组各 60 例。两组产妇的一般资料,包括年龄、BMI、孕周、行分娩镇痛即刻时宫口扩张基础值等比较差异无统计学意义($P>0.05$)。见表 1。

表 1　两组产妇的一般资料比较　($n=60$)

Tab. 1　Comparison of general information between two groups of primiparas　($n=60$)

组别	年龄(岁)[a]	BMI (kg/m^2)[a]	孕周(周)[b]	宫口扩张基础值(cm)[b]
试验组	30.51±3.03	39.22±2.37	39.50(39.00,40.00)	2(2,2)
对照组	30.73±2.74	38.51±1.95	40.00(39.00,40.25)	2(2,2)
t/Z 值	0.411	1.785	0.997	0.572
P 值	0.682	0.077	0.319	0.567

注:[a] 为以 $\bar{x}\pm s$ 表示,[b] 为以 $M(P_{25}, P_{75})$ 表示。

产妇进入产房后,开始进行胎心监护,同时开放上肢外周静脉通路,输注醋酸钠林格液 6~8 mL/(kg·h)进行补液。同时,监测产妇的心率、血压和脉搏血氧饱和度(saturation of peripheral oxygen, SpO_2)水平。当产妇要求进行分娩镇痛时,产科医师和麻醉科医师共同评估可行的硬膜外分娩镇痛方案。然后,转运人员将产妇转运至麻醉操作间。在这个过程中,产妇保持左侧卧位,麻醉医生通过手持式超声仪器确定产妇第 2~3 腰椎间隙,并用定位器标记好位置,随后消毒、铺单、进行硬膜外穿刺。确认穿刺成功后,置入硬膜外弹簧管,长度为 3~4 cm。在回抽确认没有脑脊液或血液后,通过硬膜外导管给予试验剂量的 1%利多卡因(湖北天圣药业,批准文号:国药准字 H42021839)3 mL(含有肾上腺素 1∶200 000)。观察 3~5 min,确认导管没有误入蛛网膜下腔或血管内。随后,推注硬膜外负荷量药液,0.08%罗哌卡因(浙江仙琚制药,产品批号:EE2335)复合 0.4 μg/mL 舒芬太尼(宜昌人福药业,产品批号:31A021312),剂量为12 mL。观察 15 min,使用酒精棉签擦拭法测试温觉阻滞平面,以确保双侧感觉阻滞平面达到第 10 胸椎。同时,评估产妇的宫缩痛程度,使用视觉模拟评分法(Visual Analogue Scale, VAS)进行评估。当 VAS 评分≤3 分时,表示镇痛效果良好。如果 VAS 疼痛评分仍然高于 3 分,则首先排除镇痛效果不佳的情况,并排除神经阻滞不全或导管位置不佳、堵塞等异常情况。所有产妇均连接镇痛泵进行连续硬膜外镇痛。镇痛泵的药物配方为 0.08%罗哌卡因+0.4 μg/mL 舒芬太尼,总量为 150 mL。镇痛泵的输注模式为硬膜外程控间歇式输注(programmed intermittent epidural bolus, PIEB)方案,具体设置如下:背景剂量 2 mL/h,首剂 12 mL,每隔 1 h 脉冲输注 10 mL,自控给药 8 mL/次。锁定时间为30 min。在第三产程结束后的 2 h 关闭镇痛泵。

当产妇出现爆发性疼痛(VAS≥4 分)时,首先判断硬膜外导管的位置、导管的通畅情况、检查胎方位、以及缩宫素的使用情况等,在排除这些影响因素后,试验组给予硬膜外推注 1.0%利多卡因 6 mL,对照组给予硬膜外推注 0.15%罗哌卡因 6 mL,两组均观察 20 min。如果 VAS≥4 分,则再次给予相同剂量,并观察 20 min。如果 VAS 仍然≥4 分表示镇痛效果不佳,需要重新进行椎管内穿刺,调整硬膜外导管位置,并将该产妇排除出研究。

1.3　观察指标　主要指标:给药后每 1 min 评估 1 次 VAS 疼痛评分,记录 VAS 疼痛评分下降至 3 分或 3 分以下的时间。次要指标包括:首次爆发痛发生时的宫口扩张值,产程中追加药物的次数。记录给药即刻 0 min(T_0)以及给药后 5 min(T_1)、10 min(T_2)、15 min(T_3)、20 min(T_4)的 VAS 评分。记录分娩情况(产程时间、催产素使用率、分娩后 2 h 出血量、分娩方式)。记录镇痛期间恶心呕吐、皮肤瘙痒、尿潴留、产间发热、低血压、寒战、运动神经阻滞等不良反应发生情况。记录新生儿的出生体重、出生后 1 min 以及 5 min 的 Apgar 评分、脐动脉血气分析值。

1.4　统计学方法　数据分析采用 SPSS 23.0 统计软件。符合正态分布的连续变量以 $\bar{x}\pm s$ 表示,组间比较采用独立样本 t 检验。偏态分布的连续变量以 $M(P_{25}, P_{75})$ 表示,组间比较采用 Mann-Whitney U 检验。计数数据以例(%)表示,组间比较采用χ^2 检验。P<0.05 为差异有统计学意义。

2　结　果

2.1　疼痛相关指标　两组产妇在首次发生爆发痛时的宫口扩张值及经硬膜外追加药物的次数比较差异无统计学意义(P>0.05)。与对照组相比,试验组在硬膜外追加给药后,产妇 VAS 评分下降到 3 分及以下的时间更短(P<0.05)。此外,T_1、T_2、T_3 时试验组的 VAS 评分低于对照组(P<0.05)。见表 2、表 3。

2.2　分娩相关情况　两组产妇第一产程时间、第二产程时间、第三产程时间、产后 2 h 出血量、产程中缩宫素使用占比、分娩方式及不良反应比较,差异无统计学意义(P>0.05)。见表 4、表 5。两组产妇均未出现低血压、寒战、运动神经阻滞的情况。

2.3　新生儿相关情况比较　两组产妇的新生儿出生体重、出生后 1 min 和 5 min 的 Apgar 评分、脐动脉的血气分析值比较,差异无统计学意义(P>0.05)。见表 6。

表 2　两组产妇爆发痛的相关指标　[n=60,$M(P_{25}, P_{75})$]

Tab. 2　Comparison of breakthrough pain scores between two groups of primiparas　[n=60, $M(P_{25}, P_{75})$]

组别	首次爆发痛时宫口扩张值(cm)	VAS 评分降到 3 分及以下时间(min)	追加药次数
试验组	5.00(5.00,6.00)	7(6,7)	2(1,2)
对照组	6.00(5.00,6.25)	16(16,17)	2(1,2)
Z 值	1.050	52.624	1.380
P 值	0.294	<0.001	0.168

表 3　两组产妇发生爆发痛后各时间点的 VAS 评分　[n=60, M(P_{25}, P_{75})]

Tab. 3　Comparison of VAS pain scores between two groups of primiparas at different time points　[n=60, M (P_{25}, P_{75})]

组别	T_0	T_1	T_2	T_3	T_4
试验组	6(6,7)	3(3,4)[a]	2(1,2)[a]	2(1,2)[a]	2(1,2)
对照组	6(6,7)	6(5,7)	5(4,6)	3(3,4)	2(1,2)
$F/P_{组间}$ 值	201.993/<0.001				
$F/P_{时间}$ 值	645.905/<0.001				
$F/P_{交互}$ 值	117.558/<0.001				

注：数据经转换后符合正态分布，行重复测量方差分析。与对照组比较，[a]P<0.05。

表 4　两组产妇产程相关情况　(n=60, $\bar{x}\pm s$)

Tab. 4　Comparison of delivery-related outcomes between two groups of primiparas　(n=60, $\bar{x}\pm s$)

组别	第一产程(min)	第二产程(min)	第三产程(min)	产后 2 h 出血(mL)	使用缩宫素[例(%)]
试验组	541.82±111.25	57.52±12.32	7.93±2.27	286.5±30.12	26(43.3)
对照组	503.27±105.36	57.33±13.07	7.85±1.95	287.8±25.94	35(58.3)
t/χ^2 值	1.949	0.036	0.216	0.146	2.701
P 值	0.054	0.971	0.829	0.884	0.100

表 5　两组产妇分娩方式及不良反应相关情况　[n=60, 例(%)]

Tab. 5　Comparison of delivery mode and adverse reaction between two groups of newborns　[n=60, case (%)]

组别	分娩方式			不良反应			
	自然分娩	器械助产	会阴侧切	恶心呕吐	皮肤瘙痒	尿潴留	产间发热
试验组	54(90.00)	2(3.33)	4(6.67)	4(6.67)	4(6.67)	5(8.33)	8(13.33)
对照组	52(86.67)	3(5.00)	5(8.33)	6(10.00)	3(5.00)	6(10.00)	5(8.33)
χ^2 值		0.458		0.436	0.152	0.100	0.776
P 值		0.836		0.509	0.697	0.752	0.378

表 6　两组新生儿相关情况比较　(n=60)

Tab. 6　Comparison of newborn-related outcomes between two groups of primiparas　(n=60)

组别	新生儿体重(g, $\bar{x}\pm s$)	Apgar 评分[M(P_{25}, P_{75})]		脐动脉血气($\bar{x}\pm s$)			
		1 min	5 min	pH 值	PaO_2(mmHg)	$PaCO_2$(mmHg)	乳酸(mmol/L)
试验组	3 261.51±282.22	10(9,10)	10(9,10)	7.27±0.04	17.75±0.42	53.03±0.44	3.61±0.31
对照组	3 318.61±266.23	10(9,10)	10(10,10)	7.26±0.03	17.7±0.41	52.91±0.52	3.52±0.23
t/Z 值	1.140	0.092	1.146	0.903	0.766	1.425	1.814
P 值	0.257	0.926	0.252	0.368	0.445	0.157	0.072

3　讨　论

爆发痛是指在无痛分娩期间，产妇出现难以忍受并需要额外干预处理的疼痛状态[4]。爆发痛不仅会使产妇处于紧张和焦虑的状态，不利于她们建立自然分娩的信心，还会导致产妇产生过度的应激反应。一项关于分娩镇痛产妇“顺转剖”剖宫产手术时硬膜外麻醉改全身麻醉的危险因素分析中指出，爆发痛的发生是“顺转剖”剖宫产手术椎管内麻醉失败的重要原因[8]。此外，研究还发现，产时不恰当的镇痛与产后抑郁症有一定的相关性[9]。近年来，肥胖仍然影响着一般民众的正常生活，而妊娠期肥胖不仅会对孕妇本身产生影响，如高血压、充血性心力衰竭、肺栓塞等疾病的发生率明显高于正常产妇；还会对新生儿产生影响，如巨大儿、新生儿血糖异常等。临床观察中发现肥胖产妇更容易出现爆发痛，这可能与肥胖产妇孕期体重过大常合并慢性背痛，导致痛觉敏化相关，由于爆发痛的出现，这类产妇对分娩镇痛的满意度更低[7]。因此，积极有效地处理肥胖产妇分娩镇痛期间的爆发痛至关重要。

目前关于爆发痛处理方法存在一定的争议。例如，Lee 等[11]研究比较了可乐定100 μg和芬太尼 100 μg 在处理分娩镇痛中的爆发痛时发现，两种药物的镇痛成功率和疼痛评分下降程度在 15 min 内相当。另一项研究中计天珍等[12]比较了1.5%氯普鲁卡因和0.15%罗哌卡因硬膜外给药在处理分娩镇痛中的爆发痛时发现，两者对缓解爆发痛的效果相当，对产程和母婴结局的影响无区别。然而，李敏等[13]的研究使用相同的方法处理分娩镇痛中的爆发痛时发现，氯普鲁卡因的镇痛效果更好，对母婴结局的转归也更好。尽管研究结果存在差异，但高浓度局麻药在处理分娩镇痛中的爆发痛方面的效果优于低浓度局麻药这一结论是肯定的。

利多卡因是一种常用的局麻药，用于分娩镇痛可以快速起效，并且对母婴的转归没有不良影响[14]。在一些关于分娩镇痛中爆发痛处理的文章中[11,15]，利多卡因常被用作补救措施。然而，对于利多卡因处理爆发痛的具体临床研究数据却非常有限。因此，本研究选择了 1.0%利多卡因作为研究药物，旨在观察其处理爆发痛的效果以及对母婴结局的影响。

在本研究中，两组产妇在爆发痛发生时和爆发痛处理后 20 min 的 VAS 评分比较差异无统计学意义。但试验组 T_1～T_3 的 VAS 评分明显低于对照组。此

外,试验组的 VAS 评分降至 3 分以下的时间也明显短于对照组。一方面这可能与利多卡因进入硬膜外后能够被快速、完全吸收,从而发挥镇痛作用较快有关[14],另一方面可能与利多卡因能够较好地降低痛觉敏化作用有关[16]。

本研究结果显示,两组产妇在生命体征、胎心变异率、产程时间、缩宫素使用例数和分娩方式等方面差异无统计学意义。同时,也没有出现明显的运动神经阻滞、寒战等不良反应。这表明使用利多卡因或罗哌卡因进行硬膜外推注处理爆发痛对产妇没有明显不良影响。新生儿在出生后 1 min 和 5 min 的 Apgar 评分均在正常范围内,脐动脉血气分析的结果也显示新生儿无缺氧情况。因此,本研究所采取的处理爆发痛的措施对新生儿没有明显不良影响,这与以往的研究结果一致的[11-12]。

本研究也存在一些不足之处。对于分娩镇痛中硬膜外推注利多卡因的最佳浓度和容量,仍需要进一步的研究来证实。此外,本研究的研究对象较为单一,仅包括肥胖初产妇,对于经产妇或多胎产妇,该镇痛处理方案是否会有差异,还需要进一步验证。

综上,硬膜外推注 1.0%利多卡因或 0.15%罗哌卡因都能有效抑制肥胖产妇在硬膜外分娩镇痛过程中出现的爆发痛,并且母婴转归良好。然而,1.0%利多卡因的起效时间更快,VAS 评分下降更迅速。

利益冲突　无

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