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·临床研究·

不同剂量罗哌卡因复合地佐辛硬膜外自控镇痛应用于无痛分娩的效果观察*

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摘要 目的：探讨不同剂量罗哌卡因复合地佐辛硬膜外自控镇痛（PCEA）应用于无痛分娩的临床价值。**方法：**选择 2019 年 1 月 ~12 月于北京协和医院拟行自然分娩的初产妇 180 例，按随机数余数法分为 A、B、C 三组，每组 60 例，分别采用 0.75%罗哌卡因 0.33 mL（2.50 mg）、0.50 mL（3.75 mg）、0.67 mL（5.0 mg）复合地佐辛 PCEA 分娩镇痛，宫口开至 2~3 cm 时进行无痛分娩，L2~L3 间隙穿刺，头侧置管行 PCEA，宫口开全时停止 PCEA。比较三组镇痛前（T0）、镇痛 15 min（T1）、宫口全开（T2）、胎儿娩出（T3）、胎盘娩出（T4）及缝合会阴（T5）视觉模拟评分（VAS），采用改良 Bromage 评分评估下肢运动神经阻滞效果，统计各组镇痛起效时间、镇痛开始至宫口全开时间、第一产程、第二产程和第三产程时间，统计各组达目标麻醉平面时镇痛药物用量及产妇镇痛泵按压次数，记录各组产后出血量及最终分娩方式，采用新生儿阿氏评分法（Apgar）评定新生儿窒息情况，并行脐血血气分析，统计各组分娩期间不良反应发生情况。**结果：**T1~T5 时点三组 VAS 评分均较 T0 时点降低（P<0.05），B、C 组 T1~T5 时点 VAS 评分均低于 A 组（P<0.05）；三组改良 Bromage 分级分布比较差异有统计学意义（P<0.05）；B、C 组镇痛起效时间较 A 组更快，第二产程时间、第三产程时间较 A 组缩短，达目标麻醉平面镇痛药物用量、镇痛泵按压次数、有效按压次数均较 A 组减少（P<0.05），B、C 组以上指标对比差异无统计学意义（P>0.05）；三组产后出血量、最终分娩方式、新生儿出生 1 min、5 min Apgar 评分、pH 值、血氧分压（PO_2）、二氧化碳分压（PCO_2）和不良反应发生率比较差异无统计学意义（P>0.05）。**结论：**0.75%罗哌卡因 0.50 mL（3.75 mg）复合地佐辛 PCEA 分娩镇痛在无痛分娩中镇痛效果满意，对产程、宫缩、母婴影响小，具有运动神经阻滞、感觉神经阻滞分离优势，不良反应少，安全性高。

关键词：硬膜外自控镇痛；罗哌卡因；地佐辛；分娩镇痛

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Effect Observation of Different Dose of Ropivacaine Combined with Dezocine Patient-Controlled Epidural Analgesia in the Application for Painless Labor*

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ABSTRACT Objective: To explore the value of different doses of ropivacaine combined with dezocine in patient-controlled epidural analgesia (PCEA) in the application for painless labor. **Methods:** 180 primiparas who planned to give birth naturally in Peking Union Medical College Hospital from January to December in 2019 were selected. According to the method of random remainder, they were divided into group A, B and C, with 60 cases in each group. 0.75% ropivacaine 0.33 mL (2.50 mg), 0.50 mL (3.75 mg), 0.67 mL (5.0 mg) combined with dezocine PCEA for labor analgesia were used respectively. Painless labor was performed when the uterine orifice was opened to 2~3 cm, L2~L3 interstitial puncture, a cephalic tube was placed on the PCEA, PCEA was stopped at the full time of uterine opening. The visual analogue scale (VAS) scores before analgesia (T0), analgesia 15 minutes (T1), full opening (T2), fetal delivery (T3), placental delivery (T4) and sutures Perineum (T5) were compared in the three groups. The modified Bromage score was used to evaluate the effect of lower extremity motor nerve block. The analgesic onset time, the time from the beginning of analgesia to the full opening of the uterine orifice, the first stage of labor, the second stage of labor, and the third stage of labor were counted, and the

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amount of analgesic drugs used when each group reached the target anesthesia level and the times of pressing the analgesic pump were counted. The amount of postpartum hemorrhage and final delivery methods in each group were recorded, and the neonatal Apgar score method (Apgar) was used to evaluate the neonatal asphyxia, cord blood gas analysis was performed, and the incidence of adverse reactions during delivery of each group was counted. **Results:** VAS scores of the three groups at T1~T5 time points decreased compared with those of T0 time points (P<0.05), and VAS scores at T1~T5 time points in groups B and C were all lower than those in group A (P<0.05). There was statistical significance in the modified Bromage grading distribution among the three groups (P<0.05). The onset time of analgesia in group B, C was faster than that in group A, and the time of the second stage of labor and the third stage of labor in group B, C was shorter than that in group A, the amount of analgesic drugs used when each group reached the target anesthesia level, the times of pressing the analgesic pump and the times of effective pressing were all reduced compared with those of group A (P<0.05), and there were no statistically significant difference in the above indicators between group B and group C (P>0.05). There were no statistically significant differences in the amount of postpartum hemorrhage, final delivery methods, Apgar scores at 1min and 5min after birth, pH value, blood oxygen partial pressure (PO_2), carbon dioxide partial pressure (PCO_2) and the incidence rate of adverse reactions in the three groups (P>0.05). **Conclusion:** 0.75% ropivacaine 0.50 mL (3.75 mg) combined with dezocine PCEA has satisfactory analgesic effect in painless labor, little effect on labor process, uterine contraction, mother and child, has the advantages of separation of motor nerve block and sensory nerve block, with less adverse reactions and has a high safety.

Key words: Patient-controlled epidural analgesia; Ropivacaine; Dezocine; Labor analgesia

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前言

分娩疼痛在医学上的疼痛指数被认为仅次于烧伤灼痛，提示产程开始及进展，由临产时子宫下端及宫颈扩张、子宫收缩引起，大多数女性无法耐受[1-3]。分娩剧烈疼痛不仅增加产妇焦虑、恐惧感，同时可引起机体氧耗增加、心动过速、血压上升，加重机体应激反应，交感神经兴奋，影响子宫动脉、脐血流量，最终导致产程延长，对母体及胎儿均产生不利影响[4,5]。目前我国无痛分娩率较低，部分产妇或因惧怕产痛选择剖宫产，导致社会因素所致剖宫产率上升[6]。硬膜外自控镇痛（Patient-controlled epidural analgesia，PCEA）是目前应用最多、最趋向理想化的分娩镇痛方式[7,8]。罗哌卡因是 PCEA 分娩镇痛中常用长效局麻药，对心脏及中枢神经系统毒性低，具有感觉、运动神经阻滞分离的优势，低浓度时即具备镇痛效应，安全性较高[9,10]。临床上，对于行 PCEA 的产妇分娩时，罗哌卡因镇痛剂量范围为 2.5~5.0 mg[11]，但是对于其具体使用剂量范围仍存在争议。地佐辛为新型阿片类受体混合激动 - 拮抗剂，镇痛作用强，依赖性低，对呼吸影响小，目前已广泛应用于硬膜外麻醉中[12]。本研究通过分析不同剂量罗哌卡因复合地佐辛应用于 PCEA 分娩镇痛中的效果，探究其对分娩疼痛、产程、镇痛药物用量、新生儿健康、分娩结局的影响，以期为分娩镇痛提供指导，报道如下：

1 对象与方法

1.1 研究对象

选择 2019 年 1 月 ~12 月于北京协和医院拟行自然分娩的单胎、头位、足月、无椎管内麻醉禁忌症初产妇 180 例作为研究对象。纳入标准：美国麻醉医师协会分级Ⅰ~Ⅱ级；无严重产科并发症；头盆对称；孕周 37~40 周；初产妇；年龄 22~39 岁；产前无镇痛、催眠药物应用史；获得产妇及家属知情同意，自愿签订研究同意书。排除标准：脊柱畸形；神经系统疾病；穿刺点皮肤破溃、感染；合并妊娠期高血压、糖尿病等产科疾病；肝肾功能不全；凝血功能障碍；严重心脑血管疾病；胎儿先天发育异常；阿片类药物过敏或有成瘾史；存在硬膜外置管禁忌。按随机数余数法分为 A、B、C 三组，每组 60 例。三组年龄、体质量指数、美国麻醉医师协会分级、孕次、孕周等资料对比差异无统计学意义（P>0.05）。见下表 1。

1.2 方法

三组均于宫口开至 2~3 cm 时开始进行无痛分娩，左侧卧

表 1 两组基线资料比较

Table 1 Comparison of baseline data between the two groups

Groups	n	Age(years old)	Body mass index (kg/m²)	American Society of Anesthesiologists classification(n)		Pregnancy times (times)	Gestational weeks(weeks)
				Grade Ⅰ	Grade Ⅱ		
Group A	60	26.75±2.78	26.87±4.14	34	26	2.14±0.67	38.33±1.56
Group B	60	27.14±3.15	27.12±3.98	35	25	2.16±0.70	38.31±1.65
Group C	60	26.97±3.31	25.96±5.17	36	24	2.13±0.69	38.22±1.59
F(χ^2)		0.406	1.588	(0.137)		0.086	0.174
P		0.667	0.207	0.934		0.918	0.841

位，穿刺部位消毒，L2~L3 间隙行硬膜外穿刺，头侧置管 3 cm，注入试验剂量（3~5 mL）1%利多卡因（北京紫竹药业有限公司生产，国药准字 H11022388），5 min 后确定无不良反应后，三组分别注入 0.75%罗哌卡因（宜昌人福药业有限责任公司生产，国药准字 H20103553）0.33 mL（2.50 mg）、0.50 mL（3.75 mg）、0.67 mL（5.0 mg），复合 5 mg 地佐辛（扬子江药业集团江苏海慈生物药业有限公司生产，国药准字 H20080328）加生理盐水配置成混合液 75 mL，负荷剂量 10 mL，6 mL/h 作为维持剂量，由产妇自控追加，每次 2 mL，锁定时间 15 min。直至宫口全开，关闭镇痛泵，产程结束后继续镇痛至产后 2 h，产后离开产房前，拔除硬膜外导管。产程过程中若出现滞产、胎儿宫内窘迫等需中转剖宫产者改为持续硬膜外麻醉。

1.3 观察指标

① 围产期镇痛及运动神经阻滞情况：镇痛前（T0）、镇痛 15 min（T1）、宫口全开（T2）、胎儿娩出（T3）、胎盘娩出（T4）及缝合会阴（T5）均采用视觉模拟评分（visual analogue scale，VAS）[13]评估镇痛效果；采用改良 Bromage 评分[14]评定下肢运动神经阻滞情况，分为 0~3 级，0 级：无运动神经阻滞；1 级：无法抬腿；2 级：无法屈膝；3 级；完全阻滞，无法伸踝。② 镇痛及产程情况：均统计三组镇痛起效时间（自注药至无痛宫缩时间）、镇痛开始至宫口全开时间、第一产程时间、第二产程时间和第三产程时间，并统计各组达目标麻醉平面镇痛药物用量及产妇自控镇痛泵按压次数、有效按压次数。③ 产后出血量和分娩情况。统计三组产后 2 h 出血量，记录最终分娩方式。④ 新生儿情况：产后 1 min、5 min 均采用阿氏评分法（Apgar）[15]评定新生儿窒息情况；在胎儿娩出即刻，钳夹胎儿端脐动脉，抗凝剂抽取脐动脉血 2 mL，采用美国 GEM 公司 4000 型全自动血气分析仪行血气分析，测定 pH 值、血氧分压（partial pressure of oxygen，PO_2）、二氧化碳分压（partial pressure of carbon dioxide，PCO_2）。⑤ 镇痛相关不良反应。统计三组镇痛相关恶心、呕吐、尿潴留、嗜睡、头晕、皮肤瘙痒等不良反应发生情况。

1.4 统计学方法

研究数据应用 SPPS 22.0 软件进行分析。计量资料经检验满足正态分布与方差齐性要求，以 mean±SD（$\bar{x}\pm s$）表示，多组对比应用单因素方差分析，重复测量数据应用重复测量方差分析，两两组间比较采用 LSD-t 检验，两两时点比较采用差值 t 检验；计数资料采用[n（%）]描述，采用 χ^2 检验或 Fisher 确切概率分析，等级资料（多组比较）采用 Kruskal-Wallis 秩检验（H 检验）。P<0.05 视为差异有统计学意义。

2 结果

2.1 三组镇痛不同时点 VAS 评分比较

T1~T5 时点三组 VAS 评分均较 T0 点降低，存在时间效应（P<0.05），B、C 组 T1~T5 时点 VAS 评分均低于 A 组，存在组间、交互效应（P<0.05）。见下表 2。

表 2 三组镇痛不同时点 VAS 评分比较（$\bar{x}\pm s$，分）

Table 2 Comparison of VAS scores of three groups at different time of analgesia（$\bar{x}\pm s$，scores）

Groups	n	T0	T1	T2	T3	T4	T5
Group A	60	8.92±0.56	1.73±0.42^{t}	1.67±0.36^{t}	2.37±0.54^{t}	1.34±0.36^{t}	1.93±0.51^{t}
Group B	60	8.97±0.45	1.52±0.33^{at}	1.36±0.27^{at}	1.85±0.36^{at}	1.15±0.17^{at}	1.56±0.34^{at}
Group C	60	8.86±0.63	1.46±0.26^{at}	1.31±0.32^{at}	1.77±0.39^{at}	1.13±0.23^{at}	1.47±0.43^{at}
Overall analysis	HF coefficient	0.8365					
Comparison between groups	F，P	44.673，0.000					
Intra group comparison	F，P	10373.115，0.000					
Interaction	F，P	3.832，0.000					

Note: significant marker a was compared with group A at the same time point P<0.05, and significant marker t was compared with group T0 P<α', α' was the Bonferroni corrected test level =0.05/5=0.01, and 5 was the number of fine comparison in time dimension.

2.2 三组改良 Bromage 分级比较

三组改良 Bromage 分级分布比较差异有统计学意义（P<0.05）。见下表 3。

2.3 三组镇痛及产程情况对比

三组镇痛开始至宫口全开时间、第一产程时间比较无差异（P>0.05）。B、C 组镇痛起效时间较 A 组更快（P<0.05），第二产程时间、第三产程时间较 A 组缩短（P<0.05），达目标麻醉平面镇痛药物用量、镇痛泵按压次数、有效按压次数均较 A 组减少（P<0.05），B、C 组以上指标对比差异无统计学意义（P>0.05）。见下表 4。

2.4 三组产后出血量、分娩方式比较

三组产后出血量、分娩方式比较差异无统计学意义（P>0.05），见下表 5。

2.5 三组新生儿情况对比

三组新生儿出生 1 min、5 min Apgar 评分及胎儿娩出即刻的 pH 值、PO_2、PCO_2 比较差异无统计学意义（P>0.05），见下表 6。

2.6 三组镇痛相关不良反应发生率比较

三组不良反应发生率比较差异无统计学意义（P>0.05），但 C 组略高于 A 组和 B 组。见表 7。

3 讨论

表 3 三组改良 Bromage 分级分布情况[n(%)]

Table 3 Distribution of improved Bromage grading in three groups[n(%)]

Groups	n	Grade 0	Grade 1	Grade 2	Grade 3
Group A	60	60(100.00)	0(0.00)	0(0.00)	0(0.00)
Group B	60	33(55.00)	15(25.00)	12(20.00)	0(0.00)
Group C	60	28(46.67)	27(45.00)	5(8.33)	0(0.00)
Hc			42.442		
P			<0.001		

表 4 三组镇痛及产程情况对比($\bar{x}\pm s$)

Table 4 Comparison of analgesic and labor process in three groups($\bar{x}\pm s$)

Parameters	Group A(n=60)	Group B(n=60)	Group C (n=60)	F	*P*
Analgesic onset time(min)	3.57±1.05	1.66±0.45[a]	1.53±0.51[a]	153.655	0.000
Time from the beginning of analgesia to the full opening of the uterine orifice(min)	173.25±16.52	176.52±20.02	169.73±25.79	1.268	0.284
First stage of labor(min)	559.37±126.25	566.79±150.14	556.98±163.78	0.116	0.891
Second stage of labor(min)	85.14±22.23	66.51±19.02[a]	68.23±15.79[a]	18.801	0.000
Third stage of labor(min)	14.23±3.97	12.21±2.63[a]	12.17±1.79[a]	8.991	0.000
Amount of analgesic drugs used when each group reached the target anesthesia level(mg)	36.41±7.25	29.87±8.69[a]	29.14±9.02[a]	13.106	0.000
Times of pressing the analgesic pump(times)	6.89±2.35	6.01±1.63[a]	6.23±1.11[a]	4.214	0.016
Times of effective pressing(times)	3.14±0.34	2.01±0.45[a]	2.03±0.36[a]	167.639	0.000

Note: significant markers a were compared with group A, $P<0.05$.

表 5 三组产后出血量、分娩方式比较

Table 5 Comparison of postpartum hemorrhage and delivery mode in three groups

Groups	n	2h postpartum hemorrhage(mL)	Delivery mode		
			Natural childbirth	Cesarean section	Forceps delivery
Group A	60	223.12±50.65	50(83.33%)	5(8.33%)	5(8.33%)
Group B	60	219.53±53.57	49(81.67%)	8(13.33%)	3(5.00%)
Group C	60	220.45±46.89	46(76.67%)	11(18.33%)	3(5.00%)
F(χ^2)		0.178		(3.157)	
P		0.837		0.532	

表 6 三组新生儿情况对比($\bar{x}\pm s$)

Table 6 Comparison of three groups of newborns($\bar{x}\pm s$)

Groups	n	Apgar scores at 1min after birth(scores)	Apgar scores at 5min after birth(scores)	pH value	PO_2(kPa)	PCO_2(kPa)
Group A	60	9.23±0.45	9.87±0.23	7.26±0.47	3.09±0.71	5.83±0.98
Group B	60	9.31±0.51	9.91±0.21	7.31±0.51	3.12±0.75	6.11±1.06
Group C	60	9.29±0.53	9.93±0.19	7.29±0.49	3.05±0.81	5.97±1.11
F		0.377	1.168	0.293	0.168	1.070
P		0.687	0.314	0.746	0.845	0.345

分娩疼痛主要来源于产程进展时子宫收缩、局部缺血、宫颈扩张导致子宫被膜伸展和子宫周围韧带牵拉刺激，随着产程进展，胎头逐渐降低，加重对盆底、宫颈与子宫下段神经的压迫，加剧产痛，导致产妇无法耐受[16-18]。尤其是部分初产妇，可导致其放弃自然分娩，选择剖宫产，造成社会因素所致剖宫产率逐年增加[19]。硬膜外镇痛是分娩常用镇痛方案，但仍存在起效

表 7 三组镇痛相关不良反应发生率比较[n(%)]

Table 7 Comparison of the incidence rate of analgesia related adverse reactions in the three groups[n(%)]

Groups	n	Dizzy	Drowsiness	Urinary retention	Nausea and vomiting	Skin Itch
Group A	60	1(1.67)	0(0.00)	0(0.00)	1(1.67)	0(0.00)
Group B	60	1(1.67)	1(1.67)	1(1.67)	2(3.33)	0(0.00)
Group C	60	3(5.00)	2(3.33)	2(3.33)	3(5.00)	2(3.33)
χ^2		1.646	2.034	2.034	1.034	4.045
P		0.439	0.362	0.362	1.034	0.132

速度慢,可能引起非必要运动阻滞缺陷,导致产程延长,且导管位置在一定程度上影响镇痛效果[20,21]。PCEA 是常用镇痛手段,相较静脉自控镇痛用药量小,止痛确切,作用相对持久,且安全性更高,对应激反应阻滞作用更强,可切断区域性伤害刺激、疼痛刺激向中枢传导,降低对下丘脑 - 垂体 - 肾上腺皮质轴影响,可减少围术期应激反应[22,23]。

罗哌卡因是新型酰胺类长效局麻药物,与布比卡因药代动力学特点相似,但较布比卡因对心脏毒性更低,对子宫、胎盘血流影响小,且存在感觉、运动神经阻滞分离优势,经硬膜外给药,可直接与脊髓阿片类受体结合产生镇痛效应[24,25]。低浓度局麻药物复合小剂量脂溶性阿片类药物是常用分娩镇痛方式,常用 μ 受体激动剂的镇痛效果虽然理想,但皮肤瘙痒、呼吸抑制等不良反应发生率较高[26]。地佐辛属苯吗啡烷类衍生物,通过激动 k 受体产生脊髓镇痛作用,且对 μ 受体有激动、拮抗双重效应,较吗啡药物依赖性低,呼吸抑制作用弱,但镇痛强度与吗啡类似或略强于吗啡,常用于术后镇痛中[27,28]。张炜等[29]研究认为,罗哌卡因与地佐辛复合麻醉用于分娩镇痛可达到良好的镇痛效果,但对罗哌卡因的有效应用剂量尚未完全明确。

本研究结果发现,三组镇痛后不同时点 VAS 评分较镇痛前降低,且 B、C 组降低更明显,说明不同剂量罗哌卡因复合地佐辛用于 PCEA 分娩镇痛均有肯定的镇痛效果,但以 B 组、C 组镇痛效果更好。在运动神经阻滞方面,本研究发现,三组改良 Bromage 分级分布比较差异有统计学意义(P<0.05),随着罗哌卡因使用剂量的增多,运动神经阻滞加深。在镇痛与产程进展方面,本研究发现,B、C 组镇痛起效速度更快,第二产程、第三产程时间更短,达目标麻醉平面所用镇痛药物更少,产妇镇痛泵按压次数及有效按压次数减少,说明 B、C 组阻滞、镇痛更完全,可减少产妇自控镇痛按压次数。分析其原因为罗哌卡因是纯镜像结构的长效酰胺类局麻药,具有镇痛、麻醉双重作用,当浓度较高时,对硬膜外麻醉镇痛效果较好,而当低浓度时,分离阻滞运动和感觉神经作用微弱,镇痛效果也较弱[30]。有效的分娩镇痛可减少产程中焦虑、恐惧及紧张情绪,避免子宫收缩乏力,减轻及消除宫缩痛,可改善子宫、宫颈血循环,避免宫颈充血水肿,更利于骨盆松弛,促进宫颈扩张,助于胎头下降,缩短产程进展过程中疼痛所致产妇能量消耗,促进第二产程、第三产程顺利进展,进而缩短产程,助于产妇顺利分娩。同时,三组产后出血量、最终分娩方式比较无显著差异,新生儿出生 1 min、5 min Apgar 评分及胎儿娩出即刻的脐血血气分析指标无明显差异,说明不同剂量罗哌卡因局麻药物对最终分娩方式、新生儿血气指标和新生儿窒息情况无明显影响。此外,本研究结果显示,C 组不良反应较 A、B 组略高,仍需调节罗哌卡因剂量以减少产妇分娩期间恶心、呕吐及皮肤瘙痒等不良反应,提高分娩镇痛的安全性。

综上所述,相对于 A、C 组而言,B 组给予 0.75%罗哌卡因 0.50 mL(3.75 mg)复合 5 mg 地佐辛用于分娩镇痛可获得更满意的镇痛效果,且对产程及宫缩影响较小,能实现感觉神经阻滞与运动神经阻滞分离,对分娩过程更有利,且具有不良反应相对较少的优势。同时需注意,为确保产程顺利进展,在产程中需密切监测孕妇生命体征,持续监测胎心、宫缩变化,注意宫缩节律及强弱,明确宫口进展状况,确保母婴安全。

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