

A Comparative Analysis of Ropivacaine (0.2%) and Ropivacaine (0.125%) With Fentanyl (2mcg/ML) for Epidural Labour Analgesia

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Received: 01-08-2023 / Revised: 10-08-2023 / Accepted: 26-08-2023

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Conflict of interest: Nil

Abstract:

Aim: The purpose of this study was to establish the lowest effective local anaesthetic concentration needed to deliver adequate analgesia while utilizing less opioid.

Objective: The epidural analgesic is the most efficient type of analgesia among the many labour analgesic treatments. The goal of this study was to establish the lowest effective local anaesthetic concentration needed to deliver adequate analgesia while using less opioid. This study's goal was to compare the effectiveness of 0.125% & 0.2% ropivacaine in combination with 2 g/ml of fentanyl for epidural labour analgesia.

Materials and Methods: 50 term pregnant women with vertex presentation in active labour and physical status grades I and II according to the American Society of Anesthesiologists were divided into two groups, Group R1 and Group R2, and given an initial bolus dose of 10 ml each of 0.125% ropivacaine and 0.2% ropivacaine with fentanyl 2 g/ml and intermittent top-up doses epidurally. The block's characteristics, the onset as well as duration of the analgesia, and the total amount of analgesic needed were documented. The Visual Analogue Scale score was used to evaluate the degree of pain and overall pleasure. Findings for the mother and foetus were documented.

Results: Demographic features of mothers were comparable. The ideal labour analgesia can be achieved with any concentration; however reducing the ropivacaine concentration has led to more doses being repeated, which has increased fentanyl use. Regarding motor block, hemodynamics, and neonatal outcomes, there were not significant variations between the two groups.

Conclusion: We come to the conclusion that 0.2% ropivacaine appeared superior in terms of quicker onset, longer duration, less breakthrough pain necessitating fewer top ups, and consequently reduced opiate intake. Therefore, we draw the conclusion that 0.2% ropivacaine is preferable to 0.125% ropivacaine combined with fentanyl.

Keywords: Epidural Labour Analgesia; Fentanyl; Intermittent Boluses; Ropivacaine.

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Introduction

The most intense type of agony a woman will experience in her lifetime is during delivery. It is frequently believed that having a kid is a mother's rebirth. Every expectant mother dreams of having a pain-free labour and delivery.

Despite the fact that labour analgesia has advanced from the use of ether in the 18th century to the current practice of regional techniques integrating current technology, it has not yet reached the majority of people in developing nations like India, where labour pain is still viewed as something natural and women must endure this stage, lack of support from family members, a lack of knowledge and awareness among healthcare providers along

with parturients, non-acceptance, shortage of knowledge [1-3]. Every woman should be given the option of undergoing the labour analgesia approach of her own choosing in order to realize her dream of having a pain-free delivery. The epidural analgesic is perhaps the most effective labour analgesic method currently available.

Numerous research investigations are currently underway to determine the optimal concentration of local anesthetics needed to achieve effective analgesia when combined with different adjuvants [4]. The primary objective is to reduce the associated risks and enable patients to ambulate while maintaining motor function along with

somatic sensation in the lower extremities, ultimately leading to enhanced maternal satisfaction.

Aim & Objectives

The aim of this study was to compare the effects of 0.125% ropivacaine and 0.2% ropivacaine, both combined with 2mcg/ml of fentanyl, in the context of epidural labour analgesia. Specifically, the study sought to assess the sensory and motor block features associated with each combination of treatment, as well as their impact on fetomaternal outcomes.

Materials and Methods

A randomized controlled comparison research was done to evaluate the efficacy of two different concentrations of a medication for labour analgesia. The study included individuals who were classified as Parturients of the ASA grade I and II. These individuals were between the ages of 20 and 30 years and were either primi or multigravida with a history of previous normal vaginal deliveries. They were currently experiencing a singleton pregnancy with a vertex presentation and were in established labour with a cervical dilatation of 3-5 cm. Additionally, the foetal heart rate tracing was found to be reassuring. The study excluded patients who refused to participate, individuals with elevated intracranial pressure, those with hypovolemia, those with fixed cardiac output illnesses, those with growing neurological weakening, individuals with severe coagulopathy, individuals with a platelet count less than 75,000/mm³, individuals with any localized skin infections or allergy to local anesthetics, and individuals with spinal abnormalities.

A total of 25 patients were enrolled in each group. The research population was randomly allocated into two groups using a computer-generated randomization scheme. The blinding procedure was carried out by three distinct anesthesiologists; each assigned a specific blinding condition: one was blinded to the research group, another was blinded to the medication, and the third was responsible for monitoring.

This study was conducted at a teaching hospital with tertiary care after getting clearance from the institutional ethics committee and obtaining written consent from the parturient. There were two distinct groups, namely Group R1 & Group R2, each consisting of 25 individuals who had just given birth. In the study, participants in Group R1 were administered an initial bolus dosage of 10 ml of 0.125% ropivacaine injection along with an injection of fentanyl at a concentration of 2mcg/ml. Subsequently, intermittent top up dosages of the same combination were administered epidurally. The solution was made by combining 2.5 ml of a

0.5% ropivacaine solution with 20mcg of fentanyl using a 10 ml syringe. The resulting mixture was then diluted with normal saline to get a total volume of 10 ml. Group R2 was administered an initial bolus dosage of 10 ml of 0.2% injectable ropivacaine with fentanyl 20mcg, followed by periodic epidural top up doses. The solution was formulated by incorporating a 20mcg dosage of fentanyl into a 0.2% ropivacaine solution.

Following the acquisition of informed consent in writing, the preanesthetic assessment was conducted. The parturients who were actively in labour were administered a preloaded volume of 500 ml of Ringer's lactate solution. Their vital signs, including pulse oximetry, ECG, and non-invasive blood pressure, were continuously monitored. Subsequently, the patient was positioned in the left lateral position, and the epidural space was located via a 18G Tuohy needle. The loss of resistance approach, employing air, was employed to confirm entry into the epidural space. A 20G catheter was then put in a cranial direction, ensuring an adequate length of 5 cm within the epidural space. Following the absence of negative aspiration for both CSF as well as blood, a total of 3 ml of the designated study drug was provided in accordance with the assigned group.

Following a 5-minute observation period to assess motor weakness and excluding the possibility of drug delivery through the subarachnoid route, a further 7 ml of the investigational medicine was delivered in increments of 2-3 ml. The initial bolus dosage was designated as the first dose, and the corresponding time was recorded. The evaluation of the effectiveness of pain relief was conducted at the 5-minute mark following the most recent administration, and subsequently at 2-minute intervals for a duration of 15 minutes. The patient assessed the severity using the Visual Analogue Scale (VAS) score. The adequacy of epidural analgesia was determined by a score of ≤ 3 . In cases where patients were still dissatisfied with the level of pain reduction, an additional 10 ml of the study drug (referred to as the second initial dosage) was provided. The effectiveness of analgesia was then reevaluated using the same method. The initiation of pain relief was operationally defined as the duration between the administration of the initial bolus dosage and the point at which a Visual Analogue Scale (VAS) score of 3 or lower was attained. In cases where the second initial dose failed to provide enough pain relief within 15 minutes, participants were classified as experiencing ropivacaine failure and were subsequently excluded from the research. The evaluation of motor block was conducted utilising the Modified Bromage Score, which consists of four grades: Grade 0 indicates the capacity to lift

against resistance, Grade 1 denotes the ability to bend the knees but not the leg, Grade 2 signifies the capability to move the feet but not flex the knee, and Grade 3 indicates no movement whatsoever. This assessment was performed at two-minute intervals for a duration of 15 minutes, and afterwards at 15-minute intervals. A trial walk was administered to all parturients in order to evaluate their ambulation capability. Supplementary doses of the study medicine were administered in response to patient requests for pain relief, with a minimum interval of 15 minutes between consecutive doses.

The aforementioned operation was carried out till the successful birth of the infant. The vital parameters of parturients were observed, including heart rate and blood pressure. These data were collected at 5-minute intervals during the initial 30-minute period, and at 15-minute intervals thereafter. Hypotension was operationally defined as a reduction in mean arterial blood pressure by less than 20% from the baseline.

In order to address this condition, a bolus of intravenous (IV) phenylephrine at a dosage of 100mcg was administered. Bradycardia had an operational meaning as a heart rate below 50 beats per minute (bpm) and was managed by the administration of intravenous bolus doses of atropine sulphate at a dosage of 0.6 mg. The foetal heart rate (FHR) was observed and recorded using a cardiotocograph, with particular attention given to any indications of FHR deceleration. Following the completion of the delivery process, neonates underwent evaluation utilising the Apgar score at both the 1-minute and 5-minute marks. The postpartum women were questioned following childbirth to assess their degree of satisfaction.

The primary outcome of this study was the duration of analgesia following the administration of the initial bolus dosage. This measure was chosen as it indicates the need for further doses to maintain pain relief. The secondary outcomes that were examined

in this study were obstetric outcomes, motor blockage, and medication intake within each group.

The current study aims to conduct a comparative analysis of the mean duration of analgesia between the two study groups. In the study conducted by Chhetty et al., it was observed that the average duration of analgesia for Group R1 was 72.25 ± 40.26 minutes, whereas for Group R2 it was 132 ± 56.81 minutes [4].

Statistical Analysis:

The current research's sample size of 15 was determined based on the formula for comparing two means, as developed from this particular study. The statistical analyses were conducted using IBM SPSS 20.0 software (SPSS Inc., Chicago, IL, USA). The comparison of categorical variables in each of the groups was conducted using the Chi-square test, which involved calculating the chi-square statistic value and corresponding p-value. The numerical variables were represented by their mean and standard deviation, and their comparison was conducted using the independent Student's t-test.

Results:

The demographic characteristics of both groups, including the following: age, height, weight, ASA grade, & gravida status, were found to be similar and comparable [Table 1]. Both groups demonstrated effective labour analgesia without any occurrence of motor blockage, indicating a lack of failure rate. The initial Visual Analogue Scale (VAS) ratings in both groups, Group R1 and Group R2, were found to be similar (Group R1: 9.85 compared to Group R2: 9.92) as shown in [Table 2]. Group R2 demonstrates a considerably earlier attainment of effective analgesia, defined as a Visual Analogue Scale (VAS) score of 3 or lower, compared to Group R1. Specifically, Group R2 achieved this level of analgesia within the first 5 minutes, whereas Group R1 required between 5 and 15 minutes obtaining the same level of analgesia.

Table 1: Demographic data

Variables	Group R1 (n=25)	Group R2 (n=25)	P- Value
Age	22.21±1.81	22.31±1.07	0.114
Weight (kg)	55±4	56±5	0.439
Height (cm)	158.1±4.59	156.12±4.25	0.117
Primigravidae	14	13	
Multigravidae	11	12	

Table 2: Visual Analog Scale Score

Parameters	Group R1 (n=25)	Group R2 (n=25)
Before bolus dose	9.85	9.92
5 min after bolus dose	4.80	1.63
15 min after bolus dose	0.55	0.00
30 min after bolus dose	0.30	0.00

In Group R1, the duration of analgesia following the administration of an initial bolus dosage was found to be 73.05 ± 27.24 minutes, while in Group R2, it was seen to be 126.45 ± 10.42 minutes ($P < 0.001$) [Table 3]. The mean Visual Analogue Scale (VAS) scores at various time points (0, 5, 15, 30, 45, 60, 90, & 120 minutes) after the first bolus have been compared between the two groups.

Table 3: Block characteristics

Variables	Group R1 (n=25)	Group R2 (n=25)	P- Value
Duration of analgesia with bolus dose (min)	73.05±27.24	126.4510±.42	<0.001
Mean time to 1st top up	61.34±12.32	124.381±2.34	<0.001
Mean time to 2nd top up	69.860±9.34	126.451±0.34	<0.001
Mean time to 3rd top up	72.45±09.56	-	-

The pain intensity, as measured by the Visual Analogue Scale (VAS), was 4.8 at the 5-minute mark following the administration of a bolus in Group R1.

In contrast, Group R2 exhibited a substantially lower VAS score of 1.63, indicating a fairly quick alleviation of pain in this group. A total of 10 parturients in Group R1, accounting for 40% of the sample, did not necessitate any supplementary top up doses and successfully delivered within the time

of the first bolus dosage. In contrast, a higher proportion of 18 parturients in Group R2, representing 72% of the sample, did not require any more top up dosages till delivery. In Group R1, 28% of participants necessitated a single top-up dosage, while 20% required two top-up doses, and 12% needed three top-up doses.

In comparison, only 20% of parturients in Group R2 required two top-up doses and a mere 8% required three top-up doses [Table 4].

Table 4: Dose requirement

Parameters	Group R1 (n=25)	Group R2 (n=25)
Bolus dose only	10	18
Bolus dose + 1st top up	07	05
Bolus dose + 2nd top up	05	02
Bolus dose + 3rd top up	03	00

Regarding the obstetric outcome of the parturient, it was observed that in Group R1, 88% ($n = 22$) had a normal vaginal delivery, 4% ($n = 1$) underwent forceps-assisted delivery, while 8% ($n = 2$) had a caesarean delivery. In contrast, in Group R2, 76% ($n = 19$) had a normal vaginal delivery, 8% ($n = 2$) underwent forceps-assisted delivery, while 16% ($n = 4$) had a caesarean delivery [Table 5].

Table 5: Obstetric outcome

Parameters	Group R1 (n=25)	Group R2 (n=25)
Normal vaginal delivery	22	19
Instrumental delivery	01	02
Cesarean delivery	02	04

In Group R2, a total of 2 parturients (8%) necessitated a single top-up dose, while 5 parturients (20%) required two top-up doses. The remaining 18 parturients (72%) experienced sufficient analgesia until delivery following an initial bolus dose. On the other hand, in Group R1, only 10 parturients (40%) were able to attain satisfactory pain relief up until delivery following an initial bolus dose. Additionally, 7 parturients (28%) needed a single top-up dose, 5 parturients (20%) required two top-up doses, and 3 parturients (12%) necessitated three top-up doses. In general, a considerably greater proportion of women in Group R1 ($n = 15$, 60%) needed one or more additional doses ($P < 0.001$). The time interval for the initial top-up dosage was significantly shorter in Group R1 (mean = $58.15 \pm$ standard deviation = 22.65 minutes) compared to Group R2 (mean = $131.30 \pm$

standard deviation = 57.11 minutes), with a p-value less than 0.001. The average number of top-up doses administered to each parturient was found to be substantially larger in Group R1 (0.80 ± 0.65) compared to Group R2 (0.05 ± 0.22), with a p-value less than 0.001. The overall quantity of ropivacaine utilized in both groups exhibited no significant difference ($P > 0.05$). However, the total dosage of fentanyl administered was notably greater in Group R1 (94.31 ± 4.93 mcg) compared to Group R2 (64.58 ± 2.83 mcg). The statistical significance level, denoted as $P < 0.001$, indicates that the observed results are highly unlikely to have occurred by chance alone [Table 6]. The hemodynamic parameters of both the maternal and foetal subjects were steady in both experimental groups. The Apgar scores exhibited similar results in both groups.

Table 6: Drug consumption

Total doses	Group R1 (n=25)	Group R2 (n=25)	P- Value
Ropivacaine (mg)	58.23±5.48	65.88 ±6.29	>0.05
Fentanyl (µg)	94.31±4.93	64.58±2.83	<0.001

Discussion

In the present investigation, we noticed the presence of efficient labour analgesia without any occurrence of motor blockage or failure rate in both experimental groups. Group R2 demonstrated a prolonged duration of analgesia, which can be related to the utilization of a larger dose of local anaesthetic in conjunction with a similar quantity of fentanyl, as compared to both groups. A prolonged duration of analgesia has been found to lessen the need for further doses and improve mother satisfaction by effectively minimizing instances of breakthrough pain. Despite the fact that Group R2 was administered a higher dosage of local anaesthetic medication, the number of top-up boluses required was lower compared to Group R1. Therefore, the level of fentanyl consumption was lower in Group R2 compared to Group R1, since the latter group exhibited a higher frequency of top-up doses, resulting in increased effective fentanyl consumption.

Ropivacaine is a local anaesthetic that is classified as a levo-isomer. It is recognized for its reduced risk of systemic toxicity, particularly cardiotoxicity, in comparison to bupivacaine. Additionally, ropivacaine exhibits a smaller degree of motor blockage and a greater analgesic effect. Consequently, it is the favoured choice for administering epidural labour analgesia. In their study, Paddalwar et al. discovered that the administration of ropivacaine in intermittent doses offers a safer alternative to bupivacaine due to its reduced incidence of systemic adverse effects such as cardiotoxicity. Additionally, ropivacaine demonstrated a smaller degree of motor blockade and a superior quality of sensory blockade. These findings suggest that the use of ropivacaine allows parturients to ambulate more effectively. [5]

In their comparative research on labour analgesia, Kumar et al. found that levobupivacaine yielded superior analgesic quality compared to ropivacaine. However, it is important to note that the use of levobupivacaine was associated with a higher incidence of instrumental vaginal delivery. [6]

In their study, Qian et al. (year) conducted a comparison of electromyographic activity in three groups: levobupivacaine, ropivacaine, and a control group. This comparison was carried out utilising patient-controlled epidural analgesia (PCEA) during the first stage of labour. The researchers reached the conclusion that ropivacaine did not exhibit any suppressive activity, as observed in the control group. Additionally, ropivacaine shown

comparable analgesic effects and satisfaction levels to levobupivacaine [7]. Prior research has similarly demonstrated that the incorporation of opioids, such as fentanyl, into local anaesthetics has resulted in enhanced analgesic efficacy. [8]

The current study administered epidural labour analgesia to a sample of 50 parturients using two different concentrations of ropivacaine (0.125% and 0.2%), all of which were combined with fentanyl at a concentration of 2mcg/ml. Both groups got sufficient analgesia with a success rate of 100%.

However, it was shown that the initiation of pain relief occurred more rapidly in Group R2 in comparison to Group R1, due to the higher concentration of the treatment regimen in Group R2. The duration of analgesia following the administration of the first bolus was found to be considerably longer in Group R2 as compared to Group R1.

The initiation of the first top-up was notably delayed in the group administered with 0.2% ropivacaine in comparison to the group receiving 0.1%, as reported in previous investigations. [4] The frequency of top-up doses was found to be less often in Group R2 whereas it was more frequent in Group R1, leading to a nearly comparable quantity of ropivacaine consumption in both groups. Specifically, the ropivacaine consumption in Group R1 was measured to be 58.23 ± 5.48 mg, while in Group R2 it was 65.88 ± 6.29 mg. Nevertheless, due to the frequent need for further doses in Group R1, there was a notably greater utilization of fentanyl, namely 94.31 ± 4.93 mcg, in comparison to Group R2, which had a consumption of 64.58 ± 2.83 mcg. The current practice of minimizing the concentration of adjuvant local anaesthetic agents has presented certain drawbacks, including the need for repeated top-up doses. This has led to increased opioid consumption and a higher incidence of breakthrough pain, necessitating additional staffing resources for frequent administration in labour wards with high patient volumes. The escalating use of opioids is a matter of apprehension due to its potential to induce adverse consequences including nausea, pruritus, respiratory depression, and decreased Apgar scores in new-borns.

In the study conducted by Karhade and Sardesai [9], a Visual Analogue Scale (VAS) score of 0.6 ± 1.06 was noticed within a 10-minute timeframe. This observation was made using a combination of 0.2% ropivacaine and 25 mcg fentanyl for the

initiation of the procedure. Similar results were found in our own study, specifically in Group R2. However, in Group R1, the VAS score at 5 minutes was 4.8, which aligns with the findings reported by Chhetty et al.[4]

The user did not provide any text to rewrite. Multiple studies have indicated that the intermittent bolus dosage method exhibits superior outcomes compared to continuous infusion, as seen by reduced overall drug intake, decreased rates of instrumental and aided delivery, and increased levels of mother satisfaction. [10] The user's text is already academic and does not require any rewriting. This phenomenon can be attributed to the influence of injection speed pressure and drug volume on the distribution of the medication during bolus administration. [11]

In a separate investigation conducted by Wong et al., it was observed that the administration of a drug through continuous infusion at low pressure resulted in a predominant release of the drug from the proximal orifice of the epidural catheter. Conversely, when a bolus dose was administered, it generated high pressure during drug delivery, leading to drug discharge from the distal orifices of the catheter. This mechanism facilitated a wider distribution of the drug, ultimately enhancing the analgesic efficacy. [12]

In a randomized comparative study conducted by Capogna et al., the authors investigated the efficacy of programmed intermittent epidural bolus (PIEB) versus continuous epidural infusion (CEI) for labour analgesia. The study utilised levobupivacaine 0.0625% with sufentanil 0.5 mcg/ml as the analgesic agent. The results of the study revealed a significantly higher incidence of motor block and instrumental delivery in the CEI group when compared to the PIEB group. Additionally, the PIEB group had lower levels of total medication consumption, a reduced number of patients necessitating extra PCEA boluses, and a decreased mean number of PCEA boluses per patient. [7]

Moreover, a meta-analysis conducted by George et al. examined nine randomized controlled trials (RCTs) involving a total of 694 participants. In this analysis, 344 participants received continuous epidural infusion (CEI) while 350 participants obtained intermittent epidural boluses (IEBs). The results of this meta-analysis indicated that there was no significant difference between IEB and CEI in terms of the rate of caesarean delivery, duration of labour, or the requirement for anaesthetic intervention. The use of the IEB (intermittent epidural bolus) technique has shown a modest yet statistically significant decrease in the utilization of local anesthetics, as well as an improvement in mother satisfaction ratings. [13] Therefore, in order

to provide labour analgesia with less medication intake and decreased breakthrough pain, as well as to decrease the likelihood of aided instrumental delivery and enhance mother satisfaction, we chose to use the IEB dosage regimen.

In their comparative study, Choudhary et al. examined the obstetric outcomes of two groups: the epidural analgesia group vs. the control group. The researchers determined that there was a lack of statistically significant difference between the two groups, indicating identical obstetric outcomes. In addition, the neonatal outcome, as measured by the Apgar score at 1 minute and 5 minutes, exhibited no statistically significant difference between the two groups ($P = 0.569$). [14]

Conclusion:

It is determined that the concentrations of ropivacaine and fentanyl are both efficacious in delivering sufficient epidural labour analgesia. Nevertheless, it was shown that a concentration of ropivacaine at 0.2% yielded more favorable outcomes in terms of quicker onset, extended duration of effectiveness, little motor blockage, reduced incidence of breakthrough pain necessitating fewer supplementary doses, and therefore, decreased opioid use.

Therefore, the findings of this study suggest that the use of 0.2% ropivacaine in combination with fentanyl yields a higher level of blockade quality compared to the administration of 0.125% ropivacaine with fentanyl for the purpose of labour analgesia.

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