Original Article

Comparison of efficacy and safety of three different concentrations of ropivacaine for labor pain management using patient-controlled epidural analgesia (PCEA): A double-blind, randomized controlled trial

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Abstract

Background and Aims: Labor pain is consistently ranked high on the various pain rating scales, when compared to other painful life experiences, and the experience of labor during the process of childbirth is both complex and subjective. Though patient-controlled epidural analgesia (PCEA) using dilute concentrations of local anesthetics (LAs) has been a popular method to control labor pain, yet the optimal dose and regimen for PCEA remain ambiguous. So, the present study was undertaken to evaluate the safety and efficacy of three different concentrations of ropivacaine for labor analgesia using PCEA.

Materials and Methods: Seventy-five healthy nulliparous women who gave voluntary consent for labor analgesia using PCEA were randomly assigned to three groups to receive three different ropivacaine concentrations (0.0625%, 0.1%, and 0.125%) with adjuvant fentanyl 2 μg/ml, after double-blinding. Analgesic efficacy, neuraxial blockade, vital parameters, neonatal outcomes, maternal satisfaction, and side effects were assessed. Primary outcome was total dose of ropivacaine consumed in milligrams.

Results: Number of pain breakthroughs (Visual Analog Score >4) and PCEA demand and rescue boluses were found to be statistically more in group 0.0625% ($P < 0.01$), followed by group 0.1% and were the least in 0.125%. Still, total drug consumed in milligrams was significantly less in 0.0625% group. Maternal satisfaction was comparable among the three groups ($P = 0.33$). There was no significant difference in maternal side effects and neonatal APGAR scores among the three groups.

Conclusion: When three different concentrations of ropivacaine, that is, 0.0625%, 0.1%, and 0.125%, are used for labor analgesia, the use of 0.125% ropivacaine leads to higher total amount of ropivacaine consumed. Despite the lower efficacy in terms of breakthrough pain episodes observed with a 0.0625% ropivacaine concentration for labor analgesia, maternal satisfaction remained consistent across all three doses of ropivacaine. PCEA demand and rescue boluses for the lowest concentration, that is, 0.0625%; and did not affect maternal satisfaction with the management of labor pain.

Keywords: Analgesia, APGAR score, pain, ropivacaine, satisfaction

Introduction

Epidural analgesia for labor pain management is now accepted as a component of comprehensive obstetric anesthetic care worldwide.[1,2] Patient-controlled epidural analgesia (PCEA) with low-dose mixtures of ropivacaine and an opioid has gained popularity owing to the fact that ropivacaine in low

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doses provides a selective sensory blockade with wider margin of safety and addition of opioid further reduces the requirement of local anesthetic (LA).[3] Dilute concentrations of LA with opioids in PCEA confer benefits of maternal and fetal safety, preservation of maternal ambulation and bearing down, but very low concentrations provide inadequate pain relief, which may lead to increased breakthroughs of pain and compromise overall analgesic efficacy and maternal satisfaction. The minimum effective concentration of LA for labor pain management without compromising maternal satisfaction and safety profile remains controversial.[4]

This randomized, prospective, double-blinded study was designed to evaluate the safety and efficacy of three different concentrations of ropivacaine (0.0625%, 0.1%, and 0.125%), for labor analgesia using PCEA. We hypothesized that 0.1% ropivacaine would be the optimum concentration for labor analgesia using PCEA. The primary outcome of the study was total dose of ropivacaine (in milligrams) consumed during the course of labor. Simultaneously, episodes of breakthrough pain, demand for rescue boluses, parturient satisfaction and side effects, fetal APGAR score, level of sensory blockade, and degree of motor block were also assessed.

Materials and Methods

After obtaining approval from the institution ethics committee, 75 healthy nulliparous women who voluntarily approved to participate in this study were randomized. All parturients were duly screened before institution of labor analgesia under coronavirus disease 2019 (COVID-19) clinical protocols. The trial was registered with the Clinical Trial Registry of India, and the study was conducted at a tertiary care referral hospital over 6 months period from November 1, 2020 to April 30, 2021.

Written consent as per the institutional protocols was obtained from all parturients. Healthy nulliparous women belonging to American Society of Anesthesiologists (ASA) physical status class II, aged 18–40 years, having cephalic presentation with singleton fetus and ≥37 weeks (term) gestation, and cervical dilation ≤5 cm, who requested epidural analgesia and had no contraindications for the same were included in this study.

Parturients on chronic pain medications, with a history of allergy to LAs, with a body mass index ≥35 kg/m^2, and those having premature rupture of membranes, hypertensive disorders, gestational diabetes mellitus, or a fetus with physical abnormalities or growth retardation were excluded. Patients who developed any complications such as accidental dural puncture were also excluded from the study.

All the parturients were properly explained about the functioning of PCEA pump and thoroughly counseled with respect to their expectations, its advantages and failure rates, pain relief effectiveness, fetal outcomes, and complications of the intervention to aid in their decision-making process. They were taken to the procedure room with an anesthesia machine, and a crash cart trolley was kept in the vicinity throughout the procedure. Before institution of labor epidural, baseline maternal hemodynamic parameters including heart rate (HR), blood pressure (BP), oxygen saturation (SpO2), and obstetric parameters such as gestational age, cervical effacement, and dilatation were noted. Fetal heart rate (FHR) was recorded before and intermittently throughout the process of child birth using an external cardiotocograph.

An 18-gauge peripheral vein cannula was secured and 10 ml/kg Ringer's lactate fluid was coloaded.[5] Epidural was placed before a cervical dilatation of 5 cm in all parturients. Under strict aseptic precautions, an 18-gauge Tuohy needle was inserted in L3–4/L4–5 intervertebral space and a 20-gauge epidural catheter was placed approximately 4 cm within the epidural space, which was identified by the loss of resistance (LOR) to air technique, with the parturient in a sitting position. After confirming negative aspiration for any blood/cerebrospinal fluid (CSF), a catheter was connected to the PCEA pump (Alaris™ PCA). Parturients were assigned to three groups randomly using a list of numbers generated by computer as per the concentrations of ropivacaine used:

Group A parturient: concentration used: 0.0625%.

Group B parturient: concentration used: 0.1%.

Group C parturient: concentration used: 0.125%.

The anesthesiologist who was not involved with the data collection or in the study directly prepared the epidural solution and programmed the PCEA pump. Group allocation was concealed using the sealed envelope method. Data collection and supplemental treatment were done by an anesthesiologist/a staff nurse unaware of the group allocation. Bolus dose given was 8 ml ropivacaine with fentanyl 2 μg/ml (first 3 ml was used as test dose with the same mixture and motor power confirmation was done), followed by a PCEA regimen 15 min later – basal infusion (BI): 8 ml/h, lockout interval: 10 min, and a demand bolus dose: 2 ml.

For the first 20 min, maternal vitals, Verbal Analog Score (VAS), sensory and motor functions, and FHR were recorded every 5 min. VAS (0 = no pain and 10 = worst pain imaginable) was used to assess pain and was also recorded before institution of analgesia. A rescue bolus dose of 5 ml was

administered by the anesthesiologist if the parturient complained of breakthrough pain (VAS >4) after two consecutive demand boluses. The PCEA's lockout time between the rescue bolus and the next demand bolus dose was then set to 15 min. We ensured precision in our evaluation for the effect of ropivacaine concentration by using the same concentration in all steps of analgesia (initial bolus, PCEA pump continuous infusion, demand boluses, and rescue boluses). If pain relief was inadequate and more than two rescue boluses were demanded by the parturient in 1-h interval, analgesia was provided and the patient was considered as a dropout.

Hypotension (systolic BP <20% of baseline) was treated by providing left uterine displacement and 6 mg mephentermine intravenous (IV) boluses. Level of sensory blockade was assessed using pinprick sensation and degree of motor blockade using modified Bromage scale,[5] and any incidence of instrumental delivery/cesarean delivery was documented. Total breakthrough pain episodes and demand and rescue boluses were noted, and the total consumption of ropivacaine (in mg) was calculated by summating the doses until the PCEA pump was switched off at the end of delivery and the catheter was removed. Maternal satisfaction was assessed 2 h postdelivery through a 5-point Likert's scale (level 1: totally dissatisfied = 0%–20%; level 2: dissatisfied = 20%–40%; level 3: neutral = 40%–60%; level 4: satisfied: 60%–80%; level 5: totally satisfied = 80%–100%), considering a percentage difference of 20% in each level as per the common agreement between the investigators, based on usage of similar scale in a study.[6] Neonatologist assessed the APGAR scores at 1 and 5 min after birth.

A previous study[5] using a similar protocol recorded the median PCEA use of levobupivacaine to be 50.0, 77.9, and 91.3 mg with 0.0625%, 0.1%, and 0.125% doses, respectively, where the standard deviation (SD) was assumed to be 15 mg for all three doses. Considering levobupivacaine and ropivacaine to be of comparable potency, 21 patients per group provided a 90% power for detecting a minimum difference of 15 mg for LA consumption between any two groups at an alpha level of 0.05. To increase the power of the study and to compensate for any possible dropouts, we enrolled 75 (25 per group) patients in total.

Statistical Package for the Social Sciences (SPSS) 28.0 was used to perform statistical analysis in our study. Categorical variables were represented as absolute numbers and percentages, while continuous variables were calculated as mean ± SD. Before statistical analysis, data was assessed for normality using Shapiro–Wilk test. Analysis of variance (ANOVA) test was used to compare normally distributed continuous variables. For variables that were not normally distributed, Kruskal–Wallis test was applied and Mann–Whitney U test was used for further comparisons. Chi-square test was used to analyze categorical variables. For all statistical tests, significant difference was represented by a P value less than 0.05.

Results

A total of 80 patients were enrolled for the trial, but three participants were eliminated as they refused to participate and another two were eliminated as they had accidental dural puncture while performing the procedure. The remaining 75 patients were randomly assigned to three study groups as per the concentrations of ropivacaine [Figure 1]. The groupwise distribution of demographic characteristics and obstetric examination was found to be comparable on the basis of mean and SD values in all the groups [Table 1].

Maximum sensory blockade that was achieved in all three groups ranged from T6 to T8, and no parturient complained of motor blockade throughout the procedure. The duration of active phase of the first stage, second stage of labor, as well as the total duration of epidural analgesia to delivery did not vary among the groups. Total dose of ropivacaine consumed in milligrams was significantly higher in Group C than in Group B and was the least in Group A. The number of pain breakthrough episodes and PCEA demand and rescue boluses were significantly higher in Group A and were the least in Group C [Table 2].

There was no intergroup difference in maternal hemodynamic changes [Figure 2a and b]. Maternal side effects, incidence of cesarean sections, and neonatal APGAR scores were comparable among the three groups. The maternal satisfaction score, recorded 2 h after delivery, was similar among the three groups [Figure 3 and Table 3].

Discussion

The study results revealed that the maximum amount of ropivacaine consumed was in the 0.125% group and the least consumption was in the 0.0625% group. Though the number of pain breakthroughs and PCEA demand and rescue boluses were significantly higher in Group A (0.0625%), followed by Group B (0.1%) and were the least in Group C (0.125%), the maternal satisfaction scores did not differ significantly ($P = 0.33$) among the three groups. The lowest ropivacaine concentration used, that is, 0.0625% consumed the lowest dose, had no impact on maternal satisfaction.

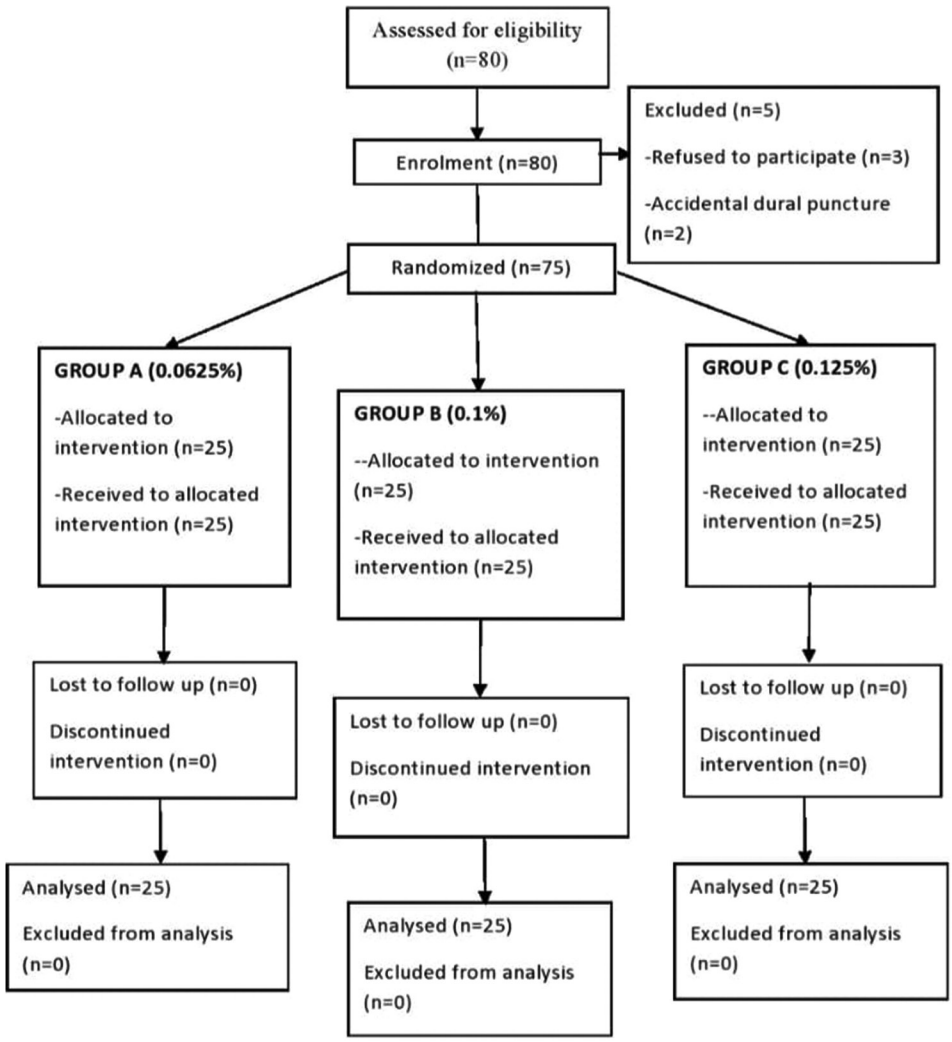

Figure 1: Consolidated Standards of Reporting Trials (CONSORT) flow chart

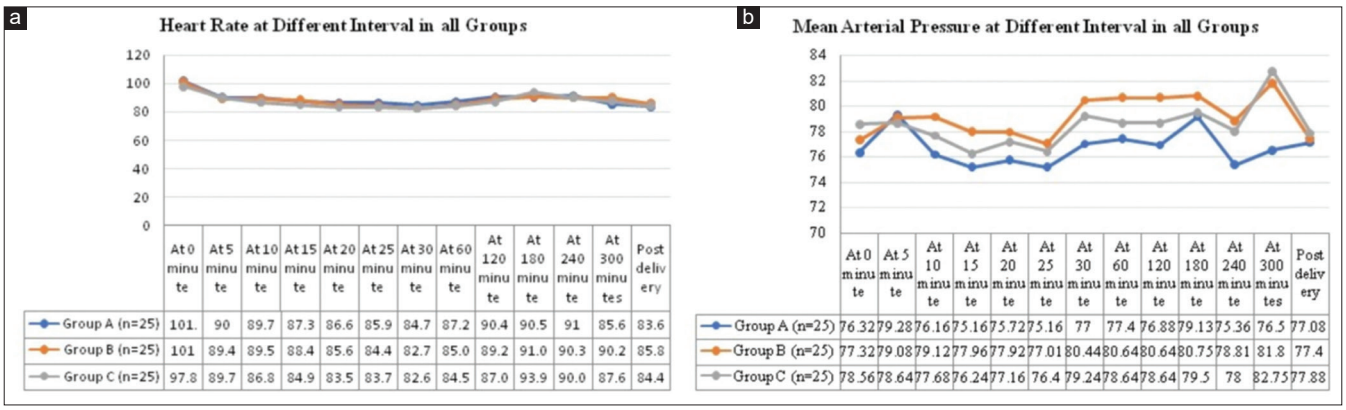

Figure 2: Heart rate and mean arterial pressure at different intervals in all groups. (a) Heart rate at different intervals in three groups, (b) Mean arterial pressure at different intervals in three group

Patients who received 0.0625% ropivacaine required more frequent PCEA and rescue boluses, but as the volume of drug infusion was the same, total dose or hourly consumption was lower than in other groups. Some studies support the finding that LA concentrations of less than 0.1% are associated with poorer analgesic effects. Wang *et al.*[7] found that higher hourly volumes of LA were infused when very low concentrations were used, but they did not compare the hourly or total dose.[8]

The advent of PCEA with usage of low-dose, selective sensory and safer LAs like ropivacaine and addition of epidural opioids made the dream of ambulatory analgesia come alive.

Table 1: Parturient Demographics, Gestational Age, Cervical Effacement and Dilatation

	Group A (*n*=25) Mean±SD	Group B (*n*=25) Mean±SD	Group C (*n*=25) Mean±SD	*P*
Age (yr)	24.28±3.52	23.08±2.79	25.16±3.64	0.09
Weight (kg)	70.32±8.28	70.08±7.84	68.08±7.42	0.54
Height (cm)	160.08±5.94	159.68±5.92	159.76±4.75	0.96
Gestational age (weeks)	37.28±0.84	37.52±0.96	37.20±0.86	0.42
Cervical Effacement (%)	79.60±10.98	77.20±13.08	78.40±13.44	0.79
Cervical Dilatation (cm)	3.96±0.67	3.88±0.66	4.0±0.71	0.81

SD=standard deviation

Table 2: Duration of Stages of Labour, Effectiveness of Labour Analgesia and Consumption of Drug in All Groups

	Median (IQR)			*P*
	Group A (*n*=25)	Group B (*n*=25)	Group C (*n*=25)	
Duration of Active Phase of First Stage of Labour (min)	180 (144-216)	192 (168-225)	180 (144-231)	0.62
Duration of Second Stage of Labour (min)	65 (50-82.5)	60 (45-72.5)	60 (50-75)	0.59
No. of Pain Breakthroughs (VAS >4)	2 (0.5-4.5)	0 (0-1)	0 (0-0)	<0.01
No. of Demand Bolus	2 (1-4)	0 (0-1)	0 (0-0)	<0.01
No. of Requests for Rescue Boluses	0 (0-0.5)	0 (0-0)	0 (0-0)	<0.01
Total Drug Used (mg)	25.82 (20.56-30.50)	37.24 (33.13-41.3)	45.4 (39.54-52.74)	<0.01

IQR=interquartile range, VAS=Visual Analog Score

Table 3: Side Effects, Mode of Delivery, Parturient Satisfaction in Study Subjects and Appearance, pulse, grimace, activity, and respiration Score of Neonates

Variable	Group A (*n*=25) (0.0625%)		Group B (*n*=25) (0.1%)		Group C (*n*=25) (0.125%)		*P*
	No.	%	No.	%	No.	%	
No side effect	22	88.0	22	88.0	20	80.0	0.65
Nausea	3	12.0	3	12.0	5	20.0	0.65
Vomiting	0	0.0	0	0.0	1	4.0	0.36
Pruritus	0	0.0	0	0.0	1	4.0	0.36
Normal Vaginal Delivery	25	100.0	25	100.0	23	92.0	0.12
Lower Segment Caesarean Section	0	0.0	0	0.0	2	8.0	0.12
	Mean±SD		Mean±SD		Mean±SD		*P*
Maternal Satisfaction	77.60±16.59		83.0±13.31		82.80±13.23		0.33
Apgar Score							
At 1 min	7.52±0.96		7.92±0.86		8.20±1.08		0.05
At 5 min	9.16±0.94		9.48±0.58		9.24±0.88		0.36

SD=standard deviation

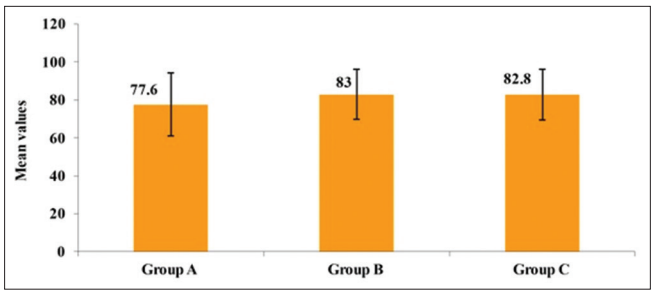

Figure 3: Comparison of maternal satisfaction in all three groups

Empirically, it is ascertained that epidural drug spread and analgesia depend on the total dose of LA irrespective of the volume and concentration of LA being administered. Greater volume of dilute LA solutions and lesser volume of concentrated LA solutions gave comparable results, suggesting that to achieve adequate pain relief, the single most prominent factor was the amount of drug delivered in milligrams.[9] One randomized trial using different low-dose concentrations of ropivacaine, levobupivacaine, and bupivacaine demonstrated less-effective analgesia and greater hourly consumption of drug with the usage of lowest doses.[7] Another study showed greater motor block and incidence of cesarean sections with higher concentration (0.125%).[5]

In a retrospective study, PCEA with a high volume of a lower concentration of LA has been shown to provide better analgesia, less-intense motor blockade, higher maternal satisfaction, and protection against short-term pelvic floor dysfunction. A randomized controlled trial (RCT), though, reported higher maternal satisfaction with 0.0625%

bupivacaine compared to 0.25% bupivacaine; different drug volumes used in these studies make their findings questionable.[10] Other studies have reported efficacious analgesia with no significant side effects with a concentrated solution of LA.[8,11]

In this study, the maximum dermatomal level of sensory blockade achieved in groups A, B, and C ranged from T6 to T8. The relatively lower doses of ropivacaine used in all three groups of the study ensured adequate sensory blockade with the added advantage of being safe. Using a lesser concentration of LA or selecting one with a high sensory: motor block properties like ropivacaine alleviates the risk of motor blockade.[12] Thus, in this study, by incorporating diluted concentrations of ropivacaine, minimal motor block was ensured in any of the three groups. Most patients usually walked around the room or to the bathroom, where they voided spending approximately 10–15 min out of bed on each occasion with an accompanying person, fulfilling the concept of "walking or mobile epidural." It not only facilitated timely progression of labor and preserved bearing down potential of the mother, but also gave her freedom and satisfaction.

In terms of maternal satisfaction, our study findings are similar to Clivatti *et al.*[13] who found that use of 0.0625% bupivacaine, though, did not provide satisfactory labor analgesia in terms of number of breakthrough pain episodes in a majority of patients, but most of them were still satisfied in terms of pain management. A descriptive study found that antenatal women know that labor is painful, but they have insufficient knowledge regarding pain-relieving opportunities.[14] Many a times, nulliparas, who underrate the extent of impending labor pain, may not be prepared for the intensity of experience, and thus have a positive effect on satisfaction even after modest pain reduction.[15] A systemic review identified the following four factors which influenced maternal satisfaction with respect to child birth process: (a) their expectations, (b) caregivers' support, (c) quality of relationship between caregivers and patients, and (d) their involvement in decision-making; it also confirmed that these factors appear to be important when women evaluate their experiences with childbirth and help in overriding effects of preparation for childbirth, environment of birth, immobility, age, socioeconomic status, pain, medical interventions involved, and the quality of care.[16] Lally *et al.*[17] identified inconsistency between maternal expectations and actual experiences and concluded that proper maternal counseling, as we provided in our study, translated to a more positive experience.

The hemodynamic stability observed in this study may be attributable to three major facts: first, the usage of low-dose concentrations in all three groups; second, addition of fentanyl as an adjuvant; and lastly, incorporation of a background infusion ensuring lesser variations in the hemodynamic parameters after establishment of blockade, by reducing the requirement of demand and rescue boluses, which might otherwise lead to maternal hypotension.

It was found that despite the maximum number of demand and rescue boluses, out of the three groups, the lowest concentration group 0.0625% recorded the least amount of total drug consumed. In the present study, a basal continuous infusion of LA was instituted in all groups as a part of PCEA protocol, so majority of the drug was administered as continuous BI. The programmed intermittent boluses mode with PCEA, which reduces LA consumption, decreases the number of rescue boluses and curtails motor block, and therefore can be a comparatively effectual epidural drug infusion mode.[18-20]

In this study, all neonates had APGAR score ≥7 and the score was comparable among the three groups. Increased incidence of cesarean delivery was recorded in the higher concentration (0.125%) group, which was not statistically significant and could be due to our smaller sample size or may be a chance finding.

Our main study finding was that, ropivacaine concentration of 0.0625%, despite having a lower labor pain management efficacy, had no effect on the levels of maternal satisfaction and also consumed the least amount of drug. Thus, all three different concentrations appear safe, and we rejected our hypothesis that 0.1% ropivacaine would be the most appropriate concentration when used for labor analgesia using PCEA.

The study limitations may include a limited sample size and inability to use elaborate sophisticated questionnaires for maternal satisfaction assessment, considering their non-applicability in the Indian population, especially the rural population. Programmed Intermittent Bolus Technique and Computer-Integrated PCEA have proved to be superior in various studies, but due to lack of availability of these devices in the institute, the same techniques could not be employed.[21]

Conclusion

In conclusion, higher ropivacaine concentrations lead to higher total doses of the drug consumed. Though labor analgesia with PCEA appears less effective with 0.0625% ropivacaine, it does not compromise overall maternal satisfaction. All the three ropivacaine concentrations appear safe and effective to provide labor analgesia.

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Conflicts of interest

There are no conflicts of interest.

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