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Single-dose intrathecal analgesia: a safe and effective method of labor analgesia for parturients in low resource areas

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Abstract

Background: Epidural analgesia is often said the gold standard of the labor analgesia. But in the areas where the availability of epidural catheters, multiparameter monitors, trained staff is scarce, we need to rethink for single-dose intrathecal analgesia as an alternate yet effective method to provide labor analgesia. The combination we chose for single-shot spinal was heavy bupivacaine 2.5 mg + fentanyl 25 μg + morphine 250 μg, so as to provide an optimal time period of analgesia and lesser need for supplemental analgesics.

Methods: The prospective open-label study was conducted on 100 parturients. Group S ($N = 50$) received intrathecal injection of 0.5 ml of heavy bupivacaine (2.5 mg) and 0.5 ml of fentanyl (25 μg), and 1 ml of preservative free morphine (250 μg/ml) was given (total volume of 2 ml) using 26 G Quincke spinal needle. Group C ($N = 50$) were managed according to the institutional protocol of programmed labor for normal vaginal delivery. The duration of analgesia, VAS score, safety and side effects, and progress of labor was noted and compared.

Results: The progress of labor, mode of delivery, and fetal parameters was similar in both the groups. But the parturients in the group S had lower VAS score with a pain-free period of 238.96 ± 21.88 min, without any noted side effects.

Conclusion: Single-dose intrathecal analgesia with heavy bupivacaine 2.5 mg + fentanyl 25 μg + morphine 250 μg can be used efficaciously covering the complete duration of labor in both primigravida and multigravida with no increase in instrumental delivery or C-section rate or other side effects.

Trial registration: Institutional Ethics Committee, Indira Gandhi Medical College, Shimla. Number: ECR/533/IST/HP/2014. Registered on 12 August 2017

Keywords: Labor analgesia, Single-dose intrathecal analgesia, Morphine, Fentanyl

Introduction

Labor is one of the most painful experiences for a woman during her lifetime, and the experience is different for each women. The lack of antenatal psychological preparation combined with fear and anxiety greatly enhance the patients' sensitivity to pain. Thus, pain relief not only provides comfort to patient but also attenuates the release of stress hormones and improves fetal nutrition and oxygen supply (Kuczkowski and Chandra 2008; Fyneface-Ogan et al. 2012; Tshibuyi et al. 2013). Eighty-five percent of surveyed women in a developing countries indicated that they would request labor analgesia if available, but only 40% received labor analgesia in practice (Anabah et al. 2015).

Anesthesiologists are now being called more frequently to provide labor analgesia, even in the developing countries like ours. The best method of labor analgesia is the one which provides adequate pain relief with minimal effect on mother, fetus, and labor.

The gold standard and the most widely used method is epidural analgesia, but unfortunately, its access in

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rural areas is limited due to non-availability and little expensive technique for most of the common rural population. Whereas intrathecal labor analgesia is more economical as compared to epidural analgesia; hence, single-dose intrathecal analgesia may prove to be a useful method in limited resource areas, especially in rural and peripheral areas where epidural catheterization may not be possible. If later, labor patient requires subsequent spinal or epidural anesthesia for caesarian section there is no contraindication. Therefore, single-dose intrathecal analgesia may prove to be a useful method in limited resource areas.

Addition of intrathecal opioids permitted reduction of the bupivacaine concentration from 0.5% to as low as 0.065% while maintaining effective analgesia and minimizing potential adverse effect on progress of labor and lower extremity motor block (Anabah et al. 2015). Also, when two drugs are combined, both local anesthetic and opioids can be administered at low concentrations, resulting in effective analgesia with patient satisfaction and minimal side effects (Mathur et al. 2017).

In a systemic review done by Mardirosoff NC and colleagues, it was seen that with intrathecal opioids, there was a significant increase in fetal bradycardia and maternal pruritis and also increase C-section due to fetal heart rate abnormalities (Madirosoff et al. 2002). Similar side effects were also seen in a prospective study done, but the analgesia and maternal satisfaction was superior (Viitanen et al. 2005). In another systemic review done by Minty RG et al., the combination of 2.5 mg of heavy bupivacaine, 25 μg of fentanyl, and 250 μg of morphine intrathecally was studied, and it was concluded that it provides 4-h window of analgesia without complications (Minty et al. 2007).

Hence, we chose this combination to be studied, in quest for the optimal labor analgesia in areas with limited resources. We intended to study single-dose intrathecal analgesia with the combination of 2.5 mg of heavy bupivacaine, 25 μg of fentanyl, and 250 μg of morphine and its effect on labor, mother, and fetus.

Material and methods

The study was conducted at Kamla Nehru State Hospital for mother and child, Indira Gandhi Medical College, Shimla from 1 January 2018 to 31 July 2018. One hundred laboring patients fitting into the inclusion criteria were recruited for this prospective open-label study after obtaining informed written consent and approval from the institutional ethics committee. Inclusion criteria were age 18–40 years, booked patients at gestation 37–42 weeks with singleton uncomplicated pregnancies with cephalic presentation with spontaneous or induced labor and cervical dilatation 4–6 cm. Exclusion criteria were pregnancy with medical disorders and pregnancy complications, parturients sensitive to local anesthetic or opioids, BMI > 30, pre-labor rupture of membranes, malpresentations, intrauterine fetal demise, intrauterine growth retardation, fetal distress, previous LSCS, and known neuromuscular disorders.

They were randomly divided into 2 groups of 50 patients each by computer-based list of random numbers. *Group S (Gs) study group* received intrathecal analgesia and other *Group C (Gc) control group* received programmed labor analgesia. Both the groups were further divided into two *subgroups* P and M (GsP and G_SM, G_CP and G_CM). The subgroup P included primigravida parturients and M included the multigravida parturients.

The obstetrician involved in the case checked cervical dilatation and fetal heart rate. At cervical dilation 4–6 cm, I.V. line was secured with 18 G cannula and started with normal saline if not started previously. Oxytocin infusion, as and when required, was decided by obstetrician. Monitors were attached, and the following parameters were recorded: maternal basal non-invasive blood pressure (MAP), SpO_2, heart rate, and maternal VAS for pain.

In study group (Gs), the patient was positioned in left lateral position. After identifying L3–L4 interspace and under all aseptic precautions, at cervical dilatation of 4–6 cm, intrathecal injection of total 2 ml of drug was given in a combination given below using 26 G spinal needle by median/paramedian approach.

Drug	Volume	Concentration	Dose
Bupivacaine	0.5 ml	5 mg/ml	2.5 mg
Fentanyl	0.5 ml	50 mcg/ml	25 mcg
Morphine	1 ml	250 mcg/ml	250 mcg

The time of injection was noted, and patient was kept in supine position for 10 min. The effect of intrathecal analgesia was recorded every minute till VAS score becomes less than 5; this was noted as onset of analgesia and ambulation grading was noted.

In control group (G_C), the patient was given programmed labor analgesia which included (Inj. pentazocine 6 mg + Inj. diazepam 2 mg I.V. + Inj. tramadol 1–1.5 mg/kg I.M.) thereafter a single dose of Inj. drotaverine 40 mg intravenously. The time of injection was noted, and the effect of programmed labor analgesia was recorded by assessing VAS score. Ambulation grading was also noted.

Rescue analgesia

Inj. ketamine 0.25–0.5 mg/kg was given intravenously in either group, if required (VAS > 5). Subsequent doses were half of the first dose and interval between two doses was 30 min.

Maternal parameters were monitored every 5 min for the first 30 min, then each 30 min until delivery. Fetal heart rate, duration of labor, type of delivery, and neonatal outcome were also noted.

1) Maternal parameters:

- Maternal blood pressure(MAP)
- Heart rate
- Respiratory rate
- SpO_2
- Maternal VAS score for pain
- Maternal nausea, vomiting, and pruritis
- Effect on ambulation grading (EOA grading): grade 1: no effect—able to walk properly or ambulate; 2: mild effect—feeling of numbness in the legs but not interfering with ability to walk or ambulate; 3: severe effect—inability to walk or ambulate.

2) Fetal heart rate: the fetal monitoring was done continuously by cardiac topography
3) Total duration of labor starting from "active first stage of labor to completion of second stage of labor" and duration of active stage and second stage of labor separately.
- Type of delivery

4) Neonatal outcome: APGAR at 1 and 5 min.

Statistical analysis

Data collected was transformed into MS excel sheet for further processing and analysis. Appropriate statistical software and tools were used for analyzing data. Parametric and non-parametric test of significance were used accordingly to find the association between different quantitative and qualitative variable of interest. *P* value less than 0.05 was considered as statistically significant.

Results

The prospective open-label study was conducted on 100 parturients to study the efficacy of single-shot dose intrathecal analgesia with opioids combination as an optimal method of labor analgesia and its effects on labor, mother, and fetal outcome (Fig. 1).

Group S

Single-shot spinal group (N = 50) received heavy bupivacaine 2.5 mg + fentanyl 25 μg + morphine 250 μg intrathecally (total volume 2 ml). Rescue analgesia (if required for VAS > 5) was administered in the form of

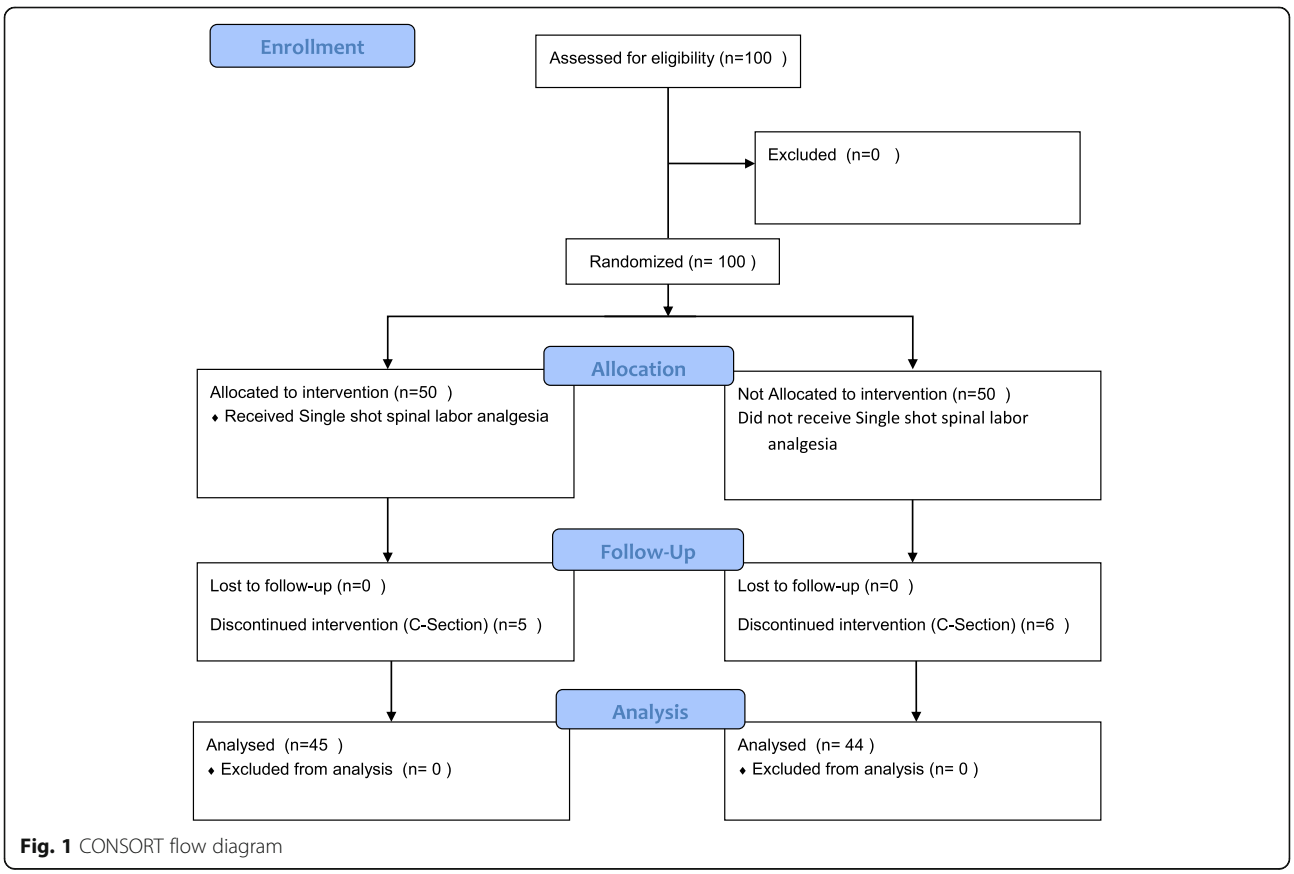

Fig. 1 CONSORT flow diagram

injection ketamine 0.5 mg/kg body weight slow I.V. over 5 min. The group S included 30 primigravida patients (60%), i.e., group sP (N = 30) and 20 parturients were multigravida (40%), i.e., group sM (N = 20) (Table 1).

Group C

Group C included patients who were managed for normal vaginal delivery according to the institutional protocol of programmed labor (N = 50). This group included 31 parturients (62%) who were primigravida, i.e., group cP (N = 31) and 19 patients (38%) were multigravida, i.e., group cM (N = 19) (Table 1).

The age, weight, height distribution, and the mean period of gestation was comparable in both the groups ($P > 0.05$).

Effect on the labor

Fifty-eight percent of parturients of group S had spontaneous onset of labor and did not differ from the group C in which 52% had spontaneous onset of labor. In the rest of the parturients, the labor was induced according to the institutional protocol. The mean cervical dilation at the time of administration of single-shot spinal was 4.86 ± 0.808 cm in group GsP and 4.92 ± 0.0804 cm in group GsM.

On comparing the duration of labor between the two groups

The mean duration of labor in group S was 244.75 ± 20.300 min and in the group C was 241.70 ± 30.923 min. The duration of labor did not differ in the two groups (P = 0.994). The duration of active phase of first stage was < 4 h in 90% (45/50) parturients in group S. The remaining 10% (5/50) had LSCS. (4 from group GsP and 1 from group GsM). Similarly, there were 44 parturients in group C who had a duration of active phase of first stage < 4 h and in 1 parturient it lasted 4.3 h. 6/50 parturients in group 2 had LSCS in the first stage (5 from group GcP and 1 from group GcM). The number of subjects who underwent C-section in first stage did not differ between the two groups (P = 0.886).

The mean duration of second stage of labor in the two groups did not differ (P = 0.359). Table 2 depicts the duration of second stage of labor in the two groups and subgroups.

In the single-dose intrathecal group (group S), 70% (35/50) had NVD (normal vaginal delivery), 20% (10/50) had IVD (instrumental vaginal delivery), and 10% (5/50) had CS (caesarean section). Similarly in parturients receiving programmed labor (group C), 72% (36/50) had NVD, 16% (8/50) had IVD, and 12% (6/50) had CS. The mode of delivery did not differ in the groups (P value was 0.826, 0.603, and 0.749, respectively, for NVD, IVD, and CS). Also, on comparing the mode of delivery between groups sP with cP and groups sM with cM, there was no statistically significant difference found (P = 0.833 and 0.789, respectively) (Table 3).

Table 1 Distribution of patients in two groups according to parity

Gravidity	Group S (n = 50)	Percentage	Group C (n = 50)	Percentage
Primigravida	30 Group sP	60	31 Group cP	62
Multigravida	20 Group sM	40	19 Group cM	38

Effect on mother and fetus

The VAS score was significantly lower in group S, with P = 0.000 (Fig. 2). The mean duration of analgesia provided by single-dose intrathecal analgesia with opioid combination was 248.96 ± 23.505 min. Also, if we compare the duration of single-dose intrathecal analgesia (248.96 ± 23.505 min) with the duration of labor (244.75 ± 20.300 min), it is seen that the single-dose intrathecal analgesia is sufficient enough to cover the total duration of labor in 90% of the parturients.

Ninety-eight percent of the parturients receiving single-shot spinal had moderate to severe (grades 2 and 3) motor weakness which caused difficulty in ambulation at 5 min of block which decreased to 0% at 30 min of the block. The mean maternal HR, NIBP, SPO_2, RR, and fetal HR was similar in the two groups ($P > 0.05$). Two parturients required rescue analgesia (5%) after single-dose intrathecal analgesia. Seven (14%) patients had side effects after single-dose intrathecal analgesia. Five (10%) patients had pruritis, which was relieved after an injection of pheniramine 25 mg I.V., and 2 (4%) patients had nausea vomiting for which an injection of ondansetron 4 mg I.V. was given.

The mean APGAR score in group S at 1 min and 5 min was 7.08 ± 0.665 and 8.42 ± 0.449, respectively, and the mean APGAR score in group C at 1 min and 5 min was 7.00 ± 0.571 and 8.46 ± 0.503, respectively. On comparing the two groups, the P value was 0.520 and 0.691 at 1 and 5 min, respectively. No neonate required resuscitation or NICU admission.

Discussion

Out of numerous pharmacological and non-pharmacological methods for labor analgesia, central neuraxial blockade has always been high ranked. But due to non-availability of epidural catheters, infusion pumps, multiparameter monitors, and trained staff in low resource areas, we need to rethink about single-shot spinal analgesia as an alternative to epidural labor analgesia. In a study done to compare single-dose spinal analgesia and epidural analgesia, it has been concluded that single-dose spinal is a good alternative to epidural analgesia in controlling labor pain, is easily performed, faster, and less expensive (AbdElBarr et al. 2014).

Table 2 Comparison of duration of second stage of labor

Second stage	Group S (n = 45)		Percentage		Group C (n = 44)		Percentage	
Duration (min)	sP	sM	sP	sM	cP	cM	cP	cM
< 30	1	2	2	4	0	1	0	2
30–60	18	14	40	31	18	15	41	34
> 60–90	6	3	13	7	7	1	16	2
> 90–120	1	0	2	0	2	0	5	0
> 120	0	0	0	0	0	0	0	0

In our study, the labor was managed partographically in the two groups and then compared. It was seen that the duration of all the stages of labor was similar in the two groups without any delay in any stage of labor. Also, on comparing the duration of labor in primigravida and multigravida, there was no difference in the two groups. This finding is opposite to the systemic review done by Minty RG and colleagues in which they stated that the combination of heavy bupivacaine 2.5 mg + fentanyl 25 μg + morphine 250 μg intrathecally for labor analgesia shorten the first stage of labor with faster rate of cervical dilatation (Minty et al. 2007).

On comparing our study with other studies on intrathecal labor analgesia, the mean duration of first stage of labor in the present study (193.82 ± 25.3min) was relatively longer as compared to the study done by Owen MD and colleagues (Owen et al. 2000) (171 ± 17.2 min) and Mathur P and co-authors (Mathur et al. 2017) (115.50 ± 27.33min). The significantly higher cervical dilatation (≥ 5 cm) at time of administration of intrathecal labor analgesia in these studies could be the reason for the faster rate of cervical dilatation as majority of subjects at 5–6 cm cervical dilatation fall into the phase of maximum slope of cervicograph (Zhang et al. 2002). Also, the duration of second stage of labor in the study conducted by Viitanen H and colleagues (Viitanen et al. 2005) was 9.6 ± 10.7 min and in our study was 50.93 ± 16.85 min. This difference is significant (P = 0.002), and it could be attributed to difference in parity, i.e., all parturients receiving intrathecal labor analgesia in the study by Viitnen H were multigravidae, and in our study, only 40% were multigravidae. Similarly, in the study done by Mathur P and colleagues (Mathur et al. 2017), the duration of second stage was significantly less (18.03 ± 8.27 min) compared to our study. It may be due to different intrathecal drug protocols. Although bupivacaine and fentanyl were given in similar doses, morphine was not administered. Moreover, baseline parturient parameters are not available in that study which also affect the duration of labor.

The VAS score reduced to 0 in all the patients at 5 min after giving single-shot spinal. The mean duration of analgesia in our study (238.96 ± 21.88 min) was longer as compared to the studies conducted by Owen MD (Owen et al. 2000), Viitanen H (Viitanen et al. 2005), and Mathur P (Mathur et al. 2017). Viitanen H (Viitanen et al. 2005) concluded that the majority of multiparous parturients found intrathecal analgesia adequate for pain relief during delivery. The difference can be attributed to the administration of morphine with fentanyl to bupivacaine in our study whereas in other studies, fentanyl and bupivacaine were used.

Although pain relief from single-dose intrathecal analgesia techniques may be effective, it is necessary that it lasts the length of the labor duration. In our study, if we compare the duration of single-dose intrathecal analgesia (248.96 ± 23.505 min) in group S with the duration of labor (244.75 ± 20.300 min), it is seen that the single-dose intrathecal analgesia is sufficient enough to cover the total duration of labor in 90% of the parturients. Also, only 5% of the parturients demanded rescue analgesia. Hence, the addition of morphine has added advantage in increasing the duration of analgesia.

Table 3 Comparison of type of delivery in two groups

Type of delivery	Group S (n = 50)	Percentage	Group C (n = 50)	Percentage	P value
Normal vaginal delivery (NVD)	35	70	36	72	0.826
Instrumental vaginal delivery (IVD)	10	20	8	16	0.603
NRFHR with poor maternal efforts	8	16	5	10	
Prolonged second stage	2	4	3	6	
Caesarean section (C-section)	5	10	6	12	0.749
Fetal tachycardia	1	2	0	0	
Fetal bradycardia	2	4	4	8	
Non-progress of labor	2	4	2	4	

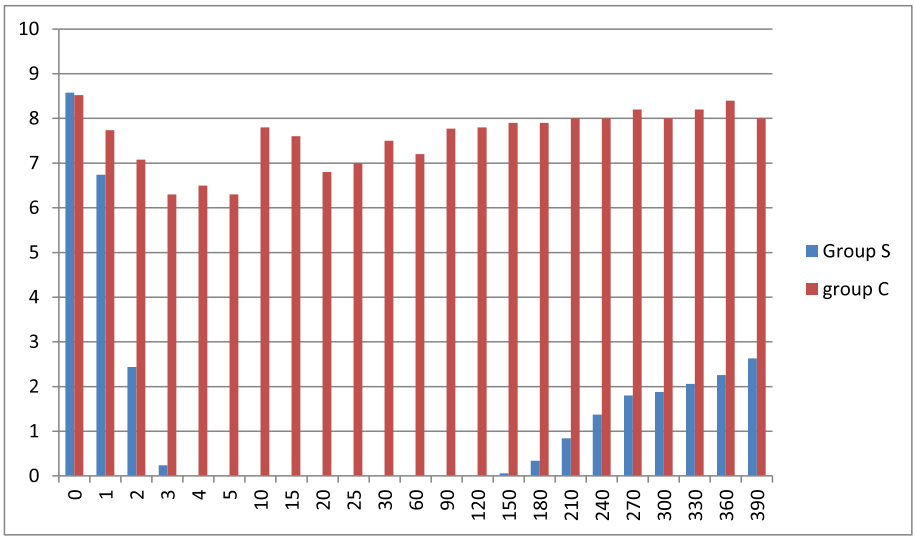

Fig. 2 Comparison of VAS score in two groups. (*x* axis represents mean VAS score and *y* axis represents time duration in minutes)

Some studies have also addressed increasing the duration of labor analgesia by using spinal analgesia as a part of combined spinal-epidural technique. Yeh HM et al. found that the addition of 150 μg of morphine sulfate to a combination of bupivacaine 2.5 mg and fentanyl 25 μg prolonged request of analgesia from 146 min to 252 min (Yeh et al. 2001). However, Hess PE and colleague demonstrated that the addition of morphine 150 μg to a mixture of intrathecal bupivacaine 2.0 mg and fentanyl 25 μg failed to prolong spinal analgesia significantly when administered as a part of combined spinal epidural techniques (Hess et al. 2003).

Side effects which were observed in the present study included pruritis (10%) and nausea vomiting (4%), which is similar to the side effects noted by Mathur P and colleagues (Mathur et al. 2017). Side effects reported by Tshibuyi PN (Tshibuyi et al. 2013) were pruritis (14.6%), nausea vomiting (8.4%), and hypotension (10.4); this is also reported in the study done by Bilge A and colleagues (Bilge et al. 2017). We also observed the effect on ambulation in 66% parturients who received spinal analgesia which did not persist at or beyond 30 min. But in a study done by Anbah T and collegaues (Anabah et al. 2015), only 12.3% of parturients had ambulatory difficulties. It may be due to the lesser dose of morphine used in this study (0.20 mg).

The overall caesarean section rate was 10% in parturients who received single-shot spinal which was similar to the other group (12%) which did not receive spinal analgesia. Therefore, there was no increase in the C-section rate after spinal analgesia. The indications were fetal tachycardia (2%), fetal bradycardia (4%), and non-progress of labor (4%). In the study done by Nelson KE and colleagues, 55% delivered vaginally, 21% had instrumental vaginal deliveries, and 24% underwent C-section (Nelson et al. 2002). In our study, 20% in the spinal group and 16% in non-intervention group had instrumental vaginal deliveries. Also, comparing the primigravidae and multigravidae in the two groups, there was no significant differences in the mode of delivery. Hence, the combination of heavy bupivacaine 2.5 mg + fentanyl 25 μg + morphine 250 μg in single-shot spinal analgesia did not increase the C-section rate or the instrumental deliveries irrespective of the parity in our study.

Conclusion

Single-shot spinal with heavy bupivacaine 2.5 mg + fentanyl 25 μg + morphine 250 μg (total volume 2 ml) can be used efficaciously covering the complete duration of labor in both primigravida and multigravida with no increase in instrumental delivery or C-section rate and without any prolongation of labor or other side effects. The only limiting side effect noted was motor weakness which lasted for a maximum of 30 min.

Abbreviations

VAS: Visual analog score; C-section/CS: Caesarean section; BMI: Body mass index; LSCS: Lower segment caesarean section; MAP: Mean arterial pressure; SPO_2: Oxygen saturation; 26 G: 26 gauge; Inj: Injection; I.V.: Intravenous; NVD: Normal vaginal delivery; IVD: Instrumental vaginal delivery; EOA: Effect on ambulation; NICU: Neonatal intensive care unit

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Authors' contributions

GC: conceptualization, methodology, project administration, supervision, and final approval of draft. PS: acquisition, analysis, and interpretation of data. AAP: supervision, acquisition and analysis of data, drafting the work, and revising it. The author(s) read and approved the final manuscript.

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Availability of data and materials
The data supporting the results of this article is included within the article. The data sets are cited in the manuscript and included in the reference list.

Ethics approval and consent to participate
The research has been performed in accordance with the Declaration of Helsinki and was approved by the Institutional Ethics Committee, Indira Gandhi Medical College, Shimla, number: ECR/533/IST/HP/2014. Registered on 12 August 2017.
Written and informed consent was taken from every participant of the study.

Consent for publication
Not applicable

Competing interests
The authors declare that they have no competing interests.

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