

Intravenous Low Dose (4 mg) Dexamethasone as an Adjunct to Epidural Labour Analgesia with 0.125% Ropivacaine in Parturients: A Randomised Controlled Study

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ABSTRACT

Introduction: Labour pain is one of the most severe pains, and the mother's demand is reason enough for the induction of labour analgesia, provided that no contraindications exist. Labour analgesia must be safe for both the mother and the child.

Aim: To assess the impact of a low dose (4 mg) of Intravenous (IV) dexamethasone used in conjunction with neuraxial labour analgesia with 0.125% Ropivacaine.

Materials and Methods: The present study was a double-blinded randomised controlled study conducted at tertiary care hospital on 80 parturients classified as American Society of Anaesthesiologists (ASA) II. The parturients were over 18 years old, in their third trimester, carrying a single live foetus that was cephalic at 36 weeks of gestation, and whose cervical dilation was greater than 3 cm and who requested epidural analgesia. All parturients were randomly divided into two equal groups. Before receiving epidural analgesia, the dexamethasone group received 4 mg of IV dexamethasone in 50 mL of normal saline. Patients in the control group received only 50 mL of normal saline. After an initial bolus of 0.125% ropivacaine (8 mL given gradually over 5 minutes), all expectant mothers received a

continuous background infusion of 0.125% ropivacaine at a rate of 5 mL/h, along with patient-controlled boluses of 5 mL of the same medication given with a lockout interval of 12 minutes using a Patient Controlled Epidural labour Analgesia (PCEA) pump through the epidural route. Yates continuity correction test (Chi-square test), Fisher's exact test, and Fisher Freeman Halton were used to compare qualitative data. For categorical data, numbers and percentages were used to summarise all continuous variables as mean±SD.

Results: Demographics such as age, height, weight, and pre-procedure obstetric-related details were comparable in both groups. There was no statistically significant difference in the average hourly medication intake between the dexamethasone group and the control group (Group D-7.64±0.88 mL/hr and Group C-8.04±1.24 mL/hr, p-value=0.09). Other factors, including pain scores, haemodynamics, administration method, and side effects, did not differ significantly between the two groups.

Conclusion: Despite having modest analgesic properties, IV dexamethasone could not significantly reduce the hourly average medication consumption of ropivacaine during epidural labour analgesia.

Keywords: Haemodynamics, Pain, Trimester

INTRODUCTION

According to the American Society of Anaesthesiologists (ASA) and the American College of Obstetricians and Gynaecologists (ACOG), there is no other situation where it is considered acceptable for an individual to experience untreated severe pain that is amenable to safe intervention while under the care of a physician. Maternal request is a valid medical rationale for pain treatment during childbirth in the absence of a medical contraindication [1]. Over the last two decades, there have been many modifications in regional anaesthesia techniques to provide effective and safe labour analgesia, with the advent of several newer and safer local anaesthetic agents. It is now well recognised that the most effective method of labour analgesia is lumbar epidural [2-4]. Along with effective pain relief, it also gives better maternal satisfaction with the ability to provide anaesthesia when required. More studies are required to find out the minimum required local anaesthetic dose for effective pain relief and the least side effects. Ropivacaine is a local anaesthetic that causes differential sensory blockade, with a dose-dependent motor blockade [5].

Adjuvants in local anaesthesia help to reduce the effective dose used and increase the quality of analgesia. The most often used adjuvant is neuraxial opioids. Recently, many studies have shown the effectiveness of clonidine and neostigmine as adjuvants in labour epidural, but they have more side effects like hypotension and bradycardia, so they are less useful for labour analgesia [6-8].

Dexamethasone, an anti-inflammatory drug, has analgesic efficacy as an adjunct. It acts as an analgesic by decreasing inflammation and blocking the transmission of nociceptive C-fibers and by stopping the ectopic discharge of the nerve [9]. It has been shown that when dexamethasone was used as an adjunct for peripheral nerve blocks, the duration of postoperative analgesia was increased [10].

There isn't much research examining the use of low-dose 4 mg dexamethasone for analgesia in pregnant women, despite several studies demonstrating that dexamethasone 8 mg is a safe, effective, and affordable option to minimise postoperative pain when administered in the preoperative period [10,11].

Thus, the current study aimed to evaluate the effect of low-dose IV dexamethasone as an adjunct to epidural labour analgesia. The hypothesis of this study was that low-dose (4 mg) IV dexamethasone used as an adjunct would improve labour analgesia without any additional side effects. The main objectives of this study were to examine the average hourly consumption of ropivacaine delivered neuraxially for the duration of epidural labour analgesia and to investigate the effects of a modest dosage (4 mg) of IV dexamethasone used in conjunction with neuraxial labour analgesia. Secondary goals were to assess the pain score (VAS scoring), the onset of sensory and motor block features of analgesia, maternal satisfaction, maternal hemodynamic parameters, Foetal Heart Rate (FHR), delivery method, APGAR ratings at 1 and 5 minutes, and adverse consequences.

MATERIALS AND METHODS

This tertiary care facility-based randomised double-blind controlled study was conducted from September 2018 to October 2019 at MDM Hospital, Jodhpur, Rajasthan, India. The study received institutional ethical approval (Reference No. F.1/Acad/C/JU/18/6916) and was registered with the Clinical Trial Registry of India (CTRI) in September 2018. The trial's final CTRI registration number is CTRI/2018/09/015751.

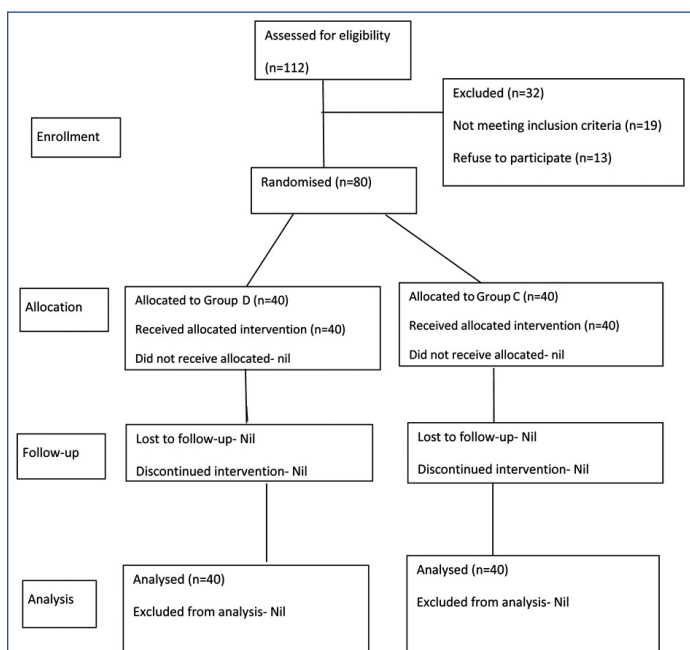
Inclusion criteria: The study included primigravida, singleton pregnant women who were at least 18 years old, weighed less than 100 kg, were taller than 150 cm, had intact or absent membranes, experienced satisfactory uterine contractions with more than 50% effacement, presented with vertex at term, and requested labour analgesia.

Exclusion criteria: Patients with any foetal anomalies, history of coagulation disorders, contraindications to epidural anaesthesia, allergy to local anaesthetics, obstetric complications, sepsis, multiple pregnancies, premature labour, uncontrolled diabetes mellitus, or inadvertent dural puncture were excluded from the study.

Sample size: The sample size of 38 per group was determined based on power analysis from previous data by Ahirwar A et al., who studied 30 patients undergoing labour epidural analgesia with patient-controlled epidural analgesia. The mean total consumption of 0.125% ropivacaine was found to be 47.42 mL, with a standard deviation of 9.7. The authors considered a 20% reduction in hourly consumption of neuraxial drug as a clinically meaningful difference, resulting in a value of 37.94 mL as the neuraxial drug consumption in the dexamethasone group [12].

With the above assumptions of 0.20 (power of 80%) and 0.05, a sample size analysis for this study showed that a sample size of 38 per group would enable the detection of a 20% difference in the total amount of epidural drug required. Therefore, it was decided to enroll 80 patients, with 40 patients in each group.

All 80 individuals were randomly divided into two groups of 40 each using a computer-generated system, after obtaining written informed consent. The CONSORT diagram in [Table/Fig-1] shows the flow of participants through each stage of the randomised trial [Table/Fig-1].



[Table/Fig-1]: CONSORT diagram showing the flow of participants through each stage of a randomised trial.

Group D - Dexamethasone group

Group C - Control (placebo) group

For Group D, 4 mg of dexamethasone mixed with normal saline (total volume 50 mL) was given intravenously to the patient over

15 minutes, approximately 45 minutes before the procedure. Group C received 50 mL of plain normal saline. The anesthesiologist who prepared the study drug and the investigator who assessed the patients were blinded to the group allocation.

After a detailed history taking, a complete general physical examination with airway and systemic examination was performed. The subjects were evaluated by the obstetrician for cervical dilatation, effacement, station, and integrity of membranes. Baseline pain scores were measured using a VAS- a 10 cm line with endpoints labeled "no pain" and "worst imaginable pain".

A 500 mL preload of intravenous Ringer lactate solution was administered to each subject. The parturients were instructed to ingest clear liquids. Baseline hemodynamic parameters, including Heart Rate (HR), Mean Arterial Pressure (MAP), Saturation (SpO₂), and FHR, were recorded.

Under aseptic conditions, the patient's back was prepared with a 5% povidone iodine solution and draped. The L2-3 or L3-4 space was identified in the sitting position by palpation. The overlying skin was infiltrated with 2-3 mL of 1% xylocaine. After skin infiltration, the intervertebral space was identified, and an 18 G Tuohy's needle was introduced into the epidural space using the loss of air resistance technique. A 20 G epidural catheter (multiport) was inserted cephalad 4-5 cm into the epidural space and securely fixed with a plaster. All parturients received an initial loading epidural dose of 8 mL of 0.125% ropivacaine, gradually administered over five minutes after negative aspiration for blood and cerebrospinal fluid. The study excluded four participants (two from each group) who had asymmetrical blocks or a VAS score of four or above in the first 30 minutes of labour.

A PCEA pump (T34L-PCAtm4 HANSRAJ NAYYAR Medical, INDIA) continuously infused 0.125% ropivacaine at a rate of 5 mL/h in all pregnant women. The programmed parameters of the PCEA pump were as follows: a bolus dose of 5 mL, a lockout time of 12 minutes, and a bolus speed of 200 mL/h. The handheld button for patient-controlled boluses was given to the expectant mothers. Written instructions on how to operate the pump were provided to each expectant mother, and they were all taught to press the button if their pain increased (VAS 3).

The primary goal of this study was to measure the total amount of ropivacaine consumed per hour via the epidural route. Secondary goals included evaluating the pain score (VAS scoring), onset of analgesia, maternal satisfaction (assessed by verbal inquiry), sensory level, and motor block characteristics (assessed using the modified Bromage scale). Changes in the mother's vital signs, FHR, length of the first and second stages of labour, mode of delivery, and APGAR scores at 1 and 5 minutes were also recorded. Adverse effects such as shivering, nausea, vomiting, respiratory depression, or urinary retention were noted and treated as necessary. All expectant mothers were monitored during and after the procedure for any procedure-related issues, such as temporary neurological symptoms, postdural puncture headaches, backaches, and catheter migration.

The mother's parameters, including HR, blood pressure, and pulse rate, were measured every five minutes for the first 30 minutes, every 15 minutes for 60 minutes, and then every half an hour until the delivery of the baby, with continuous FHR monitoring. The epidural catheter was removed after delivery in the labour room, and the site was dressed.

STATISTICAL ANALYSIS

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) 22.0 software (SPSS Inc., Chicago, IL, USA). The Yates continuity correction test (Chi-square test), Fisher's exact test, and Fisher Freeman Halton were used to compare qualitative data. For categorical data, numbers and percentages

were used to summarise the data, while continuous variables were presented as mean±SD. A p-value <0.05 was considered statistically significant.

RESULTS

The demographic details (age, height, weight) and preprocedure details (gestational age, cervical dilatation, cervical effacement) of all patients in both groups were comparable [Table/Fig-2].

Parameters	Group D (Mean±SD)	Group C (Mean±SD)	t-value	p-value
Weight (kg)	59±2.42	59.12±1.92	0.255	0.799
Height (cm)	157.9±2.78	157.77±2.34	0.217	0.828
Age (years)	22.22±2.91	22.35±2.86	0.193	0.847
Gestational age (week)	37.62±0.77	37.62±0.83	0.00	0.999
Cervical dilatation (cm)	4.52±0.55	4.62±0.66	0.729	0.468
Cervical effacement	77±12.02	81.5±11.22	1.730	0.087

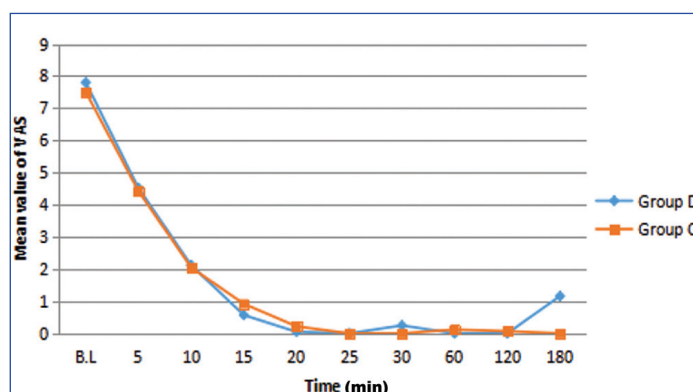
[Table/Fig-2]: Demographic details and preprocedure condition of patients. Unpaired student's t-test

The differences in the primary outcome and average hourly drug consumption in both groups were statistically insignificant (7.64±0.88 mL/hr in the dexamethasone group vs 8.04±1.24 mL/hr in the placebo group) [Table/Fig-3].

Drug consumption (mL/hr)	Group D	Group C
	N (%)	N (%)
5.84-7	8 (20)	5 (12.5)
7.1-8.99	28 (70)	27 (67.5)
9.1-10.99	4 (10)	6 (15)
≥11	0	2 (5)
Median	7.29	7.65
Range	5.84-9.71	6.75-11.66
Mean±SD	7.64±0.88	8.04±1.24
t and p-value	1.681, 0.096	

[Table/Fig-3]: Drug consumption in both groups (ML/hour).

The baseline VAS scores recorded just before epidural labour analgesia were comparable in both groups (7.8±0.68 in Group D vs 7.5±0.98 in Group C). The mean value of VAS scores was lower compared to the baseline pain scores at subsequent intervals in both groups. The mean changes in VAS scores in both groups were comparable at each time period [Table/Fig-4].



[Table/Fig-4]: Mean changes in visual analog scale in both groups.

Maternal satisfaction was assessed after delivery in terms of excellent, good, and fair. Maternal satisfaction was non-significantly higher in the dexamethasone group than the control group (p-value 0.395), but there was a significant difference in both groups for excellent satisfaction (p-value <0.05) [Table/Fig-5].

The comparison of primary and secondary outcomes of both study groups is shown in [Table/Fig-6]. There was no significant difference

Maternal satisfaction	Group D	Group C
	N (%)	N (%)
Excellent	25 (62.5)	14 (35)
Good	11 (27.5)	21 (52.5)
Fair	4 (10)	5 (12.5)
Total	40 (100)	40 (100)

[Table/Fig-5]: Maternal satisfaction. p-value 0.395

in total drug consumption between Group D (22.42±4.81) and Group C (22.57±5.10) (p-value-0.892). The onset of analgesia in both groups had a p-value of 0.427, indicating that the difference was not significant. The duration of the active phase of the first stage and second stage was comparable in both groups (p-value-0.082 and 0.302).

Parameter	Group D	Group C	t-value	p-value
Hourly drug consumption (mL/h)	7.64±0.88	8.04±1.24	1.681	0.096
Onset time for analgesia (min)	9.8±3.14	10.5±4.56	1.570	0.427
Duration of analgesia (min)	174.92±21.96	167.37±19.80	1.615	0.110
Duration of 1 st stage of labour (min)	134.92±15.53	128.62±16.44	1.761	0.082
Duration of 2 nd stage of labour (min)	40.5±8.22	38.75±6.77	1.039	0.302
Total volume of drug consumed (mL)	22.42±4.81	22.57±5.10	0.135	0.892
Maternal satisfaction (excellent)	62.5%	35%		<0.05

[Table/Fig-6]: Comparison of primary and secondary outcomes of study groups.

The maximum dermatome level of sensory blockade achieved in both groups ranged from T6 to T8. An unpaired t-test was used for this parameter. The difference was statistically not significant in both groups [Table/Fig-7]. There was no statistically significant difference in the motor block between both groups. All obstetric outcomes, duration of the first and second stages of labour, mode of delivery, and FHR were comparable in both groups.

The APGAR scores at 1 minute and 5 minutes after birth were comparable in both groups [Table/Fig-8].

Height of sensory block	Group D	Group C
	N (%)	N (%)
T6	10 (25)	13 (32.5)
T8	30 (75)	27 (67.5)
Total	40 (100)	40 (100)

[Table/Fig-7]: Height of sensory block. p-value 0.621, Unpaired student t-test

APGAR	Group D (Mean±SD)	Group C (Mean±SD)	t-value	p-value
At 1 min	7.77±0.69	7.42±0.71	2.221	0.290
At 5 min	9.92±0.26	9.87±0.33	0.738	0.462

[Table/Fig-8]: APGAR score in both groups.

Spontaneous vaginal delivery occurred in 38 parturients in Group D and 37 parturients in Group C. The data were analysed using an unpaired student t-test. There was no statistically significant difference in both groups (p-value=0.365) [Table/Fig-9].

Patients who received dexamethasone had a significantly lower incidence of nausea compared to the placebo group (2.5% in Group D vs 20% in Group C). All other side effects were comparable in both groups [Table/Fig-10].

There was no significant difference in HR and MAP in both groups [Table/Fig-11,12].

Mode of delivery	Group D	Group C
	N (%)	N (%)
Spontaneous	38 (95)	37 (92.5)
LSCS	2 (5)	3 (7.5)
Forceps	0	0
Total	40 (100)	40 (100)

[Table/Fig-9]: Mode of delivery.
p-value=0.365

Side-effects	Group D	Group C	p-value
	N (%)	N (%)	
Foetal bradycardia	3 (7.5)	3 (7.5)	1.324
Hypotension	1 (2.5)	0	1.000
Urinary retention	2 (5)	2 (5.00)	1.384
Nausea	1 (2.5)	7 (20)	0.056
Fever	0	4 (10)	0.115
Vomiting	0	1 (2.5)	1.000

[Table/Fig-10]: Comparison of side-effects in both groups.
Unpaired t-test

Time (min)	Heart Rate (HR) (bpm)		t-value	p-value
	Group D (Mean±SD)	Group C (Mean±SD)		
Baseline	102.92±4.7	102.95±4.38	0.025	0.979
5	97.32±4.78	96.27±3.38	1.133	0.26
10	93.65±4.47	91.92±3.77	1.863	0.066
15	92.05±4.88	89.82±5.26	1.96	0.053
20	89.6±5.45	87.62±4.94	1.695	0.094
25	86.37±6.05	86.22±4.97	0.121	0.904
30	84.42±2.92	83.8±7.38	0.497	0.62
60	84.35±3.40	84.47±6.21	0.111	0.911
120	88.4±7.07	88.72±6.56	0.213	0.831
180	97.85±6.38	99±7.16	0.539	0.592
Post delivery	98.07±4.49	98.3±3.09	0.26	0.794

[Table/Fig-11]: Mean changes in Heart Rate (HR) in both groups.

Time (min)	MAP (mmHg)		t-value	p-value
	Group D (Mean±SD)	Group C (Mean±SD)		
Baseline	82.95±4.81	82.3±2.91	0.73	0.467
5	81.27±3.78	80.1±2.67	1.602	0.113
10	78±4.10	77.9±3.07	0.123	0.902
15	76.7±4.73	77.35±2.61	0.759	0.449
20	77.5±4.70	78.35±3.23	0.924	0.348
25	78.1±4.68	78.6±2.31	0.605	0.546
30	77.6±4.41	78.05±2.31	0.566	0.572
60	78.57±4.59	78.15±3.21	0.479	0.633
120	78.35±2.71	78.1±2.17	0.455	0.65
180	78.96±2.71	78.5±2.74	0.562	0.577
Postdelivery	81.7±3.22	82.75±2.38	1.658	0.101

[Table/Fig-12]: Mean changes in Mean Arterial Pressure (MAP) in both groups.

DISCUSSION

The important impact of the present study was that the administration of intravenous low-dose dexamethasone (4 mg) did not decrease the hourly consumption of epidural ropivacaine in painless labour delivery.

However, a study conducted by Dube P et al., demonstrated the analgesic benefit of intravenous dexamethasone for labour analgesia and found a significant decrease in the hourly consumption of epidural local anaesthetic drugs in the dexamethasone group compared to the control group. It is important to note that the dose

of dexamethasone used in their study was higher (8 mg), and the results were inconsistent with those of the present study [13].

In a previous study by Ituk U and Thenuwara K, the effect of a single dose of intraoperative 8 mg intravenous dexamethasone on postoperative analgesia was investigated, and it was found that there was no significant reduction in 24-hour opioid consumption in the postoperative period. These findings support the findings of the present study [14]. Similar results were observed in a study by Moyano J et al., which revealed that intravenous dexamethasone given in the intraoperative period had no clinical effect on postoperative pain intensity in the first 48 hours after arthroscopic knee surgery [15]. A study conducted by Al-Qudah M and Rashdan Y also showed that dexamethasone had no superior effect in controlling early postoperative pain in patients undergoing endoscopic sinus surgery [16].

The analgesic effects of dexamethasone are believed to be due to the inhibition of phospholipase, which is required for the inflammatory pathway involving cyclooxygenase and lipoxygenase. Therefore, intravenous dexamethasone appears to be a useful adjunct for analgesia. However, the optimal dose of dexamethasone for reducing pain scores is still controversial, and multiple studies have been conducted on this topic, such as the study by De Oliveira GS et al. However, none of these studies have been done specifically for labour analgesia [16,17]. Thus, the present study was conducted with a low dose of dexamethasone to determine the effectiveness of low-dose intravenous dexamethasone (4 mg) as an adjuvant for epidural labour analgesia without an increase in side effects. De Oliveira GS et al., conducted a meta-analysis of 24 randomised clinical trials involving 2,751 patients and concluded that dexamethasone at doses higher than 0.1 mg/kg is an effective adjunct in multimodal strategies to reduce postoperative pain and opioid consumption after surgery [17].

The mean onset time of analgesia after the initial bolus dose of ropivacaine was also comparable in both groups, which delayed the onset of the analgesic effect of dexamethasone. These results were similar to the study conducted by Dube P et al., [13]. The median number of bolus doses was 4 (Interquartile Range [IQR] 3-5.75) in the Dexa group and 5 (IQR 3-6) in the Placebo group (p-value=0.162). The average hourly drug consumption was significantly lower in the Dexa group compared to the Placebo group (10.34±1.79 mL/h vs. 11.34±1.83 mL/h; mean difference 1.007, 95% CI 0.199-1.815; p-value=0.015) [13].

This study found that Group D experienced much lower rates of nausea than Group C. These outcomes are comparable to the findings of the study by De Oliveira GS et al., which examined the efficient antiemetic effects of low-dose dexamethasone [17]. Neither group reported any further serious side effects or labour-related equipment failures.

Maternal satisfaction in both groups was equivalent to the degree of labour pain alleviation, which is consistent with the research conducted by Dube P et al. In their study, the mean maternal satisfaction in the Dexa group was 91.75±3.93, and in the Placebo group, it was 90.63±4.08 (p-value=0.21) [13].

Based on the findings of this study, the routine use of low-dose intravenous dexamethasone (4 mg) as an adjuvant for epidural analgesia during painless labour delivery may not be appropriate. Further study is required to confirm or refute these findings.

Limitation(s)

The lack of estimation of dexamethasone blood levels and the fact that this was a single-center trial were limitations of the study. Another limitation was that this trial only evaluated a single dose of dexamethasone (4 mg) rather than varying doses or multiple injections.

CONCLUSION(S)

The failure of low-dose intravenous dexamethasone (4 mg) to significantly reduce the hourly average drug consumption of ropivacaine during epidural labour analgesia provided evidence of its weak analgesic effect. While dexamethasone may have a role in multimodal pain management therapy, further studies with larger sample sizes and different doses of dexamethasone are needed before its routine use can be recommended.

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