

ROPIVACAINE HYDROCHLORIDE 0.2% LOCAL INFILTRATION AND INTRAPERITONEAL INSTILLATION FOR POSTOPERATIVE PAIN RELIEF IN CAESAREAN SECTION UNDER SPINAL ANAESTHESIA: A RANDOMISED CLINICAL STUDY

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ABSTRACT

BACKGROUND

The purpose of this study was to compare Inj. Ropivacaine 0.2% local infiltration and intraperitoneal instillation with Inj. Ropivacaine 0.2% local infiltration alone for postoperative pain relief in caesarean section under spinal anaesthesia.

MATERIALS AND METHODS

Pregnant patients of ASA grade I and II posted for caesarean section under spinal anaesthesia were randomised into 3 groups (Group I, II, III of 30 patients each). Patients in group I received no local infiltration; patients in group II were given local infiltration of 20 mL Inj. Ropivacaine 0.2% at incision site before closure of skin; patients in group III received intraperitoneal instillation of 5 mL Inj. Ropivacaine 0.2% before closure of peritoneum and local infiltration of 15 mL Inj. Ropivacaine 0.2% at incision site before closure of skin. In the postoperative period, pain assessment was carried out by VAS and duration of analgesia was calculated as the time taken from the onset of sensory block to the first request for supplemental analgesia. Haemodynamics and side effects were also recorded in all patients.

RESULTS

A significant longer duration of analgesia was observed in group II and group III ($p < 0.05$) as compared to group I. The mean (\pm SD) duration of analgesia in group I, II and III was 115.67 ± 4.09 , 147.17 ± 4.67 and 170.33 ± 3.69 min. respectively. Significantly lower VAS scores were observed in group II and III as compared to group I. The mean (\pm SD) VAS scores at first analgesic request were as follows: Group I - 56.27 ± 5.009 ; group II - 36.7 ± 5.14 ; group III - 32.6 ± 6.52 .

CONCLUSIONS

We recommend the use of Inj. Ropivacaine 0.2% local infiltration and intraperitoneal instillation as it produces better post-operative analgesia in caesarean section as compared to Inj. Ropivacaine 0.2% local infiltration alone under spinal anaesthesia.

KEYWORDS

Intraperitoneal Instillation, Ropivacaine, Caesarean Section, Spinal Anaesthesia.

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BACKGROUND

Prompt and adequate postoperative pain relief is an important component of caesarean delivery that can make the period immediately after the operation less uncomfortable as well as mother can initiate early breastfeeding that helps to contract the uterus and accelerates the process of uterine involution in the postpartum period.

Short- or medium acting sedatives, narcotics and local anaesthesia have been employed during the operation as an adjunct to anaesthesia or to alleviate postoperative pain. Local anaesthetics cause reversible blockade of impulse propagation along the nerve fibres by preventing the influx of sodium ions through the cell membrane of the fibres. Several studies have

reported on use of pre-emptive local anaesthetics (local anaesthetic given during the operation to prevent or reduce pain afterwards) to relieve postoperative pain, with results ranging from being beneficial^{1,2} to conferring no benefit.^{3,4}

The local anaesthetic may be administered by pre or post-incisional abdominal nerve block (local anaesthetic injected to block the nerves before cutting the skin at the beginning of the operation, or after closing the skin at the end)⁵ or pre- or post-incisional abdominal wound infiltration.^{1,6} Local anaesthetics eventually get absorbed systemically and secreted in breast milk, but their effects on breastfed babies have not yet been documented. This is in sharp contrast to morphine or pethidine, both of which have significant transfer to breast milk and may have a sedative effect on the baby.

Ropivacaine is an amide type of local anaesthetic that is structurally related to bupivacaine. Unlike bupivacaine, which is present in a racemic mixture, ropivacaine is exclusively the S (-) enantiomer. Various clinical studies has shown that ropivacaine is equal to bupivacaine in local anaesthetic potency and is less toxic than bupivacaine in regard to the production of mild central nervous system and cardiovascular toxicity by intravenous infusion.¹

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MATERIALS AND METHODS

After ethical committee approval and written informed consent, this randomised, prospective clinical observational study was carried out on 90 pregnant patients undergoing Caesarean section of ASA grade I & II scheduled under spinal anaesthesia. Criteria for exclusion were; allergic reactions to local anaesthetics, peripheral or central neurological disease, raised intracranial tension, valvular heart diseases, significant ECG changes, renal diseases, endocrinal diseases, metabolic diseases, hepatic diseases, coagulopathy and bleeding disorders. Parturients were also excluded from the study if the procedure was performed under general or epidural anaesthesia. Ninety Pregnant women who fulfilled the eligibility criteria were chosen, explained about the procedure and written consent was taken. Patients were subsequently randomised into three groups of 30 each.

Group I (n=30) – Control group with no local infiltration.

Group II (n=30) – Local infiltration of 20 mL Inj. Ropivacaine 0.2% at incision site.

Group III (n= 30) – Local infiltration of 15 mL inj. Ropivacaine 0.2 % at incision site and intraperitoneal instillation of 5 mL Inj. Ropivacaine 0.2%.

Assessment of pain was done by Visual Analogue Scale (VAS) [Table 1]. During the preoperative interview, subjects were familiarised with the recording of scale. The top of the scale at 100 represents very severe pain while the baseline value-0 represents no pain.

On entering into the OT, after placement of standard non-invasive monitoring devices, all patients were given spinal anaesthesia using Inj. Bupivacaine 0.5% heavy according to the standard protocol. Patients in group I received no local infiltration; patients in group II were given local infiltration of 20 mL Inj. Ropivacaine 0.2% at incision site before closure of skin ; patients in group III received intraperitoneal instillation of 5 mL Inj. Ropivacaine 0.2% before closure of peritoneum and local infiltration of 15 mL inj. Ropivacaine 0.2% at incision site before closure of skin .The level of sensory block was assessed using a 26 gauge needle and recorded as loss of sensation to pinprick, checking in a caudal to cephalic direction. Motor block was recorded according to the Bromage scale [Table 2]. Baseline observations were recorded before spinal anaesthesia. Pulse rate, electrocardiogram, systolic and diastolic blood pressure, respiratory rate and peripheral arterial haemoglobin oxygen saturation were monitored perioperatively. Data monitoring performed continuously, but for statistical analysis data were recorded at 0, 5, 10, 20, 30, 45, 60 minutes after intrathecal injection and thereafter every hour up to 8 hours.

Fluid administration was continued and a decrease in mean arterial pressure greater than 30% below the pre-anaesthetic baseline value was treated with inj. Mephentermine IV & intravenous fluids. In the postoperative period, pain assessment was carried out by VAS and duration of analgesia was calculated as the time taken from the onset of sensory block to the first request for supplemental analgesia. When patients complained of pain postoperatively, VAS score at the time of first analgesia request was recorded. Then intramuscular diclofenac sodium 75 mg was prescribed and the study of that patient was taken as complete.

Patients were closely observed in the intraoperative and postoperative period for complications like nausea, vomiting,

dyspnoea, respiratory depression, chest pain, shivering, dysrhythmia, bradycardia, hypotension and any other.

The observations were recorded and subject to statistical analysis using student’s “t” test by statistics calculator Epi Calc. 2000 s, p-value <0.05 taken statistically significant.

Table 1: VAS Score Rating

- 0: No Pain
- 1-25: Mild Pain
- 26-50: Moderate Pain
- 51-75: Severe Pain
- 76-100: Very Severe Pain

Scale

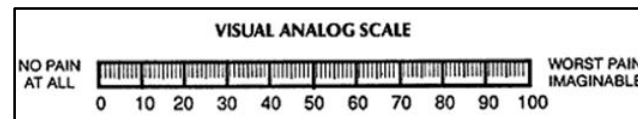


Table 2: Bromage Score

- Grade criteria
- Grade 0 - Free movement of leg and feet
- Grade 1 - Just able to flex knees with free movement of feet
- Grade 2 - Unable to flex knees and barely able to move feet
- Grade 3 - Unable to move legs and feet

RESULTS

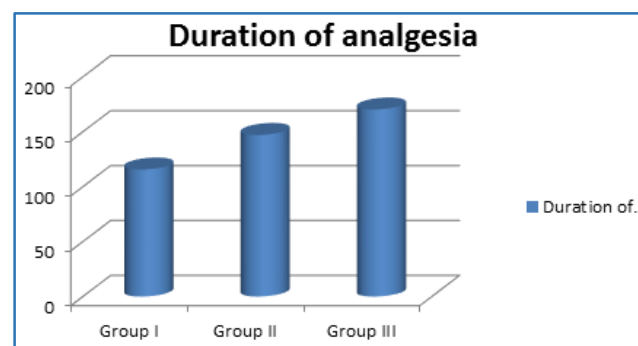
A total of 90 patients were recruited and studied. The three groups were comparable with respect to age, weight, height and duration of surgery [Table 3].

There was no significant changes in pulse rate, systolic blood pressure, diastolic blood pressure and respiratory rate among three groups (p>0.05).

Variable	Group I (n=30)	Group II (n=30)	Group III (n=30)
	Mean±SD	Mean±SD	Mean±SD
Age (yrs.)	24.37±3.65	26.5±5.871	25.1±4.4
Weight (Kg)	57.6±5.31	58.2±5.1	57.3±5.57
Height (cm)	151.7±3.21	150.73±3.16	150.97±2.73

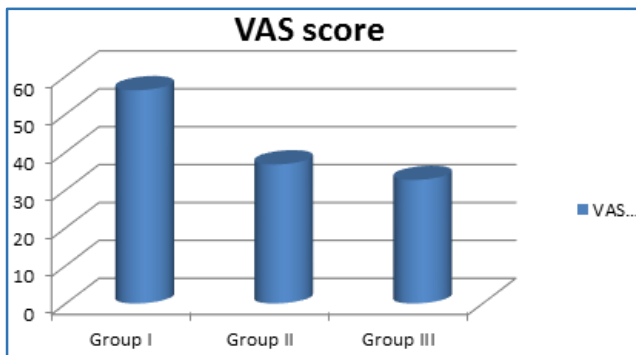
Table 3: Comparison between Demographic Data in all the Three Groups

The mean (±SD) duration of analgesia in group I, II and III was 115.67±4.09, 147.17±4.67 and 170.33±3.69 min respectively. On comparison and application of statistical analysis, there was significant prolongation in duration of analgesia between group I & II, group II & III and group I & III, i.e. there is significant prolongation of duration of analgesia in group II and group III (p<0.05) compared to group I [Graph 1].



Graph 1: Comparison of Mean (± SD) Duration of Analgesia in all the Three Groups

The mean (\pm SD) VAS score at first analgesic request in group I was 56.27 ± 5.009 , group II was 36.7 ± 5.14 and group III was 32.6 ± 6.52 respectively. There was significant ($p < 0.05$) reduction in VAS score in group II and group III when compared to group I [Graph 2].



Graph 2: Comparison of Mean (\pm SD) VAS Score in all the Three Groups

The incidence of nausea and vomiting in group II was significantly higher (6.67%) as compared to group I and III (3.33%). Similarly, incidence of shivering in group I was 13.33% as compared to 10% in group II and III. None of the patients in all the three groups had hypotension, bradycardia, dyspnoea, chest pain and dysrhythmia.

DISCUSSION

Minimising pain after caesarean section is best achieved using a multimodal approach. Local anaesthetics, ranging from lidocaine to the more recent ropivacaine, have been used as pre-emptive analgesics. The findings of this study indicate that Inj. Ropivacaine 0.2% local infiltration with intraperitoneal instillation prolongs the duration of analgesia and provides good analgesia (Lower VAS score) as compared to 0.2% ropivacaine local infiltration alone.

Local infiltration around the wound site, and even deeper in the surgical cavity, can suppress the generation and propagation of injury-induced discharge during surgical manipulations. This action may be due, in part, to inhibition of the transduction and sensitisation steps in nociception for certain local anaesthetics, for example, bupivacaine and amethocaine have been shown to block a transducing channel TRPV1-1 that plays a key role in the development of hyperalgesia after injury or inflammation.⁷ It is noteworthy that lidocaine has been shown to activate this channel, which may account for the stinging pain that accompanies s.c. injection of this local anaesthetic.⁸ Continuous delivery of local anaesthetics, from slow-release formulations or temporarily placed catheters, may extend such impulse inhibition for days after surgery. Local anaesthetics can also inhibit inflammatory and local sensitising responses, by directing suppressing some phases of inflammation, that is, neutrophil priming⁹, and by blocking some of the neuronal pathways that are activated by inflammation, that is, protein kinase C, and certain G protein-coupled receptors.^{9,10}

The mean (\pm SD) duration of analgesia in group I, II and III was 115.67 ± 4.09 , 147.17 ± 4.67 and 170.33 ± 3.69 min. respectively so there is significant prolongation of duration of analgesia in group II and group III ($p < 0.05$) compared to group I.

Nguyen K et al¹¹ also found that ropivacaine infiltration in caesarean section significantly increased the time interval to rescue analgesias compared to the control group. Labaille T et al¹² showed that intraperitoneal instillation of Ropivacaine before and after the laparoscopic surgery significantly reduces the postoperative pain compared to placebo. Similar results were obtained from other studies.^{13,14,15,16}

The mean (\pm SD) VAS score at first analgesic request in group I was 56.27 ± 5.009 , group II was 36.7 ± 5.14 and group III was 32.6 ± 6.52 respectively which shows that there was significant reduction in VAS score in group II and group III when compared to group I.

Bonnet V et al¹⁷ also showed that ropivacaine infiltration after haemorrhoid surgery lowered the VAS scores significantly and total consumption of morphine decreased. Callesen T et al¹⁸ showed that ropivacaine for combined field block and intraperitoneal instillation for pain management after laparoscopic sterilisation has significantly lesser cumulative pain score compared to placebo group during mobilisation and coughing. The maximum difference in pain scores was seen 1 hr. after operation, but after 4 hrs. there was no difference between groups.

Similar conclusions have been reported from other studies.^{19,20,21,22}

CONCLUSION

This clinical study demonstrated that Inj. Ropivacaine 0.2% local infiltration and intraperitoneal instillation produces better postoperative analgesia in caesarean section as compared to Inj. Ropivacaine 0.2% local infiltration alone under spinal anaesthesia. Inj. Ropivacaine 0.2% local infiltration with intraperitoneal instillation also prolonged the duration of analgesia and provided good analgesia (Lower VAS score) as compared to 0.2% Ropivacaine local infiltration.

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