Local Infiltration of Ropivacaine Hydrochloride 0.20% for Postoperative Analgesia in Caesarean Section under Spinal Anaesthesia - A Randomised Study

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Abstract: Smooth and complication free postoperative period is always desired after completion of surgery in every case but it becomes more important in case in caesarean section as patient has to start nurture newborn immediately. All the techniques for multimodal analgesia have some or other side effects and thus they have to be used very cautiously in postoperative caesarean section patient as they can adversely affect health of the baby also. Local infiltration of ropivacaine is effective analgesic and with lesser side effects than pharmacological drugs. Our hypothesis is that local ropivacaine infiltration reduces postoperative pain in patients undergoing caesarean section. This randomized control study was conducted on 60 patients of ASA grade 1 and 2 after taking ethics committee approval. Group I (n=30) is control group with no local infiltration and Group II (n=30) local infiltration of 20 ml Inj. Ropivacaine 0.2% at incision site. Diastolic, systolic and mean blood pressure, heart rate were measured throughout the procedure. Time of rescue analgesia and VAS score was recorded postoperatively. local infiltration of 0.2% ropivacaine provides postoperative analgesia. Mean duration of rescue analgesia in group I was 115.67±4.09 that was significant (p<0.05) in comparison to group II 147.17±4.67. local infiltration of 0.2% ropivacaine reduces postoperative pain in patients of caesarean section under spinal anaesthesia.

Keywords: Analgesia, Caeserean section, Local infiltration, Ropivacaine, Spinal anaesthesia.

INTRODUCTION

Pain is unpleasant sensory and emotional experience associated with actual and potential tissue damage [1]. The most common and distressing symptom which follows anaesthesia and surgery is pain [2].

Caeserean section is different from other surgeries as it has huge emotional component of the pregnant female and her family associated with it. There is desire and also the physiological need of patient’s body to start taking care of the newborn as soon as possible which can happen comfortably if postoperative period is complications free especially pain free.

There are so many methods of giving postoperative analgesia and traditionally maximum are pharmacological like opioids, NSAIDS, acetaminophen etc. Other methods are continuous epidural local anaesthesia, continous spinal, epidural etc.

Opioids like morphine, pethidine and other drugs provide pain relief but they also get secreted in breast milk and may cause adverse sedative effect in the newborn. Commonly used local anaesthetic agents have side-effects, although these are very rare, ranging from allergy to cardiovascular and central nervous system effects. Local anaesthetics eventually get absorbed systemically and secreted in breast milk, but their effects on breastfed babies have not yet been documented.

Ropivacaine is a long acting amide type local anaesthetic with chemical properties similar to that of bupivacaine but it is less toxic than bupivacaine [3]. In this present study ropivacaine hydrochloride 0.2% used as local infiltration at local site for postoperative pain relief.

MATERIALS AND METHODS

The present study was carried out in the Department of Anaesthesiology, G. R. Medical College and J.A. Group of hospitals, Gwalior (M.P) after...
obtaining approval from the ethics committee. The present study was carried out in 60 patients of ASA grade I & II.

Criteria for selection pregnant women undergoing Caesarean section of ASA grade I & II scheduled under spinal anaesthesia.

Exclusion Criteria for patients
- Known history of sensitivity to local anaesthetics of amide type.
- Patient’s refusal.
- Skin site infection.
- Patients on opioids.
- Raised intracranial tension, valvular heart diseases, renal diseases, endocardial diseases, metabolic diseases, hepatic diseases, coagulopathy and bleeding disorders.
- Pregnant women undergoing Caesarean section under general anaesthesia or epidural anaesthesia.

CONSENT
Details of procedure were explained to all the patients during preanaesthetic assessment and an informed and written consent was obtained.

PATIENTS’ GROUPING
60 female patients of ASA grade I & II scheduled for caesarean section under spinal anaesthesia were divided into 2 groups (n=30 each) randomly using envelope technique depending upon the infiltration.

<table>
<thead>
<tr>
<th>Group I (n=30)</th>
<th>Control group with no local infiltration</th>
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<tr>
<td>Group II (n=30)</td>
<td>Local infiltration of 20 ml Inj. Ropivacaine 0.2% at incision site</td>
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PREPARATION OF THE PATIENT
Preoperative assessment A thorough preoperative evaluation was done including history, general physical examination, systemic examination, airway and spine. Counseling was done and informed consent was taken.

Pre medication
- Intradermal sensitivity test for ropivacaine was performed
- Uniform premedication of inj. Glycopyrrolate 0.2 mg I.M was given 30 minutes before induction of anaesthesia, inj. ranitidine 50mg, inj metoclopramide 10mg.
- Preloading with Ringer Lactate in a dose of 10ml/kg BW with 18 G cannula ½ an hour before start of anaesthesia.

Anaesthesia technique
- Noninvasive sphygmo-manometer, ECG monitors and pulse oximeter were placed
- After careful aseptic cleaning and draping, a midline subarachnoid block was performed at L2/3 or L3/4 intervertebral space with the patients in the lateral decubitus position using a 25- gauge Quincke spinal needle. After free flow of CSF inj. Bupivacaine 0.5% 2 ml was injected intrathecally. Thereafter the patients were placed in the supine position for surgery. At the end of the surgery 20 ml of Ropivacaine hydrochloride 0.2% was infiltrated subcutaneously in group II while in group I, no infiltration was done.

Monitoring
Baseline observations were recorded before spinal anaesthesia. Pulse rate, electrocardiogram, systolic and diastolic blood pressure, respiratory rate and SPO2 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.

Analgesia
- Duration of analgesia i.e. the time taken from the onset of sensory block to the first request for supplemental analgesia.
- Intensity of pain and VAS score at the time of first analgesia request:
  - Assessment of pain was done by Visual Analogue Scale (VAS) which is a 10 cm scale with 100 divisions drawn on white paper representing pain. The top of the scale at 100 represents very severe pain while the baseline value-0 represents no pain.

Side effects and complications
Patients were closely observed in the intraoperative and postoperative period for complications like nausea, vomiting, dyspnoea, respiratory depression, chest pain, shivering, dysrythmia, bradycardia, hypotension and any other. The observations were recorded and subjected to statistical analysis using student’s “t” test and for qualitative variables chi square test was used. The observations recorded in all the three groups were tabulated and statistical analysis was carried out by using SPSS version 17 statistical software. For intergroup comparison, p > 0.05 and p < 0.05 were considered as insignificant & significant respectively. p< 0.01 was considered as highly significant.

Table-1: Showing demographic variables of in two groups

<table>
<thead>
<tr>
<th>Demographic data</th>
<th>Group I</th>
<th>Group II</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>24.37±3.65</td>
<td>26.5±5.87</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>57.6±5.31</td>
<td>58.2±5.1</td>
</tr>
<tr>
<td>Sex (female)</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Height (cms)</td>
<td>151.7±3.21</td>
<td>150.73±3.16</td>
</tr>
<tr>
<td>Duration of surgery (min)</td>
<td>45.66±8.87</td>
<td>42.3±5.26</td>
</tr>
</tbody>
</table>

Preoperative and intraoperative heart rate, systolic, diastolic and mean blood pressure level, SPO2 were comparable in both the groups.

DISCUSSION

The present study entitled “local infiltration of ropivacaine hydrochloride 0.2% for postoperative analgesia in caesarean section under spinal anaesthesia - a randomised study” was conducted to assess the duration of analgesia between two groups. A total of 60 pregnant women (ASA grade I and II) posted for caesarean section under spinal anesthesia were randomly divided into two groups according to the drug received as shown below:

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

Pain is the most feared component associated with any surgical procedure. A good anaesthesia is that when it makes patient pain free throughout the surgery and in the post-operative period too.

Table-2: Mean (±SD) time for first rescue analgesia in two groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group I (n=30)</th>
<th>Group II (n=30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time for first Rescue Analgesia (mins)</td>
<td>115.67±4.09</td>
<td>147.17±4.67</td>
</tr>
</tbody>
</table>

Table-3: Comparison of mean (± SD) vas scores in two groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group I (n=30)</th>
<th>Group II (n=30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS score</td>
<td>56.27±5.099</td>
<td>36.7±5.14</td>
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</table>

Significantly (p<0.05) low VAS scores in Group II compared to Group I.

Caesereean section patients should be especially made pain free and comfortable as delivered female has to look after newborn also.

There are so many methods of giving postoperative analgesia and traditionally maximum are pharmacological like opioids, NSAIDS, acetaminophen etc. Other methods are continuous epidural local anaesthesia, continuous spinal, epidural etc.

Opioids like morphine, pethidine and other drugs provide pain relief but they also get secreted in breast milk and may cause adverse sedative effect in the newborn. Commonly used local anaesthetic agents have side-effects, although these are very rare, ranging from allergy to cardiovascular and central nervous system effects. Local anaesthetics eventually get absorbed systemically and secreted in breast milk, but their effects on breastfed babies have not yet been documented.

Ropivacaine is a long acting amide type local anaesthetic with chemical properties similar to that of bupivacaine but it is less toxic than bupivacaine [3].

In present study, selected groups were comparable for the demographic variables like age, height, weight and sex parameters, type and duration of surgery and with P> 0.05. Heart rate, SBP, DBP and MAP were comparable in both the study groups throughout the perioperative period.

As shown in table 2, the mean (±SD) duration of analgesia in group I and II was 115.67±4.09 and 147.17± 4.67min respectively. On comparison and application of statistical analysis there was significant prolongation in duration of analgesia in group II when compared to group I

Goldstein a et al. [4] showed that bupivacaine and ropivacaine for preventing postoperative pain by local anesthetic instillation after laparoscopic gynecologic surgeries reduces the morphine consumption.

Nguyen K et al. [5] showed that ropivacaine infiltration in caesarean section significantly increased the time interval to rescue analgesia compared to control group which did not receive any infiltration.

Mulroy M F et al. [6] showed that Ropivacaine infiltration (0.25% and 0.75%) into the wound following hernia surgery significantly provides pain relief compared to control group.
Pasqualucci et al. [7] showed that Bupivacaine as intraperitoneal local anesthetic blockade before or after surgery reduces the postoperative pain compared to placebo.

Bamigboy A et al. [8] showed that ropivacaine used in abdominal wound infiltration and peritoneal spraying reduces amount of rescue analgesic as compared to the control group.

VAS score comparison between two groups showed lowered VAS score in group in which ropivacaine was infiltrated when compared with the control group.

Bonnet V et al. [9] showed that ropivacaine infiltration after hemorrhoid surgery the VAS scores at 1, 3 & 6 hrs after infiltration are lowered.

Dreher J et al. [10] showed women receiving ropivacaine had significantly lower pain scores 2 hrs post operatively (0.97 vs 2.03 p<0.05) compared to the control group.

Kim T H et al. [11] showed that the VAS score was significantly lower in ropivacaine intraperitoneal instillation group than in control group at 4, 8 and 12 hrs.

CONCLUSION

In the present study, the demographic data such as age, height and weight was statistically comparable between two groups (Group I and Group II). The Mean (± SD) duration of surgery was also comparable statistically between two groups (p>0.05).

The mean (±SD) duration of analgesia in group I and II was 115.67±4.09 and 147.17±4.67min respectively i.e. pain control was better in patients infiltrated with local anaesthetic than those given nothing along the suture line.

The mean (± SD) VAS score at first analgesic request in group I and II was 56.27±5.009 and 36.7±5.14 respectively. On statistical comparison there was significant reduction in VAS score in group I and II compared to group I(p<0.05).

On hemodynamic parameters, there was no significant change in mean (±SD) pulse rate, systolic blood pressure, diastolic blood pressure and respiratory rate both the groups at various time intervals.

Thus we conclude that local infiltration of the incision line with 02% ropivacaine after completion of caesarean section results in better and prolonged pain control.

REFERENCES

6. Muelroy, M. F., Burgess, F. W., & Emanuelsson, B. M. (1999). Ropivacaine 0.25% and 0.5%, but not 0.125%, provide effective wound infiltration analgesia after outpatient hernia repair, but with sustained plasma drug levels. Regional anesthesia and pain medicine, 24(2), 136.

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