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Evaluation of 0.25% Bupivacaine vs. 0.375% Ropivacaine for Postoperative Analgesia using Transversus Abdominis Plane Block for Caesarean Section: A Comparative Study

Dr. G. Udayarani[1], Dr. P. S. Arunalatha[2]

[1]PG Final year student, Department of Anaesthesia, govt. medical college, Anantapur, 515001

[2]Associate Professor, Department of Anaesthesia, Govt. Medical College, Anantapur, 515001
Mail id: *likeudaya07[at]gmail.com*

Abstract: ***Background: Pain after Caesarean section is described as moderate to severe by most patients. Transversus Abdominis Plane (TAP) block has a definite role in multimodal analgesia in lower abdominal surgeries. Hence this study was undertaken to compare 0.25% Bupivacaine with 0.375% Ropivacaine for postoperative analgesia using TAP block in caesareans ection. Methods: Forty patients were randomized into Group B (n=20) and Group R (n =20). TAP block was administered after completion of surgery using conventional landmark technique with 15mL of 0.25% Bupivacaine in Group B and 15mL of0.375% Ropivacaine in Group R on each side of the abdomen. Time to requirement of first analgesic dosage was observed in both the groups. Total analgesic requirement in the first 24 h, visual analogue scale (VAS) scores at 2, 4, 6, 8, 12 and 24h patient satisfaction and complications were also noted. Results: Mean time for the first dose of rescue analgesia after completion of surgery was 298.2±93.6 min in Group B and 447.6±85.2 min in Group R (P=0.0001). Total requirement of Diclofenac Sodium injection was 162.86±46.88mg in Group B whereas it was only 130.71± 44.49 mg in Group R (P=0.003). VASat 4, 6 and 8 h after surgery were significantly lower in the Ropivacaine group. Conclusion: 0.375% Ropivacaine provided longer duration of analgesia and resulted in lesser analgesic requirement than 0.25% Bupivacaine when used in TAP block after caesarean section.***

Keywords: Bupivacaine, ropivacaine, transverses abdominis plane block

1. Introduction

Caesarean section is one of the most common surgical procedure performed these days. Approximately 15% of childbirths occur by caesarean section and this figure continues to rise with a fairly large number of present day mothers opting for an elective caesarean section over a normal vaginal delivery. Pain after caesarean section is described as moderate to severe by most of the patients.

Failure to alleviate like sedation and respiratory depression whereas NSAIDs as a single modality are most often insufficient to treat pain after Caesarean section. Epidural analgesia is a good alternative but the gravid uterus increases chances of dural and vascular punctures during insertion of needle or catheter besides it being a time consuming and technically demanding procedure in pregnant patients. Various modalities including systemic opioids, non-steroidal anti-inflammatory drugs (NSAIDs) and epidural analgesia have been used for the purpose of reducing postoperative pain.

Opioids are associated with undesirable effects like sedation and respiratory depression whereas NSAIDs as a single modality are most often insufficient to treat pain after Caesarean section. Transversus Abdominis Plane (TAP) block is a safe regional anaesthetic technique which is now increasingly being used for postoperative analgesia for caesarean section, hysterectomy and various other surgeries involving the lower abdomen. Ropivacaine and Bupivacaine are the most commonly used local anaesthetic (LA) agents used for administering TAP block [1, 2]. There have been many studies comparing 0.5% bupivacaine and 0.75% of ropivacaine when used for various peripheral nerve blocks and most of them have shown a similar efficacy when used in above-mentioned concentrations.

We undertook this prospective randomized study to compare 0.25% bupivacaine and 0.375% ropivacaine for postoperative analgesia using TAP block in caesarean section which is half the concentration of LA generally used for this purpose. Time to requirementof first analgesic dosage was the primary outcome of thestudy. Total analgesic requirement in the first 24 h, visualanalogue scale (VAS) scores at 2, 4, 6, 8, 12, and 24 h, patient satisfaction and complications with both the local anaesthetics were the secondary outcomes.

2. Materials and Methods

After approval from Institutional ethical committee, this prospective randomized study was conducted in patients undergoing lower segment caesarean section (LSCS) surgery under spinal anaesthesia. All the patients undergoing elective LSCS under spinal anaesthesia were included in the study. Any patients with features of infection on the anterior abdominal wall, known history of allergy to the local anaesthetic drugs and coagulopathy were excluded from the study. Forty patients were randomized two groups, the Bupivacaine group (Group B, n = 20) and Ropivacaine group (Group R, n = 20) using acomputer generated algorithm and concealment done using opaque sealed

envelope. Written informed consent was taken from all patients.

All the patients were administered spinal anaesthesia in either left lateral or sitting position using 2.4 mL of 0.5% Bupivacaine (Heavy).26 Gauge Quincke's needle was used to administer the subarachnoid block in either L3-4 or L4-5 subarachnoid space. Inj Midazolam 1mg intravenous and Inj Fentanyl 0.5 mg/kg body weight was administered afterthe delivery of the child if patient required any sedation, anxiolysis or analgesia. After the completion of surgery patients were administered TAP block using conventional landmark technique on both the sides of the abdomen using a 23 Gauge needle with the point of insertion between the costal margin and iliac crest in the anterior axillary line.30mL of 0.25% Bupivacaine was administered in Group B patients with 15 mL being injected on either side and similarly 30mL of 0.375% Ropivacaine was injected in patients randomized to Group R with 15mL on either side of the abdomen. Patient were assessed for pain in the postoperative period using a 10 cm long VAS scale with 0 being no pain and 10 being the worst imaginable pain at 2, 4, 6, 12, 18, and 24h after surgery. Time to requirement of first dose of rescue analgesia was noted which was given when VAS >3. Injection Diclofenac Sodium 75 mg administered by intramuscular route was used for this purpose restricted to a maximum of 3 doses in 24h with a gap of 8h in between two doses. Adequate hydration was maintained for all the patients. Total requirement of rescue analgesia in 24h was noted in both the groups. Any postoperative complications and patient satisfaction in both the groups was recorded.

Statistical analysis:
Taking results of other similar studies performed else where we presumed that the time to first requirement of rescue analgesia would be atleast 60 min less in the Bupivacaine group when compared to Ropivacaine group. With SD of±2.5 a sample size of 20 cases was considered adequate for a study with 80% Power and 95% Confidence interval. Quantitative data is presented as mean±SD. For normally distributed data mean has been compared using unpaired *t*-test. For skewed data or scores Mann-Whitney test was applied. Categorical variables have been presented as number and percentages. Chi-square test or Fisher's exact test has been applied for categorical data. Ordinal data has also been presented as number and percentage. Between two groups it has been compared using Mann Whitney test. All calculations are two sided and were performed using SPSS version 20 (Statistical Packages for the Social Sciences, Chicago, IL). A *P* value of <0.05 has been considered statistically significant.

3. Results

Out of 50 patients assessed for eligibility, 40 patients were enrolled and randomized into Group B and Group R with 20 patients in each group. All these patients completed the study and the data obtained from them was used for statistical analysis. Both the groups were similar in terms of patient characteristics, duration of surgery and the requirement of intraoperative sedation, anxiolysis or analgesia [Table1].

Patients were followed up in the postoperative period. Mean time for the first dose of rescue analgesia after completion of surgery was 298.2±93.6 min in Group B and 447.6±85.2 min in Group R (*P*=0.0001). Total requirement of Diclofenac Sodium injection was 162.86±46.88 mg in Group B where as it was only 130.71±44.49 mg in Group R (*P*=0.003) [Table2].

VAS scores for pain in the postoperative period were compared in both the groups. No difference was noted in pain scores at 2, 12 and 24h in between both the groups but pain scores at 4, 6 and 8 h after surgery were significantly lower in the Ropivacaine group [Table3]. Both the groups were identical in terms of patient satisfaction (*P*=0.26) [Table4]. No complications related to local anaesthetics were noted in either of the groups.

4. Discussion

Severity of pain after caesarean section has been described as moderate to severe by most of the patients and this may interfere not only with care of the new born child and breast feeding but also impair the bonding between the mother and the child. Besides the risk of thrombo embolism also increases as the ambulation of the mother may be delayed because of pain. Hence it is of utmost importance that the pain is alleviated considerably to avoid the above mentioned situations. TAP block has emerged as one of the front runners among the modalities available for pain relief in such subset of patients owing to its efficacy, safety and ease of administration.

Bupivacaine and Ropivacaine are the most commonly used local anaesthetic for TAP block these days and there have been many studies comparing the efficacy of 0.5% Bupivacaine with 0.75% of Ropivacaine when used for various types of peripheral nerve blocks. However the data comparing these two agents for postoperative analgesia among patients undergoing caesarean section is lacking. We know that pregnant patients are more prone to systemic toxicity of local anaesthetics in the immediate postoperative period due to reduced albumin concentration and lower plasma binding. Hence we decided to use 0.25% of Bupivacaine and 0.375% Ropivacaine in our study which is half the concentration of LA used for such purposes. After the surgery first dose of analgesic was administered at 298.2±93.6 min in the Bupivacaine group and 447.6±85.2 min in the Ropivacaine group (*P*=0.0001).

As mentioned earlier we could not find any studies in the literature where both these agents have been compared for this subset of patients. However we could find three studies comparing bupivacaine and ropivacaine for postoperative analgesia in various other surgeries.

In the study by Fuladi N *et al.* [3] 75 adult patients undergoing elective unilateral lower abdominal surgery were randomized to undergo TAP block with ropivacaine (*n*=25), bupivacaine (*n* = 25) or normal saline (*n* = 25). At end of surgery performed under spinal anaesthesia unilateral TAP block on side of surgery was performed using 20mL of 0.5% ropivacaine or 0.25% bupivacaine or saline. Each patient was assessed postoperatively for every 5 min for half an

hour, then every 15 min till 2 h and at 4, 6, 12, 24 and 48 h postoperatively in ward. The authors found out that the mean duration of analgesia was 420.6+14.01 min in Bupivacaine group and 2187 ± 1011.09 min in Ropivacaine group and the difference was found to be statistically significant.

In the study by Sharma N *et al.* [4] 60 adult patients undergoing elective abdominal surgery under general anaesthesia were randomly divided into two groups and after induction of anaesthesia received unilateral or bilateral TAP Block (depending upon nature of incision ofsurgery) using either 15 mL of 0.5% Ropivacaine or 0.25% Bupivacaine on each side. Post-operatively patients were assessed for pain with VAS score at 0min, 30min, 4, 8, 12, 18 and 24 h. Mean duration of analgesia in Ropivacaine group and Bupivacaine group was 12.61±5.13hrsand9.92 ± 4.81 h, respectively, and the difference was found to be statistically significant.

Our study has similar findings where in the duration of analgesia in the Ropivacaine group is significantly more than the Bupivacaine group. However the duration of analgesia in our study is comparatively less than what hasbeen observed in other two studies. This could be attributed to the fact that the strength of Ropivacaine used in both the studies is 0.5% whereas in our study we used 0.375%. In the study by Fuladi N *et al.*, 20 mL of local anaesthetic was used and the surgeries were only on one side of the abdomen. In the study by Sharma N *et al.* also a lot of patients underwent surgery only on one side of the abdomen and this could have contributed to the difference in duration of analgesia achieved in their studies vis-à-vis our study. Nevertheless it is Ropivacaine which has more prolonged analgesia as observed by all three studies. Ropivacaine has some intrinsic vasoconstrictor properties and this to could have led to the difference in the duration of analgesia achieved by both the local anaesthetics.

Total requirement of Diclofenac Sodium injection over a period of 24h was 162.86±46.88 mg in Group B whereas it was only 130.71 ± 44.49 mg in Group R (P = 0.003). This difference is on anticipated lines as most of the patients required 3 doses of Diclofenac Sodium in the Bupivacaine group whereas a majority of patients in the Ropivacaine group required only 2 doses due to longer duration of analgesia achieved. Our results are different from another study where even though the total postoperative analgesic requirement in Bupivacaine group was higher than the Ropivacaine group but the difference was not statistically significant. In the study by Sinha S *et al.*, [5] 60 adults undergoing elective laparoscopic cholecystectomy were randomised to receive ultra sound guided TAP block at theend of the surgical procedure with either 0.25% bupivacaine or 0.375% ropivacaine. All patients were assessed for postoperative pain and rescue analgesic consumption at 10 min, 30 min, 1 h, 4 h, 8 h, 12 h and 24 h time points. They also did not find any difference in the 24 h cumulative analgesic requirement in between both the groups. The results of both these studies are different from us in terms of 24 h cumulative analgesic requirement but it will beprudent to note here that the subset of patients and type surgery in our study is entirely different from that in the above mentioned studies.

VAS scores for pain in the postoperative period were comparable in both the groups at 2, 12 and 24 h but pain scores at 4, 6 and 8h after surgery were significantly lower in the Ropivacaine group in our study. It is attributable to the fact that the analgesia lasted comparatively longer in the Ropivacaine group and hence better pain scores inintermediate duration. However it is similar at 2 h as the effect of local anaesthetic would be present equally in both the groups whereas at 12 and 24 h the effect would have dissipated in both the groups and hence the VAS scoreswould again be similar. Fuladi N *et al.* reported lower VAS scores with Ropivacaine at 2, 4, 6 and 12 h whereas Sharma N *et al.* reported significantly lower VAS scores at 8 and 12h after cessation of surgery. However in the study by Sinha S *et al.* VAS scores with Ropivacaine were lower only at 10, 30 and 60 min after surgery and the authors did not find any significant difference in VAS scores at 4, 8, 12 and 24h.

Patient satisfaction is an important aspect and our study is unique in this regard as not many studies had looked into patient satisfaction with the use of various drugs. Both Bupivacaine and Ropivacaine were found to have similar levels of satisfaction and none of the patients were unsatisfied with the use of either Bupivacaine or Ropivacaine in our study. Also none of the patients in either groups had any complications associated with the technique as well as Local anaesthetics.

We did not compare 0.25% Bupivacaine and 0.375% Ropivacaine with either Placebo or other conventional modalities of pain relief like NSAIDs or opioids and this is one of the limitations of the study. Besides the assessment of pain scores was not continuous but at specific time periods which could have altered the total analgesic requirement. We also could have used more volume of the drug not exceeding the toxic dose which could have further prolonged the duration of analgesia achieved with both the agents.

Nevertheless within limitations of our study we conclude that 0.375% Ropivacaine provided longer duration of analgesia than 0.25% Bupivacaine when used in TAP block for postoperative analgesia after caesarean section. Also the total analgesic requirement was lower with the use of Ropivacaine. Hence Ropivacaine can be used as a safe alternative for Bupivacaine, routinely forTAP block after caesarean section. We also recommend that further studies may be undertaken in this subset of patients using the increased concentrations or volume of both the local anaesthetics, not exceeding the safe limits of their dosage to see if more prolonged analgesia can be achieved which may further reduce the analgesic requirement, without causing any adverse effects.

Table 1: Demographic and other patient characteristics

Patient characteristics	Group B (n=20)	Group R (n=20)	P
Age (yr) Mean + SD	21.57+7.56	23.69+7.69	0.242
Weight (kg) Mean + SD	6.422+9.41	68.43+8.30	0.11
Height (Cm) Mean + SD	158.16+7.31	160.34+5.33	0.905
BMI	25.99+3.32	26.96+2.64	0.179

Mean + SD			
Duration of surgery Mean + SD	48.51+9.89	47.14+6.05	0.749
Intra operative sedation Mean + SD	9 (25.7%)	12 (34.3%)	0.353

Table 2: Postoperative rescue analgesia

Rescue analgesia	Group B (n=20)	Group R (n=20)	P
Time for first dose Mean + SD (min after surgery)	298.2 +93.6	447.6 +85.2	0.0001
Total analgesic requirement in 24 h (mg) Mean + SD	162.86 + 46.88	130.71 + 44.49	0.003

Table 3: Postoperative VAS scores

Time after surgery (h)	Group B (n=20) VAS Mean + SD	Group R (n=20) VAS, Mean + SD	P
2	0.00+ 0.66	0.00+0.00	0
4	3.23 +1.92	1.77+1.37	<0.0001
6	4.03+1.52	3.66+1.17	0.01
8	5.03+1.56	4.77+0.84	0.04
12	5.17+1.88	4.83+1.14	0.89
24	4.37+1.34	4.63+0.94	0.96

Table 4: Patient satisfaction

Patient satisfaction	Group B (n=20) Number (% Age)	Group R (n=20) Number (% Age)	P
Excellent	11 (55 %)	9 (45%)	0.28
Good	7 (35%)	7 (35%)	
Satisfactory	2 (10%)	4 (20%)	
Unsatisfactory	Nil	Nil	

Conflicts of interest
There are no conflicts of interest

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