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COMPARISON OF INTRATHECAL LEVOBUPIVACAINE WITH FENTANYL AND BUPIVACAINE WITH FENTANYL IN CESAREAN SECTION

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ABSTRACT

Backgrounds: Levobupivacaine may be preferred over bupivacaine for spinal anaesthesia (SA) in caessarian section (CS) of being less haemodynamic changes and shorter duration of motor block. Hence the present study was designed with primary objective of comparing the clinical effects of two drugs.

Methods: Group B (n=50) and group L (n=50) received 1.8 ml of 0.5% bupivacaine and levobupivacaine with 25 µg fentanyl (0.5 ml) intrathecally respectively. Motor block and sensory block were assessed with Bromage scale and pinprick method.

Results: Duration of motor block was found to be significantly shorter in group L (153.6±36 min) as compared to group B (189.9±22.6 min). Group L had longer onset, equal level and shorter duration of sensory block as compared to group B. The duration of effective analgesia was shorter in group L than in group B. Quality of surgical anaesthesia, Apgar score and side effects were similar in both the groups.

Conclusion: Levobupivacaine allowing early mobilization with lesser incidence of hypotension.

KEYWORDS : Cesarean section, bupivacaine, levobupivacaine

INTRODUCTION

The quest for safer and newer anesthetic agents has seen numerous modifications over the last two decades. [1] Till date 0.5% hyperbaric bupivacaine has been the most commonly used drug in spinal anaesthesia (SA) for cesarean section (CS). Levobupivacaine has pharmacodynamic and pharmacokinetic properties resembling those of bupivacaine but has lesser cardiotoxicity, neurotoxicity and reduced motor blockade. [2,3] Lesser duration of motor block allows early ambulation, therefore decreases the chances of deep vein thrombosis and also facilitates mother and child bonding. Hence the present study was designed with primary objective of comparing the clinical effects of two drugs.

MATERIALS AND METHODS

After Institutional Ethical Committee approval, 100 women of ASA physical status I or II scheduled for CS, were enrolled into this randomized, double-blind study. Patient refusing for SA, having any contraindication to SA, major systemic illness, psychiatric disturbances, any history of drug abuse, height < 145 cm, weight < 40 kg or > 100 kg, or not able to communicate in either hindi/English language were excluded from the study.

All Patients were explained on method of sensory, motor and pain assessment. After shifting the patient to the operating table standard monitoring were attached and baseline values of heart rate (HR), blood pressure (BP) and oxygen saturation (SpO_2) were noted. The patients were preloaded with 15 ml/Kg of Ringer's lactate solution over 15-20 minutes. SA was performed at L3/L4 intervertebral space using by 25G disposable Quincke's spinal needle. After confirming free flow of cerebrospinal fluid (CSF), randomized patients were given 1.8 ml of 0.5% hyperbaric bupivacaine with 25 µg fentanyl (0.5 ml), total 2.3 ml (group B) or 1.8 ml of 0.5% isobaric levobupivacaine with 25 µg fentanyl (0.5 ml), total 2.3 ml (group L) slowly. Sensory block was assessed by loss of sensation to pin prick using 24G disposable hypodermic needle in the mid axillary line bilaterally. Motor block was assessed by Bromage scale (0 = no paralysis, able to flex hips/knees/ankles; 1 = able to move knees, unable to raise extended legs; 2 = able to flex ankles, unable to flex knees; 3 = unable to move any part of the lower limb). Pain was assessed using a 10 cm linear visual analogue scale (VAS), where 0 means no pain and 10 means maximum pain. A hypotensive episode was defined as a Systolic BP less than 100 mm of Hg or a decrease in SBP more than or equal to 20% of baseline values. It was managed by rapid infusion of 250 ml of Ringers' lactate solution and 6 mg mephentermine intravenous (i.v) in incremental doses. Time to first analgesic request (duration of analgesia), neonatal Apgar score and any side effect like nausea, vomiting, pruritus etc were also noted. Vitals were monitored every 2 min for initial 10 min and then every 5 min till 20 min and then every 10 min till end of surgery, thereafter, every half hourly for the first two hours, then hourly during postoperative period till first analgesic request.

The data for quantitative variables was presented in terms of mean ± standard deviation (SD)/ median (range) and in terms of frequency (%) for categorical variables. The statistical significance of quantitative variables between two groups was determined using unpaired't'-test/ non parametric test, in case data do not follow normal distribution. The statistical significance of categorical variables between two groups was determined Chi Square test/ Fischer exact test.

RESULTS

A total of 50 patients in each group were included in this study. The patients' demographic profile including age, weight, height and duration of the surgery were comparable in both the groups [Table 1]. The time of onset of sensory block (loss of sensation at T12 level) and the time taken to achieve highest level of sensory block was significantly longer in group L (p= 0.0001). The highest level of sensory block achieved in maximum number of the patients was T4-T5 in both the groups. (Table 2) T4 level was achieved in greater number of patients in both the groups. The duration of sensory block (loss of sensation at T12 level to regression of sensory block to T12 level) was significantly more in group B (p=0.029). (Table 2)

The onset of motor block (Bromage score 1) was 2.62 ± 0.08 and 1.96± 0.06 min in group L and B respectively. The time taken to achieve maximum motor block (Bromage score 3) was 7.26 ± 1.18 and 6.14 ± 1.06 min in group L and B respectively. All parturient achieved Bromage 3 in the group B versus 74% parturient in the group L. The duration of motor block i.e. time to achieve Bromage score 0 after the onset, was found to be significantly shorter in group

L (153.6±36.0 min) as compared to group B (189.9 ±22.6 min) (p = 0.0001). (Table 2)

Duration of effective analgesia i.e. the time to receive the first analgesic was significantly shorter in group L than in group B. (Table 2) In group L, the quality of anaesthesia was excellent for 49 patients (98%), 1 (2%) patient complained of vague symptoms suggestive of visceral pain intraoperatively and hence had to be supplemented with one bolus of injection ketamine, therefore was graded as good quality of anaesthesia. In group B, all patients (100%) had excellent quality of anaesthesia.

Hypotension occurred in 11 patients (22%) in group L and in 21 patients (42%) in group B (p value = 0.03). Bradycardia was observed in 2 patients (4%) of group B and none of group L, which was not statistically significant. There was no significant difference between the average doses of mephentermine required to treat hypotension in both the groups. Nausea occurred in 15 (14%) patients in group B and 12 (24%) patients in group L. Vomiting was seen in 8 (16%) patients in group B and 6 (12%) patients in group L. Pruritus occurred in 17 (34%) patient in group B as compared to 15 (30%) patients in group L. (Table 3) Apgar score at 1 min and 5 min was 8.80±0.40 and 9.02±0.24 in group B, 8.74±0.44 and 8.98±0.14 in group L, respectively. These values across the two groups did not show any statistically significant difference. (Table 4)

DISCUSSION

The fentanyl dose added in our study was based on "dose– response relationships" of fentanyl with other local anesthetics used intrathecally in various study published previously. Duration of effective analgesia was longer with Group B compared to Group L in our study which was comparable with Ayesha Goyal et al. [4] In our study, anesthesia was 100 % successful with 25 mcg fentanyl added to 10 mg bupivacaine. One patient complained of vague symptoms suggestive of visceral pain with 10 mg levobupivacaine with 25 mcg fentanyl administered.

The onset of sensory block between bupivacaine and levobupivacaine is comparable with the study done by Ayesha Goyal et al who found that the onset of sensory blockade was shorter with bupivacaine than levobupivacaine. [4] Similar to our study the highest level achieved was similar in other studies. [4,5] The level of sensory block achieved in our study was T4-T5. The time taken to achieve the highest level of sensory block was shorter in bupivacaine group as compared to levobupivacaine group which are in concordance with the studies. [4,6] P. Gautier et al who also found the same results but the difference were statistically insignificant. [4] Result of the study done by Ayesha Goyal et al are contradictory to our result in which the duration was longer in levobupivacaine. [3]

With respect to onset of motor block, our results were comparable Ayesha Goyal et al, whereas Glaser C et al found an insignificant difference in the onset of motor block with bupivacaine and levobupivacaine. [3,4] In our study, less number of patients achieved Bromage 3 score in levobupivacaine group as compared to bupivacaine group. This result was comparable with studies done by Coppejans et al et al. [7] Similar to our study, the time taken to achieve the maximum motor block was significantly longer in group L as compared to group B in other studies. In our study the duration of motor blockade was shorter with levobupivacaine which was similar to other studies but there was no significant difference in the studies done by Glaser C et al. [4]

However no case reported of any fetal toxicity by use of bupivacaine and levobupivacaine during SA. The intrathecal rate of drug absorption is so low that potential fetal drug load come down to about one tenth of that given epidurally. Our results are similar to the other studies showing both the groups to be comparable with respect to the mean Apgar score at 1 and 5 min interval. In our study incidence of hypotension was significantly less in group L as compared to group B. These results were similar to the results of other studies found that the incidence of hypotension was similar with bupivacaine and levobupivacaine. There was no statistically significant difference in the incidence of bradycardia and average dose of vasopressor required to treat hypotension in our study which is similar to the studies done by other investigators except for Gulen Guler et al who found that the incidence of bradycardia was significantly more common with bupivacaine than levobupivacaine. [8]These study limitations, however, apply to most investigator-driven clinical trials in obstetric anaesthesia.

CONCLUSIONS

To conclude 0.5% isobaric levobupivacaine administered intrathecally produces an excellent quality of anaesthesia in majority of the patients undergoing cesarean section, similar to that produced by 0.5% hyperbaric bupivacaine. It produces a shorter duration of sensory and motor blockade as compared with 0.5% hyperbaric bupivacaine; allowing early mobilization of the patients after surgery with lesser incidence of hypotension.

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Conflicts of interest: none.

Table 1- Demographic Profile of Patients

Parameter	Group B Mean±SD (n = 50)	Group L Mean±SD (n = 50)	p-Value
Age (yr)	25.34±3.00	26.3±3.94	0.17
Weight (Kg)	58.16±4.55	57.66±4.67	0.58
Height (cm)	158.30±1.19	158.32±1.62	0.94
Duration of Surgery (min)	65.4±13.20	59.6±16.74	0.05

Table 2 - Characteristics of Sensory and motor block and analgesic effect

Parameter		Group B Mean±SD (n = 50)	Group L Mean±SD (n =50)	p-Value
Onset of sensory block (min)		1.52±0.58	2.14±0.75	0.0001
Time taken to achieve max level (min)		2.60±0.63	5.04±1.73	0.0001
Highest level achieved	T4	30 (60%)	37 (74%)	0.137
	T5	20 (40%)	13 (26%)	
Duration of Sensory Block (min)	203.90±21.88	193.80±23.59	0.029	
Duration of Motor Block (min)	189.90±22.64	153.60±36.05	0.0001	
Duration Of Effective Analgesia	Time for first rescue analgesia (min)	219.60±19.91	208.80±27.05	0.025
Quality Of Anaesthesia (Excellent)	50 (100%)	49 (98%)	0.315	

Table 3 – Incidence of Intraoperative hypotension and bradycardia

Parameter		Group B (% of patients) (n = 50)	Group L (% of patients) (n = 50)	p-Value
Hypotension No. of patients (%)		21 (42%)	11 (22%)	0.03
Bradycardia No. of patients (%)		2 (4%)	0 (0%)	0.15
Dose of Mephenteramine (mg) used		6.57± 1.80	6 0.0	0.30
Side effects	Nausea	15 (14%)	12 (24%)	0.49
	Vomiting	8 (16%)	6 (12%)	0.56
	Pruritus	17 (34%)	15 (30%)	0.66

Table 4 – Neonatal effect (Apgar score)

Apgar Score at time	Range (min-max)	Group B Mean ± SD (n = 50)	Group L Mean ± SD (n = 50)	p-Value
1 min	8 – 9	8.80 ± 0.40	8.74 ± 0.44	0.48
5 min	8 – 10	9.02 ± 0.24	8.98 ± 0.14	0.32

REFERENCES

1. Bajwa SJ, Kaur J.Clinical profile of levobupivacaine in regional anesthesia: a systematic review.J Anaesthesiol Clin Pharmacol. 2013; 29:530-9.
2. Bardsley H, Gristwood R, Baker H, Watson N, Nimmo W. A comparison of the cardiovascular effects of levobupivacaine and rac-bupivacaine following intravenous administration to healthy volunteers. Br J Clin Pharmacol. 1998; 46:245-9.
3. Foster RH, Markham A. Levobupivacaine: a review of its pharmacology and use as a local anaesthetic. Drugs. 2000; 59:551-79.
4. Ayesha Goyal, P. Shankaranarayan, P. Ganapathi. A randomized clinical study comparing spinal anesthesia with isobaric levobupivacaine with fentanyl and hyperbaric bupivacaine with fentanyl in elective cesarean sections. Anesthesia: Essays and Researches 2015; 9: 57–62.
5. Bremerich D, Kuschel S, Fetsch N, Zwissler B, Byhahn C, Meininger D. Levobupivacaine for parturients undergoing elective caesarean delivery. a dose-finding investigation. Anaesthesist. 2007; 56:772-9.
6. Turkmen A, Moralar DG, Ali A, Altan A. Comparison of the anesthetic effects of intrathecal levobupivacaine+fentanyl and bupivacaine+fentanyl during caesarean section. Middle East J Anaesthesiol. 2012; 21:577-82.
7. HakanErbay R, Ermumcu O, Hanci V, Atalay H. A comparison of spinal anesthesia with low-dose hyperbaric levobupivacaine and hyperbaric bupivacaine for transurethral surgery: a randomized controlled trial. Minerva Anestesiol. 2010; 76:992-1001.
8. Guler G, Cakir G, Ulgey A, Ugur F, Bicer C, Gunes I et al. A comparison of spinal anesthesia with levobupivacaine and hyperbaric bupivacaine for cesarean sections: a randomized trial. Open J Anesthesiol. 2012; 2:84-9.