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Comparison of Levobupivacaine and Fentanyl with Levobupivacaine in Patients undergoing Surgeries Under Spinal Anaesthesia

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Abstract

Aims & Objective: We experimented the comparison of levobupivacaine & fentanyl with levobupivacaine in spinal anaesthesia in lower abdominal surgeries. A total of 80 patients of ASA grade I, aged 18-60 yrs of either sex scheduled for lower abdominal surgeries were divided into 2 equal groups in a randomized pattern. Patients in group LF (n =40), received 0.5% isobaric levobupivacaine 7.5mg (1.5ml) + fentanyl 25ug(0.5ml) +Normal saline (0.5ml) and in group L (n = 40), received 0.5% levobupivacaine 10mg (2ml) + Normal saline (0.5 ml) intrathecally. The onset and duration of sensory and motor block, time to achieve maximum sensory & motor level, time to regression of sensory level, duration of analgesia, & time of ambulation were analyzed in both groups. Statistical analysis done with SPSS 17 software and p value <0.05 taken as significant. The mean time of onset of sensory & motor blockade were 2.65±.95 min and 3.68±.73 min in group LF and 2.55±.90 min &3.75 ± .67 in group L respectively. Maximum level of sensory block achieved in group LF. Time to 2 Segment Regression Level was more in group L as compared to group LF. The durations of motor block were 162.75 ± 15.02 and 185.25 ± 11.54 min respectively in group LF and group L. The duration of analgesia was 161.00 ± 15.49 min in group LF compared to 135.75 ± 15.55 min in group L (p < 0.001). Time of ambulation was 252.00 ± 23.34 and 315 ± 20.38 min respectively in group LD. There was statistically significant difference present in duration of motor blockade and analgesia and time of ambulation between 2 groups. Addition of fentanyl in spinal block with low dose levobupivaicane increase the duration of motor block with prolonged duration of analgesia and reduce ambulation time.

Keywords: Fentanyl, Spinal anaesthesia, levobupivacaine

Introduction

James Leonard Corning (1855–1923), a neurologist from New York was the first one to make use of spinal anesthesia in animals. August Bier in 1898 used the local anaesthetic cocaine as spinal anaesthesia on human being. Later many other anaesthesiologist used spinal Anaesthesia on humans using different local anaesthetics for example Braun in 1905 used procaine, Gordh in 1949 used lidocaine, Foldes and McNall in 1952 used

chlorprocaine and Emblem in 1966 used bupivacaine. Ropivacaine and levobupivacaine were used as spinal anaesthesia first in the 1980s.[1] Spinal anaesthesia is easy to perform, reliable, provides excellent operating conditions for the surgeon & less costly than general anaesthesia. A higher level of sensory block acquired by increasing the dose of long acting local anaesthetics may produce extensive sensory and motor block as well as arterial hypotension and this might result in delayed discharge from hospital[2]. In the anaesthesia line, levobupivacaine has presented a strong case against the traditional bupivacaine in last few years. Levobupivacaine is a pure S (−)-enantiomer of Bupivacaine. Levobupivacaine has been found to be equally effective as bupivacaine, but with superior pharmacokinetic implications[3]. Traditionally, a low-dose of Bupivacaine in combination with Fentanyl has been used for lower abdominal surgeries[4] but very minimal comparative data is available regarding the use of Levobupivacaine with intrathecal Fentanyl. The intrathecal usage of a combination of opioids and local anaesthetics provides agood synergistic effect without delayed hospital discharge or prolonged motor nerve block.[5,6] The objective of this study is to identify the effects of minimum dose of spinal Levobupivacaine in combination with intrathecal Fentanyl in lower abdominal surgeries regarding recovery time, ambulation time period and effects on the cardiovascular and central nervous system .

Materials and methods

The present study was approved by the Ethics Committee of the Institution. This study was conducted as prospective, randomized, placebo controlled, double blind study in Department of Anaesthesiology, Index Medical college, Indore(MP).

Eighty patients of ASA grade I**,** age group 18 to 60 years of either sex admitted for lower abdominal surgeries were included for study. Patients with contraindication to spinal block, cardiopulmonary diseases, known allergy ,coagulation dysfunction, chronic neuropathy& any patient refusal were excluded from study.

After taking written informed consent from patients, preanaesthetic assessments of all the selected patients were done with complete history and physical examination. Routine investigations like complete blood count, blood sugar, blood urea, serum creatinine, chest X-ray and ECG were done. Patients were randomized into 2 groups of 40 patients each via randomly generated number.

Group-I (LF 40) - 0.5% isobaric levobupivacaine 7.5mg (1.5ml) + fentanyl 25ug(0.5ml) +Normal saline (0.5ml)

Group-II (L 40) - 0.5% levobupivacaine 10mg (2ml) + Normal saline (0.5 ml)

Patients were kept fasting overnight and advised tab. 0.25 mg Alprax as premedication on the day before surgery.

Upon arrival of the patient in the operation theatre, intravenous access with 18 G cannula was established and patient was preloaded with Ringer's Lactate solution (10 ml/kg) over a period of 15-20 minutes. Patients were monitored by heart rate (bpm), systolic & diastolic blood pressure (mmHg), respiratory rate & oxygen saturation (SpO_2). After all aseptic precautions the patient was prepared with savlon, povidone iodine and spirit in succession followed by draping. After identifying the bony landmarks L3-4, interspinous space was identified.The 25 G Quincke needle was inserted and the subarachnoid space was identified by the clear free flow of CSF.In Group-I (LF 40) 2.5 ml of total volume 0.5% isobaric Levobupivacaine 7.5mg(1.5ml) + Fentanyl 25ugs(0.5ml) + 0.5ml normal saline and in Group- II (L 40) 0.5% Levobupivacaine 10mg(2ml) + normal saline (0.5 ml) was given. The patient was made to lie supine immediately and all monitors were attached (NIBP, ECG and SpO2).All patients were given oxygen @ 4-6 litres per minute via face mask intraoperatively. The

haemodynamic was monitored every 2 minutes for the first 10 minutes; for every 5 minutes for next half hour; every 10 minutes for next half hour and thereafter every 15 minutes till the end of the surgery.

Monitoring of sensory block

The analgesic level was determined by a loss of pin prick sensation in the midclavicular line on both sides of the body. This was monitored for every 2 minutes for the first 10 min and then as per the intraoperative chart. The surgery was allowed when adequate sensory levels were achieved. All determinations of sensory level were based on a standard dermatomal chart.

Monitoring of motor block

The intensity of motor block was graded bilaterally by the Modified BromageScale[7] with time periods identical to the monitoring of sensory block every 2 min for the first 10min, every 5 minutes for the every 2 min for the first 10min, every 5 minutes for the next half hour and then as per the intraoperative chart.

No motor block----------0

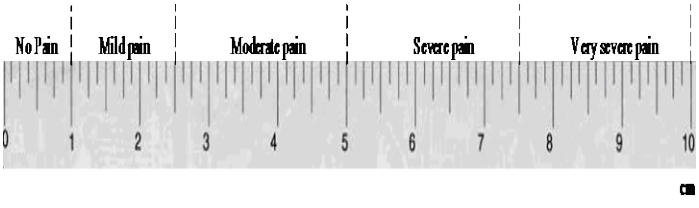
Not able to raise the extended legs----------1

Not able to flex the knee----------2

Not able to flex the foot----------3

Postoperative Pain was assessed using a visual analogue score scale in which gradations marked as '0'means no pain at all and '10'means unbearable pain when VAS score reached ≥ 4, inj. diclofenac 75 mg given intramuscularly were given. The time between end of local anaesthetic given and first analgesic requirement was noted as duration of analgesia.

VAS score rating[8]:



VAS score was recorded every 30 min in the postoperative period till the conclusion of study. Time of Ambulation is measured as time interval from intrathecal drug injection to first getting out of bed without assistance.

Patients were closely observed for bradycardia (below 20% of basal value), hypotension (below 20% of basal value) & desaturation (<85%) during intra and postoperative period. During postoperative period along with above nausea, vomiting, respiratory depression and shivering were also recorded if occurred. Any complication if occurred was treated with appropriate medications.

The observations were recorded and subjected to statistical analysis using statistics calculator SPSS 17.00 version. Student's t test was used for analysis of quantitative and χ^2 (chi square) test was used to analyze qualitative data. p-value <0.05 was taken statistically significant.

Results

The groups were well matched for age, weight & male:female ratio. Both groups had male patients predominantly. The statistical difference was insignificant (p>0.05).

Baseline haemodynamic values were comparable in both groups. Table-2 shown that In group LF time of onset of sensory block at T10 was 2.65 ± 0.95 min and in group L 2.55 ± 0.90 min. Time to achieve maximum sensory level was 4.65 ± 0.95 min in group LF and in 4.55 ± 0.90 min in group L (p>0.05). In Group LF, higher sensory level was achieved than Group L (p value< 0.001). In group LF time to two segment regression level was 75.00 ± 4.80 min and in group L was 79.13 ± 6.78 min which was statistically significant. In group LF time of Onset of motor block was 3.68 ± 0.73 min and in group L was 3.75 ± 0.67 min. In group LF time to achieve maximum modified Bromage score was 8.55 ± 0.90 min and in group L was 8.50 ± 0.88

min($p>0.05$). Maximum motor score achieved was 2 in all the patients of both the groups. Duration of motor block was 162.75 ± 15.02 min and 185.25 ± 11.54 min in group LF & group L respectively. Duration of analgesia was 161.00 ± 15.49 min and 135.75 ± 15.55 min in group LF & group L respectively. Mean time of ambulation in group LF was 252.00 ± 23.34 min and in group L was 315.00 ± 20.38 min. ($p<0.001$). There was no significant difference between group LF and group L in respect of onset time of sensory and motor blockade. Duration of analgesia and motor blockade were significantly prolonged in group LF ($p<0.001$). Intraoperative and postoperative haemodynamic data were comparable in both groups. No side effect such as nausea, vomiting, hypotension and bradycardia were seen in both groups.

Table 1: Demographic profile of 2 groups.

PARAMETERS	GROUP LF		GROUP L	
	MEAN	±SD	MEAN	±SD
AGE(Yrs)	43.98	11.75	40.5	10.69
WEIGHT(Kgs)	61.65	7.19	61.82	7.05
SEX (M:F)	39:1		38:2	

Table 2. Comparison of study parameters between 2 groups

Parameters	Group LF		Group L		
	Mean	±SD	Mean	±SD	p value
Onset time of sensory blockade at T10 (min)	2.65	0.95	2.55	0.90	0.631
Time to achieve maximum sensory level (min)	4.65	.95	4.55	.90	0.631
Maximum level of sensory block achieved (Dermatome)	7.75 T7(T6 - T8)	.67	8.55 T9 (T8 – T10)	0.90	<0.001
Time to 2 Segment Regression Level (min)	75.00	4.85	79.13	6.88	0.002
Time of Onset of motor block (min)	3.68	.73	3.75	.67	0.633
Time to Achieve Maximum Modified Bromage Score (min)	8.55	.90	8.50	.88	.808
Maximum Modified Bromage Score	2.00	.00	2.00	.00	-
Duration of motor block (min)	162.75	15.02	185.25	11.54	<0.001
Duration of effective analgesia (min)	161.00	15.49	135.75	15.55	<0.001
Time of Ambulation	252.00	23.34	315.00	20.38	<0.001

Discussion

Spinal anaesthesia is the most commonly used technique for infraumbilical Surgeries. Recent advances in anaesthesia has allowed more surgeries to be performed on day care basis. The properties of an anaesthetic agent used for day case surgeries in spinal anaesthesia should have decreased incidence of anaesthesia related complications, should provide adequate postoperative analgesia and allow early patient discharge.[9]

The usage of Levobupivacaine has increased significantly in last few years owning to its safer pharmacological profile. By using very small doses of local anaesthetic, one can limit the distribution of spinal block, but low dose bupivacaine cannot provide an adequate level of sensory block. Intrathecal opioids enhance analgesia from sub therapeutic dose of local anaesthetic and make it possible to achieve successful spinal anaesthesia using otherwise inadequate doses of local anaesthetic[10]. In our study we compared levobupivacaine & fentanyl with

levobupivacaine in spinal anaesthesia in lower abdominal surgeries.

Results of our study shown that there was no significant difference in onset of sensory & motor blockade in both groups.Our observations are in accordance with the findings of NK Girgin et al[11], Akcaboy E et al[12] & Ben-David et al[13]. Time to achieve maximum sensory level was not significant in both groups. These findings are similar to study done by Ben-David et al[13]& Kuusniemi et al[14]. Maximum level of sensory block achieved in group LF as compared to group L. Our findings were similar to the studies done by Cuvas O et al.[15] also found T9 (T4-T10) and T6 (T3-T10) in Group L and in Group LF, respectively. He concluded that levobupivacaine plus fentanyl solution is more hypobaric than the pure levobupivacaine solution. This could possibly explain the higher level of sensory block achieved in LF group[15].Time to two segment regression was more in group LF than group L.This was in accordance with studies done by Misirlioglu K et al[16] &NK Girgin et al.[11] Maximum motor score achieved was 2 in all the patients of both the groups in our study. Our findings were similar to the studies done by NK Girgin et al.[11] & Akcaboy E et al[12]. Our findings revealed that duration of motor blockade prolonged in Group LF as compared to Group L. This was in accordance with study done by Unlugenc H et al [17] &NK Girgin et al[11].

Duration of analgesia as assessed by VAS score was prolonged in Group LF as compared to Group L. Our observations are in accordance with the findings of Choi DH et al[18],M.B.Khezri et al[19] & Chung CJ et al[20]. Time of ambulation was more in group L as compared to group LF. These findings are similar to the studies done by NK Girgin et al[11].

Our findings showed that there was no signicant difference in intraoperative and postoperative heart rate and blood pressure in both groups. Our observations are in accordance with the findings of NK Girgin et al[11] & Akcaboy E et al[12].

No complication was found in both groups.

Conclusion

Combination of intrathecal fentanyl with low dose levobupivacaine provides good quality surgical anaesthesia with early motor recovery which could lead to early ambulation of the patient as a day case surgery.

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