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A COMPARATIVE STUDY TO EVALUATE THE EFFICACY OF LEVOBUPIVACAINE VERSUS ROPIVACAINE FOR POST OPERATIVE ANALGESIA UNDER SEGMENTAL SPINAL ANAESTHESIA IN LAPAROSCOPIC CHOLECYSTECTOMY.

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ABSTRACT Laparoscopic cholecystectomy is normally performed under general anaesthesia, but regional techniques like segmental spinal have been emerging and found beneficial. Nowadays laparoscopic surgeries are commonly performed on a day care basis. Although of less intensity, laparoscopic surgeries do have some amount of pain. This post-operative pain, to some extent, limits early post operative recovery and extends hospital stay. Segmental spinal provides excellent post operative analgesia. **Materials and methods:** Total 40 patients aged between 18 and 65 years of either sex, with American Society of Anaesthesiologist status(ASA) I/II and body mass index >18.5 to <25, scheduled to undergo elective laparoscopic cholecystectomy were enrolled for the study. Patients were randomized into two groups with 20 patients in each group using coded sealed envelopes. Segmental spinal anaesthesia was given at T9-10 space using 27 gauge spinal needle, Group L received 1.5ml Levobupivcaine(0.5%)+Inj Fentanyl (25mcg) while Group R received 1.5ml Ropivacaine (0.5%)+ inj Fentanyl(25mcg) intrathecally. **Results:** The demographic details and the postoperative hemodynamic were comparable in both the groups .Overall mean VAS score was statistically significant (p< 0.05) between the two study group R and L at 30 minutes,1 hour and 4 hour postoperatively. Out of 20 patients in group R, maximum number of patients i.e. 10 (50%) required rescue analgesia at 1st hour. Among group L, maximum number of patients i.e. 8 (40%) required rescue analgesia at 8th hour. **Conclusion:** In comparison to the Ropivacaine group, the duration of postoperative analgesia was significantly prolonged in the Levobupivacine group. Both Levobupivacaine and Ropivacaine provide good hemodynamic stability.

KEYWORDS : Levobupivacaine, Ropivacaine, Segmental Spinal anaesthesia, Laparoscopic cholecystectomy

INTRODUCTION

Laparoscopic cholecystectomy is the gold standard treatment of symptomatic gallstones.[1] Visceral pain following laparoscopic surgery perceived due to stretching of intraperitoneal cavity, peritoneal inflammation, and irritation of phrenic nerve whereas pain in open procedure is mainly somatic in nature. Segmental spinal anaesthesia provides excellent analgesia for both somatic and visceral pain.[2]

Ropivacaine (RB) and levobupivacaine (LB) have been compared extensively when administered in neuraxial blocks or other peripheral nerve blocks.[3] Levobupivacaine is a single-enantiomer preparation consisting of the S enantiomer of bupivacaine. Compared with racemic bupivacaine, levobupivacaine has considerably reduced CNS and cardiovascular toxicity, allowing a larger dose to be given.[4]

Ropivacaine a new long-acting amide local anaesthetic agent, is a pure S-enantiomer, with a high pKa and relatively low-lipid solubility. Because of its physical and chemical properties, ropivacaine produces a marked differential in sensory and motor blockades, with a toxic potential lower than other long-acting anesthetic solutions.[5]

MATERIALS AND METHODS

Total 40 patients aged between 18 and 65 years of either sex, with American Society of Anesthesiologists physical status I/II and body mass index >18.5 to <25, scheduled to undergo elective laparoscopic cholecystectomy were enrolled in the study. Patients with any history of drug allergy, psychiatric illness, substance abuse, severe co morbid conditions pertaining to cardiovascular, respiratory, neurological or metabolic system, pregnancy, sepsis, severe coagulopathy, complex stones with anticipated access points >2, receiving chronic opioid therapy, back or musculoskeletal deformity, cases converted to general anaesthesia and fibromyalgia were excluded from the study. The patients were randomized using coded sealed envelopes. Detailed history and pre-anaesthetic evaluation was done one day prior to surgery of all the patients to rule out any associated disease. Necessary investigations were done as an when required. Pre-operatively, all the patients were informed about the procedure. Patients were instructed on how to use a 0-10 graded Visual Analogue Scale for pain with anchors ranging from `no pain' to 'worst possible pain, in the post-operative period. The patients were asked to remain nil per oral 8 h before surgery.

In Operation theater, a good intravenous (IV) access was secured for preloading and a monitor was attached for monitoring electrocardiogram, heart rate (HR), non invasive blood pressure, oxygen saturation (SpO_2), temperature, and respiratory rate. Patients were preloaded with 500 ml lactated Ringer's solution

Patients were pre medicated with inj. Glycopyrolate (4 mcg/kg) and inj. Midazolam (1 mg) intravenously. Segmental thoracic spinal anesthesia was given using 27-gauge spinal needle, in T9-T10 inter spinous space, midline approach in sitting position. After confirming its placement by free flow of clear cerebrospinal fluid, Group-L: Patients received 1.5ml Levobupivcaine (0.5%) + Inj Fentanyl (25mcg) Intrathecally Group R: Patients received 1.5ml Ropivacaine (0.5%)+ inj Fentanyl(25mcg) Intrathecally.

Finally, the patients were turned to the supine horizontal position for the operation, and oxygen was started at 5 L/min by face mask. Onset of action and level of sensory block was judged by pin prick method every minute until the establishment of desired block. Sensory block achieved between T4-T12 was considered as adequate block.

The overall quality of intra operative muscle relaxation (poor, fair, good, or excellent) was evaluated by the surgeon at the end of the surgery. Hypotension was defined as systolic blood pressure <90 mmHg or >20% decrease in baseline values and was treated by fluids and vasopressors (mephentermine 6 mg). Bradycardia was defined as HR <50/min and was treated by 0.6 mg of atropine injection. HR, blood pressure, and SpO_2 were recorded every 5 min. Intra- and post-operative complications such as nausea, vomiting, pain, pruritus, headache, or any other side effects were recorded. For pneumoperitoneum, CO2 insufflation was done, Intra abdominal pressure was maintained between 12-15 mm Hg. To prevent shoulder tip pain due to diaphragmatic irritation Inj Fentanyl 50 mcg and Ketamine infusion at 25 mcg/kg/min was started.

Patients were assessed for post operative pain using a visual analogue scale (VAS) at 15,30 minutes and at 1, 2, 4, 8 and 12 hours. Heart rate, blood pressure, respiratory rate, Spo2 were assessed. Rescue analgesia consisted of paracetamol (1gm) and injection diclofenac sodium (75 mg) were given if the VAS score was ≥ 4.

Statistical analysis

In our study, data were presented as Mean ± SD, proportion or n (%). One-way analysis of variance (ANOVA) and t-test were used for comparison between groups and P values < 0.05 were considered significant. Statistical analysis was done using software SPSS 20.0 version.

RESULTS

A total of 40 patients were included in the study. Demographic details of group L and group R are summarized in table 1

Table 1: Demographic details of group L and group R (Mean±SD)

Variables		Group R (n=20) (Mean±SD)	Group L (n=20) (Mean±SD)	p value
Age(ye ars)		39.95±11.93	42.85±10.34	0.416
Height(cm)		155±4.87	154.45±4.88	0.723
Weight (kg)		65±9.51	60.35±10.46	0.149
Sex	Male	5(25%)	4(20%)	0.705
	Female	15(75%)	16(80%)	

Patients studied in the two study groups were between 18-65 years of age and between 45 to 85 kg. The distribution of patients according to age, sex, height and weight were found to be statistically insignificant amongst the both groups (P > 0.05) and the two groups were comparable. There was female preponderance in both study groups. M: F ratio was 1:3 (5:15) in group R and 1:4 (4:16) in group L.

Table 2: Duration Of Surgery

Variables	Group R (n=20) (Mean±SD)	Group L (n=20) (Mean±SD)	p Value
Duration of surgery(min)	70.5±7.20	69.7±6.92	0.723

Statistically no significant difference was found in overall duration of surgery in between two groups.(P > 0.05) Mean duration of surgery in group R and L was 70.5±7 and 69.7±6.92 respectively.

Table 3: Onset time of sensory block, time to achieve adequate block height and duration of sensorial block

Variable	Group R (n=20) (Mean ± SD)	Group L(n=20) (Mean ± SD)	p value
Onset time of sensory block (min)	2.975 ± 0.34	2.075 ± 0.12	<0.001
Time to achieve adequate block height (min)	7.3 ± 1.12	6.2 ± 0.95	0.0019
Duration of sensory block(min)	97.3 ± 3.74	119.2 ± 6.20	<0.001

Onset time of sensory block was 2.975±0.34 in group R and group L (2.075±0.12) which was statistically significant (p value<0.001).Time to achieve adequate block height was higher in group R(7.3±1.12) compared to Group L(6.2±0.95). Total duration of sensory block was 97.3±3.74 in group R and 119.2±6.20 in group L(p value <0.001).

Table 4: Visual analogue score in postoperative period

Time	Group R(n=20) (Mean ± SD)	Group L(n=20) (Mean ± SD)	p value
15 min	0.55 ± 0.51	0.65 ± 0.48	0.530
30 min	1.35 ± 0.48	0.60 ± 0.50	<0.001
1 hour	3.30 ± 0.80	1.90 ± 0.78	<0.001
2 hour	3.05 ± 0.75	2.50 ± 1.14	0.081
4 hour	2.25 ± 0.63	3.00 ± 0.91	0.004
8 hour	3.05 ± 0.60	3.25 ± 0.71	0.346
12 hour	2.50 ± 0.51	2.45 ± 0.51	0.759

Patients were assessed for post- operative analgesia by using VAS at 0 minute (immediate post extubation) at 15 minutes, 30 minutes, 1,2,4,8,and 12 hours. Overall mean VAS score was statistically significant (p< 0.05) between the two study group R and L at 30 minutes,1 hour and 4 hour postoperatively.

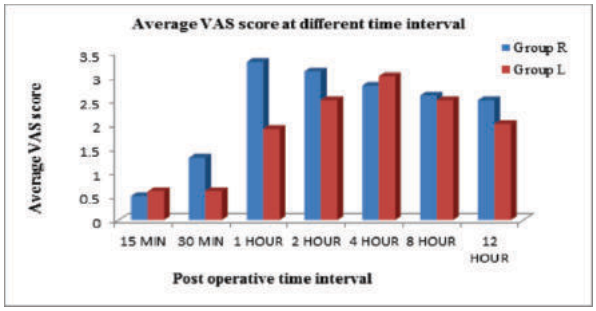

Figure 1: Average VAS score at different time interval

Rescue Analgesia Requirement

Rescue analgesia consisted of paracetamol (1gm) and injection diclofenac (75 mg) was given if the VAS score was ≥ 4. The number of patients requiring rescue analgesia at different post- operative time intervals in the three study groups is shown in the figure 2 .

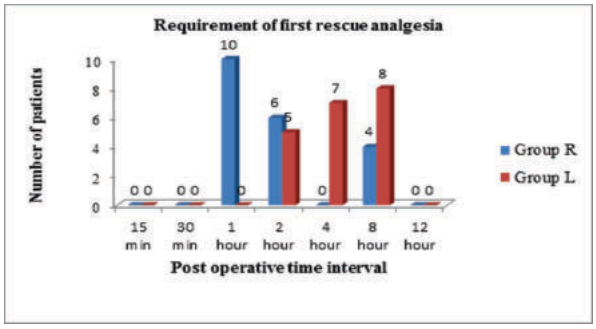

Figure 2: Requirement of first rescue analgesia

Out of 20 patients in group R, maximum number of patients i.e. 10 (50%) required rescue analgesia at 1st hour followed by 6(30%). Among group L, maximum number of patients i.e. 8 (40%) required rescue analgesia at 8th hour followed by 7 (35%) at 4th hour.

Table 5: Comparison of postoperative heart rate (HR) (Mean±SD)

Time	Group R(n=20) (Mean ± SD)	Group L(n=20) (Mean ± SD)	p value
0 min	75.65 ± 2.05	75.15 ± 3.57	0.590
30 min	89.00 ± 2.44	86.05 ± 4.83	0.019
1 hour	88.15 ± 2.20	86.00 ± 5.17	0.095
4 hour	83.15 ± 5.99	82.55 ± 6.04	0.754
8 hour	83.50 ± 5.82	79.80 ± 5.14	0.039
12 hour	82.05 ± 6.16	81.85 ± 5.93	0.917

Post operatively mean HR was on higher side in group R as compared to group L which was persistently on lower side. The difference in mean HR between the two study groups R and L was statistically significant at 30 min post- operatively (P<0.05)

Table 5: Comparison of postoperative mean arterial pressure (MAP) (Mean±SD)

Time	Group R(n=20) (Mean ± S.D)	Group L(n=20)(Mean ± S.D)	p value
0 min	79.40 ± 5.11	81.55 ± 6.23	0.240
30 min	87.80 ± 5.42	90.30 ± 4.16	0.110
1 hour	89.00 ± 4.79	83.20 ± 5.74	0.001
4 hour	84.80 ± 5.86	81.10 ± 3.93	0.024
8 hour	78.90 ± 4.39	78.20 ± 4.50	0.621
12 hour	77.25 ± 2.14	77.25 ± 3.41	1.000

The difference in MAP amongst group R and group L was significant at 1st hour post- operatively (P>0.05).

Table 6: Comparison of incidence of side effects in both group

Side effects	Group R (n=20)	Group L (n=20)
Shivering	3(10%)	2(6.66%)
Nausea and vomiting	4(13.33%)	2(6.66%)
Dyspnoea	0(0%)	0(0%)
Hypotension	0(0%)	0(0%)
Chest pain	0(0%)	0(0%)

Nausea and vomiting was seen in 4 out of 30 (13.33%) patients of group L and was seen in 2 out of 30 (6.66%) patients belonging to group R. Shivering was noted in 3 (10%) patients of group L but only in 2 (6.66%) patients in group R. No other side effects were seen in any of the groups.

DISCUSSION:

Laparoscopic surgeries being minimally invasive procedures offer many advantages to the patients and hospital services. In comparison to conventional laparotomy, laparoscopic surgeries have reduced hemorrhage, smaller and more cosmetic incision, which reduces pain, reduced risk of acquiring infections thus shorten recovery time, less hospital stay and less expenditure.

Segmental spinal anaesthesia is a technique of regional anaesthesia that can potentially be a suitable alternative to general anaesthesia for

certain cases such as laparoscopic surgeries, particularly in patients who are considered at high risk while under general anaesthesia. General anaesthesia is the standard for most surgeries; however, some drawbacks can include negative drug side effects, prolong recovery, and inadequate pain control. There is currently renewed attention to thoracic segmental spinal anaesthesia for several common surgeries. Injection of anaesthetics intrathecally into the preferred body height and above where the spinal cord terminates has been revealed to be valuable in these certain circumstances.[6]

As shown in Table 1 the (mean ±SD) age (in yrs) of patients in group R and group L were 39.95±11.93 and 42.85±10.34 respectively. The (mean ±SD) weight (in kgs) of the patients in group R and group L were 65±9.51 and 60.35±10.46 respectively. The (mean ±SD) height (in cms) of the patients in group R and group L were 155±4.87 and 154.45±4.88 respectively. There was female preponderance in both study groups.

Onset time of sensory block was 2.975±0.34 in group R and group L (2.075±0.12) which was statistically significant (p value<0.001).Time to achieve adequate block height was higher in group R(7.3±1.12) compared to Group L(6.2±0.95).Total duration of sensory block was 97.3±3.74 in group R and 119.2±6.20 in group L.(p value <0.001)

Overall mean VAS score was statistically significant (p< 0.05) between the two study groups R and L at 30 minutes,1 hour and 4 hour postoperatively. Levobupivacaine was hemodynamically more effective than Ropivacaine (p<0.05).These results were in accordance with Gupta P et al[7] and Narra G R 6.et al [8]

Higher VAS scores were observed in group R when compared to group L (<0.05). These results are similar with a study by Papagiaunopoulou et al.[9], who evaluated the analgesic efficacy of Levobupivacaine (0.5%), Ropivacaine (1%), and normal saline (0.9%) and concluded that the Levobupivacaine group had significantly lower VAS scores than the Ropivacaine group.

CONCLUSION:

This preliminary study has shown that segmental spinal anaesthesia can be used successfully and effectively for laparoscopic surgery in healthy patients. Both Levobupivacaine and Ropivacaine provide good relaxation, hemodynamic stability intra and post operatively. However, Levobupivacaine provide longer duration of sensory block and post operative analgesia than Ropivacaine.

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