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COMPARISON OF INTRAPERITONEAL AND PERIPORTAL 0.5% LEVOBUPIVACAINE AND NORMAL SALINE FOR POSTOPERATIVE PAIN RELIEF IN LAPAROSCOPIC CHOLECYSTECTOMY

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ABSTRACT

AIMS AND OBJECTIVES: To evaluate and compare the efficacy of intraperitoneal and periportal 0.5% Levobupivacaine and normal saline for postoperative pain relief in laparoscopic cholecystectomy.

MATERIAL AND METHOD: 60 patients ASA grade I & II undergoing elective cholecystectomy . Patients were classified randomly into 2 groups (thirty patients in each group). Group P (n=30): 30 ml of normal saline ,Group L (n=30): 30 ml of 0.5% Levobupivacaine hydrochlori .Randomization was done with the closed envelope technique. A 20 ml of test solution was instillated , by the operating surgeon, on the upper surface of liver and on right sub-diaphragmatic space, under the vision of camera, through the epigastric port with the help of 18 G Spinal needle. Patient was kept in Trendelenberg position for 5 minutes. At the end of procedure, intra-abdominal CO_2 was carefully vented out by the surgeon and 10 ml of the test solution was injected as skin infiltrate into all sites of incision post operatively , patients were assessed for parietal pain and visceral pain using a 100 mm VAS scale at 30 min and at 1, 2, 3, 4, 6,12 and 24 hours. Rescue analgesia consisted of an inj. Tramadol 100 mg intravenous (slow) if the VAS score was more than 50.

RESULT: Analysis revealed that there were no significant differences between the patients with respect to age, sex, weight, duration of surgery, HR and blood pressure . Duration of postoperative analgesia observed from the time of reversal to first demand of analgesia in the recovery room was more in group L compared to group P. The total analgesic consumption in 24 hours postoperatively, was more in placebo group than in Levobupivacaine group.

CONCLUSION: There was significant prolongation of duration of postoperative analgesia in Levobupivacine group as compared to placebo group. In terms of analgesic efficacy, Levobupivacaine appears to be superior to placebo .

KEYWORDS : Levobupivacain , Rescue Analgesia

INTRODUCTION:

Pain is defined as *"an unpleasant sensory and emotional experience associated with actual or potential tissue damage or in terms of such damage."*[1]

Definition of postoperative pain is *"condition of tissue injury together with muscle spasm after surgery"*[2].

Visceral pain following laparoscopic surgeryis perceived due to stretching of intraperitoneal cavity, peritoneal inflammation and irritation of phrenic nerve whereas pain in open procedures is mainly somatic in nature.

Levobupivacaine is an amino amide type of local anesthetics. The reduced toxicity of Levobupivacaine provides a wider safety margin in the daily clinical practice either as single shot or for continuous infusion, as well as for postoperative pain control[3].

MATERIAL AND METHODS:

60 patients ASA grade I & II undergoing elective cholecystectomy . Patients were classified randomly into 2 groups (thirty patients in each group). Group P (placebo) (n=30): 30 ml of 0.5% Normal saline ,Group L (n=30): 30 ml of 0.5% Levobupivacaine hydrochlori .Randomization was done with the closed envelope technique. A 20 ml of test solution was instillated, by the operating surgeon, on the upper surface of liver and on right sub-diaphragmatic space, under the vision of camera, through the epigastric port with the help of 18 G Spinal needle. Patient was kept in Trendelenberg position for 5 minutes. At the end of procedure, intra-abdominal CO_2 was carefully vented out by the surgeon and 10 ml of the test solution was injected as skin infiltrate into all sites of incisionPost operatively , patients were assessed for parietal pain and visceral pain using a 100 mm VAS scale at 30 min and at 1, 2, 3, 4, 6,12 and 24 hours.

Blood pressure and heart rate were assessed at 30 min, then at 1, 2, 3, 4, 6, 12 and 24 hours. Time to first rescue analgesia, sedation, nausea and vomiting, dizziness, backache and urinary retention were also assessed. Rescue analgesia consisted of an injection of tramadol 100 mg intravenous (slow) if the VAS score was more than 50.

The statistical analysis of this study was done by using Paired and Unpaired T test and using SPSS 20.0 version, where p value <0.05 was considered statistically significant and p value >0.05 was taken as statistically insignificant.

RESULT AND ANALYSIS :

TABLE- 1 Demographic Data in the two groups

Variable	Group L (n=30)	Group P (n=30)	p – value
	Mean±SD	Mean±SD	
Age (yrs)	41.0 ± 11.8	39.6 ± 12.5	0.46
Weight (Kgs)	60.4 ± 6.53	57.4 ± 7.23	0.10

Table showing the demographic data, the mean (±SD) age of the patients in group L and P were (41.0 ± 11.8) and (39.6 ± 12.5) respectively and the mean (±SD) weight of the patients in group L and P were (60.4 ± 6.53) and (57.4 ± 7.23) respectively.

There was no statistically significant difference in age or weight of the patients among the two groups (p>0.05).

TABLE-2 Sex (M: F) Distribution in two study groups

S. NO.	Sex	Group L		Group P	
		(n)	(%)	(n)	(%)
1.	Male	5	16.6	6	20
2.	Female	25	83.4	24	80
3.	Total	30	100	30	100

The table shows that majority of patient in both the groups were females.

TABLE -3 Duration of surgery (mins) in the two groups

Variable	Group L (n=30)	Group P (n=30)	p –value
	Mean± SD	Mean± SD	
Duration of surgery (mins)	88.54 ± 12.48	89.38±16.60	0.80

Table showing the mean (±SD) duration of surgery and the statistical comparison (p value) of duration of surgery in the two groups.

There was no statistically significant difference in duration of surgery among the two groups (p>0.05).

TABLE -4

Time		Group L	Group P
		Mean ± SD	Mean ± SD
Preoperative		87.20±12.53	90.68±12.37
POST OPERATIVE	30 min	93.80±14.30	91.65±12.04
	1 hour	90.16±13.38	89.43±12.58
	2 hour	88.20±12.46	86.26±9.93
	3 hour	87.36±9.52	86.06±10.05
	4 hour	90.86±10.51	87.26±10.80
	6 hour	86.73±13.66	84.33±8.58
	12 hour	90.16±13.38	89.43±12.58
	24 hour	88.20±12.46	86.26±9.93

Comparison of Perioperative pulse rate (Mean ± SD) in the two Groups

Table showing the pulse rate (Mean ± SD) of group L and group P at various time intervals.

TABLE -5 Comparison of Peri-operative systolic blood pressure (Mean ± SD) in the two groups

Time		Group L	Group P
		Mean ± SD	Mean ± SD
Preoperative		118.73±10.64	118.6±11.32
POST OPERATIVE	30 min	120.06±11.20	117.33±7.88
	1hour	118.26±10.04	115.13±7.00
	2 hour	116.46±9.16	114.40±7.39
	3 hour	116.80±9.34	114.93±7.27
	4 hour	116.70±9.16	115.46±6.68
	6 hour	120.60±9.52	118.33±5.82
	12 hour	118.20±7.50	116.06±7.28
	24 hour	116.36±8.05	114.66±5.61

Table showing the systolic blood pressure (Mean ± SD) of group L and group P at various time intervals.

TABLE -6 Comparison of Peri-operative diastolic blood pressure (Mean ± SD) in the two groups

Time		Group L	Group P
		Mean ± SD	Mean ± SD
PREOPERATIVE		80.13±7.53	79.13±8.57
POST OPERATIVE	30 min	78.03±9.49	77.00±7.78
	1hour	78.06±8.36	77.40±6.85
	2 hour	76.53±6.96	76.40±5.83
	3 hour	76.60±8.00	76.40±6.46
	4 hour	75.26±13.23	77.06±7.99
	6 hour	78.23±7.92	76.33±6.74
	12 hour	75.80±5.80	76.13±4.75
	24 hour	74.60±4.90	75.73±4.74

Table showing the diastolic blood pressure (Mean ± SD) of group L and group R at various time intervals.

Table -7 Mean (±SD) Time for First Rescue Analgesia in the two groups

Variable	Group L (n=30)	Group P (n=30)
	Mean+ SD	Mean+ SD
Time for First Rescue Analgesia (mins)	235.21± 25.20	10.56 ± 5.41

Table showing the Mean (±SD) time for First Rescue Analgesia in the two groups.

Time for First Rescue Analgesia is greater in group L as compared to group P.

Table -8 Statistical comparison (p value) of Time for First Rescue Analgesia (mins) in the two groups

Variable	Group L Vs. Group P
	p value
Time for first Rescue Analgesia (mins)	<0.05

Table showing the statistical comparison (p value) of Time for First Rescue Analgesia (mins) in the two groups.

The time for First Rescue Analgesia was significantly greater in group L as compared to group P(p<0.05)

TABLE -9 statistical comparison (p value) of VAS score in the two groups at different postoperative time intervals

Time		Group L	Group P	Grp L vs Grp P
		Mean ± SD	Mean ± SD	P value
POST OPERATIVE	30 min	5 ± 7.24	62.66± 8.13	<0.05
	1hour	12 ± 7.89	46.33 ± 12.01	<0.05
	2 hour	18.7 ± 4.70	35.6 ± 6.78	<0.05
	3 hour	28.7 ± 9.5	40.66 ± 6.39	<0.05
	4 hour	42.7 ± 4.09	49.33± 4.08	<0.05
	6 hour	31.08 ± 8.30	41. 68± 6.09	<0.05
	12 hour	51.33 ±8.60	50 ± 8.3	0.54
	24 hour	10 ± 7.88	11.67 ± 9.13	0.45

Table showing Statistical comparison (p value) of VAS score in the two groups at different postoperative time intervals.

Significant difference was found in the VAS score between the two groups in the first 6 hrs post operatively.

Table -10 Mean (± SD) VAS score in the two Groups

Variable	Group L (n=30)	Group P (n=30)	Grp L vs Grp P
	Mean ± SD	Mean ± SD	P value
VAS score	28.04 ± 3.23	48.83± 3.13	<0.05

Table showing the Mean (±SD) of VAS score and the statistical comparison (p value) of VAS score in the two groups.

Group L had a lower mean VAS score as compared to Group P which was statistically significant (p< 0.05).

Table -11 Statistical Analysis of total analgesic consumption in 24 hrs in the two groups

Variable	Group L (n=30)	Group P (n=30)	Grp L vs Grp P
	Mean± SD	Mean± SD	P value
Total dose of Tramadol (mg)	305.46±26.1	371.26±20.10	<0.05

Table showing the Statistical Analysis of total analgesic consumption in 24 hours in both the groups.

The consumption of tramadol was significantly lesser in Group L when compared to Group P (p<0.05)

Table -12 Comparison of Incidence of Complications in the two groups

Complications	Group L (n=30)		Group P (n=30)	
	No.	%	No.	%
Nausea and vomiting	2	6.67%	7	23.33%
Hypotension	0	0	0	0
Bradycardia	0	0	0	0
Shivering	4	13.34%	1	3.33%
Dyspnoea	0	0	0	0

Chest pain	0	0	0	0
Dysarrhythmia	0	0	0	0

Table showing the incidence of complications in both the groups.

Nausea and vomiting was seen in 2 out of 30 (6.67%) patients of group L and was seen in 7 out of 30 (23.33%) patients belonging to group P.

Shivering was noted in 4 (13.34%) patients of group L ; but only in 1(3.33%) patients in group P.

No other complication was seen in any of the groups.

DISCUSSION

Adequate postoperative relief of pain after laparoscopy is an essential goal. Postoperative pain associated with laparoscopy is due to peritoneal stretching, diaphragmatic irritation, or, to a lesser extent, abdominal puncture. The receptors involved seem to be susceptible to blockade with a relatively low dose of local anesthetic.

DEMOGRAPHIC DATA:

As shown in Table no.1 the mean (±SD) age (in yrs) of patients in group L and group P were (38.60 ±13.94) and (40.47± 13.42) respectively. The mean (±SD) weight (in kgs) of the patients in group L and group P were (59.4 ± 8.49) and (61.86± 8.69) respectively.

There were no significant difference (p>0.05) among the group L and group P with respect to mean age and weight.

The majority of patients in both the groups were noted to be females (Table-2)

DURATION OF SURGERY:

As shown in (Table no.3) the mean (±SD) duration of surgery of the patients in group L and P were (89.84 ± 13.48) and (92.16±17.60) respectively.

There were no significant difference (p>0.05) among the study groups with respect to duration of surgery

HAEMODYNAMICS:

Perioperative pulse rate in group L and group P is shown in Table no.4. comparison of pulse rate, before and after the surgery, in group P revealed that there was a significant increase in postoperative pulse rate at various time intervals as compared to baseline values (p<0.05). While in group L the increase in postoperative pulse rate was not significant with that of baseline values (p >0.05)

Similar changes were observed in other hemodynamic variables like Systolic Blood Pressur and Diastolic Blood Pressure in the two groups.

Levobupivacaine was hemodynamically more effective than Ropivacaine (p<0.05).

These results were in accordance with with **Pasqualucci et al [3] and Bhardwaj N et al** 4

TIME FOR FIRST RESCUE ANALGESIA:

As shown in (Table no.7), the mean (±SD) time for first rescue analgesia in group L was 225.83 ± 30.99 mins and group P was 14.16 ± 5.09 mins respectively.

The above findings were in accordance with **Goldstein A et al** 5

VAS SCORE:

In our study(Table 9), the mean VAS score in the initial 6 hrs of postoperative period was significantly lower in Group L when compared to the placebo group (p<0.05). In group L, the mean VAS score increased with time, until when VAS score approached 50 and patients were given 1st dose of rescue analgesia at about 4th hr postoperatively. In the placebo group, VAS score was more than 50 in the initial 30 mins of postoperative period, and the patients received there 1st dose of rescue analgesia. Later on, rescue analgesics were repeated in both the groups whenever their VAS score increased more than 50.

On statistical comparison of average VAS score values of 24 hours observation period, significantly lower VAS scores were observed in group L when compared to placebo group (p<0.05) (Table-10)

These findings were in accordance with study conducted by **Papagiaunopoulou P et al-3 , Louizos A et al-6**and **Karaman Y et al-7,Ismail M T et al-8**, **Alper I et al-9**

TOTAL ANALGESIC CONSUMPTION IN 24 HOURS:

As shown in Table no.11, on statistical comparison of total analgesic consumption in 24 hrs in the two groups, patients in group L were found to require significantly lower dose of tramadol than that in group P(p<0.05).

Papagiaunopoulou P et al3 ,Louizos A A et al6, Alper I et al9and **Karaman Y et al7**

COMPLICATIONS:

As shown in Table no.12, patients in group L experienced shivering as the most common adverse effect and those in group P experienced nausea-vomiting as the most common adverse effect. Shivering was noted in 4 (13.34%) patients of group L; but only in 1 (3.33%) patients in group P. Nausea and vomiting was seen in 2 out of 30 (6.67%) patients of group L and in 7 out of 30 (23.33%) patients belonging to group P.

There were no any incidence of hypotension, bradycardia, dyspnea, chest pain or dysrrhythmia.

CONCLUSION

There was significant prolongation of duration of postoperative analgesia in Levobupivacine group as compared to placebo group. In terms of analgesic efficacy, Levobupivacaine appears to be superior to placebo. No significant adverse effect and haemodynamic instability is seen with both Levobupivacaine and placebo. Intraperitoneal instillation combined with periportal infiltration of local anaesthetic is a useful adjunct as part of a multimodal analgesic regimen to reduce the postoperative pain in laparoscopic cholecystectomy.

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