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Intraperitoneal levobupivacaine with dexamethasone and dexamethasone for post-operative pain after laparoscopic cholecystectomy

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Abstract:
Post-operative pain after laparoscopic cholecystectomy remains clinically important and may delay early recovery despite minimally invasive surgery. This prospective observational comparative study included 70 ASA I–II patients undergoing elective laparoscopic cholecystectomy, with 35 patients receiving intraperitoneal levobupivacaine alone and 35 receiving levobupivacaine with dexamethasone. Group LD showed lower VAS score up to 8 hours, longer time to first rescue analgesia than Group LL (414.63 ± 54.48 vs 268.83 ± 75.62 minutes) and lower total rescue analgesic dose (90.00 ± 30.44 vs 115.71 ± 37.91 mg). Thus, data shows that intraperitoneal levobupivacaine with dexamethasone was associated with better early post-operative analgesic profile without clinically significant hyperglycemia or recorded side effects.

Keywords: Laparoscopic cholecystectomy; intraperitoneal analgesia; levobupivacaine; dexamethasone; post-operative pain; rescue analgesia; VAS score.

Background:
Laparoscopic cholecystectomy is the standard surgical treatment for symptomatic gallbladder disease **[1]**. It is less invasive and supports early recovery compared with open surgery **[2]**. Still, post-operative pain remains a frequent concern and may delay ambulation and discharge **[3]**. Pain after laparoscopic cholecystectomy has somatic, visceral and referred components, with peritoneal stretch and CO_2 irritation contributing to visceral pain **[4]**. Multimodal analgesia is recommended to improve pain control and reduce opioid exposure **[5]**. Non-opioid analgesic methods are useful because opioids may increase nausea, vomiting, sedation and delayed recovery **[6]**. Intraperitoneal local anaesthetic instillation is a simple method for reducing visceral pain after laparoscopic surgery **[7]**. Levobupivacaine is a long-acting local anaesthetic and has shown benefit in early pain relief after laparoscopic cholecystectomy **[8]**. Dexamethasone has anti-inflammatory and antiemetic action and may reduce post-operative nausea and vomiting **[9]**. It may also increase perioperative blood glucose, so glucose monitoring is relevant when dexamethasone is used **[10]**. Therefore, it is of interest to report the analgesic effect of intraperitoneal levobupivacaine with dexamethasone versus levobupivacaine alone after laparoscopic cholecystectomy.

Materials and Methods:
This prospective observational comparative study was conducted in the Department of Anaesthesiology, M.G.M. Medical College and M.Y. Hospital, Indore. The study was done over 12 months after Institutional Ethics Committee approval. Written informed consent was obtained from all patients. Seventy ASA grade I–II patients aged 18–65 years posted for elective laparoscopic cholecystectomy were included. Patients with allergy to study drugs, diabetes mellitus and chronic steroid use were excluded. Patients were divided according to the intraperitoneal drug regimen received. Group LL received 40 mL of 0.25% levobupivacaine. Group LD received 40 mL of 0.25% levobupivacaine with 16 mg dexamethasone. All patients underwent pre-anaesthetic assessment one day before surgery. VAS scoring was explained. Baseline clinical details, ASA grade, routine investigations, fasting blood sugar and HbA1c were recorded. General anaesthesia was given by a uniform protocol. Standard monitoring was applied. Anaesthesia was induced with fentanyl, propofol and succinylcholine. Maintenance was done with oxygen, nitrous oxide, sevoflurane and atracurium. Pneumoperitoneum was maintained at 12–14 mmHg. At the end of surgery, the study drug was instilled intraperitoneally through the umbilical port. Trendelenburg position with left-up tilt was maintained for 10 minutes. All patients received intravenous paracetamol 1 g and ondansetron 4 mg. Reversal was done with neostigmine and glycopyrrolate. Patients were extubated after standard criteria and shifted to the post-operative care unit. Post-operative pain was assessed by VAS score at 0 min, 30 min, 1 hour, 2 hours, 4 hours, 8 hours, 12 hours and 24 hours. Rescue analgesia was given as intravenous diclofenac 75 mg when VAS score was more than 3. Time to first rescue analgesia, total rescue analgesic dose, blood glucose, haemodynamic parameters, SpO_2 and adverse effects were recorded. Hyperglycemia was defined as blood glucose >200 mg/dL. Data were analysed using SPSS version 26.0. Continuous variables were expressed as mean ± SD. Categorical variables were expressed as number and percentage. Intergroup comparison was done using unpaired t-test or Mann–Whitney U test. Chi-square test or Fisher's exact test was used for categorical variables. A p value <0.05 was taken as statistically significant.

Table 1: Baseline profile of study patients

Parameter	Group LL n=35	Group LD n=35
Age in years	42.74 ± 12.81	40.57 ± 11.90
20–29 years	4 (11.4%)	7 (20.0%)
30–39 years	13 (37.1%)	10 (28.6%)
40–49 years	5 (14.3%)	7 (20.0%)
50–59 years	6 (17.1%)	8 (22.9%)
60–69 years	7 (20.0%)	3 (8.6%)
Female sex	28 (80.0%)	27 (77.1%)
Male sex	7 (20.0%)	8 (22.9%)
ASA grade I	21 (60.0%)	24 (68.6%)
ASA grade II	14 (40.0%)	11 (31.4%)
Weight in kg	58.69 ± 6.44	58.74 ± 6.37

Table 2: Intraoperative haemodynamic profile at key intervals

Parameter	Time point	Group LL n=35	Group LD n=35	p value
MAP mmHg	Preoperative	91.89 ± 3.72	90.40 ± 4.31	0.127
MAP mmHg	30 min	88.69 ± 5.99	87.23 ± 5.75	0.303
MAP mmHg	60 min	87.83 ± 5.32	87.34 ± 5.31	0.704
MAP mmHg	90 min	87.71 ± 5.95	85.91 ± 4.43	0.156
Pulse rate/min	Preoperative	84.00 ± 11.92	81.71 ± 12.50	0.436
Pulse rate/min	30 min	73.37 ± 7.86	72.43 ± 6.07	0.576
Pulse rate/min	60 min	75.09 ± 9.16	76.00 ± 9.25	0.679
Pulse rate/min	90 min	76.97 ± 8.80	77.26 ± 8.29	0.889
SBP mmHg	Preoperative	123.14 ± 6.39	121.74 ± 7.43	0.401
SBP mmHg	30 min	116.23 ± 6.90	114.11 ± 7.30	0.217
SBP mmHg	60 min	116.91 ± 10.07	115.94 ± 9.17	0.674
SBP mmHg	90 min	115.03 ± 7.71	113.71 ± 7.18	0.463
DBP mmHg	Preoperative	76.46 ± 4.44	74.80 ± 3.83	0.099
DBP mmHg	30 min	75.00 ± 6.54	73.89 ± 6.00	0.460

DBP mmHg	60 min	73.43 ± 5.06	73.20 ± 5.51	0.857
DBP mmHg	90 min	74.14 ± 6.49	72.06 ± 4.39	0.120
SpO_2 %	Preoperative	98.09 ± 0.70	97.97 ± 0.71	0.499
SpO_2 %	30 min	99.91 ± 0.28	99.86 ± 0.36	0.460
SpO_2 %	60 min	99.91 ± 0.28	99.86 ± 0.36	0.460
SpO_2 %	90 min	99.91 ± 0.28	99.86 ± 0.36	0.789

Table 3: Post-operative VAS score according to study group

Time point	Group LL n=35	Group LD n=35	p value
0 min	0.54 ± 0.51	0.00 ± 0.00	<0.001
30 min	1.49 ± 0.74	0.20 ± 0.41	<0.001
1 hour	2.31 ± 0.76	0.11 ± 0.40	<0.001
2 hours	3.31 ± 0.90	0.20 ± 0.47	<0.001
4 hours	3.60 ± 0.85	0.80 ± 0.63	<0.001
8 hours	4.29 ± 0.83	2.37 ± 1.09	<0.001
12 hours	3.26 ± 0.82	3.49 ± 1.07	0.318
24 hours	1.71 ± 1.20	2.54 ± 0.74	0.001

Table 4: Rescue analgesia and safety profile according to study group

Parameter	Group LL	Group LD	p value
Time to first rescue analgesia in minutes	268.83 ± 75.62	414.63 ± 54.48	<0.001
Total rescue analgesic dose in mg	115.71 ± 37.91	90.00 ± 30.44	0.003
Baseline fasting blood sugar mg/dL	84.34 ± 8.95	81.91 ± 7.01	0.211
Random blood sugar at 4 hours mg/dL	117.00 ± 12.83	113.32 ± 5.99	0.134
Random blood sugar at 8 hours mg/dL	140.17 ± 15.12	132.38 ± 4.97	0.006
Hyperglycemia >200 mg/dL	0 (0.0%)	0 (0.0%)	–
Nausea	0 (0.0%)	0 (0.0%)	–
Vomiting	0 (0.0%)	0 (0.0%)	–
Other side effects	0 (0.0%)	0 (0.0%)	–

Table 5: Post-operative haemodynamic and oxygenation profile

Parameter	Time point	Group LL n=35	Group LD n=35	p value
MAP mmHg	0 min	99.20 ± 4.13	90.43 ± 3.04	<0.001
MAP mmHg	1 hour	97.69 ± 2.62	91.60 ± 2.57	<0.001
MAP mmHg	4 hours	95.71 ± 3.04	90.23 ± 3.11	<0.001
MAP mmHg	8 hours	96.69 ± 2.41	88.80 ± 2.53	<0.001
MAP mmHg	24 hours	97.06 ± 2.86	88.03 ± 2.80	<0.001
Pulse rate/min	0 min	82.51 ± 7.75	77.31 ± 4.61	0.001
Pulse rate/min	1 hour	77.20 ± 9.17	68.60 ± 7.45	<0.001
Pulse rate/min	4 hours	80.06 ± 6.66	76.17 ± 7.35	0.024
Pulse rate/min	8 hours	80.03 ± 8.17	75.91 ± 6.68	0.024
Pulse rate/min	24 hours	82.71 ± 7.58	76.43 ± 6.74	<0.001
SBP mmHg	0 min	129.86 ± 8.96	121.94 ± 7.58	<0.001
SBP mmHg	1 hour	123.09 ± 3.85	117.11 ± 3.93	<0.001
SBP mmHg	4 hours	123.71 ± 6.48	118.17 ± 6.16	<0.001
SBP mmHg	8 hours	126.11 ± 5.87	119.26 ± 4.79	<0.001
SBP mmHg	24 hours	124.54 ± 6.51	117.57 ± 5.63	<0.001
DBP mmHg	0 min	83.89 ± 3.75	74.66 ± 2.92	<0.001
DBP mmHg	1 hour	85.03 ± 2.83	78.86 ± 2.25	<0.001
DBP mmHg	4 hours	81.63 ± 3.75	76.14 ± 3.29	<0.001
DBP mmHg	8 hours	82.00 ± 3.52	73.69 ± 3.15	<0.001
DBP mmHg	24 hours	83.37 ± 2.87	73.37 ± 3.68	<0.001
SpO_2 %	0 min	98.26 ± 0.82	98.14 ± 0.77	0.550
SpO_2 %	1 hour	97.91 ± 0.89	97.86 ± 0.88	0.787
SpO_2 %	8 hours	97.51 ± 0.82	97.66 ± 0.84	0.473
SpO_2 %	24 hours	98.06 ± 0.77	97.86 ± 0.69	0.255

Results and Discussion:

The two groups were comparable at baseline for age, sex distribution, ASA grade and weight, as shown in (**Table 1)**. Intraoperative haemodynamic profile was also similar in both groups, as shown in (**Table 2)**, with no significant difference in MAP, pulse rate, SBP, DBP and SpO_2. The main analgesic finding is shown in (**Table 3)**, where Group LD had lower VAS score from immediate post-operative period up to 8 hours. At 2 hours, VAS was 3.31 ± 0.90 in Group LL and 0.20 ± 0.47 in Group LD. At 8 hours, it was 4.29 ± 0.83 and 2.37 ± 1.09 respectively. The difference was not significant at 12 hours. At 24 hours, Group LL showed lower VAS score. Rescue analgesic profile is shown in (**Table 4)**. Time to first rescue analgesia was longer in Group LD, 414.63 ± 54.48 minutes compared with 268.83 ± 75.62 minutes in Group LL. Total rescue analgesic dose was also lower in Group LD, 90.00 ± 30.44 mg compared with 115.71 ± 37.91 mg. Blood sugar remained below the predefined hyperglycemia cut-off in both groups and no nausea, vomiting or other side effects were recorded. Post-operative haemodynamic findings are shown in (**Table 5)**. MAP, pulse rate, SBP and DBP were lower in Group LD at most post-operative intervals, while SpO_2 remained comparable. These findings suggest better early analgesic profile with levobupivacaine and dexamethasone, but causal inference should be limited because the study was observational. The present findings are supported by recent pooled evidence on intraperitoneal local anaesthetics. Boulianne *et al.* included 150 trials with 11,821 participants and reported reduced post-operative pain at 6 hours, 12 hours, 24 hours and 48 hours after intra-abdominal surgery. They also reported reduction in 24-hour opioid use by 10.4 mg oral morphine equivalent. The certainty of evidence was low to very low, but the direction favoured intraperitoneal local anaesthetic use **[11]**. Vandana *et al.* studied intraperitoneal bupivacaine with 16 mg dexamethasone versus bupivacaine alone after laparoscopic cholecystectomy. VAS score was significantly lower in the dexamethasone group until 2 hours. Time to first rescue analgesia was longer, 417.1 minutes compared with 219.4 minutes. Total rescue analgesic dose was also lower, 60.71 mg compared with 73.20 mg. This is close to the present study, where Group LD had first rescue analgesia at 414.63 minutes and lower rescue analgesic requirement **[12]**. Nazemroaya *et al.* showed lower VAS scores with intraperitoneal dexamethasone after laparoscopic cholecystectomy **[13]**. Jadav *et al.* used intraperitoneal ropivacaine with 8 mg dexamethasone and compared it with ropivacaine alone. NRS score was significantly lower at 6, 12 and 24 hours. Rescue analgesia was required by 52% in dexamethasone group compared with 76% in ropivacaine alone group. Time to first rescue analgesia was longer, 10.57 ± 7.83 hours versus 7.56 ± 3.56 hours. Total diclofenac use was lower, 87.5 ± 28.55 mg versus 108.62 ± 47.37 mg. This supports the analgesic-sparing role of dexamethasone as an intraperitoneal adjuvant **[14]**. Recent levobupivacaine studies with other adjuvants also showed similar direction. Jain *et al.* compared intraperitoneal levobupivacaine with clonidine versus levobupivacaine alone. Duration of analgesia was 744.10 ± 96.72 minutes in clonidine group and 525.20 ± 67.91 minutes in levobupivacaine alone group. Rescue analgesic consumption was also lower, 85.50 ± 26.29 mg compared with 153 ± 36.99 mg. This supports the role of adjuvant addition to levobupivacaine for improving post-operative analgesia **[15]**. Pareek *et al.* compared levobupivacaine alone with levobupivacaine plus dexmedetomidine after laparoscopic cholecystectomy. VAS scores at 4, 8 and 12 hours were significantly lower in the dexmedetomidine group. Fewer patients required rescue analgesia in the adjuvant group. This further supports that intraperitoneal levobupivacaine can be strengthened by suitable adjuvants **[16]**. Post-operative MAP, pulse rate, SBP and DBP

were lower in Group LD. This may reflect better pain control and lower sympathetic response. However, this should not be written as direct causation. Ahmed *et al.* also evaluated intraperitoneal gallbladder bed infiltration after laparoscopic cholecystectomy and reported that local anaesthetic infiltration improved post-operative pain outcomes. In the present study, the haemodynamic difference was interpreted along with the analgesic findings rather than as an independent primary outcome **[17]**. Blood sugar findings need careful interpretation. Baseline fasting blood sugar and 4-hour random blood sugar were comparable. At 8 hours, Group LL had higher random blood sugar than Group LD, 140.17 ± 15.12 mg/dL versus 132.38 ± 4.97 mg/dL. No patient in either group crossed the predefined hyperglycemia cut-off of >200 mg/dL. Dejen *et al.* reported post-operative hyperglycemia in 34.1% of non-diabetic surgical patients when hyperglycemia was defined as blood glucose ≥140 mg/dL. Hence, the present finding should be read according to the predefined >200 mg/dL cut-off. If a lower cut-off is used, interpretation may change **[18]**. No nausea, vomiting or other side effect was recorded in either group. This is a favourable observation, but it should be interpreted with caution. All patients received ondansetron prophylaxis. The sample size was small and only ASA I–II patients were included. Hence, the present study cannot confirm an independent antiemetic benefit of dexamethasone. The main advancement to knowledge from this study is the direct comparison of intraperitoneal levobupivacaine with dexamethasone versus levobupivacaine alone. Earlier recent studies mainly evaluated dexamethasone with bupivacaine or ropivacaine. Other levobupivacaine studies used clonidine or dexmedetomidine as adjuvants. The present study adds practical evidence that dexamethasone with levobupivacaine is associated with lower early VAS score, longer rescue analgesia time and lower rescue analgesic dose. It also adds local safety data on blood sugar and side effects in non-diabetic ASA I–II patients. This study has some limitations. It was observational and not randomized. Blinding was not clearly present. The sample size was small and the study was conducted at a single centre. VAS is subjective and depends on patient understanding. Follow-up was limited to 24 hours. Pain at rest and pain on movement were not assessed separately. Plasma drug levels were not measured. Diabetic patients and patients on chronic steroid therapy were excluded, so findings cannot be applied to high-risk metabolic patients. Intraperitoneal levobupivacaine with dexamethasone showed better early post-operative analgesic profile than levobupivacaine alone after laparoscopic cholecystectomy. It was associated with lower VAS score up to 8 hours, delayed first rescue analgesia and lower total rescue analgesic requirement. No clinically significant hyperglycemia or side effects were observed. Larger randomized and blinded studies are needed to confirm these findings.

Conclusion:

Intraperitoneal levobupivacaine with dexamethasone provided better early pain control after laparoscopic cholecystectomy. It reduced VAS score up to 8 hours and delayed rescue analgesia with lower total analgesic use. Thus, no clinically significant hyperglycemia or side effects were observed in this ASA I–II non-diabetic cohort.

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