



Original Article

Efficacy And Safety of Iv Lignocaine Versus Combination of Iv Lignocaine with Dexmedetomidine on Post Operative Pain and Functional Recovery After Laparoscopic Cholecystectomy, A Randomized Controlled Trial

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ABSTRACT

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Background: Postoperative pain and delayed recovery of bowel function are common concerns after laparoscopic cholecystectomy. Lignocaine and dexmedetomidine are known for their analgesic and anti-inflammatory properties.

Materials and Methods: This study was a prospective randomized controlled trial study, here a total of 76 patients aged 20 to 65 years undergoing elective laparoscopic cholecystectomy. Which was conducted at Government Mohan Kumaramangalam Medical College and Hospital from April 2023 to April 2025.

Results: VAS scores at all postoperative intervals were significantly lower in Group LD compared to Group L ($p < 0.001$). The requirement of rescue analgesic fentanyl was significantly reduced in Group LD (15.79 ± 15.18 mcg vs. 49.74 ± 14.42 mcg; $p < 0.001$). Gastrointestinal recovery was faster in Group LD, with earlier return of bowel sounds (14.55 ± 1.69 hrs vs. 21.84 ± 2.37 hrs) and flatus (17.53 ± 1.94 hrs vs. 25.39 ± 2.02 hrs) (both $p < 0.001$). Group LD experienced fewer adverse effects, including nausea, vomiting, and shivering. Hemodynamic parameters remained stable across both groups, and sedation scores were higher in Group LD (2.58 ± 0.50 vs. 1.55 ± 0.50 ; $p < 0.001$), indicating better comfort.

Conclusion: The combination of IV lignocaine with dexmedetomidine was more effective than IV lignocaine alone in reducing postoperative pain, minimizing opioid requirement, enhancing bowel function recovery, and reducing postoperative complications without compromising hemodynamic stability.

Keywords: Lignocaine, Dexmedetomidine, Laparoscopic Cholecystectomy, Postoperative Pain.

INTRODUCTION

The gold standard procedure for symptomatic cholelithiasis is laparoscopic cholecystectomy (LC), which has many advantages over open cholecystectomy, such as less blood loss, a smaller wound, a shorter hospital stays and an earlier return to regular activities.⁽¹⁾ Notwithstanding its minimally invasive nature, LC is not without postoperative complications. Patients complain of severe pain, especially during the first 24 hours following surgery. This scenario presents a multifactorial pain—developing from somatic incisional pain, visceral manipulation, carbon dioxide insufflation diaphragmatic irritation, and the inflammatory response^(2,3). Effective control of this postoperative pain is essential. Pain not well managed can result in delayed recovery, higher morbidity, longer hospital stay, and higher healthcare expenditure⁽⁴⁾. Opioids have been the traditional choice for pain management after LC. Their side effects, such as respiratory depression, nausea, vomiting, pruritus, sedation, constipation, urinary retention, and the potential for hyperalgesia and addiction, tend to overshadow their analgesic effect, especially in day-care laparoscopic surgeries^(5,6). This has prompted the evolution of

multimodal analgesia (MMA) protocols to ensure effective pain control without excessive opioid intake and complications. MMA often consists of non-steroidal anti-inflammatory drugs (NSAIDs), dexamethasone, local anesthetics, and systemic adjuvants like ketamine, magnesium sulfate, lidocaine, and dexmedetomidine (2, 5). Of these, intravenous lidocaine and dexmedetomidine have received growing attention. Lidocaine, an inhibitor of sodium channels, has been found to possess anti-inflammatory, anti-hyperalgesic, and analgesic actions in the perioperative period. It decreases intraoperative anesthetic needs, decreases postoperative pain scores, enhances bowel recovery, and decreases hospital stay^(1,6,7). Alternatively, dexmedetomidine, a selective α_2 -adrenergic receptor agonist, is associated with sedation, anxiolysis, and analgesia without causing respiratory depression. It has central as well as spinal cord action in inhibiting sympathetic outflow and nociceptive transmission, with the advantages of hemodynamic stability and less postoperative nausea and vomiting^(6,8). While both agents are increasingly used individually, much less direct comparative evidence between dexmedetomidine and lidocaine in laparoscopic cholecystectomy exists. Especially among the Indian population, there is little data available, and the best between the two agents to be selected as opioid-sparing adjuvants is also not well defined^(3,5).

MATERIALS AND METHODS

Design:

This study was a prospective randomized controlled trial study. Which was conducted at Government Mohan Kumaramangalam Medical College and Hospital from April 2023 to April 2025. Participants will be randomly allocated into two groups using a computer-generated random number sequence.

Participants:

A total of 76 patients aged 20 to 65 years treated during the study period. Patients were selected with the following inclusion and exclusion criteria. Inclusion criteria comprise, Patients of either gender, age 20 to 65 years, American Society of Anesthesiologists physical status class I-II, Posted for elective Laparoscopic cholecystectomy, Weight 45-80 kgs. Exclusion criteria comprise, H/o adverse reaction to any study drugs, body mass index of >30 kg/m², H/o of cardiovascular disease, renal and hepatic insufficiency, neurological or psychiatric diseases, previous treatment with anti-platelet agents.

Study procedure:

Study population will be randomly divided into two groups:

- ❖ GROUP L: Lidocaine 2% [bolus 1.5mg/kg over 10 minutes] + continuous infusion of 2mg/Kg/hr
- ❖ GROUP D: Lidocaine 2% [bolus 1.5mg/kg over 10 minutes] + continuous infusion of 2mg/kg/hr
- ❖ Dexmedetomidine [bolus 1mcg/kg over 10 minutes] + continuous infusion of 0.4mcg/kg/hr

Sample Size:

The sample size was determined assuming the expected mean and standard deviation of the post-operative pain outcome in the IV Lignocaine with Dexmedetomidine as σ_1 (20.45, 3.2) and in the IV Lignocaine as σ_0 (25.02, 9.2). 80% research power and 5% two-sided alpha error were the other factors taken into account while calculating the sample size. According to Kirkwood BR et al., the following formula was used to determine the necessary sample size.

Formula used for sample size calculation:

$$N = \frac{(u + v)^2 (\sigma_1^2 + \sigma_0^2)}{(\mu_1 - \mu_0)^2}$$

N = Sample size

μ_1, μ_0 = Difference between the means ($\mu_1=20.45$ and $\mu_0=25.02$) σ_1, σ_0 = Standard deviations ($\sigma_1=3.2$ and $\sigma_0=9.2$)

U = two sided percentage point of the normal distribution corresponding to 100 % - the power = 80%, $u=0.84$

V = Percentage point of the normal distribution corresponding to the (two sided) significance level for significance level = 5%, $v = 1.960$

The previously mentioned computation indicated that 36 people in each group were the necessary sample size. Two more participants will be added to the sample size in each group to account for a non-participation rate/loss to follow-up rate of roughly 5%. Therefore,

38 people in each group would be the total sample size needed.

Materials Required

1. 18G iv cannula

2. Drugs:

- Inj. Lidocaine 2% diluted to 50ml (8mg /ml) for iv
- Inj. Dexmedetomidine (100mcg/1ml) diluted to 50ml (2mcg / ml)

- Distilled water
- 0.9 % normal saline, Ringer Lactate

3. Emergency drugs

Inj. Ephedrine inj. Atropine inj. Adrenaline

Pre-operative assessment:

A thorough medical history, including past and current conditions, previous surgeries, and anesthesia exposure will be documented.

A history of drug use and allergies to latex and medicines will be documented.

Both routine and surgical investigations will be conducted.

The patients' general, systemic, and comprehensive airway assessments will be completed.

Pre-medication:

_Inj. Ranitidine and Inj. Metaclopramide

Monitors:

NIBP, ECG, SpO₂, Heart Rate.

IV Access: 18G IV cannula will be inserted and preloaded with RL 10ml/kg

Subjects were randomized into the groups L and LD using a sealed envelope technique and received medication by intravenous routes as follows

For group L, ivLidocaine, a bolus of 1.5mg/kg is infused over 10 mins before induction Then lidocaine of 2mg/kg is given as continuous infusion dose throughout the Surgery and till 1hr after the end of surgery.

For group LD, iv lidocaine, a bolus of 1.5mg/kg is infused over 10mins before induction then lidocaine of 2mg/kg/hr is infused as continuous dose throughout the surgery and till 1hr after the surgery. Also group LD, receives a bolus of intravenous Dexmedetomidine of 1mcg /kg over 10 minutes before induction and 0.4mcg/kg/hr as a continuous infusion dose throughout the surgery and till 1 hour after the surgery.

Baseline cardio-respiratory parameters like Heart Rate (H.R), Blood Pressure (B.P) and Oxygen saturation (SpO₂) will be recorded and at every 5mins after administration of study drugs. Time in operating room and duration of surgery will be recorded. Any side effects including hypotension, bradycardia, nausea, vomiting, sedation, and shivering will be noted. Sedation was graded by using five-point sedation scale;

Scale 1- Alert and wide awake,

Scale 2-Arousable to verbal command,

Scale 3-Arousable with gentle tactile stimulation, Scale 4-Arousable with vigorous shaking,

Scale 5-Unarousable.

All patients were transferred to PACU immediately after surgery.

At the end of surgery; after 1, 2,4,8,12,24, and 48hrs postoperative pain was assessed by the visual analog score (VAS)

Visual Analogue Scale Score of Pain

If patient complains of pain which is over 5 of VAS, then fentanyl of 30mcg will be given and also, checked for post-operative nausea and vomiting Thus finally, the requirement of opioids and other drugs were noted, in addition to lidocaine and dexmedetomidine. Then, in post-operative period, the onset of occurrence of first bowel sound and flatus were also noted.

Data analysis:

The entire data were validated by checking for and correcting any unusual values and typographic errors. All the quantitative variables will be checked for compliance with normal distribution, within each study group by using visual inspection of histograms and normality Q-Q plots. Skewness and Kurtosis Z-Values and Shapiro-Wilk test P-values will also be used for this purpose.

Data were analysed by Intention to treat (ITT) analysis. Initially all the baseline variables will be compared between the two groups, to assess any significant differences in these variables between the two study groups.

Then the key primary and secondary outcome variables were compared between the two groups, to document the efficacy and safety of the intervention.

The mean and standard deviation of the normally distributed quantitative variables will be compared between the two groups using independent sample t-test. The median and Inter quartile range (IQR) of the non-normally distributed quantitative variables will be compared between the two groups, using Mann-Whitney U test. The qualitative variables will be compared between the two methods using Chi-square test/ Fisher's exact test.

Efforts were made to control for the confounding by appropriate regression methods, for all the key outcome variables. Data were analysed (SPSS Software).

RESULTS

Table 1: Gastrointestinal Functional Recovery:

Parameter	Group L (Mean ± SD)	Group LD (Mean ± SD)	p-value
First Bowel Sound (hr)	21.84 ± 2.37	14.55 ± 1.69	0.001
First Flatus (hr)	25.39 ± 2.02	17.53 ± 1.94	0.001

Analgesic Requirement:

Parameter	Group L (Mean ± SD)	Group LD (Mean ± SD)	p-value
Fentanyl Requirement (mcg)	49.74 ± 14.42	15.79 ± 15.18	0.001

Postoperative Sedation:

Parameter	Group L (Mean ± SD)	Group LD (Mean ± SD)	p-value
Sedation Score	1.55 ± 0.50	2.58 ± 0.50	0.001

Group LD recovered gastrointestinal function significantly more rapidly. Time to first bowel sound in Group LD was 14.55 ± 1.69 hours compared with 21.84 ± 2.37 hours for Group L (p = 0.001). First flatus occurred at 17.53 ± 1.94 hours in Group LD and at 25.39 ± 2.02 hours in Group L (p = 0.001).

The average fentanyl need was much lower for Group LD (15.79 ± 15.18 mcg) than for Group L (49.74 ± 14.42 mcg) (p = 0.001).

Group LD also had a significantly greater postoperative sedation score (2.58 ± 0.50) than Group L (1.55 ± 0.50) (p = 0.001).

Table 2: Postoperative Pain Scores (VAS):

Time point	Group L (Mean ± SD)	Group LD (Mean ± SD)	p-value
Pre-op	2.05 ± 0.77	2.16 ± 0.64	0.518
15 min	4.79 ± 0.93	2.08 ± 0.43	0.001
30 min	5.55 ± 0.69	2.47 ± 0.56	0.001
1 hr	5.71 ± 0.52	2.11 ± 0.51	0.001
2 hr	5.63 ± 0.52	2.18 ± 0.31	0.001
4 hr	5.61 ± 0.54	2.16 ± 0.39	0.001
8 hr	5.71 ± 0.64	2.32 ± 0.53	0.001
12 hr	5.53 ± 0.56	2.34 ± 0.63	0.001
24 hr	5.13 ± 0.66	2.37 ± 0.59	0.001
48 hr	4.61 ± 0.68	2.32 ± 0.47	0.001

VAS scores were lower in Group LD at every time point after operation. For example, at 15 minutes, VAS was 2.08 ± 0.43 in Group LD compared with 4.79 ± 0.93 in Group L; at 1 hour, 2.11 ± 0.51 vs 5.71 ± 0.52, and at 24 hours, 2.37 ± 0.59 vs 5.13 ± 0.66 (p = 0.001 for all), reflecting better control of pain in Group LD.

Table 3: Correlation between VAS and Fentanyl Requirement:

VAS Time point	Correlation Coefficient (r)	p-value
VAS 15min	0.689	0.001
VAS 30min	0.732	0.001
VAS 1hr	0.777	0.001
VAS 2hr	0.737	0.001
VAS 4hr	0.723	0.001
VAS 8hr	0.768	0.001
VAS 12hr	0.732	0.001
VAS 24hr	0.789	0.001
VAS 48hr	0.863	0.001

There was a very high positive correlation between fentanyl consumption and VAS scores at each time point. The correlation coefficient rose over time, being greatest at 48 hours ($r = 0.863$, $p = 0.001$).

Table 4: Diastolic Blood Pressure (DBP) Comparison between Group L and Group LD

Time point	Group L (Mean \pm SD)	Group LD (Mean \pm SD)	p-value
Baseline	76.89 \pm 4.03	75.92 \pm 4.31	0.313
5 min	76.32 \pm 4.29	74.9 \pm 4.4	0.092
10 min	77.87 \pm 3.68	76.2 \pm 4.1	0.081
15 min	77.16 \pm 4.66	75.6 \pm 4.0	0.076
20 min	76.71 \pm 3.91	75.3 \pm 4.0	0.099
25 min	77.82 \pm 4.88	75.2 \pm 3.6	0.018
30 min	76.18 \pm 4.37	74.7 \pm 3.9	0.110
60 min	76.42 \pm 4.41	75.0 \pm 4.4	0.148
90 min	76.63 \pm 4.35	75.2 \pm 4.3	0.121
120 min	76.89 \pm 4.34	75.5 \pm 4.5	0.097
150 min	76.63 \pm 4.09	75.1 \pm 4.1	0.088

Baseline DBP was similar between groups ($p=0.313$). At 25 minutes, the difference achieved statistical significance ($p=0.018$) with Group LD having a smaller DBP. At other timepoints, Group LD regularly had slightly lower diastolic values.

Table 5: Mean Arterial Pressure (MAP) Comparison between Group L and Group LD

Time point	Group L (Mean \pm SD)	Group LD (Mean \pm SD)	p-value
Baseline	90.32 \pm 4.13	92.63 \pm 4.14	0.017
5 min	92.58 \pm 4.67	91.1 \pm 4.2	0.071
10 min	91.92 \pm 3.91	90.4 \pm 4.3	0.089
15 min	91.82 \pm 3.65	90.2 \pm 3.5	0.062
20 min	91.37 \pm 4.59	89.8 \pm 4.3	0.083
25 min	93.18 \pm 3.83	91.5 \pm 4.0	0.045
30 min	92.16 \pm 4.13	90.6 \pm 3.9	0.059
60 min	92.50 \pm 4.46	91.0 \pm 4.6	0.074
90 min	91.79 \pm 4.74	90.3 \pm 3.8	0.098
120 min	92.13 \pm 4.79	90.6 \pm 4.2	0.086
150 min	91.18 \pm 4.43	89.6 \pm 4.0	0.077

At baseline, Group LD had a higher MAP than Group L ($p=0.017$). MAP in Group LD was persistently lower than in Group L, with the difference at 25 minutes approaching statistical significance ($p=0.045$).

DISCUSSION

In patients having laparoscopic cholecystectomy, the current randomized controlled trial evaluated the safety and effectiveness of intravenous (IV) lignocaine alone (Group L) with the combination of IV lignocaine and dexmedetomidine (Group LD).

Statistically equal baseline clinical and demographic factors existed between the groups, such as age (Group L: 43.29 ± 13.17 vs. Group LD: 44.63 ± 13.41 years; $p = 0.661$), sex distribution ($p = 0.818$), BMI (Group L: 28.87 ± 2.60 vs. Group LD: 28.82 ± 2.78 ; $p = 0.932$), ASA grade ($p = 0.489$), comorbidities, and operation time ($p = 0.301$). These findings support those of previous research by Vidushi Nama (2023)⁽⁸⁾, Vishal Kamal (2025)⁽³⁾, and Anam Rizwan (2025)⁽⁴⁾ which ensured valid outcome comparisons by finding no significant changes in baseline variables such as age, sex, and ASA status between intervention groups.

Postoperative Gastrointestinal Recovery

The recovery of bowel function was much quicker in Group LD, with time to first bowel sound being 14.55 ± 1.69 hours compared to 21.84 ± 2.37 hours for Group L ($p = 0.001$) and time to first flatus being 17.53 ± 1.94 hours vs. 25.39 ± 2.02 hours ($p = 0.001$).

These results corroborate with the improved recovery profile with dexmedetomidine as quoted by Ruchi Kumari (2020)⁽⁶⁾ who also noted better postoperative recovery and reduced discharge readiness times using dexmedetomidine.

Analgesic Needs and Pain Scores

Analgesic need after the surgery was appreciably reduced in Group LD (15.79 ± 15.18 mcg) as opposed to Group L (49.74 ± 14.42 mcg; $p = 0.001$). VAS scores were also appreciably lower in Group LD at every time interval. For example, at 1 hour, Group LD had VAS of 2.11 ± 0.51 vs. 5.71 ± 0.52 in Group L ($p = 0.001$). This potent analgesic action persisted until 48 hours, and there was a good correlation between the use of fentanyl and VAS scores ($r = 0.863$, $p = 0.001$).

Comparable analgesic superiority of dexmedetomidine has also been documented by Vidushi Nama (2023) (8), where VAS scores were found consistently to be less than 4 and total consumption of analgesics was significantly lower ($p < 0.0001$). Vishal Kamal (2025)⁽³⁾ also found lower VAS scores in Group D at 1, 2, 8, and 12 hours, with the overall tramadol requirement paradoxically increased, indicating inconsistent patterns of analgesic use.

Sedation and Hemodynamics

Group LD had significantly greater sedation scores during the postoperative period (2.58 ± 0.50) compared to Group L (1.55 ± 0.50 ; $p = 0.001$) as per the sedative effect of dexmedetomidine. Even with increased sedation, no difference in oxygen saturation was observed, thus ensuring respiratory safety.

Kamal (2025)⁽³⁾ also found increased sedation scores in dexmedetomidine groups at 1 and 2 hours after surgery ($p < 0.001$), but reported delayed recovery and awakening.

Group LD presented slightly lower MAP values at baseline (90.32 ± 4.13 vs. 92.63 ± 4.14 ; $p = 0.017$) and at 25 minutes ($p = 0.045$), but no critical hypotension was experienced. These results agree with Barad (2023)⁽⁹⁾ and Rizwan (2025)⁽⁵⁾, who found MAP and SBP reduction in dexmedetomidine groups, but within clinical limits.

HR trends also favored Group LD stability without significant bradycardia, as opposed to Kamal (2025)⁽³⁾, who reported increased bradycardia incidence in Group D (13.3%).

Adverse Effects

Group LD experienced fewer adverse effects. Postoperative nausea in 5.3% of patients compared to 26.3% in Group L, vomiting in 2.6% compared to 18.4%, bradycardia in 2.6% compared to 15.8%, and shivering in 2.6% compared to 10.5%. These tendencies are corroborated by results in Rizwan (2025) (5), where Group D experienced lesser PONV, and by Nama (2023)⁽⁸⁾, who showed lesser opioid-related complications in the dexmedetomidine group.

The better analgesic and recovery profile of the lignocaine-dexmedetomidine combination reported in the present study is consistent with Vidushi Nama's (2023)⁽⁸⁾ suggestion of dexmedetomidine ($1 \mu\text{g}/\text{kg}$ bolus + $0.4 \mu\text{g}/\text{kg}/\text{hr}$ infusion) as an optimal adjuvant anesthetic. Ruchi Kumari (2020)⁽⁶⁾ also reported enhanced QoR (199 ± 0.92 in Group D vs. 196.65 ± 2.16 in Group L; $p = 0.0001$) and faster PADSS scores with dexmedetomidine. On the other hand, Vishal Kamal (2025)⁽³⁾ also emphasized issues of delayed awakening and increased hemodynamic variability, implying careful use in vulnerable populations.

Overall, without compromising hemodynamic stability or oxygenation, the combination of dexmedetomidine with IV lignocaine resulted in a significant increase in postoperative analgesia, a decrease in opioid use, improved bowel recovery, and a decreased incidence of side events.

These results are in close agreement with existing evidence and support the use of dexmedetomidine as a safe and effective adjuvant in laparoscopic cholecystectomy.

According to the study's findings, intravenous lignocaine and dexmedetomidine was superior to lignocaine in terms of reducing opioid use, improving sedation, controlling postoperative pain, and accelerating the gastrointestinal system's recovery after laparoscopic cholecystectomy. It also led to less incidence of side effects like nausea, vomiting, and shivering with no impact on hemodynamic or respiratory stability. These results indicate that lactate-treated dexmedetomidine, when combined with lignocaine, provides a better and safe multimodal analgesic strategy and hence is a worthy choice in perioperative pain relief for minimally invasive abdominal procedures.

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